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表 2.7.4.7- 1　年齢別の TEAE（試験 BC1-06、2 回目の解析）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Number of subjects (%) with at least one adverse event	Number of subjects (%) with at least one adverse event	141 (92.2%)	68 (95.8%)	239 (95.2%)	128 (97.7%)
Blood and lymphatic system disorders	血液およびリンパ系障害	69 (45.1%)	29 (40.8%)	98 (39.0%)	46 (35.1%)
Anaemia	貧血	51 (33.3%)	27 (38.0%)	82 (32.7%)	42 (32.1%)
Bone marrow failure	骨髄機能不全	1 (0.7%)	0	0	0
Disseminated intravascular coagulation	播種性血管内凝固	0	0	1 (0.4%)	1 (0.8%)
Erythropenia	赤血球減少症	0	0	1 (0.4%)	0
Febrile neutropenia	発熱性好中球減少症	1 (0.7%)	0	0	0
Hypochromic anaemia	低色素性貧血	0	0	0	1 (0.8%)
Leukocytosis	白血球増加症	0	0	0	0
Leukopenia	白血球減少症	10 (6.5%)	0	10 (4.0%)	1 (0.8%)
Lymphadenopathy	リンパ節症	6 (3.9%)	2 (2.8%)	5 (2.0%)	0
Lymphadenopathy mediastinal	縦隔リンパ節腫脹	0	0	0	0
Lymphopenia	リンパ球減少症	0	0	3 (1.2%)	1 (0.8%)
Neutropenia	好中球減少症	12 (7.8%)	0	9 (3.6%)	2 (1.5%)
Neutrophilia	好中球増加症	0	0	0	0
Pancytopenia	汎血球減少症	5 (3.3%)	0	5 (2.0%)	0
Thrombocythaemia	血小板血症	0	0	0	0
Thrombocytopenia	血小板減少症	23 (15.0%)	8 (11.3%)	26 (10.4%)	6 (4.6%)
Cardiac disorders	心臓障害	12 (7.8%)	2 (2.8%)	18 (7.2%)	16 (12.2%)
Acute coronary syndrome	急性冠動脈症候群	0	0	1 (0.4%)	0
Acute myocardial infarction	急性心筋梗塞	0	0	1 (0.4%)	2 (1.5%)
Angina pectoris	狭心症	2 (1.3%)	0	3 (1.2%)	1 (0.8%)
Aortic valve stenosis	大動脈弁狭窄	0	0	0	0

表 2.7.4.7- 1　年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Arrhythmia	不整脈	0	0	0	2 (1.5%)
Atrial fibrillation	心房細動	1 (0.7%)	0	4 (1.6%)	1 (0.8%)
Atrial flutter	心房粗動	0	0	0	1 (0.8%)
Atrial tachycardia	心房頻脈	0	0	0	0
Atrioventricular block complete	完全房室ブロック	0	0	0	0
Bradycardia	徐脈	1 (0.7%)	0	0	0
Cardiac arrest	心停止	0	0	0	1 (0.8%)
Cardiac failure	心不全	2 (1.3%)	1 (1.4%)	1 (0.4%)	1 (0.8%)
Cardiac failure congestive	うっ血性心不全	0	0	2 (0.8%)	1 (0.8%)
Cardiomegaly	心拡大	0	0	0	0
Cardiopulmonary failure	心肺不全	0	0	0	0
Coronary artery disease	冠動脈疾患	0	0	1 (0.4%)	0
Left ventricular dysfunction	左室機能不全	0	0	0	0
Left ventricular failure	左室不全	0	0	0	0
Myocardial infarction	心筋梗塞	0	0	0	4 (3.1%)
Myocardial ischaemia	心筋虚血	1 (0.7%)	0	0	0
Palpitations	動悸	2 (1.3%)	0	2 (0.8%)	1 (0.8%)
Pericardial effusion	心嚢液貯留	1 (0.7%)	0	0	1 (0.8%)
Sinus tachycardia	洞性頻脈	2 (1.3%)	0	1 (0.4%)	1 (0.8%)
Supraventricular tachycardia	上室性頻脈	1 (0.7%)	0	1 (0.4%)	0
Tachycardia	頻脈	0	2 (2.8%)	1 (0.4%)	1 (0.8%)
Ventricular extrasystoles	心室性期外収縮	0	0	1 (0.4%)	0
Ear and labyrinth disorders	耳および迷路障害	4 (2.6%)	0	5 (2.0%)	2 (1.5%)
Deafness	難聴	0	0	2 (0.8%)	0
Deafness unilateral	片耳難聴	0	0	0	0
Ear pain	耳痛	0	0	0	0
Hearing impaired	聴覚障害	0	0	1 (0.4%)	0

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Meniere's disease	メニエール病	0	0	0	0
Otosalpingitis	耳管炎	0	0	0	0
Tinnitus	耳鳴	2 (1.3%)	0	0	0
Vertigo	回転性めまい	2 (1.3%)	0	2 (0.8%)	1 (0.8%)
Vertigo positional	頭位性回転性めまい	0	0	0	1 (0.8%)
Endocrine disorders	内分泌障害	2 (1.3%)	1 (1.4%)	4 (1.6%)	0
Cushing's syndrome	クッシング症候群	1 (0.7%)	0	0	0
Cushingoid	クッシング様	0	1 (1.4%)	1 (0.4%)	0
Hyperparathyroidism	副甲状腺機能亢進症	0	0	1 (0.4%)	0
Hyperthyroidism	甲状腺機能亢進症	1 (0.7%)	0	0	0
Hypothyroidism	甲状腺機能低下症	0	0	2 (0.8%)	0
Eye disorders	眼障害	8 (5.2%)	3 (4.2%)	10 (4.0%)	10 (7.6%)
Asthenopia	眼精疲労	1 (0.7%)	0	0	0
Blepharitis	眼瞼炎	0	0	1 (0.4%)	0
Cataract	白内障	1 (0.7%)	0	0	0
Conjunctival haemorrhage	結膜出血	1 (0.7%)	0	0	0
Conjunctivitis	結膜炎	1 (0.7%)	0	1 (0.4%)	0
Diplopia	複視	2 (1.3%)	1 (1.4%)	3 (1.2%)	1 (0.8%)
Dry eye	眼乾燥	0	0	0	3 (2.3%)
Eye pain	眼痛	0	0	1 (0.4%)	2 (1.5%)
Eye swelling	眼部腫脹	0	0	0	1 (0.8%)
Eyelid function disorder	眼瞼機能障害	0	1 (1.4%)	0	0
Eyelid ptosis	眼瞼下垂	0	1 (1.4%)	0	1 (0.8%)
Glaucoma	緑内障	0	0	0	0
Iridocyclitis	虹彩毛様体炎	1 (0.7%)	0	0	0
Lacrimation increased	流涙増加	0	0	0	0

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Ocular hyperaemia	眼充血	0	0	1 (0.4%)	0
Ocular surface disease	オキュラーサーフェス疾患	1 (0.7%)	0	0	0
Photopsia	光視症	0	0	1 (0.4%)	0
Pupils unequal	瞳孔不同	0	1 (1.4%)	0	0
Vision blurred	霧視	0	1 (1.4%)	4 (1.6%)	2 (1.5%)
Visual acuity reduced	視力低下	0	0	0	0
Visual disturbance	視覚障害	0	0	0	1 (0.8%)
Gastrointestinal disorders	胃腸障害	95 (62.1%)	47 (66.2%)	167 (66.5%)	81 (61.8%)
Abdominal discomfort	腹部不快感	0	0	1 (0.4%)	0
Abdominal distension	腹部膨満	1 (0.7%)	0	2 (0.8%)	0
Abdominal pain	腹痛	8 (5.2%)	1 (1.4%)	10 (4.0%)	5 (3.8%)
Abdominal pain lower	下腹部痛	0	0	0	1 (0.8%)
Abdominal pain upper	上腹部痛	6 (3.9%)	1 (1.4%)	5 (2.0%)	2 (1.5%)
Anal haemorrhage	肛門出血	0	0	1 (0.4%)	0
Anal sphincter atony	肛門括約筋無緊張症	0	0	0	1 (0.8%)
Aphthous stomatitis	アフタ性口内炎	0	0	1 (0.4%)	0
Ascites	腹水	1 (0.7%)	0	2 (0.8%)	0
Colitis	大腸炎	0	0	0	0
Constipation	便秘	23 (15.0%)	21 (29.6%)	52 (20.7%)	27 (20.6%)
Defaecation urgency	便意切迫	1 (0.7%)	0	0	0
Dental caries	齲歯	0	0	1 (0.4%)	0
Diarrhoea	下痢	41 (26.8%)	10 (14.1%)	69 (27.5%)	18 (13.7%)
Dry mouth	口内乾燥	2 (1.3%)	0	3 (1.2%)	3 (2.3%)
Duodenal ulcer	十二指腸潰瘍	0	0	1 (0.4%)	0
Duodenitis	十二指腸炎	0	0	1 (0.4%)	0
Dyspepsia	消化不良	3 (2.0%)	0	12 (4.8%)	4 (3.1%)
Dysphagia	嚥下障害	2 (1.3%)	1 (1.4%)	1 (0.4%)	2 (1.5%)

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Epigastric discomfort	心窩部不快感	0	0	1 (0.4%)	0
Erosive duodenitis	びらん性十二指腸炎	1 (0.7%)	0	0	0
Eructation	おくび	1 (0.7%)	1 (1.4%)	0	1 (0.8%)
Faecal incontinence	便失禁	1 (0.7%)	0	4 (1.6%)	1 (0.8%)
Faeces discoloured	変色便	0	0	0	0
Flatulence	鼓腸	0	0	0	1 (0.8%)
Food poisoning	食中毒	0	0	0	2 (1.5%)
Frequent bowel movements	排便回数増加	0	0	0	0
Gastric hypermotility	胃運動過剰	1 (0.7%)	0	0	0
Gastric ulcer	胃潰瘍	0	0	2 (0.8%)	0
Gastritis	胃炎	1 (0.7%)	1 (1.4%)	2 (0.8%)	5 (3.8%)
Gastroduodenal ulcer	胃十二指腸潰瘍	0	0	0	0
Gastrointestinal haemorrhage	胃腸出血	0	0	1 (0.4%)	1 (0.8%)
Gastrointestinal motility disorder	消化管運動障害	0	0	1 (0.4%)	1 (0.8%)
Gastrointestinal pain	消化器痛	0	0	0	0
Gastrooesophageal reflux disease	胃食道逆流性疾患	0	1 (1.4%)	0	1 (0.8%)
Gingival bleeding	歯肉出血	0	0	0	1 (0.8%)
Gingivitis	歯肉炎	0	0	0	1 (0.8%)
Haematemesis	吐血	1 (0.7%)	0	0	0
Haemorrhoidal haemorrhage	痔出血	0	0	1 (0.4%)	0
Haemorrhoids	痔核	0	0	2 (0.8%)	1 (0.8%)
Hiatus hernia	裂孔ヘルニア	1 (0.7%)	0	1 (0.4%)	0
Hyperchlorhydria	胃酸過多	1 (0.7%)	0	0	0
Hypoaesthesia oral	口の感覚鈍麻	0	0	1 (0.4%)	0
Inguinal hernia	鼠径ヘルニア	0	0	0	0
Intestinal obstruction	腸閉塞	0	0	1 (0.4%)	0
Intestinal perforation	腸管穿孔	0	0	1 (0.4%)	1 (0.8%)
Large intestine perforation	大腸穿孔	0	1 (1.4%)	0	0

表 2.7.4.7- 1　年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Lip swelling	口唇腫脹	0	0	1 (0.4%)	0
Melaena	メレナ	0	0	1 (0.4%)	0
Mouth haemorrhage	口腔内出血	0	0	0	0
Mouth ulceration	口腔内潰瘍形成	1 (0.7%)	0	2 (0.8%)	1 (0.8%)
Nausea	悪心	52 (34.0%)	31 (43.7%)	95 (37.8%)	48 (36.6%)
Odynophagia	嚥下痛	1 (0.7%)	0	0	0
Oesophageal obstruction	食道閉塞症	0	0	0	0
Oesophageal pain	食道痛	0	0	1 (0.4%)	0
Oesophageal spasm	食道痙攣	0	0	1 (0.4%)	0
Oesophagitis	食道炎	4 (2.6%)	0	0	0
Oral pain	口腔内痛	0	0	0	2 (1.5%)
Painful defaecation	排便痛	0	0	0	0
Paresis anal sphincter	肛門括約筋不全麻痺	0	0	0	1 (0.8%)
Periodontal disease	歯周病	1 (0.7%)	0	0	0
Proctalgia	肛門周囲痛	1 (0.7%)	0	0	0
Rectal discharge	直腸分泌物	0	0	1 (0.4%)	0
Rectal haemorrhage	直腸出血	2 (1.3%)	1 (1.4%)	4 (1.6%)	2 (1.5%)
Rectal tenesmus	直腸しぶり	0	0	1 (0.4%)	1 (0.8%)
Reflux gastritis	逆流性胃炎	0	0	0	0
Reflux oesophagitis	逆流性食道炎	1 (0.7%)	0	0	0
Retching	レッチング	0	1 (1.4%)	0	1 (0.8%)
Salivary hypersecretion	流涎過多	0	0	1 (0.4%)	0
Small intestinal obstruction	小腸閉塞	0	0	1 (0.4%)	0
Stomach discomfort	胃不快感	1 (0.7%)	1 (1.4%)	2 (0.8%)	0
Stomatitis	口内炎	0	0	0	2 (1.5%)
Subileus	亜イレウス	0	1 (1.4%)	1 (0.4%)	0
Swollen tongue	舌腫脹	0	0	0	1 (0.8%)
Toothache	歯痛	2 (1.3%)	1 (1.4%)	3 (1.2%)	1 (0.8%)

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Upper gastrointestinal haemorrhage	上部消化管出血	1 (0.7%)	0	0	0
Vomiting	嘔吐	31 (20.3%)	13 (18.3%)	54 (21.5%)	16 (12.2%)
General disorders and administration site conditions	全身障害および投与局所様態	77 (50.3%)	27 (38.0%)	126 (50.2%)	64 (48.9%)
Asthenia	無力症	5 (3.3%)	4 (5.6%)	10 (4.0%)	6 (4.6%)
Chest discomfort	胸部不快感	0	0	1 (0.4%)	0
Chest pain	胸痛	0	0	1 (0.4%)	1 (0.8%)
Chills	悪寒	2 (1.3%)	0	6 (2.4%)	1 (0.8%)
Crepitations	捻髪音	0	0	0	0
Cyst	嚢胞	1 (0.7%)	0	1 (0.4%)	0
Death	死亡	1 (0.7%)	0	2 (0.8%)	0
Discomfort	不快感	1 (0.7%)	0	0	0
Drug intolerance	薬物不耐性	0	0	1 (0.4%)	1 (0.8%)
Fatigue	疲労	38 (24.8%)	17 (23.9%)	81 (32.3%)	29 (22.1%)
Feeling cold	冷感	0	0	1 (0.4%)	0
Feeling hot	熱感	0	1 (1.4%)	0	0
Gait disturbance	歩行障害	1 (0.7%)	0	1 (0.4%)	2 (1.5%)
General physical health deterioration	全身健康状態低下	11 (7.2%)	5 (7.0%)	11 (4.4%)	11 (8.4%)
Generalised oedema	全身性浮腫	0	0	0	1 (0.8%)
Hernia	ヘルニア	1 (0.7%)	0	0	0
Induration	硬結	0	0	0	0
Influenza like illness	インフルエンザ様疾患	2 (1.3%)	0	3 (1.2%)	1 (0.8%)
Infusion site erythema	注入部位紅斑	0	0	1 (0.4%)	0
Injection site pain	注射部位疼痛	1 (0.7%)	0	1 (0.4%)	0
Injection site rash	注射部位発疹	1 (0.7%)	0	0	0
Injection site reaction	注射部位反応	1 (0.7%)	0	1 (0.4%)	0
Injection site swelling	注射部位腫脹	1 (0.7%)	0	0	0

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Localised oedema	限局性浮腫	0	0	0	4 (3.1%)
Malaise	倦怠感	2 (1.3%)	0	2 (0.8%)	1 (0.8%)
Mucosal inflammation	粘膜の炎症	1 (0.7%)	0	1 (0.4%)	2 (1.5%)
Multi-organ failure	多臓器不全	0	0	0	0
Non-cardiac chest pain	非心臓性胸痛	0	0	3 (1.2%)	1 (0.8%)
Oedema	浮腫	2 (1.3%)	0	2 (0.8%)	1 (0.8%)
Oedema peripheral	末梢性浮腫	18 (11.8%)	4 (5.6%)	33 (13.1%)	19 (14.5%)
Pain	疼痛	1 (0.7%)	0	2 (0.8%)	4 (3.1%)
Peripheral coldness	末梢冷感	0	1 (1.4%)	0	0
Pitting oedema	圧痕浮腫	1 (0.7%)	0	0	1 (0.8%)
Pyrexia	発熱	18 (11.8%)	3 (4.2%)	13 (5.2%)	10 (7.6%)
Sudden death	突然死	0	0	0	1 (0.8%)
Temperature intolerance	温度変化不耐症	1 (0.7%)	0	0	0
Hepatobiliary disorders	肝胆道系障害	1 (0.7%)	0	0	0
Bile duct obstruction	胆管閉塞	0	0	0	0
Cholelithiasis	胆石症	0	0	0	0
Cholestasis	胆汁うっ滞	0	0	0	0
Hepatic failure	肝不全	0	0	0	0
Hepatic function abnormal	肝機能異常	1 (0.7%)	0	0	0
Hyperbilirubinaemia	高ビリルビン血症	0	0	0	0
Jaundice	黄疸	1 (0.7%)	0	0	0
Immune system disorders	免疫系障害	0	3 (4.2%)	0	0
Cytokine release syndrome	サイトカイン放出症候群	0	1 (1.4%)	0	0
Hypersensitivity	過敏症	0	2 (2.8%)	0	0

表 2.7.4.7- 1　年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Infections and infestations	感染症および寄生虫症	49 (32.0%)	20 (28.2%)	75 (29.9%)	45 (34.4%)
Abscess	膿瘍	0	0	0	0
Abscess jaw	顎膿瘍	0	0	0	1 (0.8%)
Arthritis infective	感染性関節炎	0	1 (1.4%)	0	0
Bacterial sepsis	細菌性敗血症	1 (0.7%)	0	0	0
Bronchitis	気管支炎	0	0	0	3 (2.3%)
Bronchopneumonia	気管支肺炎	0	0	0	0
Bursitis infective	感染性滑液包炎	0	0	1 (0.4%)	0
Campylobacter infection	カンピロバクター感染	0	1 (1.4%)	0	0
Catheter related infection	カテーテル関連感染	1 (0.7%)	0	1 (0.4%)	0
Cellulitis	蜂巣炎	0	1 (1.4%)	3 (1.2%)	2 (1.5%)
Clostridium difficile colitis	クロストリジウム・ディフィシレ大腸炎	0	0	1 (0.4%)	0
Cystitis	膀胱炎	2 (1.3%)	1 (1.4%)	3 (1.2%)	1 (0.8%)
Device related infection	医療機器関連感染	0	0	0	1 (0.8%)
Ear infection	耳感染	0	0	2 (0.8%)	0
Erysipelas	丹毒	2 (1.3%)	0	0	1 (0.8%)
Escherichia urinary tract infection	大腸菌性尿路感染	1 (0.7%)	0	0	0
Eye infection	眼感染	0	1 (1.4%)	1 (0.4%)	0
Fungal infection	真菌感染	0	0	1 (0.4%)	0
Fungal skin infection	皮膚真菌感染	0	0	0	0
Gastroenteritis	胃腸炎	1 (0.7%)	0	0	0
Gastroenteritis norovirus	ノロウイルス性胃腸炎	0	0	0	0
Gastroenteritis viral	ウイルス性胃腸炎	0	0	0	0
Gingival infection	歯肉感染	2 (1.3%)	0	0	0
Haemophilus infection	ヘモフィルス感染	0	0	0	0
Helicobacter infection	ヘリコバクター感染	0	0	1 (0.4%)	0
Herpes simplex	単純ヘルペス	0	0	0	0
Herpes zoster	帯状疱疹	1 (0.7%)	1 (1.4%)	7 (2.8%)	2 (1.5%)

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Hordeolum	麦粒腫	0	0	1 (0.4%)	0
Infection	感染	4 (2.6%)	0	7 (2.8%)	4 (3.1%)
Influenza	インフルエンザ	0	0	5 (2.0%)	0
Listeriosis	リステリア症	0	1 (1.4%)	0	0
Lobar pneumonia	大葉性肺炎	0	0	0	2 (1.5%)
Localised infection	限局性感染	0	0	0	0
Lower respiratory tract infection	下気道感染	9 (5.9%)	3 (4.2%)	9 (3.6%)	4 (3.1%)
Lower respiratory tract infection bacterial	細菌性下気道感染	0	0	0	0
Lung infection	肺感染	0	1 (1.4%)	1 (0.4%)	0
Nail infection	爪感染	1 (0.7%)	0	0	0
Nasopharyngitis	鼻咽頭炎	5 (3.3%)	0	6 (2.4%)	5 (3.8%)
Oral candidiasis	口腔カンジダ症	8 (5.2%)	2 (2.8%)	3 (1.2%)	1 (0.8%)
Oral fungal infection	口腔真菌感染	1 (0.7%)	0	2 (0.8%)	2 (1.5%)
Oral herpes	口腔ヘルペス	1 (0.7%)	0	0	0
Oral infection	口腔感染	0	0	1 (0.4%)	0
Paronychia	爪囲炎	0	0	0	0
Peritonitis bacterial	細菌性腹膜炎	1 (0.7%)	0	0	0
Pharyngitis	咽頭炎	0	0	2 (0.8%)	0
Pilonidal cyst	毛巣嚢胞	0	0	1 (0.4%)	0
Pneumonia	肺炎	6 (3.9%)	3 (4.2%)	9 (3.6%)	8 (6.1%)
Pneumonia primary atypical	原発性異型肺炎	0	0	0	0
Post procedural infection	処置後感染	0	0	0	0
Postoperative wound infection	術後創感染	0	0	0	1 (0.8%)
Pyelonephritis	腎盂腎炎	1 (0.7%)	0	0	0
Pyonephrosis	膿腎症	0	0	0	1 (0.8%)
Respiratory tract infection	気道感染	3 (2.0%)	0	2 (0.8%)	0
Respiratory tract infection viral	ウイルス性気道感染	1 (0.7%)	0	0	0

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Rhinitis	鼻炎	1 (0.7%)	0	1 (0.4%)	0
Sepsis	敗血症	2 (1.3%)	1 (1.4%)	4 (1.6%)	2 (1.5%)
Sinusitis	副鼻腔炎	0	0	0	0
Skin infection	皮膚感染	2 (1.3%)	0	0	1 (0.8%)
Soft tissue infection	軟部組織感染	0	0	1 (0.4%)	0
Staphylococcal infection	ブドウ球菌感染	0	1 (1.4%)	0	0
Subcutaneous abscess	皮下組織膿瘍	0	0	1 (0.4%)	0
Tinea pedis	足部白癬	0	0	0	0
Tooth infection	歯感染	1 (0.7%)	2 (2.8%)	0	1 (0.8%)
Upper respiratory tract infection	上気道感染	2 (1.3%)	1 (1.4%)	4 (1.6%)	3 (2.3%)
Upper respiratory tract infection bacterial	細菌性上気道感染	1 (0.7%)	0	0	0
Urinary tract infection	尿路感染	8 (5.2%)	5 (7.0%)	21 (8.4%)	11 (8.4%)
Urosepsis	尿路性敗血症	0	0	1 (0.4%)	1 (0.8%)
Viral infection	ウイルス感染	1 (0.7%)	0	1 (0.4%)	1 (0.8%)
Viral skin infection	皮膚ウイルス感染	0	0	0	1 (0.8%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	12 (7.8%)	5 (7.0%)	32 (12.7%)	9 (6.9%)
Accidental overdose	偶発的過量投与	0	0	1 (0.4%)	0
Ankle fracture	足関節部骨折	0	0	1 (0.4%)	0
Back injury	背部損傷	0	0	0	0
Compression fracture	圧迫骨折	1 (0.7%)	0	0	0
Contusion	挫傷	4 (2.6%)	2 (2.8%)	5 (2.0%)	1 (0.8%)
Cystitis radiation	放射線性膀胱炎	0	0	0	0
Device dislocation	医療機器位置異常	0	0	1 (0.4%)	1 (0.8%)
Excoriation	擦過傷	0	0	2 (0.8%)	0
Extradural haematoma	硬膜外血腫	0	0	1 (0.4%)	0

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Fall	転倒・転落	0	0	1 (0.4%)	2 (1.5%)
Femoral neck fracture	大腿骨頚部骨折	1 (0.7%)	1 (1.4%)	0	0
Foot fracture	足骨折	0	0	1 (0.4%)	0
Gastroenteritis radiation	放射線胃腸炎	0	0	0	0
Hand fracture	手骨折	0	0	0	0
Head injury	頭部損傷	0	0	1 (0.4%)	0
Hip fracture	股関節部骨折	0	0	0	0
Injury	損傷	0	0	1 (0.4%)	0
Intentional overdose	企図的過量投与	0	0	1 (0.4%)	0
Joint injury	関節損傷	0	0	3 (1.2%)	0
Joint sprain	関節捻挫	1 (0.7%)	0	1 (0.4%)	0
Laceration	裂傷	0	0	1 (0.4%)	0
Ligament injury	靭帯損傷	1 (0.7%)	0	0	0
Lower limb fracture	下肢骨折	1 (0.7%)	0	0	0
Medical device complication	医療機器合併症	0	0	0	0
Medical device pain	医療機器による疼痛	0	0	0	0
Meniscus lesion	半月板障害	1 (0.7%)	0	0	0
Mouth injury	口腔内損傷	0	0	0	0
Muscle strain	筋挫傷	0	0	1 (0.4%)	0
Nail avulsion	爪裂離	0	0	0	0
Patella fracture	膝蓋骨骨折	0	0	0	0
Post-traumatic pain	外傷後疼痛	0	0	4 (1.6%)	0
Procedural pain	処置による疼痛	0	0	2 (0.8%)	1 (0.8%)
Radiation associated pain	放射線関連痛	1 (0.7%)	0	0	0
Radiation skin injury	放射線皮膚損傷	1 (0.7%)	0	1 (0.4%)	0
Radius fracture	橈骨骨折	0	0	1 (0.4%)	1 (0.8%)
Rib fracture	肋骨骨折	0	0	1 (0.4%)	0
Skin laceration	皮膚裂傷	2 (1.3%)	0	3 (1.2%)	0

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Spinal compression fracture	脊椎圧迫骨折	0	0	1 (0.4%)	0
Stent occlusion	ステント閉塞	0	0	0	1 (0.8%)
Sternal fracture	胸骨骨折	0	0	0	0
Stomatitis radiation	放射線口内炎	0	1 (1.4%)	0	0
Stress fracture	ストレス骨折	0	0	1 (0.4%)	0
Subcutaneous haematoma	皮下血腫	0	0	1 (0.4%)	0
Tendon rupture	腱断裂	1 (0.7%)	0	0	0
Therapeutic agent toxicity	治療薬毒性	1 (0.7%)	0	0	0
Thermal burn	熱傷	0	1 (1.4%)	0	0
Tooth fracture	歯牙破折	0	0	0	1 (0.8%)
Upper limb fracture	上肢骨折	0	0	3 (1.2%)	1 (0.8%)
Wound	創傷	0	0	1 (0.4%)	0
Investigations	臨床検査	27 (17.6%)	15 (21.1%)	41 (16.3%)	30 (22.9%)
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	0	0	1 (0.4%)	1 (0.8%)
Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3 (2.0%)	1 (1.4%)	3 (1.2%)	0
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1 (0.7%)	3 (4.2%)	1 (0.4%)	5 (3.8%)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	0	0	1 (0.4%)	0
Blood creatinine increased	血中クレアチニン増加	0	0	1 (0.4%)	0
Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	3 (2.0%)	3 (4.2%)	3 (1.2%)	2 (1.5%)
Blood urea increased	血中尿素増加	1 (0.7%)	0	5 (2.0%)	2 (1.5%)
Breath sounds abnormal	呼吸音異常	1 (0.7%)	0	0	0
Cardiac murmur	心雑音	1 (0.7%)	0	0	1 (0.8%)
Coagulation factor VII level increased	凝固第ＶＩＩ因子量増加	1 (0.7%)	0	0	0
Electrocardiogram QT prolonged	心電図ＱＴ延長	0	0	1 (0.4%)	0
Fibrin D dimer increased	フィブリンＤダイマー増加	0	0	0	0
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	5 (3.3%)	2 (2.8%)	4 (1.6%)	3 (2.3%)

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Liver function test abnormal	肝機能検査異常	0	0	0	0
Prostatic specific antigen increased	前立腺特異性抗原増加	0	0	0	2 (1.5%)
Troponin T increased	トロポニンT増加	0	0	0	0
Urine analysis abnormal	尿検査異常	0	0	0	1 (0.8%)
Urine output increased	尿量増加	0	0	1 (0.4%)	0
Weight decreased	体重減少	20 (13.1%)	10 (14.1%)	28 (11.2%)	20 (15.3%)
Weight increased	体重増加	1 (0.7%)	0	0	1 (0.8%)
Metabolism and nutrition disorders	代謝および栄養障害	42 (27.5%)	18 (25.4%)	79 (31.5%)	38 (29.0%)
Anorexia	食欲不振	24 (15.7%)	11 (15.5%)	44 (17.5%)	22 (16.8%)
Cachexia	悪液質	0	0	1 (0.4%)	0
Decreased appetite	食欲減退	9 (5.9%)	3 (4.2%)	14 (5.6%)	7 (5.3%)
Dehydration	脱水	3 (2.0%)	1 (1.4%)	8 (3.2%)	1 (0.8%)
Diabetes mellitus	糖尿病	1 (0.7%)	0	0	0
Dyslipidaemia	異脂肪血症	1 (0.7%)	0	0	0
Fluid intake reduced	水分摂取量減少	0	0	0	0
Fluid overload	水分過負荷	0	0	0	0
Gout	痛風	0	0	2 (0.8%)	1 (0.8%)
Hypercalcaemia	高カルシウム血症	0	0	0	1 (0.8%)
Hypercholesterolaemia	高コレステロール血症	0	0	0	0
Hypercreatininaemia	高クレアチニン血症	0	0	4 (1.6%)	2 (1.5%)
Hyperglycaemia	高血糖	1 (0.7%)	0	2 (0.8%)	1 (0.8%)
Hyperkalaemia	高カリウム血症	0	0	1 (0.4%)	0
Hypernatraemia	高ナトリウム血症	0	0	0	0
Hyperuricaemia	高尿酸血症	0	0	0	0
Hypoalbuminaemia	低アルブミン血症	1 (0.7%)	0	1 (0.4%)	1 (0.8%)
Hypocalcaemia	低カルシウム血症	1 (0.7%)	2 (2.8%)	3 (1.2%)	1 (0.8%)
Hypoglycaemia	低血糖症	0	0	1 (0.4%)	0

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Hypokalaemia	低カリウム血症	3 (2.0%)	2 (2.8%)	5 (2.0%)	2 (1.5%)
Hypomagnesaemia	低マグネシウム血症	0	0	2 (0.8%)	0
Hyponatraemia	低ナトリウム血症	0	1 (1.4%)	1 (0.4%)	1 (0.8%)
Hypophosphataemia	低リン酸血症	1 (0.7%)	0	4 (1.6%)	0
Hypovitaminosis	ビタミン欠乏症	1 (0.7%)	0	0	0
Increased appetite	食欲亢進	0	0	1 (0.4%)	0
Magnesium deficiency	マグネシウム欠乏	0	0	0	1 (0.8%)
Malnutrition	栄養障害	0	0	1 (0.4%)	0
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	94 (61.4%)	54 (76.1%)	160 (63.7%)	91 (69.5%)
Arthralgia	関節痛	5 (3.3%)	4 (5.6%)	16 (6.4%)	4 (3.1%)
Back pain	背部痛	1 (0.7%)	0	5 (2.0%)	2 (1.5%)
Bone lesion	骨病変	1 (0.7%)	0	0	0
Bone pain	骨痛	86 (56.2%)	49 (69.0%)	134 (53.4%)	85 (64.9%)
Bursitis	滑液包炎	0	0	1 (0.4%)	1 (0.8%)
Flank pain	側腹部痛	0	0	1 (0.4%)	0
Groin pain	鼠径部痛	0	0	1 (0.4%)	0
Intervertebral disc degeneration	椎間板変性症	1 (0.7%)	0	0	0
Intervertebral disc disorder	椎間板障害	0	0	1 (0.4%)	0
Intervertebral disc protrusion	椎間板突出	0	0	1 (0.4%)	0
Joint effusion	関節滲出液	0	0	0	0
Joint instability	関節不安定	0	0	0	0
Joint lock	関節ロック	0	0	0	0
Joint range of motion decreased	関節運動範囲減少	0	0	0	1 (0.8%)
Joint stiffness	関節硬直	1 (0.7%)	0	0	0
Joint swelling	関節腫脹	0	0	1 (0.4%)	2 (1.5%)
Kyphosis	脊柱後弯症	0	0	0	0

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Mobility decreased	運動性低下	0	0	2 (0.8%)	2 (1.5%)
Muscle spasms	筋痙縮	5 (3.3%)	1 (1.4%)	4 (1.6%)	2 (1.5%)
Muscular weakness	筋力低下	2 (1.3%)	5 (7.0%)	2 (0.8%)	3 (2.3%)
Musculoskeletal chest pain	筋骨格系胸痛	1 (0.7%)	1 (1.4%)	2 (0.8%)	0
Musculoskeletal discomfort	筋骨格不快感	0	0	0	1 (0.8%)
Musculoskeletal pain	筋骨格痛	6 (3.9%)	1 (1.4%)	6 (2.4%)	4 (3.1%)
Musculoskeletal stiffness	筋骨格硬直	2 (1.3%)	0	1 (0.4%)	0
Myalgia	筋痛	5 (3.3%)	0	11 (4.4%)	4 (3.1%)
Myopathy	ミオパチー	0	0	0	0
Myositis	筋炎	0	0	1 (0.4%)	0
Neck pain	頚部痛	0	0	1 (0.4%)	0
Osteoarthritis	骨関節炎	1 (0.7%)	0	1 (0.4%)	0
Osteolysis	骨溶解	0	0	1 (0.4%)	0
Osteomalacia	骨軟化症	0	0	1 (0.4%)	0
Osteonecrosis	骨壊死	1 (0.7%)	0	2 (0.8%)	0
Osteoporosis	骨粗鬆症	0	0	1 (0.4%)	0
Pain in extremity	四肢痛	2 (1.3%)	1 (1.4%)	2 (0.8%)	2 (1.5%)
Pain in jaw	顎痛	2 (1.3%)	0	2 (0.8%)	1 (0.8%)
Pathological fracture	病的骨折	2 (1.3%)	4 (5.6%)	10 (4.0%)	7 (5.3%)
Spinal column stenosis	脊柱管狭窄症	0	0	1 (0.4%)	0
Spinal osteoarthritis	変形性脊椎炎	0	0	0	0
Synovial cyst	滑液嚢腫	0	1 (1.4%)	0	0
Tendonitis	腱炎	0	0	1 (0.4%)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	23 (15.0%)	17 (23.9%)	39 (15.5%)	28 (21.4%)
Benign neoplasm	良性新生物	0	0	2 (0.8%)	0
Benign neoplasm of bladder	膀胱の良性新生物	0	0	0	0

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Benign soft tissue neoplasm	軟部組織の良性新生物	0	0	0	0
Benign urinary tract neoplasm	尿路の良性新生物	0	1 (1.4%)	0	0
Bladder cancer	膀胱癌	0	0	0	0
Bone marrow tumour cell infiltration	腫瘍細胞の骨髄浸潤	0	0	0	0
Fibroma	線維腫	0	0	0	1 (0.8%)
Gastric cancer	胃癌	0	0	0	0
Haemangioma	血管腫	0	0	0	0
Lymphangiosis carcinomatosa	癌性リンパ管症	0	0	1 (0.4%)	0
Malignant neoplasm progression	悪性新生物進行	17 (11.1%)	13 (18.3%)	30 (12.0%)	20 (15.3%)
Metastases to bone	骨転移	1 (0.7%)	1 (1.4%)	1 (0.4%)	3 (2.3%)
Metastases to central nervous system	中枢神経系転移	4 (2.6%)	1 (1.4%)	0	1 (0.8%)
Metastases to liver	肝転移	3 (2.0%)	2 (2.8%)	2 (0.8%)	1 (0.8%)
Metastases to lung	肺転移	2 (1.3%)	0	0	0
Metastases to lymph nodes	リンパ節転移	0	0	0	1 (0.8%)
Metastases to meninges	髄膜転移	0	0	0	1 (0.8%)
Metastases to nervous system	神経系転移	0	0	1 (0.4%)	0
Metastases to skin	皮膚転移	0	0	1 (0.4%)	1 (0.8%)
Metastases to soft tissue	軟部組織転移	0	0	1 (0.4%)	1 (0.8%)
Neoplasm	新生物	0	0	0	1 (0.8%)
Neoplasm skin	皮膚の新生物	0	0	1 (0.4%)	0
Seborrhoeic keratosis	脂漏性角化症	0	0	0	0
Skin cancer	皮膚癌	0	0	0	0
Skin papilloma	皮膚乳頭腫	0	1 (1.4%)	0	0
Squamous cell carcinoma	扁平上皮癌	0	0	0	0
Squamous cell carcinoma of skin	皮膚有棘細胞癌	0	0	0	1 (0.8%)
Tumour associated fever	腫瘍熱	1 (0.7%)	0	0	0
Nervous system disorders	神経系障害	52 (34.0%)	19 (26.8%)	81 (32.3%)	55 (42.0%)

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Ageusia	味覚消失	1 (0.7%)	1 (1.4%)	1 (0.4%)	0
Amnesia	健忘	1 (0.7%)	0	1 (0.4%)	0
Aphasia	失語症	0	1 (1.4%)	0	0
Apraxia	失行症	0	0	0	0
Ataxia	運動失調	0	0	0	0
Balance disorder	平衡障害	0	0	1 (0.4%)	0
Brachial plexopathy	腕神経叢障害	0	0	0	0
Brain oedema	脳浮腫	0	0	0	1 (0.8%)
Burning sensation	灼熱感	1 (0.7%)	0	0	0
Cauda equina syndrome	馬尾症候群	0	0	0	1 (0.8%)
Cerebral haemorrhage	脳出血	1 (0.7%)	0	2 (0.8%)	0
Cerebral ischaemia	脳虚血	1 (0.7%)	0	0	1 (0.8%)
Cerebrovascular accident	脳血管発作	1 (0.7%)	0	1 (0.4%)	0
Cognitive disorder	認知障害	0	0	0	0
Convulsion	痙攣	0	0	2 (0.8%)	0
Cranial neuropathy	脳ニューロパチー	0	0	0	0
Dementia	認知症	0	0	0	0
Dementia Alzheimer's type	アルツハイマー型認知症	0	0	0	0
Disturbance in attention	注意力障害	1 (0.7%)	0	0	0
Dizziness	浮動性めまい	10 (6.5%)	4 (5.6%)	19 (7.6%)	10 (7.6%)
Dizziness postural	体位性めまい	2 (1.3%)	0	0	0
Dysaesthesia	異常感覚	0	1 (1.4%)	0	0
Dysarthria	構語障害	1 (0.7%)	1 (1.4%)	1 (0.4%)	1 (0.8%)
Dysgeusia	味覚異常	3 (2.0%)	0	10 (4.0%)	6 (4.6%)
Dysphasia	不全失語症	0	0	0	2 (1.5%)
Dystonia	ジストニー	1 (0.7%)	0	0	0
Epilepsy	てんかん	0	1 (1.4%)	0	0
Facial palsy	顔面神経麻痺	0	0	1 (0.4%)	0

表 2.7.4.7- 1　年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Facial paresis	顔面不全麻痺	0	0	0	1 (0.8%)
Haemorrhage intracranial	頭蓋内出血	0	0	0	1 (0.8%)
Headache	頭痛	5 (3.3%)	0	14 (5.6%)	9 (6.9%)
Hydrocephalus	水頭症	0	0	0	0
Hyperaesthesia	知覚過敏	0	0	0	0
Hypoaesthesia	感覚鈍麻	7 (4.6%)	1 (1.4%)	3 (1.2%)	3 (2.3%)
Ischaemic stroke	虚血性脳卒中	0	0	0	1 (0.8%)
Lethargy	嗜眠	2 (1.3%)	0	6 (2.4%)	7 (5.3%)
Loss of consciousness	意識消失	0	0	0	0
Memory impairment	記憶障害	1 (0.7%)	1 (1.4%)	1 (0.4%)	0
Migraine with aura	前兆を伴う片頭痛	0	0	0	1 (0.8%)
Monoparesis	不全単麻痺	0	1 (1.4%)	0	0
Myasthenia gravis	重症筋無力症	1 (0.7%)	0	0	0
Nerve root compression	神経根圧迫	1 (0.7%)	0	2 (0.8%)	0
Neuralgia	神経痛	2 (1.3%)	1 (1.4%)	2 (0.8%)	1 (0.8%)
Neuropathy peripheral	末梢性ニューロパチー	5 (3.3%)	0	2 (0.8%)	2 (1.5%)
Paraesthesia	錯感覚	5 (3.3%)	1 (1.4%)	10 (4.0%)	3 (2.3%)
Paraparesis	不全対麻痺	1 (0.7%)	0	1 (0.4%)	0
Paraplegia	対麻痺	0	0	0	2 (1.5%)
Paresis cranial nerve	脳神経不全麻痺	1 (0.7%)	0	0	0
Parosmia	嗅覚錯誤	0	0	0	1 (0.8%)
Peripheral motor neuropathy	末梢性運動ニューロパチー	3 (2.0%)	4 (5.6%)	1 (0.4%)	3 (2.3%)
Peripheral sensory neuropathy	末梢性感覚ニューロパチー	4 (2.6%)	2 (2.8%)	4 (1.6%)	1 (0.8%)
Peroneal nerve palsy	腓骨神経麻痺	0	0	0	1 (0.8%)
Polyneuropathy	多発ニューロパチー	1 (0.7%)	0	2 (0.8%)	0
Radicular syndrome	根症候群	0	0	1 (0.4%)	0
Restless legs syndrome	下肢静止不能症候群	1 (0.7%)	0	0	1 (0.8%)
Sciatica	坐骨神経痛	1 (0.7%)	1 (1.4%)	0	1 (0.8%)

表 2.7.4.7- 1　年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Somnolence	傾眠	0	0	2 (0.8%)	4 (3.1%)
Speech disorder	会話障害	0	0	0	0
Spinal cord compression	脊髄圧迫	7 (4.6%)	5 (7.0%)	13 (5.2%)	11 (8.4%)
Syncope	失神	1 (0.7%)	0	5 (2.0%)	0
Syncope vasovagal	血管迷走神経性失神	0	0	0	0
Tongue paralysis	舌の麻痺	0	0	1 (0.4%)	0
Transient ischaemic attack	一過性脳虚血発作	0	0	1 (0.4%)	0
Tremor	振戦	1 (0.7%)	1 (1.4%)	1 (0.4%)	1 (0.8%)
Trigeminal palsy	三叉神経麻痺	0	0	1 (0.4%)	0
VIth nerve paralysis	第６脳神経麻痺	0	0	0	1 (0.8%)
Psychiatric disorders	精神障害	29 (19.0%)	13 (18.3%)	34 (13.5%)	25 (19.1%)
Aggression	攻撃性	0	0	0	0
Agitation	激越	0	2 (2.8%)	1 (0.4%)	1 (0.8%)
Anhedonia	快感消失	0	0	0	1 (0.8%)
Anxiety	不安	4 (2.6%)	2 (2.8%)	5 (2.0%)	5 (3.8%)
Confusional state	錯乱状態	2 (1.3%)	2 (2.8%)	12 (4.8%)	5 (3.8%)
Depressed mood	抑うつ気分	2 (1.3%)	0	3 (1.2%)	1 (0.8%)
Depression	うつ病	9 (5.9%)	0	5 (2.0%)	7 (5.3%)
Disorientation	失見当識	0	0	0	0
Hallucination	幻覚	0	1 (1.4%)	0	0
Insomnia	不眠症	15 (9.8%)	7 (9.9%)	10 (4.0%)	7 (5.3%)
Intentional self-injury	故意の自傷行為	0	0	1 (0.4%)	0
Mania	躁病	0	0	1 (0.4%)	0
Mental status changes	精神状態変化	1 (0.7%)	0	0	0
Mood altered	気分変化	0	0	1 (0.4%)	1 (0.8%)
Nightmare	悪夢	1 (0.7%)	0	0	1 (0.8%)
Sleep disorder	睡眠障害	1 (0.7%)	0	1 (0.4%)	1 (0.8%)

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Suicide attempt	自殺企図	0	1 (1.4%)	0	0
Renal and urinary disorders	腎および尿路障害	25 (16.3%)	16 (22.5%)	41 (16.3%)	26 (19.8%)
Acute prerenal failure	急性腎前性腎不全	1 (0.7%)	0	0	0
Calculus ureteric	尿管結石	0	0	0	0
Chromaturia	着色尿	0	0	0	0
Dysuria	排尿困難	3 (2.0%)	2 (2.8%)	4 (1.6%)	4 (3.1%)
Haematuria	血尿	5 (3.3%)	5 (7.0%)	10 (4.0%)	6 (4.6%)
Haemorrhage urinary tract	尿路出血	0	1 (1.4%)	0	0
Hydronephrosis	水腎症	2 (1.3%)	1 (1.4%)	7 (2.8%)	1 (0.8%)
Hypertonic bladder	緊張性膀胱	0	0	0	0
Micturition disorder	排尿異常	1 (0.7%)	0	0	0
Micturition frequency decreased	排尿回数減少	0	0	1 (0.4%)	0
Micturition urgency	尿意切迫	1 (0.7%)	0	1 (0.4%)	2 (1.5%)
Mixed incontinence	混合性尿失禁	0	0	0	1 (0.8%)
Nephrolithiasis	腎結石症	2 (1.3%)	1 (1.4%)	0	0
Nocturia	夜間頻尿	6 (3.9%)	2 (2.8%)	2 (0.8%)	2 (1.5%)
Pollakiuria	頻尿	8 (5.2%)	1 (1.4%)	0	1 (0.8%)
Renal failure	腎不全	3 (2.0%)	2 (2.8%)	3 (1.2%)	0
Renal failure acute	急性腎不全	2 (1.3%)	0	1 (0.4%)	0
Renal impairment	腎機能障害	1 (0.7%)	0	1 (0.4%)	0
Renal tubular necrosis	腎尿細管壊死	0	0	1 (0.4%)	0
Strangury	有痛性排尿困難	1 (0.7%)	0	0	0
Stress urinary incontinence	腹圧性尿失禁	0	0	0	1 (0.8%)
Ureteric obstruction	尿管閉塞	0	1 (1.4%)	1 (0.4%)	0
Urethral obstruction	尿道閉塞	0	0	0	1 (0.8%)
Urge incontinence	切迫性尿失禁	0	0	1 (0.4%)	0
Urinary bladder haemorrhage	膀胱出血	0	1 (1.4%)	1 (0.4%)	0

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Urinary hesitation	排尿躊躇	0	0	1 (0.4%)	0
Urinary incontinence	尿失禁	2 (1.3%)	0	8 (3.2%)	2 (1.5%)
Urinary retention	尿閉	4 (2.6%)	5 (7.0%)	11 (4.4%)	7 (5.3%)
Urinary tract obstruction	尿路閉塞	1 (0.7%)	0	1 (0.4%)	3 (2.3%)
Urine flow decreased	尿流量減少	0	1 (1.4%)	1 (0.4%)	0
Urogenital disorder	尿生殖器障害	0	1 (1.4%)	0	0
Reproductive system and breast disorders	生殖系および乳房障害	3 (2.0%)	2 (2.8%)	9 (3.6%)	6 (4.6%)
Benign prostatic hyperplasia	良性前立腺肥大症	0	0	0	0
Breast mass	乳房腫瘤	1 (0.7%)	0	0	0
Breast pain	乳房痛	1 (0.7%)	0	0	0
Breast tenderness	乳房圧痛	1 (0.7%)	0	1 (0.4%)	1 (0.8%)
Genital pain	生殖器痛	0	0	0	1 (0.8%)
Gynaecomastia	女性化乳房	0	1 (1.4%)	2 (0.8%)	2 (1.5%)
Nipple pain	乳頭痛	0	0	0	1 (0.8%)
Oedema genital	性器浮腫	0	1 (1.4%)	1 (0.4%)	2 (1.5%)
Pelvic pain	骨盤痛	0	0	2 (0.8%)	1 (0.8%)
Perineal pain	会陰痛	0	0	1 (0.4%)	0
Posthitis	包皮炎	1 (0.7%)	0	0	0
Prostatic haemorrhage	前立腺出血	1 (0.7%)	0	0	0
Prostatitis	前立腺炎	0	0	0	0
Scrotal oedema	陰嚢浮腫	0	0	1 (0.4%)	0
Scrotal swelling	陰嚢腫脹	0	0	1 (0.4%)	0
Scrotal ulcer	陰嚢潰瘍	0	0	0	0
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	30 (19.6%)	11 (15.5%)	48 (19.1%)	26 (19.8%)
Acute pulmonary oedema	急性肺水腫	0	0	1 (0.4%)	0

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Atelectasis	無気肺	0	0	0	1 (0.8%)
Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	0	0	1 (0.4%)	3 (2.3%)
Chronic respiratory failure	慢性呼吸不全	0	0	0	0
Cough	咳嗽	6 (3.9%)	1 (1.4%)	11 (4.4%)	5 (3.8%)
Dysphonia	発声障害	0	0	0	1 (0.8%)
Dyspnoea	呼吸困難	13 (8.5%)	4 (5.6%)	16 (6.4%)	12 (9.2%)
Dyspnoea exertional	労作性呼吸困難	1 (0.7%)	0	6 (2.4%)	1 (0.8%)
Epistaxis	鼻出血	2 (1.3%)	0	3 (1.2%)	4 (3.1%)
Haemoptysis	喀血	0	0	0	1 (0.8%)
Hiccups	しゃっくり	0	0	0	0
Hypoxia	低酸素症	0	0	0	0
Increased bronchial secretion	気管支分泌増加	0	0	2 (0.8%)	0
Increased upper airway secretion	上気道分泌増加	0	0	0	1 (0.8%)
Lung consolidation	肺硬化	0	0	0	0
Nasal congestion	鼻閉	0	0	1 (0.4%)	1 (0.8%)
Nasal discomfort	鼻部不快感	0	1 (1.4%)	0	0
Pharyngolaryngeal pain	咽喉頭疼痛	1 (0.7%)	2 (2.8%)	1 (0.4%)	0
Pleural effusion	胸水	5 (3.3%)	2 (2.8%)	4 (1.6%)	3 (2.3%)
Pleurisy	胸膜炎	0	0	1 (0.4%)	0
Pleuritic pain	胸膜痛	0	0	1 (0.4%)	1 (0.8%)
Pneumonia aspiration	嚥下性肺炎	0	1 (1.4%)	0	0
Pneumonitis	肺臓炎	0	0	0	0
Postnasal drip	後鼻漏	0	0	1 (0.4%)	0
Productive cough	湿性咳嗽	2 (1.3%)	1 (1.4%)	3 (1.2%)	1 (0.8%)
Pulmonary congestion	肺うっ血	1 (0.7%)	0	0	0
Pulmonary embolism	肺塞栓症	1 (0.7%)	0	5 (2.0%)	3 (2.3%)
Pulmonary haemorrhage	肺出血	1 (0.7%)	0	0	0
Pulmonary hypertension	肺高血圧症	1 (0.7%)	0	0	0

表 2.7.4.7- 1　年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Pulmonary oedema	肺水腫	0	0	1 (0.4%)	0
Rales	ラ音	1 (0.7%)	0	0	0
Respiratory failure	呼吸不全	1 (0.7%)	1 (1.4%)	0	1 (0.8%)
Rhinorrhoea	鼻漏	0	1 (1.4%)	0	0
Tachypnoea	頻呼吸	0	0	0	0
Vasomotor rhinitis	血管運動性鼻炎	1 (0.7%)	0	0	0
Wheezing	喘鳴	1 (0.7%)	0	0	0
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	22 (14.4%)	7 (9.9%)	24 (9.6%)	15 (11.5%)
Actinic keratosis	日光性角化症	0	0	0	0
Alopecia	脱毛症	0	0	1 (0.4%)	0
Decubitus ulcer	褥瘡性潰瘍	1 (0.7%)	1 (1.4%)	1 (0.4%)	3 (2.3%)
Dermatitis	皮膚炎	0	0	0	1 (0.8%)
Dermatitis acneiform	ざ瘡様皮膚炎	0	0	1 (0.4%)	0
Dermatitis allergic	アレルギー性皮膚炎	0	0	2 (0.8%)	0
Dermatitis contact	接触性皮膚炎	0	0	0	1 (0.8%)
Dry skin	皮膚乾燥	2 (1.3%)	0	0	0
Eczema	湿疹	0	0	1 (0.4%)	0
Erythema	紅斑	0	1 (1.4%)	0	0
Hyperhidrosis	多汗症	2 (1.3%)	2 (2.8%)	4 (1.6%)	3 (2.3%)
Hypoaesthesia facial	顔面感覚鈍麻	1 (0.7%)	0	0	1 (0.8%)
Increased tendency to bruise	挫傷発生の増加傾向	0	0	0	0
Ingrowing nail	嵌入爪	0	0	0	1 (0.8%)
Intertrigo	間擦疹	0	1 (1.4%)	0	0
Nail disorder	爪の障害	0	0	1 (0.4%)	0
Night sweats	寝汗	4 (2.6%)	0	1 (0.4%)	2 (1.5%)
Onycholysis	爪甲離床症	0	0	1 (0.4%)	0
Pain of skin	皮膚疼痛	1 (0.7%)	0	0	0

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Palmar erythema	手掌紅斑	0	0	1 (0.4%)	0
Periorbital oedema	眼窩周囲浮腫	1 (0.7%)	1 (1.4%)	0	0
Petechiae	点状出血	2 (1.3%)	0	1 (0.4%)	0
Pigmentation disorder	色素沈着障害	1 (0.7%)	0	1 (0.4%)	0
Pruritus	そう痒症	2 (1.3%)	0	2 (0.8%)	1 (0.8%)
Psoriasis	乾癬	0	0	1 (0.4%)	0
Purpura	紫斑	0	0	1 (0.4%)	0
Rash	発疹	4 (2.6%)	0	7 (2.8%)	3 (2.3%)
Rash erythematous	紅斑性皮疹	1 (0.7%)	0	0	0
Rash pruritic	そう痒性皮疹	1 (0.7%)	0	1 (0.4%)	0
Skin atrophy	皮膚萎縮	1 (0.7%)	0	1 (0.4%)	0
Skin discolouration	皮膚変色	1 (0.7%)	0	0	0
Skin disorder	皮膚障害	0	1 (1.4%)	0	0
Skin exfoliation	皮膚剥脱	1 (0.7%)	0	0	0
Skin hyperpigmentation	皮膚色素過剰	1 (0.7%)	0	1 (0.4%)	0
Skin irritation	皮膚刺激	0	0	0	0
Skin lesion	皮膚病変	0	0	1 (0.4%)	0
Skin nodule	皮膚小結節	1 (0.7%)	0	0	0
Skin odour abnormal	皮膚異常臭	1 (0.7%)	0	0	0
Skin reaction	皮膚反応	1 (0.7%)	0	2 (0.8%)	0
Swelling face	顔面腫脹	0	0	0	0
Urticaria	蕁麻疹	0	1 (1.4%)	0	1 (0.8%)
Surgical and medical procedures	外科および内科処置	1 (0.7%)	0	0	0
Tooth extraction	抜歯	1 (0.7%)	0	0	0
Vascular disorders	血管障害	12 (7.8%)	5 (7.0%)	18 (7.2%)	13 (9.9%)
Circulatory collapse	循環虚脱	0	0	1 (0.4%)	0

表 2.7.4.7- 1　年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	<65 years BAY 88-8223 N=153 (100%)	<65 years Placebo N=71 (100%)	65-74 years BAY 88-8223 N=251 (100%)	65-74 years Placebo N=131 (100%)
Deep vein thrombosis	深部静脈血栓症	1 (0.7%)	1 (1.4%)	4 (1.6%)	0
Flushing	潮紅	0	0	0	2 (1.5%)
Haematoma	血腫	0	0	1 (0.4%)	0
Hot flush	ほてり	1 (0.7%)	0	2 (0.8%)	2 (1.5%)
Hypertension	高血圧	4 (2.6%)	1 (1.4%)	6 (2.4%)	
Hypertensive crisis	高血圧性クリーゼ	0	0	1 (0.4%)	
Hypotension	低血圧	3 (2.0%)	1 (1.4%)	2 (0.8%)	
Orthostatic hypotension	起立性低血圧	1 (0.7%)	0	0	
Pallor	蒼白	0	0	1 (0.4%)	
Phlebitis	静脈炎	0	0	0	
Thrombophlebitis	血栓性静脈炎	2 (1.3%)	0	0	
Thrombosis	血栓症	1 (0.7%)	0	0	
Vasculitis	血管炎	0	0	1 (0.4%)	
Venous thrombosis	静脈血栓症	1 (0.7%)	1 (1.4%)	0	
Venous thrombosis limb	四肢静脈血栓症	0	1 (1.4%)	0	

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
Number of subjects (%) with at least one adverse event	Number of subjects (%) with at least one adverse event	176 (93.6%)	88 (95.7%)	7 (87.5%)	7 (100.0%)
Blood and lymphatic system disorders	血液およびリンパ系障害	63 (33.5%)	30 (32.6%)	3 (37.5%)	1 (14.3%)
Anaemia	貧血	53 (28.2%)	22 (23.9%)	1 (12.5%)	1 (14.3%)
Bone marrow failure	骨髄機能不全	0	0	0	0
Disseminated intravascular coagulation	播種性血管内凝固	0	0	0	0
Erythropenia	赤血球減少症	0	0	0	0
Febrile neutropenia	発熱性好中球減少症	0	1 (1.1%)	0	0
Hypochromic anaemia	低色素性貧血	0	0	0	0
Leukocytosis	白血球増加症	1 (0.5%)	0	0	0
Leukopenia	白血球減少症	4 (2.1%)	0	1 (12.5%)	0
Lymphadenopathy	リンパ節症	5 (2.7%)	2 (2.2%)	0	0
Lymphadenopathy mediastinal	縦隔リンパ節腫脹	1 (0.5%)	0	0	0
Lymphopenia	リンパ球減少症	2 (1.1%)	0	0	0
Neutropenia	好中球減少症	9 (4.8%)	1 (1.1%)	0	0
Neutrophilia	好中球増加症	0	1 (1.1%)	0	0
Pancytopenia	汎血球減少症	2 (1.1%)	0	0	0
Thrombocythaemia	血小板血症	1 (0.5%)	0	0	0
Thrombocytopenia	血小板減少症	18 (9.6%)	3 (3.3%)	2 (25.0%)	0
Cardiac disorders	心臓障害	19 (10.1%)	10 (10.9%)	1 (12.5%)	1 (14.3%)
Acute coronary syndrome	急性冠動脈症候群	0	0	0	0
Acute myocardial infarction	急性心筋梗塞	0	1 (1.1%)	0	0
Angina pectoris	狭心症	3 (1.6%)	1 (1.1%)	0	0
Aortic valve stenosis	大動脈弁狭窄	1 (0.5%)	0	0	0
Arrhythmia	不整脈	1 (0.5%)	0	0	0
Atrial fibrillation	心房細動	3 (1.6%)	4 (4.3%)	1 (12.5%)	1 (14.3%)

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
Atrial flutter	心房粗動	1 (0.5%)	1 (1.1%)	0	0
Atrial tachycardia	心房頻脈	1 (0.5%)	0	0	0
Atrioventricular block complete	完全房室ブロック	0	1 (1.1%)	0	0
Bradycardia	徐脈	0	0	0	0
Cardiac arrest	心停止	0	0	0	0
Cardiac failure	心不全	1 (0.5%)	2 (2.2%)	0	0
Cardiac failure congestive	うっ血性心不全	3 (1.6%)	1 (1.1%)	0	0
Cardiomegaly	心拡大	1 (0.5%)	0	0	0
Cardiopulmonary failure	心肺不全	1 (0.5%)	1 (1.1%)	0	0
Coronary artery disease	冠動脈疾患	0	0	0	0
Left ventricular dysfunction	左室機能不全	1 (0.5%)	1 (1.1%)	0	0
Left ventricular failure	左室不全	0	0	0	1 (14.3%)
Myocardial infarction	心筋梗塞	3 (1.6%)	0	0	0
Myocardial ischaemia	心筋虚血	1 (0.5%)	0	0	0
Palpitations	動悸	1 (0.5%)	0	0	0
Pericardial effusion	心嚢液貯留	0	0	0	0
Sinus tachycardia	洞性頻脈	0	0	0	0
Supraventricular tachycardia	上室性頻脈	1 (0.5%)	0	0	0
Tachycardia	頻脈	0	2 (2.2%)	0	0
Ventricular extrasystoles	心室性期外収縮	0	0	0	0
Ear and labyrinth disorders	耳および迷路障害	5 (2.7%)	2 (2.2%)	0	1 (14.3%)
Deafness	難聴	1 (0.5%)	1 (1.1%)	0	0
Deafness unilateral	片耳難聴	0	0	0	1 (14.3%)
Ear pain	耳痛	0	1 (1.1%)	0	0
Hearing impaired	聴覚障害	0	0	0	0
Meniere's disease	メニエール病	1 (0.5%)	0	0	0
Otosalpingitis	耳管炎	1 (0.5%)	0	0	0

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
Tinnitus	耳鳴	1 (0.5%)	0	0	0
Vertigo	回転性めまい	2 (1.1%)	0	0	0
Vertigo positional	頭位性回転性めまい	0	0	0	0
Endocrine disorders	内分泌障害	1 (0.5%)	0	0	0
Cushing's syndrome	クッシング症候群	0	0	0	0
Cushingoid	クッシング様	0	0	0	0
Hyperparathyroidism	副甲状腺機能亢進症	0	0	0	0
Hyperthyroidism	甲状腺機能亢進症	1 (0.5%)	0	0	0
Hypothyroidism	甲状腺機能低下症	0	0	0	0
Eye disorders	眼障害	5 (2.7%)	4 (4.3%)	0	0
Asthenopia	眼精疲労	0	0	0	0
Blepharitis	眼瞼炎	0	0	0	0
Cataract	白内障	2 (1.1%)	0	0	0
Conjunctival haemorrhage	結膜出血	0	0	0	0
Conjunctivitis	結膜炎	0	1 (1.1%)	0	0
Diplopia	複視	0	0	0	0
Dry eye	眼乾燥	0	0	0	0
Eye pain	眼痛	0	0	0	0
Eye swelling	眼部腫脹	0	0	0	0
Eyelid function disorder	眼瞼機能障害	0	0	0	0
Eyelid ptosis	眼瞼下垂	0	0	0	0
Glaucoma	緑内障	0	1 (1.1%)	0	0
Iridocyclitis	虹彩毛様体炎	0	0	0	0
Lacrimation increased	流涙増加	0	1 (1.1%)	0	0
Ocular hyperaemia	眼充血	0	0	0	0
Ocular surface disease	オキュラーサーフェス疾患	0	0	0	0

表 2.7.4.7- 1　年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
Photopsia	光視症	0	0	0	0
Pupils unequal	瞳孔不同	0	0	0	0
Vision blurred	霧視	2 (1.1%)	1 (1.1%)	0	0
Visual acuity reduced	視力低下	1 (0.5%)	0	0	0
Visual disturbance	視覚障害	0	0	0	0
Gastrointestinal disorders	胃腸障害	119 (63.3%)	46 (50.0%)	5 (62.5%)	3 (42.9%)
Abdominal discomfort	腹部不快感	0	0	0	0
Abdominal distension	腹部膨満	4 (2.1%)	0	0	0
Abdominal pain	腹痛	4 (2.1%)	6 (6.5%)	1 (12.5%)	1 (14.3%)
Abdominal pain lower	下腹部痛	0	1 (1.1%)	0	0
Abdominal pain upper	上腹部痛	7 (3.7%)	0	0	0
Anal haemorrhage	肛門出血	0	0	0	0
Anal sphincter atony	肛門括約筋無緊張症	0	0	0	0
Aphthous stomatitis	アフタ性口内炎	0	0	0	0
Ascites	腹水	0	0	0	0
Colitis	大腸炎	1 (0.5%)	0	0	0
Constipation	便秘	33 (17.6%)	16 (17.4%)	1 (12.5%)	0
Defaecation urgency	便意切迫	2 (1.1%)	0	0	0
Dental caries	齲歯	0	1 (1.1%)	0	0
Diarrhoea	下痢	42 (22.3%)	16 (17.4%)	2 (25.0%)	1 (14.3%)
Dry mouth	口内乾燥	4 (2.1%)	2 (2.2%)	1 (12.5%)	0
Duodenal ulcer	十二指腸潰瘍	0	0	0	0
Duodenitis	十二指腸炎	1 (0.5%)	0	0	0
Dyspepsia	消化不良	8 (4.3%)	2 (2.2%)	0	0
Dysphagia	嚥下障害	1 (0.5%)	1 (1.1%)	2 (25.0%)	0
Epigastric discomfort	心窩部不快感	0	1 (1.1%)	0	0
Erosive duodenitis	びらん性十二指腸炎	0	0	0	0

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
Eructation	おくび	2 (1.1%)	0	0	0
Faecal incontinence	便失禁	1 (0.5%)	2 (2.2%)	0	0
Faeces discoloured	変色便	0	1 (1.1%)	0	0
Flatulence	鼓腸	0	0	0	0
Food poisoning	食中毒	0	0	0	0
Frequent bowel movements	排便回数増加	2 (1.1%)	0	0	0
Gastric hypermotility	胃運動過剰	0	0	0	0
Gastric ulcer	胃潰瘍	0	0	0	0
Gastritis	胃炎	1 (0.5%)	3 (3.3%)	0	0
Gastroduodenal ulcer	胃十二指腸潰瘍	0	1 (1.1%)	0	0
Gastrointestinal haemorrhage	胃腸出血	0	0	0	0
Gastrointestinal motility disorder	消化管運動障害	0	0	0	0
Gastrointestinal pain	消化器痛	1 (0.5%)	0	0	0
Gastrooesophageal reflux disease	胃食道逆流性疾患	0	1 (1.1%)	0	0
Gingival bleeding	歯肉出血	0	0	0	0
Gingivitis	歯肉炎	0	0	0	0
Haematemesis	吐血	1 (0.5%)	0	0	0
Haemorrhoidal haemorrhage	痔出血	0	0	0	0
Haemorrhoids	痔核	0	2 (2.2%)	0	0
Hiatus hernia	裂孔ヘルニア	0	0	0	0
Hyperchlorhydria	胃酸過多	3 (1.6%)	0	0	0
Hypoaesthesia oral	口の感覚鈍麻	0	0	0	0
Inguinal hernia	鼠径ヘルニア	1 (0.5%)	0	0	0
Intestinal obstruction	腸閉塞	0	0	0	0
Intestinal perforation	腸管穿孔	0	0	0	0
Large intestine perforation	大腸穿孔	0	0	0	0
Lip swelling	口唇腫脹	0	0	0	0
Melaena	メレナ	0	0	0	0

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
Mouth haemorrhage	口腔内出血	1 (0.5%)	0	0	0
Mouth ulceration	口腔内潰瘍形成	1 (0.5%)	0	0	0
Nausea	悪心	65 (34.6%)	21 (22.8%)	1 (12.5%)	2 (28.6%)
Odynophagia	嚥下痛	1 (0.5%)	0	0	0
Oesophageal obstruction	食道閉塞症	1 (0.5%)	0	0	0
Oesophageal pain	食道痛	0	0	0	0
Oesophageal spasm	食道痙攣	0	0	0	0
Oesophagitis	食道炎	0	0	0	0
Oral pain	口腔内痛	0	0	0	0
Painful defaecation	排便痛	0	1 (1.1%)	0	0
Paresis anal sphincter	肛門括約筋不全麻痺	0	1 (1.1%)	0	0
Periodontal disease	歯周病	0	0	0	0
Proctalgia	肛門周囲痛	0	0	0	0
Rectal discharge	直腸分泌物	0	0	0	0
Rectal haemorrhage	直腸出血	1 (0.5%)	0	0	0
Rectal tenesmus	直腸しぶり	1 (0.5%)	0	0	0
Reflux gastritis	逆流性胃炎	1 (0.5%)	0	0	0
Reflux oesophagitis	逆流性食道炎	0	0	0	0
Retching	レッチング	0	0	0	0
Salivary hypersecretion	流涎過多	0	0	0	0
Small intestinal obstruction	小腸閉塞	0	0	0	0
Stomach discomfort	胃不快感	0	0	0	0
Stomatitis	口内炎	1 (0.5%)	1 (1.1%)	0	0
Subileus	亜イレウス	0	0	0	0
Swollen tongue	舌腫脹	0	0	0	0
Toothache	歯痛	1 (0.5%)	1 (1.1%)	0	0
Upper gastrointestinal haemorrhage	上部消化管出血	0	0	0	0
Vomiting	嘔吐	30 (16.0%)	11 (12.0%)	0	1 (14.3%)

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
General disorders and administration site conditions	全身障害および投与局所様態	78 (41.5%)	48 (52.2%)	4 (50.0%)	3 (42.9%)
Asthenia	無力症	19 (10.1%)	7 (7.6%)	1 (12.5%)	1 (14.3%)
Chest discomfort	胸部不快感	0	1 (1.1%)	0	0
Chest pain	胸痛	0	0	0	0
Chills	悪寒	5 (2.7%)	2 (2.2%)	0	0
Crepitations	捻髪音	1 (0.5%)	0	0	0
Cyst	嚢胞	0	0	0	0
Death	死亡	1 (0.5%)	1 (1.1%)	0	0
Discomfort	不快感	0	0	0	0
Drug intolerance	薬物不耐性	1 (0.5%)	0	0	0
Fatigue	疲労	39 (20.7%)	29 (31.5%)	1 (12.5%)	3 (42.9%)
Feeling cold	冷感	1 (0.5%)	0	0	0
Feeling hot	熱感	0	0	0	0
Gait disturbance	歩行障害	0	2 (2.2%)	0	0
General physical health deterioration	全身健康状態低下	6 (3.2%)	5 (5.4%)	1 (12.5%)	0
Generalised oedema	全身性浮腫	0	0	0	0
Hernia	ヘルニア	0	0	0	0
Induration	硬結	1 (0.5%)	0	0	0
Influenza like illness	インフルエンザ様疾患	1 (0.5%)	0	0	0
Infusion site erythema	注入部位紅斑	0	0	0	0
Injection site pain	注射部位疼痛	0	0	0	0
Injection site rash	注射部位発疹	0	0	0	0
Injection site reaction	注射部位反応	0	0	0	0
Injection site swelling	注射部位腫脹	0	0	0	0
Localised oedema	限局性浮腫	1 (0.5%)	0	0	0
Malaise	倦怠感	3 (1.6%)	0	0	0

表 2.7.4.7- 1　年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
Mucosal inflammation	粘膜の炎症	1 (0.5%)	1 (1.1%)	0	0
Multi-organ failure	多臓器不全	2 (1.1%)	0	0	0
Non-cardiac chest pain	非心臓性胸痛	2 (1.1%)	0	0	0
Oedema	浮腫	2 (1.1%)	2 (2.2%)	0	0
Oedema peripheral	末梢性浮腫	23 (12.2%)	6 (6.5%)	3 (37.5%)	1 (14.3%)
Pain	疼痛	1 (0.5%)	2 (2.2%)	0	0
Peripheral coldness	末梢冷感	1 (0.5%)	0	0	0
Pitting oedema	圧痕浮腫	0	0	0	0
Pyrexia	発熱	9 (4.8%)	6 (6.5%)	0	0
Sudden death	突然死	0	0	0	0
Temperature intolerance	温度変化不耐症	0	0	0	0
Hepatobiliary disorders	肝胆道系障害	3 (1.6%)	0	1 (12.5%)	0
Bile duct obstruction	胆管閉塞	1 (0.5%)	0	0	0
Cholelithiasis	胆石症	0	0	1 (12.5%)	0
Cholestasis	胆汁うっ滞	1 (0.5%)	0	0	0
Hepatic failure	肝不全	1 (0.5%)	0	0	0
Hepatic function abnormal	肝機能異常	0	0	0	0
Hyperbilirubinaemia	高ビリルビン血症	1 (0.5%)	0	0	0
Jaundice	黄疸	0	0	0	0
Immune system disorders	免疫系障害	0	0	0	0
Cytokine release syndrome	サイトカイン放出症候群	0	0	0	0
Hypersensitivity	過敏症	0	0	0	0
Infections and infestations	感染症および寄生虫症	58 (30.9%)	34 (37.0%)	2 (25.0%)	2 (28.6%)
Abscess	膿瘍	0	1 (1.1%)	0	0
Abscess jaw	顎膿瘍	0	0	0	0

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
Arthritis infective	感染性関節炎	0	0	0	0
Bacterial sepsis	細菌性敗血症	0	0	0	0
Bronchitis	気管支炎	2 (1.1%)	1 (1.1%)	0	0
Bronchopneumonia	気管支肺炎	2 (1.1%)	0	0	0
Bursitis infective	感染性滑液包炎	0	0	0	0
Campylobacter infection	カンピロバクター感染	1 (0.5%)	0	0	0
Catheter related infection	カテーテル関連感染	0	0	0	0
Cellulitis	蜂巣炎	2 (1.1%)	0	0	0
Clostridium difficile colitis	クロストリジウム・ディフィシレ大腸炎	0	0	0	0
Cystitis	膀胱炎	3 (1.6%)	5 (5.4%)	0	0
Device related infection	医療機器関連感染	0	0	0	0
Ear infection	耳感染	0	1 (1.1%)	0	0
Erysipelas	丹毒	0	0	0	0
Escherichia urinary tract infection	大腸菌性尿路感染	0	0	0	0
Eye infection	眼感染	3 (1.6%)	0	0	0
Fungal infection	真菌感染	0	0	0	0
Fungal skin infection	皮膚真菌感染	1 (0.5%)	2 (2.2%)	0	0
Gastroenteritis	胃腸炎	1 (0.5%)	0	0	0
Gastroenteritis norovirus	ノロウイルス性胃腸炎	0	1 (1.1%)	0	0
Gastroenteritis viral	ウイルス性胃腸炎	2 (1.1%)	0	0	0
Gingival infection	歯肉感染	0	0	0	0
Haemophilus infection	ヘモフィルス感染	1 (0.5%)	0	0	0
Helicobacter infection	ヘリコバクター感染	0	0	0	0
Herpes simplex	単純ヘルペス	0	0	1 (12.5%)	0
Herpes zoster	帯状疱疹	0	1 (1.1%)	0	0
Hordeolum	麦粒腫	1 (0.5%)	0	0	0
Infection	感染	4 (2.1%)	3 (3.3%)	0	0
Influenza	インフルエンザ	2 (1.1%)	3 (3.3%)	0	0

表 2.7.4.7- 1　年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
Listeriosis	リステリア症	0	0	0	0
Lobar pneumonia	大葉性肺炎	0	0	0	0
Localised infection	限局性感染	1 (0.5%)	0	0	0
Lower respiratory tract infection	下気道感染	3 (1.6%)	1 (1.1%)	0	0
Lower respiratory tract infection bacterial	細菌性下気道感染	1 (0.5%)	0	0	0
Lung infection	肺感染	1 (0.5%)	0	0	0
Nail infection	爪感染	0	0	0	0
Nasopharyngitis	鼻咽頭炎	2 (1.1%)	2 (2.2%)	0	1 (14.3%)
Oral candidiasis	口腔カンジダ症	1 (0.5%)	3 (3.3%)	1 (12.5%)	0
Oral fungal infection	口腔真菌感染	1 (0.5%)	0	0	0
Oral herpes	口腔ヘルペス	0	0	0	0
Oral infection	口腔感染	0	0	0	0
Paronychia	爪囲炎	1 (0.5%)	0	0	0
Peritonitis bacterial	細菌性腹膜炎	0	0	0	0
Pharyngitis	咽頭炎	2 (1.1%)	0	0	0
Pilonidal cyst	毛巣嚢胞	0	0	0	0
Pneumonia	肺炎	4 (2.1%)	5 (5.4%)	0	0
Pneumonia primary atypical	原発性異型肺炎	1 (0.5%)	0	0	0
Post procedural infection	処置後感染	0	1 (1.1%)	0	1 (14.3%)
Postoperative wound infection	術後創感染	0	0	0	0
Pyelonephritis	腎盂腎炎	0	0	0	0
Pyonephrosis	膿腎症	0	0	0	0
Respiratory tract infection	気道感染	2 (1.1%)	1 (1.1%)	0	0
Respiratory tract infection viral	ウイルス性気道感染	0	0	0	0
Rhinitis	鼻炎	1 (0.5%)	0	0	0
Sepsis	敗血症	1 (0.5%)	3 (3.3%)	0	0
Sinusitis	副鼻腔炎	0	1 (1.1%)	0	0

表 2.7.4.7- 1　年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
Skin infection	皮膚感染	0	0	0	0
Soft tissue infection	軟部組織感染	1 (0.5%)	0	0	0
Staphylococcal infection	ブドウ球菌感染	0	0	0	0
Subcutaneous abscess	皮下組織膿瘍	0	0	0	0
Tinea pedis	足部白癬	1 (0.5%)	0	0	0
Tooth infection	歯感染	1 (0.5%)	0	0	0
Upper respiratory tract infection	上気道感染	0	0	0	0
Upper respiratory tract infection bacterial	細菌性上気道感染	0	0	0	0
Urinary tract infection	尿路感染	17 (9.0%)	11 (12.0%)	2 (25.0%)	1 (14.3%)
Urosepsis	尿路性敗血症	0	0	0	0
Viral infection	ウイルス感染	2 (1.1%)	0	0	0
Viral skin infection	皮膚ウイルス感染	0	0	0	0
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	23 (12.2%)	3 (3.3%)	1 (12.5%)	1 (14.3%)
Accidental overdose	偶発的過量投与	0	0	0	0
Ankle fracture	足関節部骨折	0	0	0	0
Back injury	背部損傷	2 (1.1%)	0	0	0
Compression fracture	圧迫骨折	0	0	0	0
Contusion	挫傷	3 (1.6%)	0	0	1 (14.3%)
Cystitis radiation	放射線性膀胱炎	1 (0.5%)	0	0	0
Device dislocation	医療機器位置異常	0	0	0	0
Excoriation	擦過傷	0	0	1 (12.5%)	0
Extradural haematoma	硬膜外血腫	0	0	0	0
Fall	転倒・転落	5 (2.7%)	1 (1.1%)	0	0
Femoral neck fracture	大腿骨頚部骨折	0	0	0	0
Foot fracture	足骨折	0	0	0	0

表 2.7.4.7- 1　年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
Gastroenteritis radiation	放射線胃腸炎	0	1 (1.1%)	0	0
Hand fracture	手骨折	0	1 (1.1%)	0	0
Head injury	頭部損傷	0	0	0	0
Hip fracture	股関節部骨折	1 (0.5%)	0	0	0
Injury	損傷	0	0	0	0
Intentional overdose	企図的過量投与	0	0	0	0
Joint injury	関節損傷	0	0	0	0
Joint sprain	関節捻挫	0	0	0	0
Laceration	裂傷	0	1 (1.1%)	0	0
Ligament injury	靭帯損傷	0	0	0	0
Lower limb fracture	下肢骨折	0	0	0	0
Medical device complication	医療機器合併症	1 (0.5%)	0	0	0
Medical device pain	医療機器による疼痛	0	1 (1.1%)	0	0
Meniscus lesion	半月板障害	0	0	0	0
Mouth injury	口腔内損傷	1 (0.5%)	0	0	0
Muscle strain	筋挫傷	0	0	0	0
Nail avulsion	爪裂離	1 (0.5%)	0	0	0
Patella fracture	膝蓋骨骨折	1 (0.5%)	0	0	0
Post-traumatic pain	外傷後疼痛	1 (0.5%)	1 (1.1%)	0	0
Procedural pain	処置による疼痛	0	0	0	0
Radiation associated pain	放射線関連痛	0	0	0	0
Radiation skin injury	放射線皮膚損傷	1 (0.5%)	0	0	0
Radius fracture	橈骨骨折	0	0	0	0
Rib fracture	肋骨骨折	0	0	0	0
Skin laceration	皮膚裂傷	1 (0.5%)	0	0	0
Spinal compression fracture	脊椎圧迫骨折	2 (1.1%)	0	0	0
Stent occlusion	ステント閉塞	0	0	0	0
Sternal fracture	胸骨骨折	1 (0.5%)	0	0	0

表 2.7.4.7- 1　年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
Stomatitis radiation	放射線口内炎	0	0	0	0
Stress fracture	ストレス骨折	0	0	0	0
Subcutaneous haematoma	皮下血腫	0	0	0	0
Tendon rupture	腱断裂	0	0	0	0
Therapeutic agent toxicity	治療薬毒性	0	0	0	0
Thermal burn	熱傷	0	0	0	0
Tooth fracture	歯牙破折	0	0	0	0
Upper limb fracture	上肢骨折	0	0	0	0
Wound	創傷	2 (1.1%)	0	0	0
Investigations	臨床検査	35 (18.6%)	19 (20.7%)	3 (37.5%)	3 (42.9%)
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	3 (1.6%)	1 (1.1%)	0	0
Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3 (1.6%)	1 (1.1%)	0	1 (14.3%)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	4 (2.1%)	3 (3.3%)	1 (12.5%)	0
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	0	0	0	0
Blood creatinine increased	血中クレアチニン増加	0	0	0	0
Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	2 (1.1%)	3 (3.3%)	0	0
Blood urea increased	血中尿素増加	1 (0.5%)	2 (2.2%)	0	0
Breath sounds abnormal	呼吸音異常	1 (0.5%)	0	0	0
Cardiac murmur	心雑音	0	1 (1.1%)	0	0
Coagulation factor VII level increased	凝固第ＶＩＩ因子量増加	0	0	0	0
Electrocardiogram QT prolonged	心電図ＱＴ延長	0	0	0	0
Fibrin D dimer increased	フィブリンＤダイマー増加	1 (0.5%)	0	0	0
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	2 (1.1%)	1 (1.1%)	1 (12.5%)	0
Liver function test abnormal	肝機能検査異常	1 (0.5%)	0	0	0
Prostatic specific antigen increased	前立腺特異性抗原増加	0	0	0	0
Troponin T increased	トロポニンＴ増加	1 (0.5%)	0	0	0
Urine analysis abnormal	尿検査異常	0	0	0	0

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
Urine output increased	尿量増加	0	0	0	0
Weight decreased	体重減少	24 (12.8%)	12 (13.0%)	1 (12.5%)	2 (28.6%)
Weight increased	体重増加	1 (0.5%)	0	0	0
Metabolism and nutrition disorders	代謝および栄養障害	62 (33.0%)	32 (34.8%)	4 (50.0%)	4 (57.1%)
Anorexia	食欲不振	36 (19.1%)	19 (20.7%)	3 (37.5%)	2 (28.6%)
Cachexia	悪液質	2 (1.1%)	2 (2.2%)	0	0
Decreased appetite	食欲減退	13 (6.9%)	2 (2.2%)	0	1 (14.3%)
Dehydration	脱水	8 (4.3%)	2 (2.2%)	1 (12.5%)	1 (14.3%)
Diabetes mellitus	糖尿病	0	2 (2.2%)	0	0
Dyslipidaemia	異脂肪血症	0	0	0	0
Fluid intake reduced	水分摂取量減少	1 (0.5%)	0	0	0
Fluid overload	水分過負荷	1 (0.5%)	0	0	0
Gout	痛風	0	0	0	0
Hypercalcaemia	高カルシウム血症	1 (0.5%)	0	0	0
Hypercholesterolaemia	高コレステロール血症	1 (0.5%)	0	0	0
Hypercreatininaemia	高クレアチニン血症	0	2 (2.2%)	0	0
Hyperglycaemia	高血糖	1 (0.5%)	0	0	0
Hyperkalaemia	高カリウム血症	1 (0.5%)	2 (2.2%)	0	0
Hypernatraemia	高ナトリウム血症	0	1 (1.1%)	0	0
Hyperuricaemia	高尿酸血症	1 (0.5%)	1 (1.1%)	0	0
Hypoalbuminaemia	低アルブミン血症	1 (0.5%)	0	0	0
Hypocalcaemia	低カルシウム血症	2 (1.1%)	1 (1.1%)	0	0
Hypoglycaemia	低血糖症	0	0	0	0
Hypokalaemia	低カリウム血症	6 (3.2%)	2 (2.2%)	0	0
Hypomagnesaemia	低マグネシウム血症	1 (0.5%)	0	0	0
Hyponatraemia	低ナトリウム血症	0	0	0	0
Hypophosphataemia	低リン酸血症	2 (1.1%)	2 (2.2%)	0	0

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
Hypovitaminosis	ビタミン欠乏症	0	0	0	0
Increased appetite	食欲亢進	0	0	0	0
Magnesium deficiency	マグネシウム欠乏	0	0	0	0
Malnutrition	栄養障害	0	0	0	0
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	102 (54.3%)	62 (67.4%)	4 (50.0%)	6 (85.7%)
Arthralgia	関節痛	8 (4.3%)	3 (3.3%)	0	0
Back pain	背部痛	1 (0.5%)	2 (2.2%)	0	0
Bone lesion	骨病変	0	0	0	0
Bone pain	骨痛	86 (45.7%)	51 (55.4%)	4 (50.0%)	6 (85.7%)
Bursitis	滑液包炎	0	0	0	0
Flank pain	側腹部痛	0	0	0	0
Groin pain	鼠径部痛	0	0	0	0
Intervertebral disc degeneration	椎間板変性症	0	0	0	0
Intervertebral disc disorder	椎間板障害	0	0	0	0
Intervertebral disc protrusion	椎間板突出	0	0	0	0
Joint effusion	関節滲出液	1 (0.5%)	0	0	0
Joint instability	関節不安定	1 (0.5%)	0	0	0
Joint lock	関節ロック	0	0	0	1 (14.3%)
Joint range of motion decreased	関節運動範囲減少	0	0	0	0
Joint stiffness	関節硬直	0	1 (1.1%)	0	0
Joint swelling	関節腫脹	1 (0.5%)	1 (1.1%)	0	0
Kyphosis	脊柱後弯症	1 (0.5%)	0	0	0
Mobility decreased	運動性低下	5 (2.7%)	0	0	0
Muscle spasms	筋痙縮	0	1 (1.1%)	0	0
Muscular weakness	筋力低下	5 (2.7%)	8 (8.7%)	0	0
Musculoskeletal chest pain	筋骨格系胸痛	1 (0.5%)	0	0	1 (14.3%)

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
Musculoskeletal discomfort	筋骨格不快感	0	0	0	0
Musculoskeletal pain	筋骨格痛	10 (5.3%)	3 (3.3%)	0	2 (28.6%)
Musculoskeletal stiffness	筋骨格硬直	1 (0.5%)	0	0	0
Myalgia	筋痛	3 (1.6%)	5 (5.4%)	0	0
Myopathy	ミオパチー	1 (0.5%)	1 (1.1%)	0	0
Myositis	筋炎	0	0	0	0
Neck pain	頚部痛	0	0	0	0
Osteoarthritis	骨関節炎	0	0	0	0
Osteolysis	骨溶解	0	0	0	0
Osteomalacia	骨軟化症	0	0	0	0
Osteonecrosis	骨壊死	0	0	0	0
Osteoporosis	骨粗鬆症	1 (0.5%)	1 (1.1%)	0	0
Pain in extremity	四肢痛	3 (1.6%)	1 (1.1%)	0	0
Pain in jaw	顎痛	0	0	0	0
Pathological fracture	病的骨折	11 (5.9%)	4 (4.3%)	1 (12.5%)	0
Spinal column stenosis	脊柱管狭窄症	0	0	0	0
Spinal osteoarthritis	変形性脊椎炎	0	1 (1.1%)	0	0
Synovial cyst	滑液嚢腫	0	0	0	0
Tendonitis	腱炎	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	39 (20.7%)	14 (15.2%)	1 (12.5%)	0
Benign neoplasm	良性新生物	0	0	0	0
Benign neoplasm of bladder	膀胱の良性新生物	1 (0.5%)	0	0	0
Benign soft tissue neoplasm	軟部組織の良性新生物	1 (0.5%)	0	0	0
Benign urinary tract neoplasm	尿路の良性新生物	0	0	0	0
Bladder cancer	膀胱癌	1 (0.5%)	0	0	0
Bone marrow tumour cell infiltration	腫瘍細胞の骨髄浸潤	1 (0.5%)	0	0	0

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
Fibroma	線維腫	0	0	0	0
Gastric cancer	胃癌	0	1 (1.1%)	0	0
Haemangioma	血管腫	1 (0.5%)	0	0	0
Lymphangiosis carcinomatosa	癌性リンパ管症	0	0	0	0
Malignant neoplasm progression	悪性新生物進行	28 (14.9%)	12 (13.0%)	1 (12.5%)	0
Metastases to bone	骨転移	1 (0.5%)	1 (1.1%)	0	0
Metastases to central nervous system	中枢神経系転移	3 (1.6%)	0	0	0
Metastases to liver	肝転移	0	0	0	0
Metastases to lung	肺転移	1 (0.5%)	0	0	0
Metastases to lymph nodes	リンパ節転移	0	0	0	0
Metastases to meninges	髄膜転移	0	0	0	0
Metastases to nervous system	神経系転移	0	0	0	0
Metastases to skin	皮膚転移	0	0	0	0
Metastases to soft tissue	軟部組織転移	0	0	0	0
Neoplasm	新生物	0	0	0	0
Neoplasm skin	皮膚の新生物	0	0	0	0
Seborrhoeic keratosis	脂漏性角化症	1 (0.5%)	0	0	0
Skin cancer	皮膚癌	1 (0.5%)	0	0	0
Skin papilloma	皮膚乳頭腫	0	0	0	0
Squamous cell carcinoma	扁平上皮癌	1 (0.5%)	0	0	0
Squamous cell carcinoma of skin	皮膚有棘細胞癌	0	0	0	0
Tumour associated fever	腫瘍熱	0	0	0	0
Nervous system disorders	神経系障害	41 (21.8%)	41 (44.6%)	2 (25.0%)	2 (28.6%)
Ageusia	味覚消失	0	0	0	0
Amnesia	健忘	0	1 (1.1%)	0	0
Aphasia	失語症	1 (0.5%)	0	0	0
Apraxia	失行症	0	1 (1.1%)	0	0

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
Ataxia	運動失調	1 (0.5%)	0	0	0
Balance disorder	平衡障害	3 (1.6%)	1 (1.1%)	0	0
Brachial plexopathy	腕神経叢障害	0	1 (1.1%)	0	0
Brain oedema	脳浮腫	0	0	0	0
Burning sensation	灼熱感	0	1 (1.1%)	0	0
Cauda equina syndrome	馬尾症候群	1 (0.5%)	0	0	0
Cerebral haemorrhage	脳出血	0	2 (2.2%)	0	0
Cerebral ischaemia	脳虚血	0	3 (3.3%)	0	0
Cerebrovascular accident	脳血管発作	1 (0.5%)	0	0	0
Cognitive disorder	認知障害	0	1 (1.1%)	0	0
Convulsion	痙攣	0	1 (1.1%)	0	0
Cranial neuropathy	脳ニューロパチー	0	1 (1.1%)	0	0
Dementia	認知症	0	1 (1.1%)	0	0
Dementia Alzheimer's type	アルツハイマー型認知症	1 (0.5%)	0	0	0
Disturbance in attention	注意力障害	1 (0.5%)	0	0	0
Dizziness	浮動性めまい	16 (8.5%)	11 (12.0%)	0	1 (14.3%)
Dizziness postural	体位性めまい	1 (0.5%)	0	0	0
Dysaesthesia	異常感覚	0	0	0	0
Dysarthria	構語障害	1 (0.5%)	0	0	0
Dysgeusia	味覚異常	3 (1.6%)	1 (1.1%)	0	0
Dysphasia	不全失語症	1 (0.5%)	0	0	0
Dystonia	ジストニー	0	0	0	0
Epilepsy	てんかん	0	1 (1.1%)	0	0
Facial palsy	顔面神経麻痺	0	0	0	1 (14.3%)
Facial paresis	顔面不全麻痺	0	0	0	0
Haemorrhage intracranial	頭蓋内出血	0	0	0	0
Headache	頭痛	5 (2.7%)	0	1 (12.5%)	0
Hydrocephalus	水頭症	1 (0.5%)	1 (1.1%)	0	0

表 2.7.4.7- 1　年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
Hyperaesthesia	知覚過敏	1 (0.5%)	0	0	0
Hypoaesthesia	感覚鈍麻	4 (2.1%)	2 (2.2%)	0	1 (14.3%)
Ischaemic stroke	虚血性脳卒中	0	0	0	0
Lethargy	嗜眠	4 (2.1%)	5 (5.4%)	0	0
Loss of consciousness	意識消失	1 (0.5%)	0	0	0
Memory impairment	記憶障害	0	0	0	0
Migraine with aura	前兆を伴う片頭痛	0	0	0	0
Monoparesis	不全単麻痺	0	0	0	0
Myasthenia gravis	重症筋無力症	0	0	0	0
Nerve root compression	神経根圧迫	1 (0.5%)	0	0	0
Neuralgia	神経痛	1 (0.5%)	0	0	0
Neuropathy peripheral	末梢性ニューロパチー	0	0	0	0
Paraesthesia	錯感覚	2 (1.1%)	0	0	0
Paraparesis	不全対麻痺	0	0	0	0
Paraplegia	対麻痺	0	0	0	0
Paresis cranial nerve	脳神経不全麻痺	0	0	0	0
Parosmia	嗅覚錯誤	0	0	0	0
Peripheral motor neuropathy	末梢性運動ニューロパチー	2 (1.1%)	6 (6.5%)	1 (12.5%)	0
Peripheral sensory neuropathy	末梢性感覚ニューロパチー	0	2 (2.2%)	1 (12.5%)	0
Peroneal nerve palsy	腓骨神経麻痺	0	0	0	0
Polyneuropathy	多発ニューロパチー	0	1 (1.1%)	0	0
Radicular syndrome	根症候群	0	0	0	0
Restless legs syndrome	下肢静止不能症候群	0	0	0	0
Sciatica	坐骨神経痛	0	0	0	0
Somnolence	傾眠	0	0	1 (12.5%)	0
Speech disorder	会話障害	1 (0.5%)	0	0	0
Spinal cord compression	脊髄圧迫	4 (2.1%)	7 (7.6%)	1 (12.5%)	0
Syncope	失神	0	2 (2.2%)	0	0

表 2.7.4.7- 1　年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
Syncope vasovagal	血管迷走神経性失神	1 (0.5%)	0	0	0
Tongue paralysis	舌の麻痺	0	0	0	0
Transient ischaemic attack	一過性脳虚血発作	0	1 (1.1%)	0	0
Tremor	振戦	1 (0.5%)	0	0	0
Trigeminal palsy	三叉神経麻痺	0	0	0	0
VIth nerve paralysis	第６脳神経麻痺	0	0	0	0
Psychiatric disorders	精神障害	26 (13.8%)	15 (16.3%)	1 (12.5%)	1 (14.3%)
Aggression	攻撃性	1 (0.5%)	0	0	0
Agitation	激越	1 (0.5%)	0	0	0
Anhedonia	快感消失	0	0	0	0
Anxiety	不安	2 (1.1%)	4 (4.3%)	0	0
Confusional state	錯乱状態	8 (4.3%)	5 (5.4%)	1 (12.5%)	0
Depressed mood	抑うつ気分	2 (1.1%)	0	0	0
Depression	うつ病	5 (2.7%)	5 (5.4%)	1 (12.5%)	1 (14.3%)
Disorientation	失見当識	0	1 (1.1%)	0	0
Hallucination	幻覚	1 (0.5%)	0	0	0
Insomnia	不眠症	6 (3.2%)	3 (3.3%)	0	0
Intentional self-injury	故意の自傷行為	0	0	0	0
Mania	躁病	1 (0.5%)	0	0	0
Mental status changes	精神状態変化	0	0	0	0
Mood altered	気分変化	1 (0.5%)	0	0	0
Nightmare	悪夢	0	0	0	0
Sleep disorder	睡眠障害	2 (1.1%)	0	0	0
Suicide attempt	自殺企図	0	0	0	0
Renal and urinary disorders	腎および尿路障害	44 (23.4%)	21 (22.8%)	0	0
Acute prerenal failure	急性腎前性腎不全	0	0	0	0

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
Calculus ureteric	尿管結石	1 (0.5%)	0	0	0
Chromaturia	着色尿	1 (0.5%)	1 (1.1%)	0	0
Dysuria	排尿困難	6 (3.2%)	1 (1.1%)	0	0
Haematuria	血尿	14 (7.4%)	4 (4.3%)	0	0
Haemorrhage urinary tract	尿路出血	0	1 (1.1%)	0	0
Hydronephrosis	水腎症	3 (1.6%)	0	0	0
Hypertonic bladder	緊張性膀胱	1 (0.5%)	0	0	0
Micturition disorder	排尿異常	2 (1.1%)	2 (2.2%)	0	0
Micturition frequency decreased	排尿回数減少	0	0	0	0
Micturition urgency	尿意切迫	0	0	0	0
Mixed incontinence	混合性尿失禁	0	0	0	0
Nephrolithiasis	腎結石症	0	0	0	0
Nocturia	夜間頻尿	2 (1.1%)	2 (2.2%)	0	0
Pollakiuria	頻尿	6 (3.2%)	3 (3.3%)	0	0
Renal failure	腎不全	5 (2.7%)	0	0	0
Renal failure acute	急性腎不全	1 (0.5%)	1 (1.1%)	0	0
Renal impairment	腎機能障害	0	0	0	0
Renal tubular necrosis	腎尿細管壊死	0	0	0	0
Strangury	有痛性排尿困難	0	0	0	0
Stress urinary incontinence	腹圧性尿失禁	0	0	0	0
Ureteric obstruction	尿管閉塞	0	0	0	0
Urethral obstruction	尿道閉塞	0	0	0	0
Urge incontinence	切迫性尿失禁	0	0	0	0
Urinary bladder haemorrhage	膀胱出血	0	0	0	0
Urinary hesitation	排尿躊躇	0	0	0	0
Urinary incontinence	尿失禁	6 (3.2%)	3 (3.3%)	0	0
Urinary retention	尿閉	12 (6.4%)	7 (7.6%)	0	0
Urinary tract obstruction	尿路閉塞	0	0	0	0

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
Urine flow decreased	尿流量減少	1 (0.5%)	1 (1.1%)	0	0
Urogenital disorder	尿生殖器障害	0	0	0	0
Reproductive system and breast disorders	生殖系および乳房障害	7 (3.7%)	0	0	0
Benign prostatic hyperplasia	良性前立腺肥大症	1 (0.5%)	0	0	0
Breast mass	乳房腫瘤	0	0	0	0
Breast pain	乳房痛	0	0	0	0
Breast tenderness	乳房圧痛	0	0	0	0
Genital pain	生殖器痛	0	0	0	0
Gynaecomastia	女性化乳房	2 (1.1%)	0	0	0
Nipple pain	乳頭痛	0	0	0	0
Oedema genital	性器浮腫	3 (1.6%)	0	0	0
Pelvic pain	骨盤痛	0	0	0	0
Perineal pain	会陰痛	0	0	0	0
Posthitis	包皮炎	0	0	0	0
Prostatic haemorrhage	前立腺出血	0	0	0	0
Prostatitis	前立腺炎	1 (0.5%)	0	0	0
Scrotal oedema	陰嚢浮腫	0	0	0	0
Scrotal swelling	陰嚢腫脹	0	0	0	0
Scrotal ulcer	陰嚢潰瘍	1 (0.5%)	0	0	0
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	37 (19.7%)	22 (23.9%)	2 (25.0%)	1 (14.3%)
Acute pulmonary oedema	急性肺水腫	0	0	0	0
Atelectasis	無気肺	0	0	0	0
Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	1 (0.5%)	1 (1.1%)	0	0
Chronic respiratory failure	慢性呼吸不全	0	1 (1.1%)	0	0
Cough	咳嗽	10 (5.3%)	5 (5.4%)	1 (12.5%)	0

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
Dysphonia	発声障害	0	0	1 (12.5%)	0
Dyspnoea	呼吸困難	18 (9.6%)	10 (10.9%)	1 (12.5%)	0
Dyspnoea exertional	労作性呼吸困難	2 (1.1%)	1 (1.1%)	0	0
Epistaxis	鼻出血	0	2 (2.2%)	0	0
Haemoptysis	喀血	0	0	0	0
Hiccups	しゃっくり	2 (1.1%)	0	0	0
Hypoxia	低酸素症	1 (0.5%)	1 (1.1%)	0	0
Increased bronchial secretion	気管支分泌増加	0	0	0	0
Increased upper airway secretion	上気道分泌増加	1 (0.5%)	0	0	0
Lung consolidation	肺硬化	1 (0.5%)	0	0	0
Nasal congestion	鼻閉	0	1 (1.1%)	0	0
Nasal discomfort	鼻部不快感	0	0	0	0
Pharyngolaryngeal pain	咽喉頭疼痛	0	1 (1.1%)	0	0
Pleural effusion	胸水	5 (2.7%)	1 (1.1%)	0	1 (14.3%)
Pleurisy	胸膜炎	0	0	0	0
Pleuritic pain	胸膜痛	0	0	0	0
Pneumonia aspiration	嚥下性肺炎	0	1 (1.1%)	0	0
Pneumonitis	肺臓炎	1 (0.5%)	0	0	0
Postnasal drip	後鼻漏	0	0	0	0
Productive cough	湿性咳嗽	0	1 (1.1%)	0	0
Pulmonary congestion	肺うっ血	0	0	0	0
Pulmonary embolism	肺塞栓症	2 (1.1%)	3 (3.3%)	0	0
Pulmonary haemorrhage	肺出血	0	0	0	0
Pulmonary hypertension	肺高血圧症	0	0	0	0
Pulmonary oedema	肺水腫	2 (1.1%)	1 (1.1%)	0	0
Rales	ラ音	0	0	0	0
Respiratory failure	呼吸不全	0	1 (1.1%)	0	0
Rhinorrhoea	鼻漏	1 (0.5%)	1 (1.1%)	0	0

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
Tachypnoea	頻呼吸	0	1 (1.1%)	0	0
Vasomotor rhinitis	血管運動性鼻炎	0	0	0	0
Wheezing	喘鳴	1 (0.5%)	0	0	0
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	23 (12.2%)	12 (13.0%)	1 (12.5%)	0
Actinic keratosis	日光性角化症	2 (1.1%)	0	0	0
Alopecia	脱毛症	3 (1.6%)	0	0	0
Decubitus ulcer	褥瘡性潰瘍	1 (0.5%)	0	1 (12.5%)	0
Dermatitis	皮膚炎	0	1 (1.1%)	0	0
Dermatitis acneiform	ざ瘡様皮膚炎	0	0	0	0
Dermatitis allergic	アレルギー性皮膚炎	0	0	0	0
Dermatitis contact	接触性皮膚炎	0	0	0	0
Dry skin	皮膚乾燥	2 (1.1%)	0	0	0
Eczema	湿疹	0	0	0	0
Erythema	紅斑	0	2 (2.2%)	0	0
Hyperhidrosis	多汗症	2 (1.1%)	1 (1.1%)	0	0
Hypoaesthesia facial	顔面感覚鈍麻	0	1 (1.1%)	0	0
Increased tendency to bruise	挫傷発生の増加傾向	1 (0.5%)	0	0	0
Ingrowing nail	嵌入爪	0	0	0	0
Intertrigo	間擦疹	0	0	0	0
Nail disorder	爪の障害	0	0	0	0
Night sweats	寝汗	2 (1.1%)	1 (1.1%)	0	0
Onycholysis	爪甲離床症	0	0	0	0
Pain of skin	皮膚疼痛	0	0	0	0
Palmar erythema	手掌紅斑	0	0	0	0
Periorbital oedema	眼窩周囲浮腫	1 (0.5%)	0	0	0
Petechiae	点状出血	0	0	0	0
Pigmentation disorder	色素沈着障害	0	0	0	0

表 2.7.4.7- 1 年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
Pruritus	そう痒症	2 (1.1%)	2 (2.2%)	0	0
Psoriasis	乾癬	0	1 (1.1%)	0	0
Purpura	紫斑	0	0	0	0
Rash	発疹	6 (3.2%)	3 (3.3%)	0	0
Rash erythematous	紅斑性皮疹	0	0	0	0
Rash pruritic	そう痒性皮疹	0	1 (1.1%)	0	0
Skin atrophy	皮膚萎縮	0	0	0	0
Skin discolouration	皮膚変色	1 (0.5%)	0	0	0
Skin disorder	皮膚障害	0	0	0	0
Skin exfoliation	皮膚剥脱	0	0	0	0
Skin hyperpigmentation	皮膚色素過剰	0	0	0	0
Skin irritation	皮膚刺激	1 (0.5%)	0	0	0
Skin lesion	皮膚病変	0	1 (1.1%)	0	0
Skin nodule	皮膚小結節	0	0	0	0
Skin odour abnormal	皮膚異常臭	0	0	0	0
Skin reaction	皮膚反応	0	0	0	0
Swelling face	顔面腫脹	0	1 (1.1%)	0	0
Urticaria	蕁麻疹	0	0	0	0
Surgical and medical procedures	外科および内科処置	0	0	0	0
Tooth extraction	抜歯	0	0	0	0
Vascular disorders	血管障害	12 (6.4%)	8 (8.7%)	0	1 (14.3%)
Circulatory collapse	循環虚脱	0	0	0	0
Deep vein thrombosis	深部静脈血栓症	1 (0.5%)	0	0	0
Flushing	潮紅	0	0	0	1 (14.3%)
Haematoma	血腫	2 (1.1%)	0	0	0
Hot flush	ほてり	1 (0.5%)	2 (2.2%)	0	0

表 2.7.4.7- 1　年齢別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	75-84 years BAY 88-8223 N=188 (100%)	75-84 years Placebo N=92 (100%)	>=84 years BAY 88-8223 N=8 (100%)	>=84 years Placebo N=7 (100%)
Hypertension	高血圧	3 (1.6%)	0	0	0
Hypertensive crisis	高血圧性クリーゼ	0	0	0	0
Hypotension	低血圧	3 (1.6%)	4 (4.3%)	0	0
Orthostatic hypotension	起立性低血圧	1 (0.5%)	1 (1.1%)	0	0
Pallor	蒼白	1 (0.5%)	0	0	0
Phlebitis	静脈炎	0	0	0	0
Thrombophlebitis	血栓性静脈炎	0	0	0	0
Thrombosis	血栓症	0	1 (1.1%)	0	0
Vasculitis	血管炎	0	0	0	0
Venous thrombosis	静脈血栓症	0	0	0	0
Venous thrombosis limb	四肢静脈血栓症	0	0	0	0

Source: 5.3.5.1.4 BC1-06_J-table 2/Table 1.1/3

表 2.7.4.7- 2　ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Number of subjects (%) with at least one adverse event	Number of subjects (%) with at least one adverse event	333 (96.0%)	169 (98.8%)	230 (90.9%)	122 (93.8%)
Blood and lymphatic system disorders	血液およびリンパ系障害	154 (44.4%)	68 (39.8%)	79 (31.2%)	38 (29.2%)
Anaemia	貧血	120 (34.6%)	61 (35.7%)	67 (26.5%)	31 (23.8%)
Bone marrow failure	骨髄機能不全	1 (0.3%)	0	0	0
Disseminated intravascular coagulation	播種性血管内凝固	0	1 (0.6%)	1 (0.4%)	0
Erythropenia	赤血球減少症	1 (0.3%)	0	0	0
Febrile neutropenia	発熱性好中球減少症	0	0	1 (0.4%)	1 (0.8%)
Hypochromic anaemia	低色素性貧血	0	1 (0.6%)	0	0
Leukocytosis	白血球増加症	0	0	1 (0.4%)	0
Leukopenia	白血球減少症	21 (6.1%)	1 (0.6%)	4 (1.6%)	0
Lymphadenopathy	リンパ節症	13 (3.7%)	2 (1.2%)	3 (1.2%)	2 (1.5%)
Lymphadenopathy mediastinal	縦隔リンパ節腫脹	1 (0.3%)	0	0	0
Lymphopenia	リンパ球減少症	3 (0.9%)	1 (0.6%)	2 (0.8%)	0
Neutropenia	好中球減少症	24 (6.9%)	2 (1.2%)	6 (2.4%)	1 (0.8%)
Neutrophilia	好中球増加症	0	0	0	1 (0.8%)
Pancytopenia	汎血球減少症	10 (2.9%)	0	2 (0.8%)	0
Thrombocythaemia	血小板血症	1 (0.3%)	0	0	0
Thrombocytopenia	血小板減少症	53 (15.3%)	13 (7.6%)	16 (6.3%)	4 (3.1%)
Cardiac disorders	心臓障害	30 (8.6%)	18 (10.5%)	20 (7.9%)	11 (8.5%)
Acute coronary syndrome	急性冠動脈症候群	1 (0.3%)	0	0	0
Acute myocardial infarction	急性心筋梗塞	0	1 (0.6%)	1 (0.4%)	2 (1.5%)
Angina pectoris	狭心症	6 (1.7%)	0	2 (0.8%)	2 (1.5%)

表 2.7.4.7- 2　ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Aortic valve stenosis	大動脈弁狭窄	0	0	1 (0.4%)	0
Arrhythmia	不整脈	0	1 (0.6%)	1 (0.4%)	1 (0.8%)
Atrial fibrillation	心房細動	7 (2.0%)	3 (1.8%)	2 (0.8%)	3 (2.3%)
Atrial flutter	心房粗動	1 (0.3%)	2 (1.2%)	0	0
Atrial tachycardia	心房頻脈	0	0	1 (0.4%)	0
Atrioventricular block complete	完全房室ブロック	0	0	0	1 (0.8%)
Bradycardia	徐脈	1 (0.3%)	0	0	0
Cardiac arrest	心停止	0	1 (0.6%)	0	0
Cardiac failure	心不全	3 (0.9%)	2 (1.2%)	1 (0.4%)	2 (1.5%)
Cardiac failure congestive	うっ血性心不全	2 (0.6%)	1 (0.6%)	3 (1.2%)	1 (0.8%)
Cardiomegaly	心拡大	1 (0.3%)	0	0	0
Cardiopulmonary failure	心肺不全	0	0	1 (0.4%)	1 (0.8%)
Coronary artery disease	冠動脈疾患	1 (0.3%)	0	0	0
Left ventricular dysfunction	左室機能不全	0	1 (0.6%)	1 (0.4%)	0
Left ventricular failure	左室不全	0	0	0	1 (0.8%)
Myocardial infarction	心筋梗塞	0	3 (1.8%)	3 (1.2%)	1 (0.8%)
Myocardial ischaemia	心筋虚血	1 (0.3%)	0	1 (0.4%)	0
Palpitations	動悸	4 (1.2%)	1 (0.6%)	1 (0.4%)	0
Pericardial effusion	心嚢液貯留	1 (0.3%)	1 (0.6%)	0	0
Sinus tachycardia	洞性頻脈	3 (0.9%)	1 (0.6%)	0	0
Supraventricular tachycardia	上室性頻脈	2 (0.6%)	0	1 (0.4%)	0
Tachycardia	頻脈	0	1 (0.6%)	1 (0.4%)	4 (3.1%)
Ventricular extrasystoles	心室性期外収縮	0	0	1 (0.4%)	0
Ear and labyrinth disorders	耳および迷路障害	9 (2.6%)	3 (1.8%)	5 (2.0%)	2 (1.5%)
Deafness	難聴	1 (0.3%)	1 (0.6%)	2 (0.8%)	0
Deafness unilateral	片耳難聴	0	0	0	1 (0.8%)

表 2.7.4.7- 2　ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Ear pain	耳痛	0	1 (0.6%)	0	0
Hearing impaired	聴覚障害	1 (0.3%)	0	0	0
Meniere's disease	メニエール病	0	0	1 (0.4%)	0
Otosalpingitis	耳管炎	0	0	1 (0.4%)	0
Tinnitus	耳鳴	2 (0.6%)	0	1 (0.4%)	0
Vertigo	回転性めまい	5 (1.4%)	1 (0.6%)	1 (0.4%)	0
Vertigo positional	頭位性回転性めまい	0	0	0	1 (0.8%)
Endocrine disorders	内分泌障害	5 (1.4%)	1 (0.6%)	2 (0.8%)	0
Cushing's syndrome	クッシング症候群	1 (0.3%)	0	0	0
Cushingoid	クッシング様	1 (0.3%)	1 (0.6%)	0	0
Hyperparathyroidism	副甲状腺機能亢進症	1 (0.3%)	0	0	0
Hyperthyroidism	甲状腺機能亢進症	1 (0.3%)	0	1 (0.4%)	0
Hypothyroidism	甲状腺機能低下症	1 (0.3%)	0	1 (0.4%)	0
Eye disorders	眼障害	16 (4.6%)	11 (6.4%)	7 (2.8%)	6 (4.6%)
Asthenopia	眼精疲労	1 (0.3%)	0	0	0
Blepharitis	眼瞼炎	0	0	1 (0.4%)	0
Cataract	白内障	2 (0.6%)	0	1 (0.4%)	0
Conjunctival haemorrhage	結膜出血	1 (0.3%)	0	0	0
Conjunctivitis	結膜炎	2 (0.6%)	1 (0.6%)	0	0
Diplopia	複視	3 (0.9%)	2 (1.2%)	2 (0.8%)	0
Dry eye	眼乾燥	0	1 (0.6%)	0	2 (1.5%)
Eye pain	眼痛	0	1 (0.6%)	1 (0.4%)	1 (0.8%)
Eye swelling	眼部腫脹	0	0	0	1 (0.8%)
Eyelid function disorder	眼瞼機能障害	0	1 (0.6%)	0	0
Eyelid ptosis	眼瞼下垂	0	2 (1.2%)	0	0

表 2.7.4.7- 2 ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Glaucoma	緑内障	0	1 (0.6%)	0	0
Iridocyclitis	虹彩毛様体炎	1 (0.3%)	0	0	0
Lacrimation increased	流涙増加	0	0	0	1 (0.8%)
Ocular hyperaemia	眼充血	0	0	1 (0.4%)	0
Ocular surface disease	オキュラーサーフェス疾患	1 (0.3%)	0	0	0
Photopsia	光視症	1 (0.3%)	0	0	0
Pupils unequal	瞳孔不同	0	1 (0.6%)	0	0
Vision blurred	霧視	4 (1.2%)	2 (1.2%)	2 (0.8%)	2 (1.5%)
Visual acuity reduced	視力低下	0	0	1 (0.4%)	0
Visual disturbance	視覚障害	0	1 (0.6%)	0	0
Gastrointestinal disorders	胃腸障害	234 (67.4%)	113 (66.1%)	152 (60.1%)	64 (49.2%)
Abdominal discomfort	腹部不快感	1 (0.3%)	0	0	0
Abdominal distension	腹部膨満	3 (0.9%)	0	4 (1.6%)	0
Abdominal pain	腹痛	16 (4.6%)	5 (2.9%)	7 (2.8%)	8 (6.2%)
Abdominal pain lower	下腹部痛	0	0	0	2 (1.5%)
Abdominal pain upper	上腹部痛	7 (2.0%)	2 (1.2%)	11 (4.3%)	1 (0.8%)
Anal haemorrhage	肛門出血	0	0	1 (0.4%)	0
Anal sphincter atony	肛門括約筋無緊張症	0	1 (0.6%)	0	0
Aphthous stomatitis	アフタ性口内炎	0	0	1 (0.4%)	0
Ascites	腹水	3 (0.9%)	0	0	0
Colitis	大腸炎	1 (0.3%)	0	0	0
Constipation	便秘	62 (17.9%)	35 (20.5%)	47 (18.6%)	29 (22.3%)
Defaecation urgency	便意切迫	1 (0.3%)	0	2 (0.8%)	0
Dental caries	齲歯	1 (0.3%)	0	0	1 (0.8%)
Diarrhoea	下痢	88 (25.4%)	30 (17.5%)	66 (26.1%)	15 (11.5%)
Dry mouth	口内乾燥	3 (0.9%)	3 (1.8%)	7 (2.8%)	2 (1.5%)

表 2.7.4.7- 2　ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Duodenal ulcer	十二指腸潰瘍	0	0	1 (0.4%)	0
Duodenitis	十二指腸炎	1 (0.3%)	0	1 (0.4%)	0
Dyspepsia	消化不良	12 (3.5%)	3 (1.8%)	11 (4.3%)	3 (2.3%)
Dysphagia	嚥下障害	1 (0.3%)	4 (2.3%)	5 (2.0%)	0
Epigastric discomfort	心窩部不快感	1 (0.3%)	0	0	1 (0.8%)
Erosive duodenitis	びらん性十二指腸炎	1 (0.3%)	0	0	0
Eructation	おくび	2 (0.6%)	1 (0.6%)	1 (0.4%)	1 (0.8%)
Faecal incontinence	便失禁	4 (1.2%)	1 (0.6%)	2 (0.8%)	2 (1.5%)
Faeces discoloured	変色便	0	0	0	1 (0.8%)
Flatulence	鼓腸	0	0	0	1 (0.8%)
Food poisoning	食中毒	0	2 (1.2%)	0	0
Frequent bowel movements	排便回数増加	0	0	2 (0.8%)	0
Gastric hypermotility	胃運動過剰	0	0	1 (0.4%)	0
Gastric ulcer	胃潰瘍	1 (0.3%)	0	1 (0.4%)	0
Gastritis	胃炎	2 (0.6%)	6 (3.5%)	2 (0.8%)	3 (2.3%)
Gastroduodenal ulcer	胃十二指腸潰瘍	0	0	0	1 (0.8%)
Gastrointestinal haemorrhage	胃腸出血	0	0	1 (0.4%)	1 (0.8%)
Gastrointestinal motility disorder	消化管運動障害	1 (0.3%)	1 (0.6%)	0	0
Gastrointestinal pain	消化器痛	1 (0.3%)	0	0	0
Gastrooesophageal reflux disease	胃食道逆流性疾患	0	1 (0.6%)	0	2 (1.5%)
Gingival bleeding	歯肉出血	0	1 (0.6%)	0	0
Gingivitis	歯肉炎	0	0	0	1 (0.8%)
Haematemesis	吐血	1 (0.3%)	0	1 (0.4%)	0
Haemorrhoidal haemorrhage	痔出血	1 (0.3%)	0	0	0
Haemorrhoids	痔核	2 (0.6%)	1 (0.6%)	0	2 (1.5%)

表 2.7.4.7- 2 ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Hiatus hernia	裂孔ヘルニア	0	0	2 (0.8%)	0
Hyperchlorhydria	胃酸過多	2 (0.6%)	0	2 (0.8%)	0
Hypoaesthesia oral	口の感覚鈍麻	0	0	1 (0.4%)	0
Inguinal hernia	鼠径ヘルニア	0	0	1 (0.4%)	0
Intestinal obstruction	腸閉塞	0	0	1 (0.4%)	0
Intestinal perforation	腸管穿孔	1 (0.3%)	1 (0.6%)	0	0
Large intestine perforation	大腸穿孔	0	1 (0.6%)	0	0
Lip swelling	口唇腫脹	0	0	1 (0.4%)	0
Melaena	メレナ	0	0	1 (0.4%)	0
Mouth haemorrhage	口腔内出血	1 (0.3%)	0	0	0
Mouth ulceration	口腔内潰瘍形成	4 (1.2%)	1 (0.6%)	0	0
Nausea	悪心	139 (40.1%)	70 (40.9%)	74 (29.2%)	32 (24.6%)
Odynophagia	嚥下痛	2 (0.6%)	0	0	0
Oesophageal obstruction	食道閉塞症	1 (0.3%)	0	0	0
Oesophageal pain	食道痛	1 (0.3%)	0	0	0
Oesophageal spasm	食道痙攣	1 (0.3%)	0	0	0
Oesophagitis	食道炎	3 (0.9%)	0	1 (0.4%)	0
Oral pain	口腔内痛	0	2 (1.2%)	0	0
Painful defaecation	排便痛	0	1 (0.6%)	0	0
Paresis anal sphincter	肛門括約筋不全麻痺	0	2 (1.2%)	0	0
Periodontal disease	歯周病	1 (0.3%)	0	0	0
Proctalgia	肛門周囲痛	0	0	1 (0.4%)	0
Rectal discharge	直腸分泌物	1 (0.3%)	0	0	0
Rectal haemorrhage	直腸出血	3 (0.9%)	3 (1.8%)	4 (1.6%)	0
Rectal tenesmus	直腸しぶり	2 (0.6%)	1 (0.6%)	0	0
Reflux gastritis	逆流性胃炎	1 (0.3%)	0	0	0
Reflux oesophagitis	逆流性食道炎	1 (0.3%)	0	0	0

表 2.7.4.7- 2　ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Retching	レッチング	0	1 (0.6%)	0	1 (0.8%)
Salivary hypersecretion	流涎過多	1 (0.3%)	0	0	0
Small intestinal obstruction	小腸閉塞	1 (0.3%)	0	0	0
Stomach discomfort	胃不快感	2 (0.6%)	1 (0.6%)	1 (0.4%)	0
Stomatitis	口内炎	0	3 (1.8%)	1 (0.4%)	0
Subileus	亜イレウス	1 (0.3%)	1 (0.6%)	0	0
Swollen tongue	舌腫脹	0	1 (0.6%)	0	0
Toothache	歯痛	4 (1.2%)	1 (0.6%)	2 (0.8%)	2 (1.5%)
Upper gastrointestinal haemorrhage	上部消化管出血	1 (0.3%)	0	0	0
Vomiting	嘔吐	87 (25.1%)	24 (14.0%)	28 (11.1%)	17 (13.1%)
General disorders and administration site conditions	全身障害および投与局所様態	176 (50.7%)	89 (52.0%)	109 (43.1%)	53 (40.8%)
Asthenia	無力症	18 (5.2%)	10 (5.8%)	17 (6.7%)	8 (6.2%)
Chest discomfort	胸部不快感	0	0	1 (0.4%)	1 (0.8%)
Chest pain	胸痛	1 (0.3%)	0	0	1 (0.8%)
Chills	悪寒	5 (1.4%)	1 (0.6%)	8 (3.2%)	2 (1.5%)
Crepitations	捻髪音	1 (0.3%)	0	0	0
Cyst	嚢胞	1 (0.3%)	0	1 (0.4%)	0
Death	死亡	3 (0.9%)	1 (0.6%)	1 (0.4%)	0
Discomfort	不快感	1 (0.3%)	0	0	0
Drug intolerance	薬物不耐性	2 (0.6%)	1 (0.6%)	0	0
Fatigue	疲労	96 (27.7%)	47 (27.5%)	63 (24.9%)	31 (23.8%)
Feeling cold	冷感	0	0	2 (0.8%)	0
Feeling hot	熱感	0	1 (0.6%)	0	0
Gait disturbance	歩行障害	1 (0.3%)	2 (1.2%)	1 (0.4%)	2 (1.5%)

表 2.7.4.7- 2　ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
General physical health deterioration	全身健康状態低下	18 (5.2%)	16 (9.4%)	11 (4.3%)	5 (3.8%)
Generalised oedema	全身性浮腫	0	0	0	1 (0.8%)
Hernia	ヘルニア	0	0	1 (0.4%)	0
Induration	硬結	1 (0.3%)	0	0	0
Influenza like illness	インフルエンザ様疾患	5 (1.4%)	0	1 (0.4%)	1 (0.8%)
Infusion site erythema	注入部位紅斑	0	0	1 (0.4%)	0
Injection site pain	注射部位疼痛	1 (0.3%)	0	1 (0.4%)	0
Injection site rash	注射部位発疹	1 (0.3%)	0	0	0
Injection site reaction	注射部位反応	2 (0.6%)	0	0	0
Injection site swelling	注射部位腫脹	0	0	1 (0.4%)	0
Localised oedema	限局性浮腫	1 (0.3%)	4 (2.3%)	0	0
Malaise	倦怠感	5 (1.4%)	0	2 (0.8%)	1 (0.8%)
Mucosal inflammation	粘膜の炎症	1 (0.3%)	1 (0.6%)	2 (0.8%)	2 (1.5%)
Multi-organ failure	多臓器不全	1 (0.3%)	0	1 (0.4%)	0
Non-cardiac chest pain	非心臓性胸痛	2 (0.6%)	1 (0.6%)	3 (1.2%)	0
Oedema	浮腫	4 (1.2%)	0	2 (0.8%)	3 (2.3%)
Oedema peripheral	末梢性浮腫	40 (11.5%)	20 (11.7%)	37 (14.6%)	10 (7.7%)
Pain	疼痛	2 (0.6%)	5 (2.9%)	2 (0.8%)	1 (0.8%)
Peripheral coldness	末梢冷感	0	0	1 (0.4%)	1 (0.8%)
Pitting oedema	圧痕浮腫	1 (0.3%)	1 (0.6%)	0	0
Pyrexia	発熱	33 (9.5%)	13 (7.6%)	7 (2.8%)	6 (4.6%)
Sudden death	突然死	0	0	0	1 (0.8%)
Temperature intolerance	温度変化不耐症	1 (0.3%)	0	0	0
Hepatobiliary disorders	肝胆道系障害	1 (0.3%)	0	4 (1.6%)	0
Bile duct obstruction	胆管閉塞	0	0	1 (0.4%)	0

表 2.7.4.7- 2　ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Cholelithiasis	胆石症	0	0	1 (0.4%)	0
Cholestasis	胆汁うっ滞	0	0	1 (0.4%)	0
Hepatic failure	肝不全	0	0	1 (0.4%)	0
Hepatic function abnormal	肝機能異常	1 (0.3%)	0	0	0
Hyperbilirubinaemia	高ビリルビン血症	0	0	1 (0.4%)	0
Jaundice	黄疸	1 (0.3%)	0	0	0
Immune system disorders	免疫系障害	0	0	0	3 (2.3%)
Cytokine release syndrome	サイトカイン放出症候群	0	0	0	1 (0.8%)
Hypersensitivity	過敏症	0	0	0	2 (1.5%)
Infections and infestations	感染症および寄生虫症	110 (31.7%)	63 (36.8%)	74 (29.2%)	38 (29.2%)
Abscess	膿瘍	0	0	0	1 (0.8%)
Abscess jaw	顎膿瘍	0	1 (0.6%)	0	0
Arthritis infective	感染性関節炎	0	1 (0.6%)	0	0
Bacterial sepsis	細菌性敗血症	1 (0.3%)	0	0	0
Bronchitis	気管支炎	0	4 (2.3%)	2 (0.8%)	0
Bronchopneumonia	気管支肺炎	0	0	2 (0.8%)	0
Bursitis infective	感染性滑液包炎	0	0	1 (0.4%)	0
Campylobacter infection	カンピロバクター感染	0	1 (0.6%)	1 (0.4%)	0
Catheter related infection	カテーテル関連感染	1 (0.3%)	0	1 (0.4%)	0
Cellulitis	蜂巣炎	2 (0.6%)	3 (1.8%)	3 (1.2%)	0
Clostridium difficile colitis	クロストリジウム・ディフィシレ大腸炎	0	0	1 (0.4%)	0
Cystitis	膀胱炎	6 (1.7%)	3 (1.8%)	2 (0.8%)	4 (3.1%)
Device related infection	医療機器関連感染	0	1 (0.6%)	0	0
Ear infection	耳感染	1 (0.3%)	1 (0.6%)	1 (0.4%)	0
Erysipelas	丹毒	2 (0.6%)	1 (0.6%)	0	0

表 2.7.4.7- 2 ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Escherichia urinary tract infection	大腸菌性尿路感染	0	0	1 (0.4%)	0
Eye infection	眼感染	2 (0.6%)	1 (0.6%)	2 (0.8%)	0
Fungal infection	真菌感染	1 (0.3%)	0	0	0
Fungal skin infection	皮膚真菌感染	0	1 (0.6%)	1 (0.4%)	1 (0.8%)
Gastroenteritis	胃腸炎	1 (0.3%)	0	1 (0.4%)	0
Gastroenteritis norovirus	ノロウイルス性胃腸炎	0	1 (0.6%)	0	0
Gastroenteritis viral	ウイルス性胃腸炎	1 (0.3%)	0	1 (0.4%)	0
Gingival infection	歯肉感染	2 (0.6%)	0	0	0
Haemophilus infection	ヘモフィルス感染	0	0	1 (0.4%)	0
Helicobacter infection	ヘリコバクター感染	0	0	1 (0.4%)	0
Herpes simplex	単純ヘルペス	0	0	1 (0.4%)	0
Herpes zoster	帯状疱疹	7 (2.0%)	3 (1.8%)	1 (0.4%)	1 (0.8%)
Hordeolum	麦粒腫	1 (0.3%)	0	1 (0.4%)	0
Infection	感染	14 (4.0%)	5 (2.9%)	1 (0.4%)	2 (1.5%)
Influenza	インフルエンザ	2 (0.6%)	2 (1.2%)	5 (2.0%)	1 (0.8%)
Listeriosis	リステリア症	0	1 (0.6%)	0	0
Lobar pneumonia	大葉性肺炎	0	2 (1.2%)	0	0
Localised infection	限局性感染	1 (0.3%)	0	0	0
Lower respiratory tract infection	下気道感染	10 (2.9%)	5 (2.9%)	11 (4.3%)	3 (2.3%)
Lower respiratory tract infection bacterial	細菌性下気道感染	1 (0.3%)	0	0	0
Lung infection	肺感染	1 (0.3%)	1 (0.6%)	1 (0.4%)	0
Nail infection	爪感染	1 (0.3%)	0	0	0
Nasopharyngitis	鼻咽頭炎	9 (2.6%)	5 (2.9%)	4 (1.6%)	3 (2.3%)
Oral candidiasis	口腔カンジダ症	9 (2.6%)	4 (2.3%)	4 (1.6%)	2 (1.5%)

表 2.7.4.7- 2　ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Oral fungal infection	口腔真菌感染	3 (0.9%)	2 (1.2%)	1 (0.4%)	0
Oral herpes	口腔ヘルペス	0	0	1 (0.4%)	0
Oral infection	口腔感染	1 (0.3%)	0	0	0
Paronychia	爪囲炎	0	0	1 (0.4%)	0
Peritonitis bacterial	細菌性腹膜炎	1 (0.3%)	0	0	0
Pharyngitis	咽頭炎	4 (1.2%)	0	0	0
Pilonidal cyst	毛巣嚢胞	1 (0.3%)	0	0	0
Pneumonia	肺炎	13 (3.7%)	11 (6.4%)	6 (2.4%)	5 (3.8%)
Pneumonia primary atypical	原発性異型肺炎	1 (0.3%)	0	0	0
Post procedural infection	処置後感染	0	1 (0.6%)	0	1 (0.8%)
Postoperative wound infection	術後創感染	0	0	0	1 (0.8%)
Pyelonephritis	腎盂腎炎	1 (0.3%)	0	0	0
Pyonephrosis	膿腎症	0	1 (0.6%)	0	0
Respiratory tract infection	気道感染	5 (1.4%)	1 (0.6%)	2 (0.8%)	0
Respiratory tract infection viral	ウイルス性気道感染	0	0	1 (0.4%)	0
Rhinitis	鼻炎	2 (0.6%)	0	1 (0.4%)	0
Sepsis	敗血症	6 (1.7%)	2 (1.2%)	1 (0.4%)	4 (3.1%)
Sinusitis	副鼻腔炎	0	1 (0.6%)	0	0
Skin infection	皮膚感染	1 (0.3%)	1 (0.6%)	1 (0.4%)	0
Soft tissue infection	軟部組織感染	1 (0.3%)	0	1 (0.4%)	0
Staphylococcal infection	ブドウ球菌感染	0	0	0	1 (0.8%)
Subcutaneous abscess	皮下組織膿瘍	1 (0.3%)	0	0	0
Tinea pedis	足部白癬	0	0	1 (0.4%)	0
Tooth infection	歯感染	1 (0.3%)	2 (1.2%)	1 (0.4%)	1 (0.8%)
Upper respiratory tract infection	上気道感染	4 (1.2%)	1 (0.6%)	2 (0.8%)	3 (2.3%)

表 2.7.4.7- 2　ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Upper respiratory tract infection bacterial	細菌性上気道感染	1 (0.3%)	0	0	0
Urinary tract infection	尿路感染	27 (7.8%)	17 (9.9%)	21 (8.3%)	11 (8.5%)
Urosepsis	尿路性敗血症	1 (0.3%)	1 (0.6%)	0	0
Viral infection	ウイルス感染	2 (0.6%)	0	2 (0.8%)	1 (0.8%)
Viral skin infection	皮膚ウイルス感染	0	1 (0.6%)	0	0
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	38 (11.0%)	12 (7.0%)	30 (11.9%)	6 (4.6%)
Accidental overdose	偶発的過量投与	1 (0.3%)	0	0	0
Ankle fracture	足関節部骨折	1 (0.3%)	0	0	0
Back injury	背部損傷	0	0	2 (0.8%)	0
Compression fracture	圧迫骨折	0	0	1 (0.4%)	0
Contusion	挫傷	6 (1.7%)	3 (1.8%)	6 (2.4%)	1 (0.8%)
Cystitis radiation	放射線性膀胱炎	1 (0.3%)	0	0	0
Device dislocation	医療機器位置異常	0	1 (0.6%)	1 (0.4%)	0
Excoriation	擦過傷	1 (0.3%)	0	2 (0.8%)	0
Extradural haematoma	硬膜外血腫	0	0	1 (0.4%)	0
Fall	転倒・転落	3 (0.9%)	1 (0.6%)	3 (1.2%)	2 (1.5%)
Femoral neck fracture	大腿骨頚部骨折	1 (0.3%)	1 (0.6%)	0	0
Foot fracture	足骨折	1 (0.3%)	0	0	0
Gastroenteritis radiation	放射線胃腸炎	0	0	0	1 (0.8%)
Hand fracture	手骨折	0	0	0	1 (0.8%)
Head injury	頭部損傷	0	0	1 (0.4%)	0
Hip fracture	股関節部骨折	0	0	1 (0.4%)	0
Injury	損傷	1 (0.3%)	0	0	0
Intentional overdose	企図的過量投与	0	0	1 (0.4%)	0

表 2.7.4.7- 2　ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Joint injury	関節損傷	1 (0.3%)	0	2 (0.8%)	0
Joint sprain	関節捻挫	2 (0.6%)	0	0	0
Laceration	裂傷	1 (0.3%)	0	0	1 (0.8%)
Ligament injury	靭帯損傷	0	0	1 (0.4%)	0
Lower limb fracture	下肢骨折	0	0	1 (0.4%)	0
Medical device complication	医療機器合併症	1 (0.3%)	0	0	0
Medical device pain	医療機器による疼痛	0	0	0	1 (0.8%)
Meniscus lesion	半月板障害	1 (0.3%)	0	0	0
Mouth injury	口腔内損傷	0	0	1 (0.4%)	0
Muscle strain	筋挫傷	1 (0.3%)	0	0	0
Nail avulsion	爪裂離	1 (0.3%)	0	0	0
Patella fracture	膝蓋骨骨折	1 (0.3%)	0	0	0
Post-traumatic pain	外傷後疼痛	4 (1.2%)	0	1 (0.4%)	1 (0.8%)
Procedural pain	処置による疼痛	1 (0.3%)	1 (0.6%)	1 (0.4%)	0
Radiation associated pain	放射線関連痛	1 (0.3%)	0	0	0
Radiation skin injury	放射線皮膚損傷	2 (0.6%)	0	1 (0.4%)	0
Radius fracture	橈骨骨折	0	0	1 (0.4%)	1 (0.8%)
Rib fracture	肋骨骨折	1 (0.3%)	0	0	0
Skin laceration	皮膚裂傷	3 (0.9%)	0	3 (1.2%)	0
Spinal compression fracture	脊椎圧迫骨折	2 (0.6%)	0	1 (0.4%)	0
Stent occlusion	ステント閉塞	0	1 (0.6%)	0	0
Sternal fracture	胸骨骨折	0	0	1 (0.4%)	0
Stomatitis radiation	放射線口内炎	0	1 (0.6%)	0	0
Stress fracture	ストレス骨折	0	0	1 (0.4%)	0
Subcutaneous haematoma	皮下血腫	1 (0.3%)	0	0	0
Tendon rupture	腱断裂	1 (0.3%)	0	0	0
Therapeutic agent toxicity	治療薬毒性	1 (0.3%)	0	0	0

表 2.7.4.7- 2　ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Thermal burn	熱傷	0	1 (0.6%)	0	0
Tooth fracture	歯牙破折	0	1 (0.6%)	0	0
Upper limb fracture	上肢骨折	2 (0.6%)	1 (0.6%)	1 (0.4%)	0
Wound	創傷	3 (0.9%)	0	0	0
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Investigations	臨床検査	69 (19.9%)	46 (26.9%)	37 (14.6%)	21 (16.2%)
Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	3 (0.9%)	0	1 (0.4%)	2 (1.5%)
Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	7 (2.0%)	2 (1.2%)	2 (0.8%)	1 (0.8%)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2 (0.6%)	6 (3.5%)	5 (2.0%)	5 (3.8%)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	1 (0.3%)	0	0	0
Blood creatinine increased	血中クレアチニン増加	1 (0.3%)	0	0	0
Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	6 (1.7%)	5 (2.9%)	2 (0.8%)	3 (2.3%)
Blood urea increased	血中尿素増加	4 (1.2%)	1 (0.6%)	3 (1.2%)	3 (2.3%)
Breath sounds abnormal	呼吸音異常	2 (0.6%)	0	0	0
Cardiac murmur	心雑音	0	1 (0.6%)	1 (0.4%)	1 (0.8%)
Coagulation factor VII level increased	凝固第ＶＩＩ因子量増加	1 (0.3%)	0	0	0
Electrocardiogram QT prolonged	心電図ＱＴ延長	0	0	1 (0.4%)	0
Fibrin D dimer increased	フィブリンＤダイマー増加	1 (0.3%)	0	0	0
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	8 (2.3%)	4 (2.3%)	4 (1.6%)	2 (1.5%)
Liver function test abnormal	肝機能検査異常	0	0	1 (0.4%)	0

表 2.7.4.7- 2　ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Prostatic specific antigen increased	前立腺特異性抗原増加	0	2 (1.2%)	0	0
Troponin T increased	トロポニンＴ増加	0	0	1 (0.4%)	0
Urine analysis abnormal	尿検査異常	0	0	0	1 (0.8%)
Urine output increased	尿量増加	1 (0.3%)	0	0	0
Weight decreased	体重減少	50 (14.4%)	33 (19.3%)	23 (9.1%)	11 (8.5%)
Weight increased	体重増加	1 (0.3%)	1 (0.6%)	1 (0.4%)	0
Metabolism and nutrition disorders	代謝および栄養障害	110 (31.7%)	53 (31.0%)	77 (30.4%)	39 (30.0%)
Anorexia	食欲不振	62 (17.9%)	33 (19.3%)	45 (17.8%)	21 (16.2%)
Cachexia	悪液質	2 (0.6%)	1 (0.6%)	1 (0.4%)	1 (0.8%)
Decreased appetite	食欲減退	18 (5.2%)	7 (4.1%)	18 (7.1%)	6 (4.6%)
Dehydration	脱水	11 (3.2%)	2 (1.2%)	9 (3.6%)	3 (2.3%)
Diabetes mellitus	糖尿病	1 (0.3%)	0	0	2 (1.5%)
Dyslipidaemia	異脂肪血症	1 (0.3%)	0	0	0
Fluid intake reduced	水分摂取量減少	0	0	1 (0.4%)	0
Fluid overload	水分過負荷	0	0	1 (0.4%)	0
Gout	痛風	1 (0.3%)	1 (0.6%)	1 (0.4%)	0
Hypercalcaemia	高カルシウム血症	1 (0.3%)	1 (0.6%)	0	0
Hypercholesterolaemia	高コレステロール血症	0	0	1 (0.4%)	0
Hypercreatininaemia	高クレアチニン血症	3 (0.9%)	3 (1.8%)	1 (0.4%)	1 (0.8%)
Hyperglycaemia	高血糖	3 (0.9%)	1 (0.6%)	1 (0.4%)	0
Hyperkalaemia	高カリウム血症	0	1 (0.6%)	2 (0.8%)	1 (0.8%)
Hypernatraemia	高ナトリウム血症	0	0	0	1 (0.8%)
Hyperuricaemia	高尿酸血症	0	1 (0.6%)	1 (0.4%)	0
Hypoalbuminaemia	低アルブミン血症	2 (0.6%)	0	1 (0.4%)	1 (0.8%)

表 2.7.4.7- 2 ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Hypocalcaemia	低カルシウム血症	2 (0.6%)	4 (2.3%)	4 (1.6%)	0
Hypoglycaemia	低血糖症	0	0	1 (0.4%)	0
Hypokalaemia	低カリウム血症	11 (3.2%)	5 (2.9%)	3 (1.2%)	1 (0.8%)
Hypomagnesaemia	低マグネシウム血症	3 (0.9%)	0	0	0
Hyponatraemia	低ナトリウム血症	0	1 (0.6%)	1 (0.4%)	1 (0.8%)
Hypophosphataemia	低リン酸血症	3 (0.9%)	0	4 (1.6%)	2 (1.5%)
Hypovitaminosis	ビタミン欠乏症	1 (0.3%)	0	0	0
Increased appetite	食欲亢進	0	0	1 (0.4%)	0
Magnesium deficiency	マグネシウム欠乏	0	0	0	1 (0.8%)
Malnutrition	栄養障害	1 (0.3%)	0	0	0
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	225 (64.8%)	130 (76.0%)	135 (53.4%)	83 (63.8%)
Arthralgia	関節痛	16 (4.6%)	6 (3.5%)	13 (5.1%)	5 (3.8%)
Back pain	背部痛	3 (0.9%)	3 (1.8%)	4 (1.6%)	1 (0.8%)
Bone lesion	骨病変	0	0	1 (0.4%)	0
Bone pain	骨痛	194 (55.9%)	120 (70.2%)	116 (45.8%)	71 (54.6%)
Bursitis	滑液包炎	1 (0.3%)	0	0	1 (0.8%)
Flank pain	側腹部痛	0	0	1 (0.4%)	0
Groin pain	鼠径部痛	1 (0.3%)	0	0	0
Intervertebral disc degeneration	椎間板変性症	1 (0.3%)	0	0	0
Intervertebral disc disorder	椎間板障害	0	0	1 (0.4%)	0
Intervertebral disc protrusion	椎間板突出	0	0	1 (0.4%)	0
Joint effusion	関節滲出液	0	0	1 (0.4%)	0
Joint instability	関節不安定	0	0	1 (0.4%)	0
Joint lock	関節ロック	0	0	0	1 (0.8%)

表 2.7.4.7- 2　ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Joint range of motion decreased	関節運動範囲減少	0	1 (0.6%)	0	0
Joint stiffness	関節硬直	1 (0.3%)	1 (0.6%)	0	0
Joint swelling	関節腫脹	1 (0.3%)	2 (1.2%)	1 (0.4%)	1 (0.8%)
Kyphosis	脊柱後弯症	0	0	1 (0.4%)	0
Mobility decreased	運動性低下	4 (1.2%)	1 (0.6%)	3 (1.2%)	1 (0.8%)
Muscle spasms	筋痙縮	6 (1.7%)	3 (1.8%)	3 (1.2%)	1 (0.8%)
Muscular weakness	筋力低下	7 (2.0%)	9 (5.3%)	2 (0.8%)	7 (5.4%)
Musculoskeletal chest pain	筋骨格系胸痛	4 (1.2%)	0	0	2 (1.5%)
Musculoskeletal discomfort	筋骨格不快感	0	0	0	1 (0.8%)
Musculoskeletal pain	筋骨格痛	15 (4.3%)	4 (2.3%)	7 (2.8%)	6 (4.6%)
Musculoskeletal stiffness	筋骨格硬直	2 (0.6%)	0	2 (0.8%)	0
Myalgia	筋痛	12 (3.5%)	6 (3.5%)	7 (2.8%)	3 (2.3%)
Myopathy	ミオパチー	0	0	1 (0.4%)	1 (0.8%)
Myositis	筋炎	1 (0.3%)	0	0	0
Neck pain	頚部痛	0	0	1 (0.4%)	0
Osteoarthritis	骨関節炎	1 (0.3%)	0	1 (0.4%)	0
Osteolysis	骨溶解	1 (0.3%)	0	0	0
Osteomalacia	骨軟化症	1 (0.3%)	0	0	0
Osteonecrosis	骨壊死	3 (0.9%)	0	0	0
Osteoporosis	骨粗鬆症	2 (0.6%)	0	0	1 (0.8%)
Pain in extremity	四肢痛	3 (0.9%)	3 (1.8%)	4 (1.6%)	1 (0.8%)
Pain in jaw	顎痛	2 (0.6%)	1 (0.6%)	2 (0.8%)	0
Pathological fracture	病的骨折	12 (3.5%)	9 (5.3%)	12 (4.7%)	6 (4.6%)
Spinal column stenosis	脊柱管狭窄症	0	0	1 (0.4%)	0
Spinal osteoarthritis	変形性脊椎炎	0	0	0	1 (0.8%)
Synovial cyst	滑液嚢腫	0	0	0	1 (0.8%)
Tendonitis	腱炎	1 (0.3%)	0	0	0

表 2.7.4.7- 2 ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	55 (15.9%)	35 (20.5%)	47 (18.6%)	24 (18.5%)
Benign neoplasm	良性新生物	0	0	2 (0.8%)	0
Benign neoplasm of bladder	膀胱の良性新生物	0	0	1 (0.4%)	0
Benign soft tissue neoplasm	軟部組織の良性新生物	0	0	1 (0.4%)	0
Benign urinary tract neoplasm	尿路の良性新生物	0	1 (0.6%)	0	0
Bladder cancer	膀胱癌	1 (0.3%)	0	0	0
Bone marrow tumour cell infiltration	腫瘍細胞の骨髄浸潤	0	0	1 (0.4%)	0
Fibroma	線維腫	0	0	0	1 (0.8%)
Gastric cancer	胃癌	0	1 (0.6%)	0	0
Haemangioma	血管腫	1 (0.3%)	0	0	0
Lymphangiosis carcinomatosa	癌性リンパ管症	0	0	1 (0.4%)	0
Malignant neoplasm progression	悪性新生物進行	41 (11.8%)	24 (14.0%)	35 (13.8%)	21 (16.2%)
Metastases to bone	骨転移	1 (0.3%)	4 (2.3%)	2 (0.8%)	1 (0.8%)
Metastases to central nervous system	中枢神経系転移	5 (1.4%)	2 (1.2%)	2 (0.8%)	0
Metastases to liver	肝転移	5 (1.4%)	2 (1.2%)	0	1 (0.8%)
Metastases to lung	肺転移	3 (0.9%)	0	0	0
Metastases to lymph nodes	リンパ節転移	0	1 (0.6%)	0	0
Metastases to meninges	髄膜転移	0	1 (0.6%)	0	0
Metastases to nervous system	神経系転移	1 (0.3%)	0	0	0
Metastases to skin	皮膚転移	1 (0.3%)	1 (0.6%)	0	0
Metastases to soft tissue	軟部組織転移	1 (0.3%)	1 (0.6%)	0	0
Neoplasm	新生物	0	1 (0.6%)	0	0

表 2.7.4.7- 2 ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Neoplasm skin	皮膚の新生物	0	0	1 (0.4%)	0
Seborrhoeic keratosis	脂漏性角化症	1 (0.3%)	0	0	0
Skin cancer	皮膚癌	0	0	1 (0.4%)	0
Skin papilloma	皮膚乳頭腫	0	0	0	1 (0.8%)
Squamous cell carcinoma	扁平上皮癌	1 (0.3%)	0	0	0
Squamous cell carcinoma of skin	皮膚有棘細胞癌	0	1 (0.6%)	0	0
Tumour associated fever	腫瘍熱	1 (0.3%)	0	0	0
Nervous system disorders	神経系障害	112 (32.3%)	74 (43.3%)	64 (25.3%)	43 (33.1%)
Ageusia	味覚消失	1 (0.3%)	1 (0.6%)	1 (0.4%)	0
Amnesia	健忘	2 (0.6%)	0	0	1 (0.8%)
Aphasia	失語症	0	1 (0.6%)	1 (0.4%)	0
Apraxia	失行症	0	0	0	1 (0.8%)
Ataxia	運動失調	0	0	1 (0.4%)	0
Balance disorder	平衡障害	1 (0.3%)	0	3 (1.2%)	1 (0.8%)
Brachial plexopathy	腕神経叢障害	0	1 (0.6%)	0	0
Brain oedema	脳浮腫	0	0	0	1 (0.8%)
Burning sensation	灼熱感	1 (0.3%)	0	0	1 (0.8%)
Cauda equina syndrome	馬尾症候群	0	1 (0.6%)	1 (0.4%)	0
Cerebral haemorrhage	脳出血	3 (0.9%)	2 (1.2%)	0	0
Cerebral ischaemia	脳虚血	1 (0.3%)	1 (0.6%)	0	3 (2.3%)
Cerebrovascular accident	脳血管発作	3 (0.9%)	0	0	0
Cognitive disorder	認知障害	0	0	0	1 (0.8%)
Convulsion	痙攣	2 (0.6%)	0	0	1 (0.8%)
Cranial neuropathy	脳ニューロパチー	0	1 (0.6%)	0	0
Dementia	認知症	0	0	0	1 (0.8%)
Dementia Alzheimer's type	アルツハイマー型認知症	0	0	1 (0.4%)	0

表 2.7.4.7- 2 ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Disturbance in attention	注意力障害	1 (0.3%)	0	1 (0.4%)	0
Dizziness	浮動性めまい	25 (7.2%)	14 (8.2%)	20 (7.9%)	12 (9.2%)
Dizziness postural	体位性めまい	3 (0.9%)	0	0	0
Dysaesthesia	異常感覚	0	1 (0.6%)	0	0
Dysarthria	構語障害	1 (0.3%)	2 (1.2%)	2 (0.8%)	0
Dysgeusia	味覚異常	7 (2.0%)	6 (3.5%)	9 (3.6%)	1 (0.8%)
Dysphasia	不全失語症	0	1 (0.6%)	1 (0.4%)	1 (0.8%)
Dystonia	ジストニー	1 (0.3%)	0	0	0
Epilepsy	てんかん	0	2 (1.2%)	0	0
Facial palsy	顔面神経麻痺	1 (0.3%)	0	0	1 (0.8%)
Facial paresis	顔面不全麻痺	0	1 (0.6%)	0	0
Haemorrhage intracranial	頭蓋内出血	0	1 (0.6%)	0	0
Headache	頭痛	14 (4.0%)	8 (4.7%)	11 (4.3%)	1 (0.8%)
Hydrocephalus	水頭症	1 (0.3%)	0	0	1 (0.8%)
Hyperaesthesia	知覚過敏	0	0	1 (0.4%)	0
Hypoaesthesia	感覚鈍麻	11 (3.2%)	6 (3.5%)	3 (1.2%)	1 (0.8%)
Ischaemic stroke	虚血性脳卒中	0	0	0	1 (0.8%)
Lethargy	嗜眠	5 (1.4%)	8 (4.7%)	7 (2.8%)	4 (3.1%)
Loss of consciousness	意識消失	0	0	1 (0.4%)	0
Memory impairment	記憶障害	1 (0.3%)	1 (0.6%)	1 (0.4%)	0
Migraine with aura	前兆を伴う片頭痛	0	1 (0.6%)	0	0
Monoparesis	不全単麻痺	0	1 (0.6%)	0	0
Myasthenia gravis	重症筋無力症	1 (0.3%)	0	0	0
Nerve root compression	神経根圧迫	4 (1.2%)	0	0	0
Neuralgia	神経痛	4 (1.2%)	2 (1.2%)	1 (0.4%)	0
Neuropathy peripheral	末梢性ニューロパチー	5 (1.4%)	2 (1.2%)	2 (0.8%)	0
Paraesthesia	錯感覚	11 (3.2%)	2 (1.2%)	6 (2.4%)	2 (1.5%)

表 2.7.4.7- 2　ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Paraparesis	不全対麻痺	2 (0.6%)	0	0	0
Paraplegia	対麻痺	0	1 (0.6%)	0	1 (0.8%)
Paresis cranial nerve	脳神経不全麻痺	1 (0.3%)	0	0	0
Parosmia	嗅覚錯誤	0	1 (0.6%)	0	0
Peripheral motor neuropathy	末梢性運動ニューロパチー	3 (0.9%)	7 (4.1%)	4 (1.6%)	6 (4.6%)
Peripheral sensory neuropathy	末梢性感覚ニューロパチー	7 (2.0%)	4 (2.3%)	2 (0.8%)	1 (0.8%)
Peroneal nerve palsy	腓骨神経麻痺	0	1 (0.6%)	0	0
Polyneuropathy	多発ニューロパチー	3 (0.9%)	1 (0.6%)	0	0
Radicular syndrome	根症候群	0	0	1 (0.4%)	0
Restless legs syndrome	下肢静止不能症候群	0	1 (0.6%)	1 (0.4%)	0
Sciatica	坐骨神経痛	0	1 (0.6%)	1 (0.4%)	1 (0.8%)
Somnolence	傾眠	1 (0.3%)	2 (1.2%)	2 (0.8%)	2 (1.5%)
Speech disorder	会話障害	0	0	1 (0.4%)	0
Spinal cord compression	脊髄圧迫	17 (4.9%)	14 (8.2%)	8 (3.2%)	9 (6.9%)
Syncope	失神	4 (1.2%)	1 (0.6%)	2 (0.8%)	1 (0.8%)
Syncope vasovagal	血管迷走神経性失神	0	0	1 (0.4%)	0
Tongue paralysis	舌の麻痺	0	0	1 (0.4%)	0
Transient ischaemic attack	一過性脳虚血発作	1 (0.3%)	0	0	1 (0.8%)
Tremor	振戦	1 (0.3%)	2 (1.2%)	2 (0.8%)	0
Trigeminal palsy	三叉神経麻痺	1 (0.3%)	0	0	0
VIth nerve paralysis	第６脳神経麻痺	0	1 (0.6%)	0	0
Psychiatric disorders	精神障害	52 (15.0%)	30 (17.5%)	38 (15.0%)	24 (18.5%)
Aggression	攻撃性	0	0	1 (0.4%)	0
Agitation	激越	0	2 (1.2%)	2 (0.8%)	1 (0.8%)
Anhedonia	快感消失	0	1 (0.6%)	0	0
Anxiety	不安	5 (1.4%)	6 (3.5%)	6 (2.4%)	5 (3.8%)
Confusional state	錯乱状態	14 (4.0%)	7 (4.1%)	9 (3.6%)	5 (3.8%)

表 2.7.4.7- 2　ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Depressed mood	抑うつ気分	3 (0.9%)	0	4 (1.6%)	1 (0.8%)
Depression	うつ病	11 (3.2%)	6 (3.5%)	9 (3.6%)	7 (5.4%)
Disorientation	失見当識	0	0	0	1 (0.8%)
Hallucination	幻覚	0	1 (0.6%)	1 (0.4%)	0
Insomnia	不眠症	21 (6.1%)	11 (6.4%)	10 (4.0%)	6 (4.6%)
Intentional self-injury	故意の自傷行為	0	0	1 (0.4%)	0
Mania	躁病	1 (0.3%)	0	1 (0.4%)	0
Mental status changes	精神状態変化	0	0	1 (0.4%)	0
Mood altered	気分変化	2 (0.6%)	1 (0.6%)	0	0
Nightmare	悪夢	1 (0.3%)	1 (0.6%)	0	0
Sleep disorder	睡眠障害	2 (0.6%)	0	2 (0.8%)	1 (0.8%)
Suicide attempt	自殺企図	0	1 (0.6%)	0	0
Renal and urinary disorders	腎および尿路障害	63 (18.2%)	34 (19.9%)	47 (18.6%)	29 (22.3%)
Acute prerenal failure	急性腎前性腎不全	1 (0.3%)	0	0	0
Calculus ureteric	尿管結石	0	0	1 (0.4%)	0
Chromaturia	着色尿	0	0	1 (0.4%)	1 (0.8%)
Dysuria	排尿困難	7 (2.0%)	5 (2.9%)	6 (2.4%)	2 (1.5%)
Haematuria	血尿	15 (4.3%)	8 (4.7%)	14 (5.5%)	7 (5.4%)
Haemorrhage urinary tract	尿路出血	0	1 (0.6%)	0	1 (0.8%)
Hydronephrosis	水腎症	9 (2.6%)	1 (0.6%)	3 (1.2%)	1 (0.8%)
Hypertonic bladder	緊張性膀胱	1 (0.3%)	0	0	0
Micturition disorder	排尿異常	2 (0.6%)	0	1 (0.4%)	2 (1.5%)
Micturition frequency decreased	排尿回数減少	0	0	1 (0.4%)	0
Micturition urgency	尿意切迫	2 (0.6%)	1 (0.6%)	0	1 (0.8%)
Mixed incontinence	混合性尿失禁	0	0	0	1 (0.8%)
Nephrolithiasis	腎結石症	2 (0.6%)	1 (0.6%)	0	0

表 2.7.4.7- 2 ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Nocturia	夜間頻尿	8 (2.3%)	1 (0.6%)	2 (0.8%)	5 (3.8%)
Pollakiuria	頻尿	6 (1.7%)	2 (1.2%)	8 (3.2%)	3 (2.3%)
Renal failure	腎不全	6 (1.7%)	1 (0.6%)	5 (2.0%)	1 (0.8%)
Renal failure acute	急性腎不全	2 (0.6%)	0	2 (0.8%)	1 (0.8%)
Renal impairment	腎機能障害	1 (0.3%)	0	1 (0.4%)	0
Renal tubular necrosis	腎尿細管壊死	0	0	1 (0.4%)	0
Strangury	有痛性排尿困難	1 (0.3%)	0	0	0
Stress urinary incontinence	腹圧性尿失禁	0	1 (0.6%)	0	0
Ureteric obstruction	尿管閉塞	1 (0.3%)	1 (0.6%)	0	0
Urethral obstruction	尿道閉塞	0	1 (0.6%)	0	0
Urge incontinence	切迫性尿失禁	0	0	1 (0.4%)	0
Urinary bladder haemorrhage	膀胱出血	1 (0.3%)	0	0	1 (0.8%)
Urinary hesitation	排尿躊躇	1 (0.3%)	0	0	0
Urinary incontinence	尿失禁	8 (2.3%)	3 (1.8%)	8 (3.2%)	2 (1.5%)
Urinary retention	尿閉	19 (5.5%)	14 (8.2%)	8 (3.2%)	5 (3.8%)
Urinary tract obstruction	尿路閉塞	1 (0.3%)	2 (1.2%)	1 (0.4%)	1 (0.8%)
Urine flow decreased	尿流量減少	0	1 (0.6%)	2 (0.8%)	1 (0.8%)
Urogenital disorder	尿生殖器障害	0	0	0	1 (0.8%)
Reproductive system and breast disorders	生殖系および乳房障害	13 (3.7%)	6 (3.5%)	6 (2.4%)	2 (1.5%)
Benign prostatic hyperplasia	良性前立腺肥大症	1 (0.3%)	0	0	0
Breast mass	乳房腫瘤	1 (0.3%)	0	0	0
Breast pain	乳房痛	1 (0.3%)	0	0	0
Breast tenderness	乳房圧痛	1 (0.3%)	1 (0.6%)	1 (0.4%)	0
Genital pain	生殖器痛	0	1 (0.6%)	0	0
Gynaecomastia	女性化乳房	1 (0.3%)	2 (1.2%)	3 (1.2%)	1 (0.8%)

表 2.7.4.7- 2　ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Nipple pain	乳頭痛	0	1 (0.6%)	0	0
Oedema genital	性器浮腫	3 (0.9%)	2 (1.2%)	1 (0.4%)	1 (0.8%)
Pelvic pain	骨盤痛	2 (0.6%)	1 (0.6%)	0	0
Perineal pain	会陰痛	1 (0.3%)	0	0	0
Posthitis	包皮炎	1 (0.3%)	0	0	0
Prostatic haemorrhage	前立腺出血	1 (0.3%)	0	0	0
Prostatitis	前立腺炎	1 (0.3%)	0	0	0
Scrotal oedema	陰嚢浮腫	0	0	1 (0.4%)	0
Scrotal swelling	陰嚢腫脹	1 (0.3%)	0	0	0
Scrotal ulcer	陰嚢潰瘍	1 (0.3%)	0	0	0
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	64 (18.4%)	33 (19.3%)	53 (20.9%)	27 (20.8%)
Acute pulmonary oedema	急性肺水腫	0	0	1 (0.4%)	0
Atelectasis	無気肺	0	1 (0.6%)	0	0
Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	0	2 (1.2%)	2 (0.8%)	2 (1.5%)
Chronic respiratory failure	慢性呼吸不全	0	0	0	1 (0.8%)
Cough	咳嗽	15 (4.3%)	4 (2.3%)	13 (5.1%)	7 (5.4%)
Dysphonia	発声障害	0	1 (0.6%)	1 (0.4%)	0
Dyspnoea	呼吸困難	29 (8.4%)	15 (8.8%)	19 (7.5%)	11 (8.5%)
Dyspnoea exertional	労作性呼吸困難	5 (1.4%)	1 (0.6%)	4 (1.6%)	1 (0.8%)
Epistaxis	鼻出血	3 (0.9%)	4 (2.3%)	2 (0.8%)	2 (1.5%)
Haemoptysis	喀血	0	1 (0.6%)	0	0
Hiccups	しゃっくり	0	0	2 (0.8%)	0
Hypoxia	低酸素症	0	0	1 (0.4%)	1 (0.8%)
Increased bronchial secretion	気管支分泌増加	1 (0.3%)	0	1 (0.4%)	0

表 2.7.4.7- 2　ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Increased upper airway secretion	上気道分泌増加	0	1 (0.6%)	1 (0.4%)	0
Lung consolidation	肺硬化	0	0	1 (0.4%)	0
Nasal congestion	鼻閉	0	1 (0.6%)	1 (0.4%)	1 (0.8%)
Nasal discomfort	鼻部不快感	0	0	0	1 (0.8%)
Pharyngolaryngeal pain	咽喉頭疼痛	2 (0.6%)	1 (0.6%)	0	2 (1.5%)
Pleural effusion	胸水	8 (2.3%)	4 (2.3%)	6 (2.4%)	3 (2.3%)
Pleurisy	胸膜炎	0	0	1 (0.4%)	0
Pleuritic pain	胸膜痛	1 (0.3%)	1 (0.6%)	0	0
Pneumonia aspiration	嚥下性肺炎	0	2 (1.2%)	0	0
Pneumonitis	肺臓炎	0	0	1 (0.4%)	0
Postnasal drip	後鼻漏	1 (0.3%)	0	0	0
Productive cough	湿性咳嗽	4 (1.2%)	2 (1.2%)	1 (0.4%)	1 (0.8%)
Pulmonary congestion	肺うっ血	1 (0.3%)	0	0	0
Pulmonary embolism	肺塞栓症	6 (1.7%)	0	2 (0.8%)	6 (4.6%)
Pulmonary haemorrhage	肺出血	1 (0.3%)	0	0	0
Pulmonary hypertension	肺高血圧症	1 (0.3%)	0	0	0
Pulmonary oedema	肺水腫	1 (0.3%)	1 (0.6%)	2 (0.8%)	0
Rales	ラ音	1 (0.3%)	0	0	0
Respiratory failure	呼吸不全	0	2 (1.2%)	1 (0.4%)	1 (0.8%)
Rhinorrhoea	鼻漏	0	0	1 (0.4%)	2 (1.5%)
Tachypnoea	頻呼吸	0	0	0	1 (0.8%)
Vasomotor rhinitis	血管運動性鼻炎	0	0	1 (0.4%)	0
Wheezing	喘鳴	1 (0.3%)	0	1 (0.4%)	0
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	41 (11.8%)	22 (12.9%)	29 (11.5%)	12 (9.2%)

表 2.7.4.7- 2　ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Actinic keratosis	日光性角化症	1 (0.3%)	0	1 (0.4%)	0
Alopecia	脱毛症	0	0	4 (1.6%)	0
Decubitus ulcer	褥瘡性潰瘍	2 (0.6%)	3 (1.8%)	2 (0.8%)	1 (0.8%)
Dermatitis	皮膚炎	0	2 (1.2%)	0	0
Dermatitis acneiform	ざ瘡様皮膚炎	1 (0.3%)	0	0	0
Dermatitis allergic	アレルギー性皮膚炎	2 (0.6%)	0	0	0
Dermatitis contact	接触性皮膚炎	0	1 (0.6%)	0	0
Dry skin	皮膚乾燥	2 (0.6%)	0	2 (0.8%)	0
Eczema	湿疹	0	0	1 (0.4%)	0
Erythema	紅斑	0	0	0	3 (2.3%)
Hyperhidrosis	多汗症	4 (1.2%)	6 (3.5%)	4 (1.6%)	0
Hypoaesthesia facial	顔面感覚鈍麻	1 (0.3%)	1 (0.6%)	0	1 (0.8%)
Increased tendency to bruise	挫傷発生の増加傾向	1 (0.3%)	0	0	0
Ingrowing nail	嵌入爪	0	0	0	1 (0.8%)
Intertrigo	間擦疹	0	1 (0.6%)	0	0
Nail disorder	爪の障害	1 (0.3%)	0	0	0
Night sweats	寝汗	6 (1.7%)	2 (1.2%)	1 (0.4%)	1 (0.8%)
Onycholysis	爪甲離床症	1 (0.3%)	0	0	0
Pain of skin	皮膚疼痛	1 (0.3%)	0	0	0
Palmar erythema	手掌紅斑	1 (0.3%)	0	0	0
Periorbital oedema	眼窩周囲浮腫	1 (0.3%)	1 (0.6%)	1 (0.4%)	0
Petechiae	点状出血	3 (0.9%)	0	0	0
Pigmentation disorder	色素沈着障害	2 (0.6%)	0	0	0
Pruritus	そう痒症	3 (0.9%)	2 (1.2%)	3 (1.2%)	1 (0.8%)
Psoriasis	乾癬	1 (0.3%)	1 (0.6%)	0	0
Purpura	紫斑	1 (0.3%)	0	0	0
Rash	発疹	10 (2.9%)	3 (1.8%)	7 (2.8%)	3 (2.3%)

表 2.7.4.7- 2　ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Rash erythematous	紅斑性皮疹	0	0	1 (0.4%)	0
Rash pruritic	そう痒性皮疹	1 (0.3%)	0	1 (0.4%)	1 (0.8%)
Skin atrophy	皮膚萎縮	2 (0.6%)	0	0	0
Skin discolouration	皮膚変色	2 (0.6%)	0	0	0
Skin disorder	皮膚障害	0	1 (0.6%)	0	0
Skin exfoliation	皮膚剥脱	1 (0.3%)	0	0	0
Skin hyperpigmentation	皮膚色素過剰	1 (0.3%)	0	1 (0.4%)	0
Skin irritation	皮膚刺激	0	0	1 (0.4%)	0
Skin lesion	皮膚病変	0	0	1 (0.4%)	1 (0.8%)
Skin nodule	皮膚小結節	1 (0.3%)	0	0	0
Skin odour abnormal	皮膚異常臭	1 (0.3%)	0	0	0
Skin reaction	皮膚反応	2 (0.6%)	0	1 (0.4%)	0
Swelling face	顔面腫脹	0	0	0	1 (0.8%)
Urticaria	蕁麻疹	0	2 (1.2%)	0	0
Surgical and medical procedures	外科および内科処置	1 (0.3%)	0	0	0
Tooth extraction	抜歯	1 (0.3%)	0	0	0
Vascular disorders	血管障害	24 (6.9%)	16 (9.4%)	18 (7.1%)	11 (8.5%)
Circulatory collapse	循環虚脱	1 (0.3%)	0	0	0
Deep vein thrombosis	深部静脈血栓症	3 (0.9%)	0	3 (1.2%)	1 (0.8%)
Flushing	潮紅	0	2 (1.2%)	0	1 (0.8%)
Haematoma	血腫	2 (0.6%)	0	1 (0.4%)	0
Hot flush	ほてり	3 (0.9%)	3 (1.8%)	1 (0.4%)	1 (0.8%)
Hypertension	高血圧	5 (1.4%)	2 (1.2%)	8 (3.2%)	0
Hypertensive crisis	高血圧性クリーゼ	0	0	1 (0.4%)	0
Hypotension	低血圧	3 (0.9%)	3 (1.8%)	5 (2.0%)	4 (3.1%)

表 2.7.4.7- 2　ドセタキセルの治療歴の有無別の TEAE（試験 BC1-06、2 回目の解析）（続き）

Primary system organ class Preferred term MedDRA version 11.0	Primary system organ class Preferred term MedDRA version 11.0	Prior use of Docetaxel: YES BAY 88-8223 N=347 (100%)	Prior use of Docetaxel: YES Placebo N=171 (100%)	Prior use of Docetaxel: No BAY 88-8223 N=253 (100%)	Prior use of Docetaxel: No Placebo N=130 (100%)
Orthostatic hypotension	起立性低血圧	1 (0.3%)	0	1 (0.4%)	1 (0.8%)
Pallor	蒼白	1 (0.3%)	2 (1.2%)	1 (0.4%)	0
Phlebitis	静脈炎	0	1 (0.6%)	0	0
Thrombophlebitis	血栓性静脈炎	2 (0.6%)	1 (0.6%)	0	1 (0.8%)
Thrombosis	血栓症	1 (0.3%)	1 (0.6%)	0	1 (0.8%)
Vasculitis	血管炎	1 (0.3%)	0	0	0
Venous thrombosis	静脈血栓症	1 (0.3%)	0	0	1 (0.8%)
Venous thrombosis limb	四肢静脈血栓症	0	1 (0.6%)	0	0

Source: 5.3.5.1.4 BC1-06_J-table 2/Table 1.1/4

表 2.7.4.7- 3　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
001003	Norway	67/M/C	Nausea	悪心	1	N	TE	23	1	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	23	1	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	28	29	Y	None	Not recovered, but no changes expected
			Nausea	悪心	2	N	TE	31	12	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	31	12	Y	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	35	11	Y	None	Recovered
			Nausea	悪心	2	N	TE	56	8	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	56	8	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	56		Y	None	Not recovered, but no changes expected
			Weight decreased	体重減少	2	N	TE	84		Y	None	Not recovered, but no changes expected
			Nausea	悪心	2	N	TE	87	8	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	87	8	Y	None	Recovered
			Nausea	悪心	2	N	TE	114	40	Y	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	2	N	TE	114	40	Y	Not applicable	Recovered with sequelae
			Pathological fracture	病的骨折	2	N	TE	115		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	Y	TE	127	15	N	None	Recovered
			Nausea	悪心	3	Y	TE	153	6	Y	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	3	Y	TE	153	6	Y	Not applicable	Recovered with sequelae
			Nausea	悪心	2	N	TE	158	17	Y	None	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	174	5	Y	Not applicable	Recovered with sequelae

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	3	Y	TE	174	5	Y	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	3	Y	TE	174	5	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	3	N	TE	174	5	Y	Not applicable	Ongoing at study termination / withdrawal
			Infection	感染	1	Y	TE	174	5	Y	Not applicable	Recovered
			Bone pain	骨痛	2	Y	TE	174	5	Y	Not applicable	Recovered
			Nausea	悪心	2	N	TE	178		Y	None	Ongoing at study termination / withdrawal
			General physical health deterioration	全身健康状態低下	2	N	TE	178		Y	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	Y	TE	192	2	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	197	14	Y	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	2	Y	TE	197	14	N	Not applicable	Recovered with sequelae
			Infection	感染	2	Y	TE	197	14	N	Not applicable	Recovered
001012	Norway	52/M/C	Bone pain	骨痛	2	Y	TE	105	2	N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	106		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	Y	TE	141	4	N	Not applicable	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	2	N	TE	166	57	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	Y	TE	184	3	N	Not applicable	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	TE	222		N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	2	N	TE	222		N	Not applicable	Not recovered, but no changes expected
001019	Norway	70/M/C	Ankle fracture	足関節部骨折	2	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE	118	56	Y	None	Recovered
			Chest pain	胸痛	2	Y	TE	133	2	Y	None	Recovered
			Anaemia	貧血	2	N	TE	145	63	Y	Not applicable	Recovered with sequelae
			Dysgeusia	味覚異常	2	N	TE	145	29	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	207	4	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	TE	210		Y	Not applicable	Ongoing at study termination / withdrawal
001021	Norway	66/M/C	Lung infection	肺感染	2	Y	Pre	-13	5	N	Not applicable	Recovered
			Anaemia	貧血	2	N	Pre	1		Y	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	57	1	Y	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dizziness	浮動性めまい	1	N	TE	57		Y	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	112	6	Y	None	Recovered
			Nausea	悪心	2	N	TE	148		Y	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	148		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	156		Y	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	2	N	TE	183		Y	None	Ongoing at study termination / withdrawal
001023	Norway	62/M/C	Bone pain	骨痛	2	N	Pre	1		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	29		Y	None	Ongoing at study termination / withdrawal
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	57		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	TE	57		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	57		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	57	19	N	Drug permanently withdrawn	Death
			Metastases to liver	肝転移	3	Y	TE	57		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	75	1	N	Drug permanently withdrawn	Death
001025	Norway	77/M/C	Bone pain	骨痛	2	Y	Pre	-14	2	N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	57	16	N	None	Recovered
			Nausea	悪心	2	N	TE	69		Y	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	2	N	TE	85		Y	None	Ongoing at study termination / withdrawal
001029	Norway	66/M/C	Diarrhoea	下痢	1	N	TE	3	8	Y	None	Recovered
			Nausea	悪心	2	N	TE	3	4	Y	None	Recovered
			Fatigue	疲労	1	N	TE	57		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	57		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	87	7	Y	Drug administration postponed	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	90	4	Y	Drug administration postponed	Recovered
			Nausea	悪心	2	N	TE	90	4	Y	Drug administration postponed	Recovered
			Dehydration	脱水	2	Y	TE	90	4	Y	Drug administration postponed	Recovered
			Weight decreased	体重減少	2	N	TE	106	29	Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	Y	TE	134	2	Y	Drug permanently withdrawn	Recovered with sequelae
			Leukopenia	白血球減少症	2	Y	TE	134		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	3	Y	TE	134		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	3	N	TE	134		Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	135		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
001035	Norway	75/M/C	Anaemia	貧血	2	N	TE	3	8	Y	None	Recovered
			Nausea	悪心	2	N	TE	3	8	Y	None	Recovered
			Infection	感染	2	Y	TE	3	8	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
002006	Norway	66/M/C	Bone pain	骨痛	2	N	Pre			N	None	Ongoing at study termination / withdrawal
			Urinary tract infection	尿路感染	3	N	TE	10	10	N	None	Recovered
			Anaemia	貧血	2	N	TE	29	34	N	None	Recovered
			Bone pain	骨痛	1	N	Pre	29	29	N	None	Ongoing at study termination / withdrawal
			Ascites	腹水	1	N	TE	57	6	N	None	Recovered
			Bone pain	骨痛	2	N	Pre	57		N	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	Y	TE	62	18	N	Drug permanently withdrawn	Recovered with sequelae
			Fungal infection	真菌感染	2	N	TE	76	5	N	None	Recovered
			Anxiety	不安	2	N	TE	77		N	None	Not recovered, but no changes expected
			Sepsis	敗血症	4	Y	TE	79	5	N	Not applicable	Death
			Anaemia	貧血	2	N	TE	81	2	N	None	Recovered
			Sepsis	敗血症	5	Y	TE	83	1	N	Not applicable	Death
002008	Norway	69/M/C	Nausea	悪心	1	N	TE	29	3	N	None	Recovered
			Nausea	悪心	1	N	TE	34		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	105	21	N	None	Recovered
			Constipation	便秘	1	N	TE	120		Y	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	125	5	N	None	Recovered
			Hyperglycaemia	高血糖	4	Y	TE	159	4	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	161	3	N	Not applicable	Recovered
			Ascites	腹水	1	N	TE	176		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	183	2	N	Not applicable	Recovered
			Infection	感染	2	N	TE	183	3	N	Not applicable	Recovered
			Infection	感染	3	Y	TE	185	5	N	Not applicable	Recovered
			Anaemia	貧血	4	Y	TE	216	2	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	4	Y	TE	216		Y	Not applicable	Ongoing at time of death
002009	Norway	73/M/C	Diarrhoea	下痢	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	2	N	TE	2	3	Y	None	Recovered
			Osteoporosis	骨粗鬆症	3	Y	TE	39	6	N	None	Recovered with sequelae
			Atrial fibrillation	心房細動	2	N	TE	71	2	N	None	Recovered
			Pneumonia	肺炎	2	N	TE	71	14	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	71	14	N	None	Recovered with sequelae
			Urinary retention	尿閉	2	N	TE	71	14	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oral infection	口腔感染	2	N	TE	79	5	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	79	2	N	None	Recovered
			Bone pain	骨痛	3	N	TE	113		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	132	47	N	None	Recovered with sequelae
			Constipation	便秘	2	N	TE	225		N	None	Not recovered, but no changes expected
002013	Norway	69/M/C	Vision blurred	霧視	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	2	5	Y	None	Recovered
			Metastases to skin	皮膚転移	1	N	TE	57		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	85		N	None	Ongoing at study termination / withdrawal
			Metastases to soft tissue	軟部組織転移	1	N	TE	86		N	None	Ongoing at time of death
			Cerebral haemorrhage	脳出血	3	Y	TE	100	38	Y	Drug permanently withdrawn	Death
			Anaemia	貧血	2	N	TE	110		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	111		Y	Not applicable	Ongoing at time of death
			Cerebral haemorrhage	脳出血	5	Y	TE	137	1	Y	Drug permanently withdrawn	Death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
003001	Norway	64/M/C	Dizziness	浮動性めまい	1	N	TE			Y	None	Ongoing at study termination / withdrawal
			Constipation	便秘	1	N	TE	1	21	Y	None	Recovered
			Nausea	悪心	1	N	TE	2	82	Y	None	Recovered
			Insomnia	不眠症	2	N	TE	2		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	8	18	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	28	98	N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	Y	TE	84		Y	Not applicable	Ongoing at time of death
			Leukopenia	白血球減少症	1	N	TE	84		Y	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	1	N	TE	84		Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	N	TE	112	2	Y	Drug administration postponed	Recovered
			Neutropenia	好中球減少症	3	Y	TE	112	3	Y	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	112		Y	Drug administration postponed	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	125	52	Y	Drug permanently withdrawn	Recovered with sequelae

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Leukopenia	白血球減少症	1	N	TE	125		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	1	N	TE	125		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	3	N	TE	125		N	None	Ongoing at study termination / withdrawal
			Pyrexia	発熱	2	N	TE	131	5	Y	Not applicable	Recovered
003005	Norway	58/M/C	Spinal cord compression	脊髄圧迫	2	N	TE			N	Not applicable	Ongoing at time of death
			Nasopharyngitis	鼻咽頭炎	2	N	Pre	-1	9	N	None	Recovered
			Bone pain	骨痛	1	N	Pre	-1	9	N	None	Recovered
			Nausea	悪心	1	N	TE	29	30	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	64	84	Y	None	Recovered
			Nausea	悪心	1	N	TE	87	33	Y	None	Recovered
			Anaemia	貧血	2	N	TE	119	123	Y	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	1	N	TE	119		Y	None	Ongoing at study termination / withdrawal
			Muscular weakness	筋力低下	2	N	TE	147		N	None	Ongoing at study termination / withdrawal
			Pneumonia	肺炎	3	Y	TE	187	3	N	Not applicable	Recovered
			Pneumonia	肺炎	1	N	TE	189	25	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pleural effusion	胸水	3	N	TE	209	5	N	Not applicable	Recovered with sequelae
			Hypovitaminosis	ビタミン欠乏症	1	N	TE	211		N	Not applicable	Ongoing at time of death
			Pleural effusion	胸水	3	Y	TE	213	6	N	Not applicable	Recovered with sequelae
			Insomnia	不眠症	1	N	TE	221		N	Not applicable	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	221		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	1	N	TE	241		Y	None	Ongoing at study termination / withdrawal
003007	Norway	51/M/C	Anxiety	不安	1	N	Pre			N	None	Ongoing at study termination / withdrawal
			Radiation associated pain	放射線関連痛	2	N	TE	17	4	N	None	Recovered
			Hypoaesthesia	感覚鈍麻	2	N	TE	20	123	N	None	Recovered with sequelae
			Radiation associated pain	放射線関連痛	3	N	TE	32	55	N	None	Ongoing at study termination / withdrawal
			Radiation associated pain	放射線関連痛	2	N	TE	86		N	None	Ongoing at study termination / withdrawal
			Hypoaesthesia	感覚鈍麻	1	N	TE	86	60	N	None	Recovered
			Neuralgia	神経痛	1	N	TE	86	29	N	None	Recovered
			Micturition urgency	尿意切迫	2	N	TE	144	2	N	Not applicable	Recovered
			Micturition urgency	尿意切迫	1	Y	TE	145	5	N	Not applicable	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hydronephrosis	水腎症	3	N	TE	195	39	N	Not applicable	Recovered
003015	Norway	72/M/C	Oral candidiasis	口腔カンジダ症	1	N	TE	15	43	N	None	Recovered
			Sinus tachycardia	洞性頻脈	3	N	TE	57	29	N	None	Not recovered, but no changes expected
			Rib fracture	肋骨骨折	2	Y	TE	82	4	N	None	Recovered with sequelae
			Sinus tachycardia	洞性頻脈	1	N	TE	85		N	None	Not recovered, but no changes expected
			Herpes zoster	帯状疱疹	3	N	TE	98	9	N	None	Recovered
			Herpes zoster	帯状疱疹	1	N	TE	106	36	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	141		N	None	Ongoing at time of death
003016	Norway	77/M/C	Spinal compression fracture	脊椎圧迫骨折	1	N	TE	95	5	N	None	Recovered
			Constipation	便秘	3	Y	TE	99	2	Y	None	Recovered
			Nausea	悪心	2	N	TE	99	49	N	None	Recovered
			Spinal compression fracture	脊椎圧迫骨折	3	Y	TE	99	7	N	None	Recovered
			Insomnia	不眠症	1	N	TE	99		N	None	Not recovered, but no changes expected
			Constipation	便秘	1	N	TE	100	1	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	105	38	N	None	Recovered with sequelae
004001	Norway	60/M/C	Dysgeusia	味覚異常	1	N	TE	2	28	Y	None	Recovered
			Anaemia	貧血	1	N	TE	92	24	Y	None	Recovered
			Anaemia	貧血	1	N	TE	92	24	Y	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	92	113	Y	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	2	N	TE	120		Y	None	Ongoing at time of death
			Respiratory tract infection viral	ウイルス性気道感染	2	N	TE	134	11	N	None	Recovered
			Anaemia	貧血	2	N	TE	144		Y	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	2	N	TE	148	37	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	148	12	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	148	12	Y	None	Recovered with sequelae
			Pancytopenia	汎血球減少症	3	N	TE	155	5	Y	Not applicable	Recovered with sequelae
			Pancytopenia	汎血球減少症	3	Y	TE	159	11	Y	Not applicable	Recovered with sequelae
			Oedema	浮腫	2	Y	TE	159	11	Y	Not applicable	Recovered with sequelae
			Dyspnoea	呼吸困難	3	Y	TE	159	11	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	Y	TE	159	11	Y	Not applicable	Recovered with sequelae
			Pancytopenia	汎血球減少症	2	N	TE	169	16	Y	Not applicable	Recovered with sequelae
			Dyspnoea	呼吸困難	2	N	TE	169	16	Y	Not applicable	Recovered
			Pleural effusion	胸水	1	N	TE	170	15	Y	Not applicable	Recovered
			Pancytopenia	汎血球減少症	3	Y	TE	184	15	Y	Not applicable	Recovered with sequelae

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	3	Y	TE	184	15	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	Y	TE	184	15	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	Y	TE	184	15	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	198	7	Y	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	198	7	Y	Not applicable	Recovered with sequelae
			Pancytopenia	汎血球減少症	4	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	204		Y	Not applicable	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	3	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Pleural effusion	胸水	2	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Renal failure	腎不全	5	Y	TE	208	1	N	Not applicable	Death
005002	Norway	75/M/C	Bone pain	骨痛	1	N	TE			N	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	85		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	162	36	N	Not applicable	Recovered
			Pneumonia	肺炎	3	Y	TE	169	15	N	Not applicable	Recovered
			Atrial fibrillation	心房細動	2	Y	TE	180	1	N	Not applicable	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	197	7	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	198	6	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	1	N	TE	203		Y	Not applicable	Ongoing at time of death
			Pulmonary embolism	肺塞栓症	4	Y	TE	222	5	Y	Not applicable	Death
			Pulmonary embolism	肺塞栓症	5	Y	TE	226	1	Y	Not applicable	Death
006001	Norway	76/M/C	Bone pain	骨痛	2	N	TE	75	20	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	82	13	N	None	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	82	13	N	Drug administration postponed	Recovered
			Bone pain	骨痛	3	N	TE	113	27	N	None	Recovered
			Renal failure	腎不全	3	Y	TE	113	8	N	None	Recovered
			Reflux gastritis	逆流性胃炎	1	N	TE	114		N	None	Recovered
			Anaemia	貧血	2	N	TE	167	2	N	Not applicable	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	167	86	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	167	3	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	1	N	TE	168		N	Not applicable	Ongoing at time of death
			Hypomagnesaemia	低マグネシウム血症	2	N	TE	191	62	N	None	Not recovered, but no changes expected
			Hypomagnesaemia	低マグネシウム血症	1	N	TE	252		N	None	Not recovered, but no changes expected

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
006004	Norway	53/M/C	Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE			Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	2	15	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	2	4	Y	None	Recovered
			Nausea	悪心	2	N	TE	15	68	Y	None	Recovered
			Anorexia	食欲不振	2	N	TE	56		N	None	Not recovered, but no changes expected
			Insomnia	不眠症	2	N	TE	166		N	None	Not recovered, but no changes expected
			Upper respiratory tract infection	上気道感染	2	Y	TE	180	10	N	Not applicable	Recovered
			Oesophagitis	食道炎	2	N	TE	217		N	Not applicable	Not recovered, but no changes expected
006005	Norway	72/M/C	Diarrhoea	下痢	1	N	TE	3	1	Y	None	Recovered
			Pyrexia	発熱	2	Y	TE	22	7	N	None	Recovered
			Dehydration	脱水	2	Y	TE	22	7	N	None	Recovered
			Vomiting	嘔吐	1	Y	TE	38	1	N	None	Recovered
			Pyrexia	発熱	2	Y	TE	38	1	Y	None	Recovered
			Dehydration	脱水	2	Y	TE	38	6	Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	2	Y	TE	38	6	N	None	Recovered
			Vomiting	嘔吐	2	Y	TE	62	11	Y	None	Recovered
			Dehydration	脱水	2	Y	TE	62	11	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	62	11	N	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	85	15	N	None	Recovered with sequelae
			Dyspepsia	消化不良	2	N	TE	86		N	None	Ongoing at time of death
			Depression	うつ病	2	N	TE	99		N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pneumonia	肺炎	3	Y	TE	176	2	N	Not applicable	Death
			Bone pain	骨痛	3	Y	TE	176		N	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	5	Y	TE	177	1	N	Not applicable	Death
006008	Norway	70/M/C	Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	Pre	-1	29	N	None	Ongoing at time of death
			Hydronephrosis	水腎症	3	Y	Pre	-1	3	N	None	Recovered
			Constipation	便秘	2	N	TE	2	25	Y	None	Recovered
			Nausea	悪心	1	N	TE	2	6	Y	None	Recovered
			Fatigue	疲労	2	N	TE	2	6	N	None	Recovered
			Hyperhidrosis	多汗症	2	N	TE	2	6	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	17	11	N	None	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	Pre	28		N	None	Ongoing at time of death
			Small intestinal obstruction	小腸閉塞	3	Y	TE	55	3	N	Drug administration postponed	Recovered
			Death	死亡	5	Y	TE	60	1	N	Drug permanently withdrawn	Death
006009	Norway	75/M/C	Dizziness	浮動性めまい	1	N	TE			N	None	Recovered
			Diarrhoea	下痢	1	N	TE	2	1	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	2	2	Y	None	Recovered
			Fatigue	疲労	3	Y	TE	16	9	Y	None	Recovered
			Dehydration	脱水	2	N	TE	19	6	Y	None	Recovered
			Influenza	インフルエンザ	1	N	TE	43	8	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	73	12	Y	None	Recovered
			Nausea	悪心	1	N	TE	84	37	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	84		Y	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	84	29	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	84	29	Y	None	Ongoing at study termination / withdrawal
			Mood altered	気分変化	1	N	TE	84		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	107		N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	112	5	Y	None	Recovered
			Anorexia	食欲不振	2	N	TE	112		Y	None	Ongoing at study termination / withdrawal
			Cachexia	悪液質	2	N	TE	112		N	Not applicable	Ongoing at study termination / withdrawal
006011	Norway	68/M/C	Weight decreased	体重減少	2	N	TE	2		Y	None	Not recovered, but no changes expected
			Diarrhoea	下痢	1	N	TE	8	10	N	None	Recovered
			Nausea	悪心	1	N	TE	8	10	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	8	10	N	None	Recovered
			Bone pain	骨痛	2	N	TE	28	29	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	36	10	N	None	Recovered
			Nausea	悪心	1	N	TE	36	10	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	36	10	N	None	Recovered
			Bone pain	骨痛	2	N	TE	103	6	N	None	Recovered
			Nausea	悪心	1	N	TE	114	27	Y	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	1	N	TE	114		Y	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	114	27	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	140	16	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	Y	TE	155	13	N	Not applicable	Recovered with sequelae
			Nausea	悪心	2	N	TE	157	11	N	None	Recovered
			Anaemia	貧血	2	N	TE	225		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	225	64	N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	225	4	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	4	N	TE	288		N	Not applicable	Ongoing at time of death
006016	Norway	59/M/C	Thrombocytopenia	血小板減少症	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	92	8	N	None	Recovered
			Venous thrombosis	静脈血栓症	2	N	TE	105		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	132		N	None	Ongoing at time of death
			Prostatic haemorrhage	前立腺出血	3	Y	TE	132	29	N	Drug administration postponed	Recovered
			Bone pain	骨痛	2	N	TE	141		N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Catheter related infection	カテーテル関連感染	3	Y	TE	166		N	Drug permanently withdrawn	Recovered
006017	Norway	59/M/C	Nausea	悪心	1	N	TE	10	3	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	10	1	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	10	75	N	None	Recovered
			Bone pain	骨痛	2	N	TE	10	75	N	None	Recovered
			Anaemia	貧血	3	Y	TE	84	6	Y	-	
			Thrombocytopenia	血小板減少症	4	Y	TE	84	58	Y	Drug permanently withdrawn	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	84		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	Y	TE	89	3	Y	-	
			Anaemia	貧血	2	Y	TE	91	8	Y	-	
			Anaemia	貧血	3	Y	TE	98	13	Y	-	
			Anaemia	貧血	2	Y	TE	110	2	Y	-	
			Anaemia	貧血	3	Y	TE	111	2	Y	-	
			Anaemia	貧血	2	Y	TE	112	2	Y	-	
			Anaemia	貧血	1	Y	TE	113	2	Y	-	
			Cerebral haemorrhage	脳出血	2	Y	TE	113		Y	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	114	19	Y	-	
			Anaemia	貧血	1	Y	TE	132	3	Y	-	
			Anaemia	貧血	2	Y	TE	134	2	Y	-	
			Anaemia	貧血	1	Y	TE	135	2	Y	-	
			Anaemia	貧血	2	Y	TE	136	3	Y	Drug permanently withdrawn	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	Y	TE	138	3	Y	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	140		Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	Y	TE	141	2	Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	Y	TE	142		Y	Drug permanently withdrawn	Ongoing at time of death
006018	Norway	62/M/C	Pyrexia	発熱	2	N	TE	25	2	Y	None	Recovered
			Pyrexia	発熱	1	N	TE	26	2	Y	None	Recovered
			Weight decreased	体重減少	1	N	TE	33	29	N	None	Not recovered, but no changes expected
			Nausea	悪心	2	N	TE	37	2	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	37	2	N	None	Recovered
			Pyrexia	発熱	2	Y	TE	37	8	Y	None	Recovered
			Anaemia	貧血	2	N	TE	40	3	Y	None	Recovered
			Nausea	悪心	2	N	TE	48	29	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	48	2	N	None	Recovered
			Pyrexia	発熱	2	Y	TE	49	21	Y	None	Recovered
			Anaemia	貧血	2	N	TE	59	2	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	61		N	None	Not recovered, but no changes expected
			Pyrexia	発熱	2	Y	TE	76	2	Y	None	Recovered with sequelae
			Dyspnoea	呼吸困難	1	N	TE	76	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	89	2	N	None	Recovered
			Bone pain	骨痛	2	N	TE	89	26	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	114	20	N	-	
			Pyrexia	発熱	2	N	TE	114	4	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	114	7	N	None	Recovered
			Pyrexia	発熱	2	N	TE	120		Y	None	Recovered
			Spinal cord compression	脊髄圧迫	2	Y	TE	132	7	N	None	Recovered
			Anaemia	貧血	1	N	TE	133	1	N	-	
			Anaemia	貧血	2	N	TE	133	9	N	-	
			Anaemia	貧血	1	N	TE	141	28	N	-	
			Anaemia	貧血	2	N	TE	168	9	N	-	
			Leukopenia	白血球減少症	2	N	TE	168	15	N	None	Recovered
			Neutropenia	好中球減少症	1	N	TE	168	14	N	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	168	31	N	None	Recovered
			Anaemia	貧血	1	N	TE	176	7	N	-	
			Anorexia	食欲不振	1	N	TE	176	14	N	None	Recovered
			Bone pain	骨痛	2	N	TE	176	14	N	None	Recovered
			Bone pain	骨痛	2	N	TE	176	54	N	None	Recovered
			Diplopia	複視	2	N	TE	177	53	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	181	10	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	TE	182	8	N	-	
			Leukopenia	白血球減少症	1	N	TE	182	8	N	None	Recovered
			Pyrexia	発熱	2	N	TE	182	1	Y	None	Recovered
			Pyrexia	発熱	1	N	TE	182	5	Y	None	Recovered
			Anaemia	貧血	1	N	TE	189	10	N	-	
			Leukopenia	白血球減少症	3	N	TE	189	41	N	None	Recovered
			Neutropenia	好中球減少症	2	N	TE	189	10	N	None	Recovered
			Bone pain	骨痛	1	N	TE	190	40	N	None	Recovered
			Anaemia	貧血	2	N	TE	198	35	N	None	Not recovered, but no changes expected
			Neutropenia	好中球減少症	3	N	TE	198	32	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	198	32	N	None	Recovered
			Diplopia	複視	1	N	TE	229		N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	232		N	None	Not recovered, but no changes expected
006020	Norway	77/M/C	Nausea	悪心	1	N	TE			N	None	Recovered
			Anorexia	食欲不振	1	N	TE	28	134	N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	64	36	N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	2	N	TE	99		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	161		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	198	22	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	TE	205	6	N	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	1	N	TE	210		N	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	219		N	None	Not recovered, but no changes expected
			Constipation	便秘	2	N	TE	232	3	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	232	4	N	Not applicable	Recovered with sequelae
006024	Norway	67/M/C	Gastrointestinal pain	消化器痛	3	Y	Pre	-9	2	N	None	Recovered
			Constipation	便秘	2	N	Pre	-1	29	N	None	Recovered
			Fatigue	疲労	2	N	TE	28	92	N	None	Recovered
			Arthralgia	関節痛	1	N	TE	91	29	N	None	Not recovered, but no changes expected
			Paraesthesia	錯感覚	1	N	TE	91	29	N	None	Recovered
			Arthralgia	関節痛	2	N	TE	119	36	N	None	Not recovered, but no changes expected

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Arthralgia	関節痛	1	N	TE	154		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	182	64	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	245		N	None	Not recovered, but no changes expected
006026	Norway	71/M/C	Nausea	悪心	1	N	TE			Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	2	8	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	55	10	N	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	64	11	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	70	3	Y	-	Ongoing at study termination / withdrawal
			Insomnia	不眠症	2	N	TE	71		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	72		Y	-	Ongoing at study termination / withdrawal
			Accidental overdose	偶発的過量投与	2	Y	TE	75	2	N	None	Recovered
			Infection	感染	3	N	TE	87		N	Not applicable	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	Y	TE	87		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Confusional state	錯乱状態	2	N	TE	87		N	None	Ongoing at study termination / withdrawal
006030	Norway	64/M/C	Insomnia	不眠症	1	N	TE			N	None	Lost to follow-up
			Spinal cord compression	脊髄圧迫	3	Y	TE	12	7	N	Drug administration postponed	Recovered
			Weight decreased	体重減少	2	N	TE	47	57	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	62	14	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	103	29	N	None	Recovered
			Bone pain	骨痛	1	N	TE	103		Y	None	Ongoing at study termination / withdrawal
			Leukopenia	白血球減少症	2	N	TE	131	29	Y	None	Recovered
			Neutropenia	好中球減少症	2	N	TE	131	29	Y	None	Recovered
			Leukopenia	白血球減少症	1	N	TE	159	92	Y	None	Recovered
			Neutropenia	好中球減少症	1	N	TE	159	31	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	159		Y	None	Ongoing at study termination / withdrawal
			Metastases to central nervous system	中枢神経系転移	3	Y	TE	184	27	N	Not applicable	Recovered with sequelae
			Nausea	悪心	2	N	TE	195		N	Not applicable	Recovered
			Vomiting	嘔吐	2	N	TE	195		N	Not applicable	Recovered
			Dysarthria	構語障害	2	N	TE	195	16	N	Not applicable	Recovered
006032	Norway	77/M/C	Musculoskeletal pain	筋骨格痛	1	Y	Pre	-5	2	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	Pre	-1	29	N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	28		N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	1	N	TE	30	62	N	None	Recovered
			Nausea	悪心	1	N	TE	31	4	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	31	4	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	91		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	91	65	N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	92	64	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	119	37	N	None	Recovered
			Urinary retention	尿閉	2	N	TE	119		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	155		N	None	Ongoing at time of death
006036	Norway	76/M/C	Patella fracture	膝蓋骨骨折	2	Y	TE	12	2	N	None	Recovered with sequelae
			Patella fracture	膝蓋骨骨折	2	N	TE	13	16	N	None	Recovered
			Anaemia	貧血	1	N	TE	28	85	N	-	
			Neutropenia	好中球減少症	1	N	TE	28	113	N	None	Recovered
			Nausea	悪心	2	N	TE	28	29	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	28	57	N	None	Recovered
			Anorexia	食欲不振	2	N	TE	28	85	N	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	56		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	56	85	N	None	Recovered with sequelae
			Oedema genital	性器浮腫	2	N	TE	80	5	N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	1	N	TE	84	57	N	None	Recovered
			Oedema genital	性器浮腫	1	N	TE	84	57	N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	112	72	N	-	
			Nausea	悪心	1	N	TE	140		N	None	Ongoing at time of death
			Localised oedema	限局性浮腫	1	N	TE	140	18	N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	140	18	N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	140		N	None	Ongoing at time of death
			Oedema genital	性器浮腫	2	N	TE	140		N	None	Ongoing at time of death
			Lymphadenopathy mediastinal	縦隔リンパ節腫脹	2	N	TE	154		N	None	Ongoing at time of death
			Metastases to lung	肺転移	2	N	TE	154		N	None	Ongoing at time of death
			Localised oedema	限局性浮腫	2	N	TE	157		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	157		N	None	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	TE	170	8	N	None	Recovered
			Anaemia	貧血	1	N	TE	183	15	N	-	
			Pleural effusion	胸水	2	N	TE	196	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	197	5	N	-	
			Haematuria	血尿	3	Y	TE	197	21	N	Not applicable	Recovered
			Pneumonia	肺炎	2	N	TE	200	19	N	None	Recovered
			Anaemia	貧血	1	N	TE	201	2	N	-	
			Anaemia	貧血	2	N	TE	202	2	N	-	
			Anaemia	貧血	1	N	TE	203	4	N	-	

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	206	3	N	-	
			Anaemia	貧血	1	N	TE	208	5	N	-	
			Anaemia	貧血	2	N	TE	212	2	N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	213		N	None	Ongoing at time of death
006038	Norway	60/M/C	Bone pain	骨痛	3	Y	Pre	-46	3	N	Not applicable	Recovered
			Pyelonephritis	腎盂腎炎	3	Y	TE	61	10	N	None	Recovered
			Constipation	便秘	2	N	TE	63		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	64	2	N	-	
			Anaemia	貧血	1	N	TE	65	13	N	-	
			Anaemia	貧血	2	N	TE	77	28	N	-	
			Vomiting	嘔吐	2	N	TE	77	3	Y	None	Recovered
			General physical health deterioration	全身健康状態低下	3	Y	TE	77	16	N	Drug administration postponed	Recovered with sequelae
			Infection	感染	3	Y	TE	77	16	N	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	78	18	N	Not applicable	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	78	18	N	None	Recovered with sequelae
			Pyrexia	発熱	1	N	TE	79	8	Y	None	Recovered
			Pyrexia	発熱	2	N	TE	86	2	Y	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			General physical health deterioration	全身健康状態低下	2	N	TE	90		N	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	2	N	TE	95	7	N	Not applicable	Ongoing at study termination / withdrawal
			Pyrexia	発熱	1	N	TE	95	3	Y	None	Recovered
			Bone pain	骨痛	3	Y	TE	95	11	N	None	Recovered with sequelae
			Pyrexia	発熱	2	N	TE	97	4	Y	None	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	101		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	N	TE	104		N	Not applicable	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	105		N	None	Ongoing at study termination / withdrawal
006039	Norway	72/M/C	Nausea	悪心	1	N	TE	2	8	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	72	36	N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	82	26	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	99	34	N	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	2	N	TE	99		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	111	11	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	111	11	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	111	11	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	2	N	TE	131	7	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	N	TE	131		N	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	Y	TE	131		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Urinary retention	尿閉	2	N	TE	131		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	N	TE	132	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	133	9	N	None	Recovered
006040	Norway	72/M/C	Pain	疼痛	1	N	Pre	-1	29	N	None	Recovered
			Bone pain	骨痛	2	N	TE	84	14	N	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	97	4	N	None	Recovered with sequelae
			Insomnia	不眠症	2	N	TE	97		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	98	5	N	None	Recovered
			Bone pain	骨痛	2	N	TE	99	9	Y	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	102	5	N	None	Recovered
			Vomiting	嘔吐	2	Y	TE	102	10	N	None	Recovered
			Infection	感染	3	N	TE	102	6	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	105	7	N	None	Recovered
			Nausea	悪心	1	N	TE	106	6	N	None	Recovered
			Infection	感染	2	N	TE	107	3	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE	107		Y	None	Ongoing at study termination / withdrawal
			Infection	感染	1	N	TE	109	3	N	None	Recovered
			Nausea	悪心	2	N	TE	117	5	Y	None	Recovered
			Vomiting	嘔吐	2	Y	TE	117	8	N	None	Recovered
			Infection	感染	3	N	TE	117	5	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	119		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	121	9	Y	None	Recovered
			Infection	感染	2	N	TE	121	11	Y	None	Recovered
			Duodenitis	十二指腸炎	1	N	TE	124		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	129	3	Y	None	Recovered
			Vomiting	嘔吐	2	Y	TE	129	3	N	None	Recovered
			Nausea	悪心	2	N	TE	136		Y	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	3	Y	TE	136		N	None	Ongoing at study termination / withdrawal
			Infection	感染	2	N	TE	136		N	None	Ongoing at study termination / withdrawal
			Hypomagnesaemia	低マグネシウム血症	1	N	TE	138		N	None	Ongoing at study termination / withdrawal
			Constipation	便秘	2	N	TE	140		Y	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pulmonary oedema	肺水腫	2	N	TE	141	3	N	None	Recovered
006041	Norway	56/M/C	Nausea	悪心	1	N	TE	1	8	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	8	161	Y	None	Recovered
			Nausea	悪心	1	N	TE	29	19	Y	None	Recovered
			Nausea	悪心	1	N	TE	65	14	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	65	14	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	98	71	Y	None	Recovered
			Nausea	悪心	1	N	TE	99	4	Y	None	Recovered
			Pneumonia	肺炎	2	Y	TE	104	6	N	None	Recovered
			Nausea	悪心	1	N	TE	135	59	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	135	35	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	169	25	Y	None	Recovered
			Pyrexia	発熱	1	N	TE	173	4	Y	Not applicable	Recovered
			Infection	感染	2	Y	TE	173	8	N	Not applicable	Recovered
			Bone pain	骨痛	3	N	TE	173	4	N	Not applicable	Recovered
			Leukopenia	白血球減少症	2	N	TE	176	21	Y	Not applicable	Recovered
			Neutropenia	好中球減少症	1	N	TE	177	2	Y	Not applicable	Recovered
			Neutropenia	好中球減少症	2	N	TE	178	19	Y	Not applicable	Recovered
			Leukopenia	白血球減少症	1	N	TE	196	48	Y	Not applicable	Recovered
			Neutropenia	好中球減少症	1	N	TE	196	48	Y	Not applicable	Recovered
008001	Norway	66/M/C	Haemorrhoids	痔核	1	N	TE			N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Decreased appetite	食欲減退	2	N	TE			N	None	Ongoing at time of death
			Depressed mood	抑うつ気分	2	N	TE			N	None	Ongoing at time of death
			Pathological fracture	病的骨折	3	Y	Pre	-48	14	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	Pre	-26	15	Y	-	
			Post procedural infection	処置後感染	3	Y	Pre	-26	29	N	Drug administration postponed	Recovered
			Nausea	悪心	1	N	Pre	-20	77	N	None	Recovered
			Vomiting	嘔吐	1	N	Pre	-20	77	N	None	Recovered
			Anaemia	貧血	1	N	Pre	-12	4	Y	-	
			Anaemia	貧血	2	N	Pre	-9	86	Y	-	
			Soft tissue infection	軟部組織感染	2	N	TE	3		N	None	Recovered
			Nausea	悪心	2	N	TE	57	14	N	None	Recovered
			Fatigue	疲労	2	N	TE	57		N	None	Ongoing at time of death
			Nausea	悪心	2	Y	TE	70	11	N	None	Recovered
			Anaemia	貧血	1	N	Pre	77	51	Y	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	86	7	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	92		N	Not applicable	Ongoing at time of death
			Pyrexia	発熱	2	N	TE	112	1	N	None	Recovered
			Anaemia	貧血	2	N	Pre	127		Y	None	Ongoing at time of death
008003	Norway	79/M/C	Nausea	悪心	2	N	Pre	1	25	N	None	Recovered
			Nausea	悪心	2	Y	TE	25	4	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	1	N	TE	25		N	None	Ongoing at time of death
			Hypercalcaemia	高カルシウム血症	1	N	TE	25	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	27	2	Y	None	Recovered
			Nausea	悪心	2	N	TE	28		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	35	25	N	Drug permanently withdrawn	Recovered
			Dehydration	脱水	2	N	TE	51		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	59	1	N	Not applicable	Death
008007	Norway	62/M/C	Fatigue	疲労	1	N	TE			N	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE			N	Not applicable	Recovered
			Anaemia	貧血	1	N	Pre	1	85	Y	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	21	78	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	85	16	Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	98		N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	98	13	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	99	1	N	Not applicable	Recovered
			Anaemia	貧血	1	N	TE	100		Y	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	1	N	TE	106		N	Not applicable	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	106	1	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	110		N	Not applicable	Ongoing at time of death
			Infection	感染	3	Y	TE	112	6	N	Not applicable	Recovered
008008	Norway	74/M/C	Anorexia	食欲不振	1	N	TE			Y	None	Not recovered, but no changes expected
			Fatigue	疲労	2	N	Pre	-1		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	1		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	29	40	Y	None	Recovered
			Anorexia	食欲不振	2	N	TE	29		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	3	Y	TE	68	1	Y	None	Recovered
			Anaemia	貧血	2	N	TE	68	78	Y	-	
			Atrial fibrillation	心房細動	3	N	TE	68	1	Y	None	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	131	38	Y	-	
			Leukopenia	白血球減少症	2	N	TE	141	14	Y	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	145	1	Y	-	
			Anaemia	貧血	2	N	TE	145	16	Y	-	
			Leukopenia	白血球減少症	1	N	TE	154	7	Y	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	160	7	Y	-	
			Leukopenia	白血球減少症	2	N	TE	160	35	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	166	18	Y	-	

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	4	N	TE	168	7	Y	-	
			General physical health deterioration	全身健康状態低下	2	Y	TE	168	2	Y	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	169		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	174	28	Y	-	
			Anaemia	貧血	3	N	TE	183	7	Y	-	
			Anaemia	貧血	2	N	TE	189	13	Y	-	
			Anaemia	貧血	1	N	TE	201	8	Y	-	
			Thrombocytopenia	血小板減少症	4	N	TE	201	39	Y	-	
			Anaemia	貧血	2	N	TE	208	31	Y	-	
			Leukopenia	白血球減少症	3	N	Post	236	2	Y	-	
			Leukopenia	白血球減少症	2	N	Post	237	17	Y	-	
			Anaemia	貧血	1	N	TE	238	2	Y	-	
			Anaemia	貧血	2	N	TE	239	15	Y	-	
			Thrombocytopenia	血小板減少症	3	N	TE	239	7	Y	-	
			Thrombocytopenia	血小板減少症	4	N	TE	245	16	Y	-	
			Anaemia	貧血	1	N	TE	253	5	Y	-	
			Leukopenia	白血球減少症	3	N	Post	253	11	Y	-	
			Anaemia	貧血	2	N	TE	257	2	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	258	13	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	260	3	Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	262		Y	Drug permanently withdrawn	Ongoing at time of death
			Leukopenia	白血球減少症	4	N	Post	263	5	Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Leukopenia	白血球減少症	3	N	Post	267	4	Y	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	270		Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	Post	270		Y	Not applicable	Ongoing at time of death
008011	Norway	69/M/C	Nausea	悪心	1	N	TE			N	None	Recovered
			Vomiting	嘔吐	1	N	TE			N	None	Recovered
			Fatigue	疲労	1	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE	2	2	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	2	2	N	None	Recovered
			Tendonitis	腱炎	2	N	TE	35		N	None	Recovered
			Constipation	便秘	1	N	TE	37		N	None	Recovered
			Nausea	悪心	1	N	TE	37	5	N	None	Recovered
			Musculoskeletal stiffness	筋骨格硬直	2	N	TE	99	15	N	None	Recovered
			Pharyngitis	咽頭炎	1	N	TE	138	3	N	None	Recovered
			Pathological fracture	病的骨折	2	N	TE	149		N	Not applicable	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	149	9	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	2	N	TE	157	10	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	166	6	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	167	22	N	None	Recovered
			Spinal cord compression	脊髄圧迫	3	N	TE	171	42	N	Not applicable	Ongoing at time of death
			Subileus	亜イレウス	2	Y	TE	181	4	N	Not applicable	Recovered
			Oesophageal pain	食道痛	1	N	TE	198	1	N	Not applicable	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cystitis	膀胱炎	1	N	TE	201	11	N	Not applicable	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	212	1	N	Not applicable	Death
008013	Norway	77/M/C	Weight decreased	体重減少	2	N	TE	15		Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	1	N	TE	29		N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	29	50	N	None	Recovered
			Nausea	悪心	1	N	TE	57	22	N	None	Recovered
			Pathological fracture	病的骨折	2	N	TE	73		N	None	Not recovered, but no changes expected
			Atrial fibrillation	心房細動	3	Y	TE	221	5	N	Not applicable	Recovered
008015	Norway	63/M/C	Vomiting	嘔吐	1	N	TE			N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	2	N	TE			N	None	Not recovered, but no changes expected
			Diarrhoea	下痢	1	N	TE	1	9	Y	None	Recovered
			Nausea	悪心	1	N	TE	1	9	Y	None	Recovered
			Skin laceration	皮膚裂傷	2	N	TE	28	1	N	None	Recovered
			Anaemia	貧血	1	N	TE	29		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	74	45	N	None	Not recovered, but no changes expected
			Constipation	便秘	2	N	TE	114		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	116	3	N	None	Recovered
			Nausea	悪心	2	N	TE	117	29	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	118	8	N	None	Not recovered, but no changes expected

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	125		N	None	Not recovered, but no changes expected
011006	Czech Republic	68/M/C	Diarrhoea	下痢	1	N	TE	2	11	Y	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	150	256	Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	Y	TE	405		Y	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	4	Y	Post	405	2	Y	Not applicable	Death
			Pneumonia	肺炎	5	Y	Post	406	1	Y	Not applicable	Death
012001	Czech Republic	60/M/C	Blood testosterone abnormal	血中テストステロン異常	1	Y	Pre	-35	4	N	None	Recovered
			Anaemia	貧血	3	Y	TE	169	2	Y	Not applicable	Recovered
017003	Czech Republic	80/M/C	Cachexia	悪液質	4	Y	TE	115	10	N	None	Death
			Pneumonitis	肺臓炎	3	N	TE	115		N	None	Ongoing at time of death
			Cachexia	悪液質	5	Y	TE	124	1	N	None	Death
017004	Czech Republic	83/M/C	Angina pectoris	狭心症	3	Y	TE	105	15	N	None	Recovered with sequelae
			Depression	うつ病	2	N	TE	105	8	N	Drug administration postponed	Recovered
			Angina pectoris	狭心症	2	N	TE	119	184	N	None	Death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hypokalaemia	低カリウム血症	1	N	TE	119		N	None	Not recovered, but no changes expected
			Angina pectoris	狭心症	5	Y	TE	302	1	N	None	Death
017005	Czech Republic	80/M/C	Anaemia	貧血	4	Y	TE	168	7	N	Not applicable	Recovered
			Anorexia	食欲不振	1	N	TE	174		N	None	Not recovered, but no changes expected
017007	Czech Republic	80/M/C	Malignant neoplasm progression	悪性新生物進行	4	Y	TE	178	3	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	180	1	N	Not applicable	Death
017017	Czech Republic	77/M/C	General physical health deterioration	全身健康状態低下	4	Y	TE	151	2	N	Not applicable	Death
			General physical health deterioration	全身健康状態低下	5	Y	TE	152	1	N	Not applicable	Death
017018	Czech Republic	76/M/C	Bone pain	骨痛	1	Y	Pre	-61	10	N	None	Recovered
			Myocardial ischaemia	心筋虚血	4	Y	TE	146		N	Not applicable	Ongoing at time of death
			Myocardial infarction	心筋梗塞	5	Y	TE	154	1	N	Not applicable	Death
018004	Czech Republic	62/M/C	Bone pain	骨痛	2	N	TE	19	18	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	1	N	TE	19		N	None	Ongoing at time of death
			Gastritis	胃炎	1	Y	TE	127	4	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pancytopenia	汎血球減少症	4	Y	TE	169	44	Y	Not applicable	Recovered
			Gastritis	胃炎	1	N	TE	169		N	None	Ongoing at time of death
			Metastases to central nervous system	中枢神経系転移	3	N	TE	178		N	None	Ongoing at time of death
020005	Sweden	71/M/C	Anorexia	食欲不振	2	N	TE			N	None	Ongoing at time of death
			Micturition urgency	尿意切迫	2	N	Pre			N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	1	4	Y	None	Recovered
			Fatigue	疲労	2	N	TE	1		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	1		Y	None	Not recovered, but no changes expected
			Musculoskeletal pain	筋骨格痛	1	N	TE	1	4	Y	None	Recovered
			Haematuria	血尿	2	N	TE	11		N	None	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	17	3	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	33	5	Y	None	Recovered
			Constipation	便秘	3	N	TE	39		N	None	Ongoing at study termination / withdrawal
			Chills	悪寒	1	N	TE	54		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	Y	TE	75	14	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	91	22	N	Drug permanently withdrawn	Death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	112	1	N	Drug permanently withdrawn	Death
020015	Sweden	74/M/C	Nausea	悪心	1	N	Pre			N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE			N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	N	TE			Y	None	Ongoing at time of death
			Myalgia	筋痛	1	N	Pre			N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE			Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	19		Y	None	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	3	Y	TE	28	15	Y	Drug administration postponed	Recovered with sequelae
			Constipation	便秘	2	N	TE	28		Y	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	28	15	Y	None	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	1	N	TE	42		Y	None	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE	42		Y	None	Ongoing at time of death
021002	Sweden	63/M/C	Vomiting	嘔吐	1	N	TE	2	49	N	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	26	10	N	None	Recovered
			Cough	咳嗽	1	N	TE	26		N	None	Recovered
			Nausea	悪心	2	N	TE	30	21	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Erosive duodenitis	びらん性十二指腸炎	3	Y	TE	32	6	Y	None	Recovered
			Erosive duodenitis	びらん性十二指腸炎	2	N	TE	38	16	Y	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	44		N	None	Ongoing at time of death
			Nausea	悪心	3	Y	TE	50	4	N	None	Recovered
			Vomiting	嘔吐	3	Y	TE	50	4	N	None	Recovered
			Anorexia	食欲不振	3	Y	TE	50	4	N	None	Recovered
			Dehydration	脱水	3	Y	TE	50	4	N	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	50	4	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	57	29	N	None	Recovered
			Anxiety	不安	1	N	TE	57		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	63	79	N	None	Recovered
			Bone pain	骨痛	2	N	TE	96	5	N	None	Recovered
			Bone pain	骨痛	2	N	TE	100	42	N	None	Recovered
			Abdominal pain	腹痛	2	N	TE	130	32	N	None	Recovered
			Nausea	悪心	2	N	TE	130	32	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	147	15	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	204	6	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	209	4	N	Not applicable	Recovered
			Oedema peripheral	末梢性浮腫	3	N	TE	210		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	210	3	N	Not applicable	Recovered with sequelae
			Hypoaesthesia	感覚鈍麻	2	N	TE	210		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	212		N	Not applicable	Not recovered, but no changes expected

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	213	42	N	None	Recovered
021003	Sweden	63/M/C	Bone pain	骨痛	2	N	Pre	-10	40	N	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	Pre	-7	5	N	None	Recovered
			Weight decreased	体重減少	3	N	Pre	-2		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	Pre	-2	149	N	None	Recovered
			Nausea	悪心	1	N	TE	1		N	None	Recovered
			Paraesthesia	錯感覚	1	N	Pre	1		N	None	Recovered
			Fatigue	疲労	2	N	TE	15	42	N	None	Recovered
			Diarrhoea	下痢	2	Y	TE	29	5	N	None	Recovered
			Myasthenia gravis	重症筋無力症	2	N	TE	29	442	N	None	Recovered
			Myasthenia gravis	重症筋無力症	1	N	TE	29	29	N	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	29		N	None	Recovered
			Pyrexia	発熱	2	Y	TE	44	13	Y	None	Recovered
			Headache	頭痛	1	N	TE	44	11	N	None	Recovered
			Dysphagia	嚥下障害	1	N	TE	57	57	N	None	Recovered
			Pyrexia	発熱	1	N	TE	59	3	N	None	Recovered
			Myalgia	筋痛	1	N	TE	66	4	N	None	Recovered
			Bone pain	骨痛	2	N	TE	72		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	138	12	N	None	Recovered
			Respiratory tract infection	気道感染	1	N	TE	142	12	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	216	82	N	Not applicable	Recovered
022004	Sweden	84/M/C	Weight decreased	体重減少	1	N	TE	25	151	N	None	Recovered
			Increased upper airway secretion	上気道分泌増加	1	N	TE	98	15	N	None	Recovered
			Nausea	悪心	1	N	TE	101	75	Y	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	116	60	N	None	Recovered with sequelae
			Cystitis	膀胱炎	2	N	TE	141	35	N	None	Recovered
			Sternal fracture	胸骨骨折	2	Y	TE	190	7	N	Not applicable	Recovered
			Anaemia	貧血	1	N	TE	226		N	None	Not recovered, but no changes expected
024007	Sweden	63/M/C	Insomnia	不眠症	1	N	Pre	-2		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	Pre	-1		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	1	2	Y	None	Recovered
			Cystitis	膀胱炎	2	N	TE	30	41	N	None	Recovered
			Oedema	浮腫	2	N	TE	63	106	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	75		N	None	Not recovered, but no changes expected
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	114		N	None	Not recovered, but no changes expected
			Erysipelas	丹毒	2	N	TE	128		N	None	Recovered
			Thrombophlebitis	血栓性静脈炎	1	N	TE	128		N	None	Recovered
			Bone pain	骨痛	3	Y	TE	138		N	None	Ongoing at time of death
			Metastases to liver	肝転移	3	N	TE	141	28	N	Not applicable	Death
			Anaemia	貧血	2	N	TE	158	4	Y	Not applicable	Recovered
			Metastases to liver	肝転移	5	Y	TE	168	1	N	Not applicable	Death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
024010	Sweden	75/M/C	Anaemia	貧血	2	N	TE			N	Not applicable	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	Y	Pre	1	12	N	None	Recovered with sequelae
			Pathological fracture	病的骨折	2	N	TE	5	145	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	31		Y	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	59		N	None	Not recovered, but no changes expected
			Rash	発疹	1	N	TE	66	84	N	None	Recovered
			Abdominal pain upper	上腹部痛	2	N	TE	78	38	N	None	Recovered
			Anaemia	貧血	1	N	TE	114	37	Y	None	Recovered
			Nausea	悪心	2	N	TE	131		N	None	Recovered
			Oedema genital	性器浮腫	1	N	TE	150		N	None	Not recovered, but no changes expected
			Metastases to central nervous system	中枢神経系転移	3	N	TE	198		N	None	Not recovered, but no changes expected
			Pathological fracture	病的骨折	3	N	TE	213		N	None	Not recovered, but no changes expected
024011	Sweden	87/M/C	Diarrhoea	下痢	1	N	Pre	-5	2	N	None	Recovered
			Anaemia	貧血	2	N	Pre	-1	30	N	None	Recovered
			Bone pain	骨痛	3	N	Pre	-1	30	N	None	Recovered
			Dysgeusia	味覚異常	1	N	Pre	1		N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	49		N	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	2	N	TE	60		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	63	18	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	82	11	N	None	Recovered with sequelae

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	91		N	None	Ongoing at study termination / withdrawal
			Dry mouth	口内乾燥	1	N	TE	91		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	135		N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	2	N	TE	135		N	None	Ongoing at study termination / withdrawal
024016	Sweden	73/M/C	Injury	損傷	3	Y	TE			N	-	Recovered with sequelae
			Post-traumatic pain	外傷後疼痛	3	Y	TE			N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	3	N	TE			N	None	Not recovered, but no changes expected
			Fatigue	疲労	1	N	TE	29		N	None	Not recovered, but no changes expected
			Cushingoid	クッシング様	2	N	TE	57		N	None	Not recovered, but no changes expected
			Oedema peripheral	末梢性浮腫	2	N	TE	57		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	113	29	N	None	Recovered
024017	Sweden	73/M/C	Bone pain	骨痛	2	N	TE	34		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	64	27	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	64		N	None	Not recovered, but no changes expected

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	117	30	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	204	1	N	Not applicable	Death
024023	Sweden	81/M/C	Bone pain	骨痛	2	Y	TE	16	2	N	None	Recovered
			Bone pain	骨痛	3	N	TE	28		N	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	2	N	TE	29		N	None	Ongoing at study termination / withdrawal
			Rash	発疹	2	N	TE	29		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	57		N	None	Ongoing at study termination / withdrawal
025001	Sweden	66/M/C	Pyrexia	発熱	2	N	TE			N	Not applicable	Recovered
			Cough	咳嗽	1	N	TE			N	Not applicable	Recovered
			Arrhythmia	不整脈	1	N	Pre	-1		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	4	6	N	None	Recovered
			Anaemia	貧血	3	Y	TE	57	4	Y	Drug permanently withdrawn	Recovered
			Thrombocytopenia	血小板減少症	2	Y	TE	57	4	Y	None	Recovered with sequelae
			Dyspnoea	呼吸困難	2	N	TE	57	4	Y	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	59	39	N	Not applicable	Recovered
			Polyneuropathy	多発ニューロパチー	2	N	TE	94		N	Not applicable	Not recovered, but no changes expected
025004	Sweden	63/M/C	Fatigue	疲労	1	N	TE	31	-1	Y	None	Recovered
			Upper respiratory tract infection bacterial	細菌性上気道感染	1	N	TE	48	12	N	None	Recovered
			Haematuria	血尿	3	Y	TE	82		N	Drug administration postponed	Ongoing at time of death
			Cardiac failure	心不全	4	Y	TE	90	2	N	Drug permanently withdrawn	Death
			Cardiac failure	心不全	5	Y	TE	91	1	N	Drug permanently withdrawn	Death
025012	Sweden	74/M/C	Vomiting	嘔吐	2	N	TE	53	1	N	None	Recovered
			Hydronephrosis	水腎症	2	Y	TE	172	7	N	Not applicable	Recovered
			Hypercreatininaemia	高クレアチニン血症	2	N	TE	175		N	None	Ongoing at time of death
			Ureteric obstruction	尿管閉塞	3	N	TE	175		N	Not applicable	Not recovered, but no changes expected
025013	Sweden	71/M/C	Dry mouth	口内乾燥	1	N	TE			N	None	Recovered
			Increased bronchial secretion	気管支分泌増加	1	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	Pre	1		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pyrexia	発熱	1	N	TE	79	12	N	None	Recovered
			Leukopenia	白血球減少症	2	N	TE	102	104	N	None	Recovered
			Anaemia	貧血	2	N	TE	121		N	None	Ongoing at time of death
			Infection	感染	2	N	TE	137	2	N	Drug administration postponed	Recovered
			Infection	感染	3	Y	TE	138	4	N	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	148	29	N	Drug administration postponed	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	176	57	N	Drug administration postponed	Ongoing at time of death
			Pyrexia	発熱	2	Y	TE	185	6	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	4	N	TE	232		N	Drug administration postponed	Ongoing at time of death
025014	Sweden	82/M/C	Haematuria	血尿	2	N	Pre			N	None	Recovered
			Fatigue	疲労	3	N	TE	29		N	Drug permanently withdrawn	Ongoing at time of death
			Hepatic failure	肝不全	3	Y	TE	29	9	N	Drug permanently withdrawn	Death
			Bone pain	骨痛	2	Y	TE	29		N	Drug permanently withdrawn	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hepatic failure	肝不全	5	Y	TE	37	1	N	Drug permanently withdrawn	Death
025015	Sweden	72/M/C	Fatigue	疲労	2	N	TE	57		N	None	Ongoing at study termination / withdrawal
			Lymphadenopathy	リンパ節症	2	N	TE	62		N	None	Ongoing at time of death
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	TE	62		N	None	Ongoing at study termination / withdrawal
			Metastases to liver	肝転移	5	Y	TE	88	1	N	Not applicable	Death
025020	Sweden	61/M/C	Bone pain	骨痛	2	Y	TE	42	3	N	None	Recovered
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE	70	71	N	None	Recovered
			Bone pain	骨痛	1	N	TE	127		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	132	8	N	None	Recovered
			Sepsis	敗血症	4	Y	TE	160	11	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	4	Y	TE	160	14	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	166		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	220	1	N	Not applicable	Death
026001	Sweden	78/M/C	Bone pain	骨痛	3	N	TE			N	None	Not recovered, but no changes expected

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	3		N	None	Not recovered, but no changes expected
			Haematuria	血尿	1	N	TE	106	4	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	114		N	None	Ongoing at time of death
			Dehydration	脱水	2	Y	TE	117	12	N	None	Recovered
			Confusional state	錯乱状態	2	Y	TE	117	12	N	None	Recovered with sequelae
			Urinary retention	尿閉	2	N	TE	118		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	137	2	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	138	1	N	Drug permanently withdrawn	Death
026002	Sweden	66/M/C	Oesophageal spasm	食道痙攣	1	N	TE			N	None	Recovered
			Bone pain	骨痛	3	Y	Pre	-2	8	N	Not applicable	Recovered with sequelae
			Polyneuropathy	多発ニューロパチー	1	Y	TE	91	4	N	None	Recovered with sequelae
			Faecal incontinence	便失禁	3	Y	TE	108	8	N	None	Recovered with sequelae
			Hyperglycaemia	高血糖	3	Y	TE	108	8	N	None	Recovered with sequelae
			Urinary incontinence	尿失禁	3	Y	TE	108	8	N	None	Recovered with sequelae
			Pancytopenia	汎血球減少症	2	N	TE	124	6	N	Drug permanently withdrawn	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fall	転倒・転落	3	Y	TE	124		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	124	13	N	None	Death
			Urinary retention	尿閉	2	N	TE	124		N	Not applicable	Ongoing at time of death
			Mouth ulceration	口腔内潰瘍形成	2	N	TE	125		N	Not applicable	Ongoing at time of death
			Pancytopenia	汎血球減少症	3	Y	TE	129		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	136	1	N	None	Death
026003	Sweden	55/M/C	Nausea	悪心	1	N	TE			Y	None	Not recovered, but no changes expected
			Fatigue	疲労	1	N	TE			N	None	Not recovered, but no changes expected
			Pneumonia	肺炎	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			Y	None	Not recovered, but no changes expected
			Sciatica	坐骨神経痛	2	N	TE			N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	2	2	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	2	2	Y	None	Recovered
			Nausea	悪心	1	N	TE	31	2	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	31	2	Y	None	Recovered
			Anorexia	食欲不振	2	N	TE	116	119	N	None	Recovered
			Anaemia	貧血	2	N	TE	197		Y	None	
			General physical health deterioration	全身健康状態低下	2	Y	TE	219	5	N	Not applicable	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pneumonia	肺炎	3	Y	TE	219	15	N	Not applicable	Recovered
			Compression fracture	圧迫骨折	1	N	TE	220		N	Not applicable	Not recovered, but no changes expected
026005	Sweden	66/M/C	Lymphadenopathy	リンパ節症	1	N	Pre			N	Not applicable	Ongoing at time of death
			Toothache	歯痛	1	N	TE			N	None	Recovered
			Dizziness	浮動性めまい	1	N	TE			N	Not applicable	Recovered
			Insomnia	不眠症	2	N	Pre	1		N	Not applicable	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	TE	109		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	127		N	None	Ongoing at time of death
			Hydronephrosis	水腎症	3	Y	TE	136	5	N	None	Recovered with sequelae
			Weight decreased	体重減少	1	N	TE	147		N	Not applicable	Ongoing at time of death
			Anxiety	不安	2	N	TE	147		N	None	Ongoing at time of death
			Hyponatraemia	低ナトリウム血症	1	N	TE	161	26	N	None	Recovered
			Depression	うつ病	2	N	TE	161		N	None	Recovered with sequelae
			Rectal haemorrhage	直腸出血	3	Y	TE	167	4	N	Not applicable	Recovered
			General physical health deterioration	全身健康状態低下	1	Y	TE	167	4	N	Not applicable	Recovered
			Lymphadenopathy	リンパ節症	2	N	TE	171		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oral fungal infection	口腔真菌感染	1	N	TE	186		N	Not applicable	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	186	6	N	Not applicable	Recovered
			Dehydration	脱水	2	Y	TE	199	3	N	Not applicable	Recovered
			Bone pain	骨痛	2	Y	TE	199	3	N	Not applicable	Recovered
026007	Sweden	66/M/C	Nausea	悪心	1	N	TE			Y	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE			Y	Not applicable	Recovered
			Upper respiratory tract infection	上気道感染	1	N	TE			N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			N	None	Recovered
			Stent occlusion	ステント閉塞	2	Y	Pre	-10	5	N	None	Recovered
			Herpes zoster	帯状疱疹	2	N	TE	6	10	N	None	Recovered
			Lymphadenopathy	リンパ節症	2	N	TE	119	43	N	None	Recovered with sequelae
026010	Sweden	66/M/C	Bone pain	骨痛	2	N	TE	3	4	Y	None	Recovered
			Anaemia	貧血	2	N	TE	170		Y	None	Not recovered, but no changes expected
			Convulsion	痙攣	4	Y	TE	193	3	N	Not applicable	Recovered with sequelae
			Metastases to nervous system	神経系転移	2	N	TE	195		N	Not applicable	Ongoing at time of death
027001	Sweden	72/M/C	Dry mouth	口内乾燥	1	N	TE	29	204	Y	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	1	N	TE	29	204	Y	None	Recovered with sequelae
			Anorexia	食欲不振	2	N	TE	29	141	Y	None	Recovered
			Arthralgia	関節痛	2	N	TE	29	56	N	None	Not recovered, but no changes expected
			Arthralgia	関節痛	1	N	TE	84		N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	113	120	Y	None	Recovered
			Circulatory collapse	循環虚脱	4	Y	TE	176	9	N	Not applicable	Recovered
028001	Belgium	63/M/C	Bone pain	骨痛	2	N	Pre	-102	103	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	Pre	1		N	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	2	N	TE	18	103	Y	None	Recovered with sequelae
			Sinus tachycardia	洞性頻脈	1	N	TE	26	73	N	None	Recovered
			Hepatic function abnormal	肝機能異常	2	N	TE	28		N	None	Ongoing at time of death
			Jaundice	黄疸	3	N	TE	28	10	N	None	Recovered
			Jaundice	黄疸	1	N	TE	37	48	N	None	Recovered
			Hypotension	低血圧	2	N	TE	37	62	N	None	Recovered
			Anaemia	貧血	2	N	TE	56	29	Y	Drug permanently withdrawn	Recovered with sequelae
			Leukopenia	白血球減少症	1	N	TE	56	29	Y	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	56	29	Y	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	56	29	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	56	65	N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	2	N	TE	56	29	N	None	Recovered with sequelae
			Dyspnoea	呼吸困難	2	N	TE	72	13	N	None	Recovered with sequelae
			Vomiting	嘔吐	2	N	TE	77	8	N	None	Recovered
			Anaemia	貧血	4	Y	TE	84	15	Y	Drug permanently withdrawn	Recovered with sequelae
			Leukopenia	白血球減少症	2	N	TE	84	49	Y	None	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	84	15	Y	None	Ongoing at time of death
			Vomiting	嘔吐	1	Y	TE	84	2	N	None	Recovered
			Anorexia	食欲不振	1	Y	TE	84	2	N	None	Recovered with sequelae
			Dyspnoea	呼吸困難	2	Y	TE	84	2	N	None	Recovered with sequelae
			Anorexia	食欲不振	1	N	TE	85		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	98	23	Y	Not applicable	Recovered with sequelae
			Thrombocytopenia	血小板減少症	4	N	TE	98		Y	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	120	2	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	3	Y	TE	120	2	Y	Not applicable	Recovered with sequelae
			Weight decreased	体重減少	2	N	TE	120		N	None	Ongoing at time of death
			Cough	咳嗽	1	N	TE	120		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	121	12	Y	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			General physical health deterioration	全身健康状態低下	2	N	TE	121	12	Y	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	132		Y	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	3	Y	TE	132	4	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	2	N	TE	135	8	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	3	Y	TE	142	2	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	2	N	TE	143	10	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	3	Y	TE	152	4	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	2	N	Post	155		Y	Not applicable	Ongoing at time of death
028002	Belgium	72/M/C	General physical health deterioration	全身健康状態低下	2	Y	Pre	-9	19	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	Y	Pre	-9	19	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	3	N	Pre	-1	2	N	None	Recovered
			Anal ulcer	肛門潰瘍	2	N	Pre	-1	88	N	None	Recovered
			General physical health deterioration	全身健康状態低下	1	N	Pre	10		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	Pre	10		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	3	Y	TE	29	7	Y	Drug administration postponed	Recovered
			Weight decreased	体重減少	2	N	TE	29	28	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	3	N	TE	56	28	N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	56		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	Y	TE	83		Y	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	3	Y	TE	83	24	N	Drug permanently withdrawn	Death
			Anorexia	食欲不振	1	N	TE	83		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	87	20	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	91		N	Drug permanently withdrawn	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	105		N	Not applicable	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	5	Y	TE	106	1	N	Drug permanently withdrawn	Death
028003	Belgium	83/M/C	Nausea	悪心	1	N	TE	2	1	Y	None	Recovered
			Fatigue	疲労	1	N	TE	29		N	None	Ongoing at time of death
			Skin irritation	皮膚刺激	2	N	TE	50	15	N	None	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	55		Y	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	4	Y	TE	55		N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Renal failure	腎不全	4	Y	TE	55		N	Drug permanently withdrawn	Ongoing at time of death
			Pulmonary oedema	肺水腫	4	Y	TE	55		N	None	Ongoing at time of death
			Multi-organ failure	多臓器不全	4	Y	TE	59	6	N	None	Death
			Multi-organ failure	多臓器不全	5	Y	TE	64	1	N	None	Death
028004	Belgium	84/M/C	Transient ischaemic attack	一過性脳虚血発作	2	Y	Pre	-13	55	N	Not applicable	Recovered
			Urinary retention	尿閉	2	N	Pre	-7	6	N	None	Recovered
			Pruritus	そう痒症	1	N	TE	8	7	N	None	Recovered with sequelae
			Pruritus	そう痒症	1	N	TE	8	27	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	14	48	N	None	Recovered
			Urinary tract infection	尿路感染	1	N	TE	28	29	N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	30		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	51		N	None	Ongoing at time of death
			Hypercholesterolaemia	高コレステロール血症	2	N	TE	51		N	None	Ongoing at time of death
			Inguinal hernia	鼠径ヘルニア	1	N	TE	55	14	N	None	Recovered
			Bone pain	骨痛	3	N	TE	57		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	93	1	N	Not applicable	Death
028007	Belgium	65/M/C	Fatigue	疲労	1	N	TE	28		Y	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Feeling cold	冷感	1	N	TE	28	36	Y	None	Recovered
			Pallor	蒼白	1	N	TE	28		Y	None	Ongoing at study termination / withdrawal
			Pyrexia	発熱	2	N	TE	50	6	N	None	Recovered
			Urinary retention	尿閉	3	Y	TE	50	2	N	None	Recovered with sequelae
			Anaemia	貧血	3	N	TE	55	9	Y	None	Recovered with sequelae
			Pleurisy	胸膜炎	2	N	TE	56	23	N	None	Recovered
			Anaemia	貧血	2	N	TE	63		Y	None	Ongoing at study termination / withdrawal
			Tachycardia	頻脈	2	N	TE	91	15	N	None	Recovered
			Pleural effusion	胸水	2	N	TE	167	15	N	Not applicable	Recovered
			Paraesthesia	錯感覚	2	N	TE	168		N	None	Ongoing at study termination / withdrawal
			Lymphangiosis carcinomatosa	癌性リンパ管症	4	Y	TE	181	19	N	Not applicable	Recovered with sequelae
			Pleural effusion	胸水	4	Y	TE	181	2	N	Not applicable	Recovered
			Lymphangiosis carcinomatosa	癌性リンパ管症	4	N	TE	199	5	N	Not applicable	Recovered with sequelae
			Lymphangiosis carcinomatosa	癌性リンパ管症	5	Y	TE	203	1	N	Not applicable	Death
033005	UK	83/M/C	Bone pain	骨痛	1	N	TE	1	3	Y	None	Recovered
			Myocardial infarction	心筋梗塞	4	Y	TE	82	3	N	None	Death
			Myocardial infarction	心筋梗塞	5	Y	TE	84	1	N	None	Death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
033006	UK	76/M/C	Bone pain	骨痛	2	N	TE			N	None	Not recovered, but no changes expected
			Constipation	便秘	3	Y	TE	77	10	N	Drug administration postponed	Recovered
			Cellulitis	蜂巣炎	3	Y	TE	77	10	N	Drug administration postponed	Recovered
			Pneumonia	肺炎	3	Y	TE	89		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Pathological fracture	病的骨折	3	Y	TE	89		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
033011	UK	84/M/C	Abdominal distension	腹部膨満	2	N	TE			N	None	Recovered
			Fatigue	疲労	1	N	TE			Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE			N	None	Recovered with sequelae
			Contusion	挫傷	1	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Balance disorder	平衡障害	1	N	TE			N	None	Not recovered, but no changes expected
			Hallucination	幻覚	1	N	TE			N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	2	N	TE			N	None	Not recovered, but no changes expected
			Orthostatic hypotension	起立性低血圧	1	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	71	43	N	None	Recovered with sequelae
			Haematemesis	吐血	3	Y	TE	195	5	N	Not applicable	Recovered
			Hyperaesthesia	知覚過敏	2	N	TE	214		N	None	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	214		N	None	Ongoing at time of death
033012	UK	72/M/C	Constipation	便秘	2	N	TE			N	None	Recovered
			Mouth ulceration	口腔内潰瘍形成	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Mobility decreased	運動性低下	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Dizziness	浮動性めまい	2	N	TE	11	1	N	None	Recovered
			Dizziness	浮動性めまい	2	N	TE	47	1	N	None	Recovered
			Bone pain	骨痛	3	N	TE	55		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	106	16	N	Drug administration postponed	Recovered
			Hypokalaemia	低カリウム血症	3	N	TE	111	3	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	142		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	144	15	N	None	Recovered with sequelae
			Nausea	悪心	1	N	TE	158		Y	None	Not recovered, but no changes expected

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	158	8	N	None	Recovered with sequelae
033019	UK	71/M/C	Oedema peripheral	末梢性浮腫	1	N	TE			N	None	Not recovered, but no changes expected
			Spinal compression fracture	脊椎圧迫骨折	2	N	TE			Y	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Not recovered, but no changes expected
			Paraesthesia	錯感覚	1	N	TE			N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	2	N	Pre			N	None	Not recovered, but no changes expected
			Pleuritic pain	胸膜痛	1	N	TE			N	None	Recovered
			Spinal cord compression	脊髄圧迫	3	N	Pre	-6	13	N	None	Recovered
			Anaemia	貧血	1	N	TE	2	181	Y	None	Not recovered, but no changes expected
			Deep vein thrombosis	深部静脈血栓症	2	Y	TE	26	4	N	Drug administration postponed	Recovered with sequelae
			Deep vein thrombosis	深部静脈血栓症	1	N	TE	29		N	Drug administration postponed	Recovered with sequelae
			Deep vein thrombosis	深部静脈血栓症	1	N	TE	29		N	None	Not recovered, but no changes expected
			Pulmonary embolism	肺塞栓症	3	Y	TE	59	79	N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	3	N	TE	169		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	182	65	Y	None	Recovered
033022	UK	82/M/C	Constipation	便秘	2	N	TE			N	None	Recovered
			Nausea	悪心	2	N	TE			N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	2	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			N	Drug permanently withdrawn	Recovered with sequelae
			Bone pain	骨痛	3	N	TE	77	15	N	Drug permanently withdrawn	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	77	15	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	91		N	Not applicable	Ongoing at time of death
033023	UK	69/M/C	Post-traumatic pain	外傷後疼痛	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at time of death
			Muscular weakness	筋力低下	3	N	TE			N	None	Ongoing at time of death
			Pathological fracture	病的骨折	2	N	TE			N	None	Not recovered, but no changes expected
			Constipation	便秘	1	N	Pre	-673	882	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	28		N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	85	65	N	None	Recovered with sequelae

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pathological fracture	病的骨折	3	Y	TE	149	20	Y	Drug administration postponed	Recovered
			Mobility decreased	運動性低下	2	N	TE	168	42	N	None	Ongoing at time of death
			Pathological fracture	病的骨折	2	N	TE	168		Y	None	Not recovered, but no changes expected
			Paraesthesia	錯感覚	1	Y	TE	175	5	N	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	178	7	N	None	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	178	32	N	None	Ongoing at time of death
			Upper limb fracture	上肢骨折	3	Y	TE	202		Y	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	5	Y	TE	209	1	N	Not applicable	Death
033027	UK	58/M/C	Nausea	悪心	1	N	TE			Y	None	Recovered
			Gingival infection	歯肉感染	1	N	TE			N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE			N	None	Recovered
			Pain in jaw	顎痛	1	N	TE			Y	None	Recovered
			Hypoaesthesia	感覚鈍麻	1	N	TE			N	None	Not recovered, but no changes expected
			Palpitations	動悸	2	N	TE	40	1	N	None	Recovered
			Dyspepsia	消化不良	2	N	TE	40		N	None	Ongoing at time of death
			Hyperhidrosis	多汗症	2	N	TE	40	1	N	None	Recovered
			Vomiting	嘔吐	3	Y	TE	44	3	N	None	Recovered
			Nausea	悪心	1	N	TE	57		N	None	Recovered
			Diarrhoea	下痢	1	N	TE	60	10	Y	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
034004	UK	63/M/C	Nausea	悪心	1	N	TE	8		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	8		Y	None	Ongoing at time of death
			Oral candidiasis	口腔カンジダ症	1	N	TE	8		N	None	Ongoing at time of death
			Dizziness	浮動性めまい	1	N	TE	8		N	None	Ongoing at time of death
			Cerebral ischaemia	脳虚血	4	Y	TE	43	5	N	None	Recovered with sequelae
			Anorexia	食欲不振	3	N	TE	53		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	92	9	N	Not applicable	Recovered
			Diarrhoea	下痢	3	N	TE	95	6	Y	Not applicable	Recovered
			Vomiting	嘔吐	3	N	TE	95	6	N	Not applicable	Recovered
			Anaemia	貧血	4	N	TE	98	2	N	Not applicable	Recovered
			Bone marrow failure	骨髄機能不全	4	Y	TE	98	9	N	Not applicable	Death
			Sinus tachycardia	洞性頻脈	1	N	TE	98		N	Not applicable	Ongoing at time of death
			Confusional state	錯乱状態	3	N	TE	98	2	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	98	2	N	Not applicable	Recovered
			Rash	発疹	2	N	TE	98		N	None	Ongoing at time of death
			Haematemesis	吐血	3	N	TE	99	2	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oesophagitis	食道炎	2	N	TE	99		N	Not applicable	Ongoing at time of death
			Bone marrow failure	骨髄機能不全	5	Y	TE	106	1	N	Not applicable	Death
035006	UK	62/M/C	Fatigue	疲労	1	N	Pre	-22	23	N	None	Recovered
			Conjunctivitis	結膜炎	1	N	TE	13	15	N	None	Recovered
			Polyneuropathy	多発ニューロパチー	1	N	TE	27	28	N	None	Recovered
			Paresis cranial nerve	脳神経不全麻痺	3	Y	TE	30		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	84	35	N	None	Recovered
			Constipation	便秘	1	N	TE	85		N	None	Ongoing at study termination / withdrawal
			Oral candidiasis	口腔カンジダ症	2	N	TE	86		N	None	Recovered
			Respiratory tract infection	気道感染	1	N	TE	86		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	87		N	None	Ongoing at time of death
			Urinary tract obstruction	尿路閉塞	2	N	TE	101		N	None	Recovered with sequelae
			Decreased appetite	食欲減退	1	N	TE	111	2	N	None	Recovered
035016	UK	62/M/C	Diarrhoea	下痢	2	N	TE	3	11	N	None	Recovered
			Nausea	悪心	2	N	TE	3	11	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	109	9	N	None	Recovered
			Constipation	便秘	1	N	TE	111	8	N	None	Recovered
			Oral candidiasis	口腔カンジダ症	2	N	TE	112	42	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	112	7	N	Drug administration postponed	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspepsia	消化不良	1	N	TE	113	3	N	None	Recovered
			Nausea	悪心	1	N	TE	113	3	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	113		N	None	Recovered
			Bone pain	骨痛	3	N	TE	118	36	N	None	Not recovered, but no changes expected
			Diarrhoea	下痢	3	Y	TE	150	4	Y	Not applicable	Recovered
			Vomiting	嘔吐	3	Y	TE	150	4	Y	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	153		N	None	Not recovered, but no changes expected
035019	UK	67/M/C	Nausea	悪心	2	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	Pre	1	4	Y	None	Recovered
			Bone pain	骨痛	2	Y	TE	106	5	N	None	Recovered with sequelae
			Urinary tract infection	尿路感染	1	N	TE	128	11	N	None	Recovered
			Constipation	便秘	1	N	TE	132	5	N	None	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	152	6	Y	Not applicable	Recovered
			Nausea	悪心	1	N	TE	158	46	N	Not applicable	Recovered
			Fatigue	疲労	1	N	TE	163		N	Not applicable	Not recovered, but no changes expected
035023	UK	70/M/C	Fatigue	疲労	1	N	TE	66		Y	None	Not recovered, but no changes expected
			Fatigue	疲労	2	N	TE	66		Y	None	Not recovered, but no changes expected
			Dyspepsia	消化不良	2	N	TE	70		N	None	Not recovered, but no changes expected

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Decreased appetite	食欲減退	2	N	TE	70		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	84		Y	None	Not recovered, but no changes expected
			Gastrointestinal haemorrhage	胃腸出血	3	Y	TE	94	8	N	None	Recovered
			Electrocardiogram QT prolonged	心電図ＱＴ延長	1	N	TE	105		N	Not applicable	Not recovered, but no changes expected
			Clostridium difficile colitis	クロストリジウム・ディフィシレ大腸炎	2	Y	TE	110	9	N	Not applicable	Recovered
			Clostridium difficile colitis	クロストリジウム・ディフィシレ大腸炎	1	N	TE	150	9	N	None	Recovered
035027	UK	68/M/C	Decreased appetite	食欲減退	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	1	3	Y	None	Recovered
			Constipation	便秘	2	N	TE	44		Y	None	Ongoing at time of death
			Intestinal obstruction	腸閉塞	4	Y	TE	54	2	Y	None	Death
			Intestinal obstruction	腸閉塞	5	Y	TE	55	1	Y	None	Death
035028	UK	70/M/C	Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Recovered
			Urine flow decreased	尿流量減少	1	N	TE	11	19	N	None	Recovered
			Bone pain	骨痛	2	N	TE	29		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	44	18	N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	44		N	None	Recovered
			Constipation	便秘	2	Y	TE	66	6	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	71	79	N	Not applicable	Death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	1	N	TE	72	42	N	None	Recovered
036001	UK	82/M/C	Bone pain	骨痛	1	N	TE	43		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	56	8	N	None	Recovered
			Bone pain	骨痛	4	Y	TE	63	11	N	None	Recovered
			Arrhythmia	不整脈	3	Y	TE	111	16	N	None	Recovered
			Anaemia	貧血	2	N	TE	149		Y	Not applicable	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	149		N	None	Ongoing at study termination / withdrawal
037007	UK	72/M/C	Constipation	便秘	1	N	TE			Y	None	Recovered
			Vomiting	嘔吐	1	N	TE			N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE			N	None	Recovered
			Muscle spasms	筋痙縮	2	N	TE			N	None	Not recovered, but no changes expected
			Hypertension	高血圧	1	N	TE			Y	None	Not recovered, but no changes expected
			Diarrhoea	下痢	3	N	TE	2	3	Y	None	Recovered
			Nausea	悪心	1	N	TE	2	8	Y	None	Recovered
			Fatigue	疲労	1	N	TE	2	7	Y	None	Recovered
			Influenza	インフルエンザ	2	N	TE	11	8	Y	None	Recovered
			Cough	咳嗽	1	N	TE	18	12	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	54	4	Y	None	Recovered
			Chills	悪寒	1	N	TE	54	1	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	54	10	N	None	Recovered
			Cough	咳嗽	1	N	TE	64	9	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	1	N	TE	68	3	Y	None	Recovered
			Urge incontinence	切迫性尿失禁	1	N	TE	68	1	N	None	Recovered
			Nausea	悪心	1	Y	TE	72	1	Y	None	Recovered
			Vomiting	嘔吐	1	Y	TE	72	1	Y	None	Recovered
			Hydronephrosis	水腎症	3	Y	TE	72	12	N	None	Recovered with sequelae
			Renal failure	腎不全	3	Y	TE	72	4	N	Drug administration postponed	Recovered with sequelae
			Renal failure	腎不全	2	N	TE	75		N	None	Not recovered, but no changes expected
			Catheter related infection	カテーテル関連感染	2	N	TE	152	40	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	160	3	N	None	Recovered
			Gynaecomastia	女性化乳房	1	N	TE	162	30	N	None	Recovered
037008	UK	81/M/C	Mobility decreased	運動性低下	2	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	2	1	N	None	Recovered
			Musculoskeletal pain	筋骨格痛	1	N	TE	2	1	N	None	Recovered
			Constipation	便秘	1	N	TE	63		N	None	Not recovered, but no changes expected
			Eye infection	眼感染	2	N	TE	99	19	N	None	Recovered
			Gastritis	胃炎	2	N	TE	221	3	N	Not applicable	Recovered
			Gastritis	胃炎	3	Y	TE	223	2	N	Not applicable	Recovered
037012	UK	67/M/C	Abdominal pain	腹痛	1	N	TE			N	None	Not recovered, but no changes expected
			Hiatus hernia	裂孔ヘルニア	2	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE			N	None	Recovered
			Pain in jaw	顎痛	1	N	TE			N	None	Ongoing at time of death
			Deep vein thrombosis	深部静脈血栓症	3	N	TE			Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	28	2	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	113		N	None	Ongoing at time of death
			Osteoarthritis	骨関節炎	1	N	TE	163		N	None	Not recovered, but no changes expected
			Dyspnoea exertional	労作性呼吸困難	1	N	TE	171		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	198		N	None	Ongoing at time of death
			Head injury	頭部損傷	3	N	TE	212	1	N	None	Recovered with sequelae
			Disseminated intravascular coagulation	播種性血管内凝固	3	N	TE	214		N	None	Not recovered, but no changes expected
			Thrombocytopenia	血小板減少症	3	Y	TE	214		N	Not applicable	Ongoing at time of death
			Extradural haematoma	硬膜外血腫	5	Y	TE	214	1	N	Not applicable	Death
037013	UK	70/M/C	Anorexia	食欲不振	1	N	TE			Y	None	Recovered
			Dysarthria	構語障害	1	N	TE			N	None	Not recovered, but no changes expected
			Non-cardiac chest pain	非心臓性胸痛	1	N	TE	3	8	N	None	Recovered
			Non-cardiac chest pain	非心臓性胸痛	2	N	TE	10	24	N	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	19	6	N	None	Recovered
			Bursitis infective	感染性滑液包炎	1	N	TE	30	8	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Confusional state	錯乱状態	1	N	TE	30		N	None	Not recovered, but no changes expected
			Bursitis infective	感染性滑液包炎	2	Y	TE	37	3	N	None	Recovered
			Nausea	悪心	1	N	TE	46	4	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	48	2	Y	None	Recovered
			Lethargy	嗜眠	1	N	TE	59		Y	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	61	4	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	118	9	Y	None	Recovered
			Rectal haemorrhage	直腸出血	1	N	TE	118	1	Y	None	Recovered
			Nausea	悪心	1	N	TE	141		Y	None	Not recovered, but no changes expected
			Diarrhoea	下痢	1	N	TE	143	3	Y	None	Recovered
039005	UK	72/M/C	Constipation	便秘	3	N	TE	4	38	N	None	Recovered
			Nausea	悪心	3	N	TE	13	29	N	None	Recovered
			Nausea	悪心	3	N	TE	35	7	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	35		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	N	TE	35	8	N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	42	1	N	None	Death
039007	UK	68/M/C	Bone pain	骨痛	1	N	Pre			N	None	Ongoing at time of death
			Anaemia	貧血	1	Y	Pre	-23	2	N	Drug administration postponed	Recovered
			Decreased appetite	食欲減退	1	N	Pre	-11		N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	Pre	-11		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	-11	5	N	None	Recovered
			Nausea	悪心	1	N	Pre	-4		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	Pre	-4		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	4	23	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	27		Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	29	36	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	60		Y	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	70	1	N	None	Recovered
			Anaemia	貧血	2	N	TE	92		Y	Drug administration postponed	Ongoing at time of death
			Joint injury	関節損傷	2	N	TE	94		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	95		Y	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	118	2	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	180	2	Y	Not applicable	Recovered
			Skin lesion	皮膚病変	3	N	TE	183		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	214	1	N	Not applicable	Death
039012	UK	82/M/C	Anaemia	貧血	3	N	TE			N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hyperchlorhydria	胃酸過多	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	2	N	Pre	-2	26	N	None	Recovered
			Hypoaesthesia	感覚鈍麻	2	N	Pre	-2		N	None	Ongoing at study termination / withdrawal
			Hypoaesthesia	感覚鈍麻	2	N	TE	8		N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	2	N	TE	8		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	24		N	None	Ongoing at time of death
			Pathological fracture	病的骨折	3	Y	TE	35	33	N	Drug administration postponed	Recovered
			Nausea	悪心	2	N	TE	71	86	Y	None	Ongoing at time of death
			Dry mouth	口内乾燥	3	N	TE	87	70	N	None	Ongoing at time of death
			Back injury	背部損傷	3	N	TE	91	66	N	None	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	125		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	156	1	N	None	Death
039015	UK	79/M/C	Abdominal distension	腹部膨満	2	N	TE			N	None	Recovered
			Nausea	悪心	2	N	TE			Y	None	Recovered
			Fatigue	疲労	3	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	Pre	1	85	N	None	Recovered
			Bone pain	骨痛	2	N	Pre	1	85	N	None	Recovered
			Bone pain	骨痛	2	N	Pre	1	111	N	None	Recovered
			Incontinence	失禁	2	N	Pre	1	85	N	None	Recovered
			Decreased appetite	食欲減退	2	N	TE	29		N	None	Ongoing at study termination / withdrawal
			Haematuria	血尿	3	Y	TE	85	7	N	Drug administration postponed	Recovered
			Cystitis radiation	放射線性膀胱炎	3	Y	TE	93	5	N	Drug administration postponed	Recovered
			Cystitis radiation	放射線性膀胱炎	2	N	TE	97		N	None	Recovered
			Urinary tract infection	尿路感染	3	N	TE	146	18	N	None	Recovered
			Urinary tract infection	尿路感染	3	N	TE	167		N	None	Recovered
			Oesophageal obstruction	食道閉塞症	3	N	TE	176		N	None	Ongoing at study termination / withdrawal
			Hyperchlorhydria	胃酸過多	2	N	TE	179		N	None	Ongoing at time of death
039016	UK	69/M/C	Fatigue	疲労	2	N	TE			Y	None	Recovered
			Cellulitis	蜂巣炎	3	N	Pre			N	None	Recovered
			Rhinitis	鼻炎	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	Pre			N	None	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	7	9	N	None	Recovered
			Oedema peripheral	末梢性浮腫	3	N	TE	25	296	N	None	Recovered
			Dyspnoea	呼吸困難	2	N	TE	146		N	None	Not recovered, but no changes expected

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
039027	UK	74/M/C	Nausea	悪心	2	N	TE	1		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	1		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	2	N	Pre	1		N	None	Ongoing at time of death
			Dizziness	浮動性めまい	2	N	TE	1		N	None	Ongoing at time of death
			Headache	頭痛	1	N	TE	1		N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	1	N	TE	1		N	None	Ongoing at time of death
			Dehydration	脱水	3	Y	TE	8	7	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	18	20	N	Drug administration postponed	Death
			Renal failure	腎不全	3	Y	TE	18	1	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	N	TE	19	4	N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	37	1	N	Drug administration postponed	Death
041001	UK	56/M/C	Pulmonary embolism	肺塞栓症	4	Y	Pre	-39	8	N	Not applicable	Recovered with sequelae
			Intertrigo	間擦疹	2	N	Pre	-33	30	N	None	Recovered
			Nausea	悪心	1	N	Pre	1	57	N	None	Recovered
			Decreased appetite	食欲減退	1	N	Pre	1	113	N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Diarrhoea	下痢	2	N	TE	2	4	Y	None	Recovered
			Fatigue	疲労	1	N	TE	2	15	N	None	Recovered
			Bone pain	骨痛	2	N	TE	2	112	Y	None	Recovered
			Weight decreased	体重減少	1	N	TE	29	85	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	46	96	N	None	Recovered
			Pain in extremity	四肢痛	2	N	TE	46		N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	57	203	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	57		N	None	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	3	Y	TE	81	5	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	113		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	3	N	TE	113	57	N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	141	8	N	None	Recovered
			Bone pain	骨痛	3	N	TE	148	21	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	168		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	169		N	None	Ongoing at time of death
			Night sweats	寝汗	2	N	TE	192		N	None	Ongoing at time of death
			Oral candidiasis	口腔カンジダ症	2	N	TE	202		N	None	Ongoing at time of death
			Abdominal pain upper	上腹部痛	1	N	TE	223		N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE	223		N	None	Ongoing at time of death
041003	UK	59/M/C	Dry mouth	口内乾燥	1	N	TE			N	None	Ongoing at time of death
			Abdominal distension	腹部膨満	1	N	Pre	-13	52	N	None	Recovered
			Bone pain	骨痛	3	N	Pre	-13	4	N	None	Recovered
			Joint swelling	関節腫脹	1	N	Pre	-13		N	None	Ongoing at time of death
			Hot flush	ほてり	1	N	Pre	-13		N	None	Ongoing at time of death
			Pitting oedema	圧痕浮腫	1	N	Pre	1	39	N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	1	N	Pre	1		N	None	Ongoing at time of death
			Lethargy	嗜眠	2	N	TE	2	52	Y	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	4	50	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	30	140	N	None	Recovered
			Insomnia	不眠症	1	N	TE	30	124	N	None	Ongoing at time of death
			Depressed mood	抑うつ気分	1	N	TE	42		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	43	15	Y	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	43	69	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	44	126	N	None	Recovered
			Pain in jaw	顎痛	1	N	TE	44	4	N	None	Recovered
			Bone pain	骨痛	2	N	TE	50	8	N	None	Recovered
			Lethargy	嗜眠	3	N	TE	53		Y	None	Ongoing at time of death
			Musculoskeletal stiffness	筋骨格硬直	1	N	TE	55	57	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	1	N	TE	57	55	N	None	Ongoing at time of death
			Ligament injury	靭帯損傷	2	N	TE	74	38	N	None	Recovered
			Lower limb fracture	下肢骨折	2	N	TE	74		N	None	Ongoing at time of death
			Dysgeusia	味覚異常	1	N	TE	83		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	103	3	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	105	2	Y	None	Recovered
			Oral herpes	口腔ヘルペス	2	N	TE	107		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	111	16	Y	-	
			Weight decreased	体重減少	2	N	TE	111		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	2	N	TE	111	59	N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	124	1	Y	None	Recovered
			Anaemia	貧血	2	N	TE	126	12	Y	-	
			Vomiting	嘔吐	1	N	TE	126	1	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	129	1	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	136	1	Y	None	Recovered
			Anaemia	貧血	3	N	TE	137	5	Y	-	
			Anaemia	貧血	2	N	TE	141		Y	None	Ongoing at time of death
			Insomnia	不眠症	2	N	TE	153		N	None	Ongoing at time of death
			Restless legs syndrome	下肢静止不能症候群	2	N	TE	165		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	169		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	169	50	N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	218		N	None	Ongoing at time of death
			Epistaxis	鼻出血	1	N	TE	218		N	None	Ongoing at time of death
041005	UK	76/M/C	Bone pain	骨痛	2	N	TE	7	191	N	None	Not recovered, but no changes expected
			Defaecation urgency	便意切迫	1	N	TE	8	21	Y	None	Recovered
			Frequent bowel movements	排便回数増加	1	N	TE	8	21	Y	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	78	5	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	80	1	Y	None	Recovered
			Pathological fracture	病的骨折	2	Y	TE	118	51	N	None	Recovered
			Bone pain	骨痛	3	N	TE	197		N	None	Not recovered, but no changes expected
			Musculoskeletal stiffness	筋骨格硬直	1	N	TE	197		N	None	Not recovered, but no changes expected
			Pain in extremity	四肢痛	1	N	TE	197		N	None	Not recovered, but no changes expected
			Soft tissue infection	軟部組織感染	2	N	TE	222		N	None	Not recovered, but no changes expected
041006	UK	64/M/C	Lower respiratory tract infection	下気道感染	2	Y	Pre	-65	8	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	2	2	Y	None	Recovered
			Contusion	挫傷	1	N	TE	39	110	N	None	Recovered
			Joint sprain	関節捻挫	1	N	TE	39	110	N	None	Recovered
			Skin laceration	皮膚裂傷	1	N	TE	39	110	N	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	60	7	N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	Y	TE	66	20	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Therapeutic agent toxicity	治療薬毒性	4	Y	TE	73	1	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	92	6	Y	None	Recovered
			Bone pain	骨痛	3	Y	TE	100	17	N	None	Recovered
			Bone pain	骨痛	3	N	TE	116	2	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	117	25	N	None	Recovered
			Bone pain	骨痛	2	N	TE	141		N	None	Not recovered, but no changes expected
041008	UK	74/M/C	Anaemia	貧血	2	N	Pre	1	29	N	Drug administration postponed	Recovered
			Nausea	悪心	2	N	TE	1	3	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	1	3	N	None	Recovered
			Anaemia	貧血	2	Y	TE	29	4	N	Drug administration postponed	Recovered
			Acute myocardial infarction	急性心筋梗塞	4	Y	TE	29	4	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	32	19	N	Drug administration postponed	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE	35	13	N	None	Recovered
			Anaemia	貧血	3	Y	TE	50	4	N	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	50	3	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	52		N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血		Y	TE	76		N	Drug administration postponed	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	5	Y	TE	79	1	N	None	Death
042015	UK	72/M/C	Increased appetite	食欲亢進	1	N	TE			N	None	Recovered
			Somnolence	傾眠	2	N	TE			N	None	Recovered
			Diplopia	複視	3	N	TE	14	10	Y	None	Recovered
			Balance disorder	平衡障害	1	N	TE	14	10	N	None	Recovered
			Confusional state	錯乱状態	3	N	TE	14	10	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	15	15	Y	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	53	6	N	None	Recovered
			Agitation	激越	2	N	TE	114	2	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	115	1	N	None	Death
			Increased bronchial secretion	気管支分泌増加	2	N	TE	115	1	N	None	Recovered
042020	UK	73/M/C	Aphthous stomatitis	アフタ性口内炎	1	N	TE			N	None	Recovered
			Diarrhoea	下痢	1	N	TE	4	6	Y	None	Recovered
			Decreased appetite	食欲減退	2	N	TE	4	150	N	None	Ongoing at time of death
			Lethargy	嗜眠	2	N	TE	4	146	N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	23		N	None	Ongoing at time of death
			Radius fracture	橈骨骨折	3	N	TE	48	33	N	None	Recovered
			Bone pain	骨痛	2	N	TE	63		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	67	122	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Diarrhoea	下痢	2	N	TE	89	71	N	None	Recovered
			Melaena	メレナ	1	N	TE	99		N	None	Ongoing at time of death
			Haematuria	血尿	1	Y	TE	125	2	N	None	Recovered
			Haematuria	血尿	2	N	TE	140	4	N	Drug administration postponed	Recovered
			Haematuria	血尿	2	Y	TE	143	2	N	Drug administration postponed	Recovered
			Lethargy	嗜眠	1	N	TE	149		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	153		N	None	Ongoing at time of death
			Renal tubular necrosis	腎尿細管壊死	3	Y	TE	210	89	N	Not applicable	Recovered
042030	UK	61/M/C	Nausea	悪心	1	N	TE	1		N	None	
			Vomiting	嘔吐	1	N	TE	1		N	None	Recovered
			Bone pain	骨痛	1	N	TE	2	28	Y	None	Recovered
			Haematuria	血尿	3	Y	TE	12	5	N	None	Recovered
			Constipation	便秘	1	N	TE	29	39	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	52		N	None	Recovered
			Renal failure acute	急性腎不全	3	Y	TE	52	8	N	Drug administration postponed	Recovered
			Hypotension	低血圧	2	N	TE	52		N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	3	Y	TE	67	6	N	Drug administration postponed	Recovered
043003	UK	64/M/C	Anaemia	貧血	1	N	Pre	-5	99	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	1	29	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	1	6	Y	None	Recovered
			Mouth ulceration	口腔内潰瘍形成	2	N	TE	73	29	N	None	Recovered
			Bone pain	骨痛	2	N	TE	75	6	N	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	96	6	N	None	Recovered
			Bone pain	骨痛	2	N	TE	96		Y	None	Not recovered, but no changes expected
			Lower respiratory tract infection	下気道感染	3	Y	TE	101	3	N	None	Recovered
			Metastases to central nervous system	中枢神経系転移	4	Y	TE	121	9	N	Drug permanently withdrawn	Recovered
			Fatigue	疲労	1	N	TE	175	6	Y	None	Recovered
043005	UK	66/M/C	Bone pain	骨痛	2	N	Pre	-5	29	N	Not applicable	Recovered
			Myalgia	筋痛	1	N	TE	52	29	N	None	Recovered
			Myalgia	筋痛	1	N	TE	52	29	N	None	Recovered
			Fatigue	疲労	1	N	TE	108	42	N	None	Recovered
			Myalgia	筋痛	1	N	TE	148		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	216	3	N	Not applicable	Recovered
043007	UK	60/M/A	Urinary retention	尿閉	2	N	TE			N	Not applicable	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Diarrhoea	下痢	2	N	TE	1		Y	None	Recovered
			Fatigue	疲労	1	N	TE	1		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	Pre	1	9	N	None	Recovered
			Bone pain	骨痛	2	N	TE	29	1	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	47	3	Y	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	85	29	N	None	Recovered
			Skin nodule	皮膚小結節	1	N	TE	85	29	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	94	4	Y	None	Recovered
			Cough	咳嗽	1	N	TE	94	7	Y	None	Recovered
			Skin discolouration	皮膚変色	1	N	TE	107		Y	None	Recovered
			Bone pain	骨痛	1	N	TE	113		N	None	Not recovered, but no changes expected
			Dysuria	排尿困難	3	N	TE	122		N	None	Recovered with sequelae
			Urinary retention	尿閉	3	Y	TE	152	4	N	Not applicable	Recovered
			Micturition disorder	排尿異常	2	N	TE	156		N	Not applicable	Not recovered, but no changes expected
			Vertigo	回転性めまい	2	N	TE	198	41	N	None	Recovered
			Bone pain	骨痛	2	N	TE	198		N	None	Not recovered, but no changes expected
043011	UK	77/M/A	Vision blurred	霧視	1	N	TE			N	None	Recovered
			Diarrhoea	下痢	1	N	TE			Y	None	Recovered
			Paraesthesia	錯感覚	1	N	TE			N	None	Not recovered, but no changes expected
			Fatigue	疲労	2	N	TE	1		Y	None	Not recovered, but no changes expected
			Hypocalcaemia	低カルシウム血症	2	N	TE	10		N	None	Not recovered, but no changes expected
			Dizziness	浮動性めまい	2	Y	TE	36	2	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Lymphadenopathy	リンパ節症	1	N	TE	56	29	N	None	Recovered
			Dizziness	浮動性めまい	2	N	TE	84	6	N	None	Recovered
			Skin discolouration	皮膚変色	1	N	TE	86		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	2	Y	TE	88	2	Y	None	Recovered
044004	UK	76/M/C	Vomiting	嘔吐	1	N	TE			Y	None	
			Haematuria	血尿	1	N	TE			N	None	Recovered
			Ataxia	運動失調	2	N	TE	23		N	None	
			Speech disorder	会話障害	3	N	TE	23	29	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	23		N	None	
			Deafness	難聴	2	N	TE	51		N	None	
			Tinnitus	耳鳴	2	N	TE	51		N	None	
			Fatigue	疲労	1	N	TE	71		Y	None	
			Radiation skin injury	放射線皮膚損傷	1	N	TE	71		N	None	
			Arthralgia	関節痛	2	N	TE	71		Y	None	
			Alopecia	脱毛症	1	N	TE	71		N	None	
			Faecal incontinence	便失禁	1	N	TE	75	1	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	76	1	N	None	Recovered
			Urinary tract infection	尿路感染	1	N	TE	76		N	None	Recovered
			Aphasia	失語症	3	Y	TE	76	4	N	None	Recovered
			Bone pain	骨痛	1	N	TE	78	2	N	None	Recovered
			Bone pain	骨痛	1	N	TE	99		Y	None	
			Bone pain	骨痛	2	N	TE	121		N	None	Not recovered, but no changes expected
			Confusional state	錯乱状態	2	N	TE	121	15	N	None	Recovered
			Mobility decreased	運動性低下	2	N	TE	135		N	None	Ongoing at time of death
044005	UK	76/M/C	Cardiac failure congestive	うっ血性心不全	4	N	TE			N	Drug administration postponed	Death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE			Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	7	1	Y	None	Recovered
			Left ventricular dysfunction	左室機能不全	3	N	TE	54	73	N	Drug administration postponed	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	54	73	N	Drug administration postponed	Ongoing at time of death
			Dyspnoea	呼吸困難	3	N	TE	54	17	N	Drug administration postponed	Ongoing at time of death
			Troponin T increased	トロポニンT増加	4	N	TE	57	70	N	Drug administration postponed	Ongoing at time of death
			Pleural effusion	胸水	2	N	TE	57	70	N	Drug administration postponed	Ongoing at time of death
			Pulmonary embolism	肺塞栓症	3	Y	TE	57	3	N	Drug permanently withdrawn	Recovered with sequelae
			Pulmonary oedema	肺水腫	1	N	TE	58	69	N	Drug administration postponed	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	70	57	N	Drug administration postponed	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	5	Y	TE	126	1	N	Drug administration postponed	Death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
045009	UK	57/M/C	Neutropenia	好中球減少症	4	N	TE	154	15	Y	Drug administration postponed	Recovered
			Bone pain	骨痛	2	N	TE	169	37	Y	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	176	31	N	Not applicable	Recovered
046002	UK	78/M/C	Urinary tract infection	尿路感染	2	N	TE			N	None	Recovered
			Urinary incontinence	尿失禁	1	N	TE			N	None	Recovered
			Anaemia	貧血	2	N	Post	250	138	Y	Not applicable	Recovered
			Anaemia	貧血	3	Y	Post	387	2	Y	Not applicable	Recovered
046004	UK	64/M/C	Nausea	悪心		N	TE			Y	None	Recovered
			Vomiting	嘔吐		N	TE			Y	None	Recovered
			Bone pain	骨痛	3	N	TE			Y	None	Ongoing at study termination / withdrawal
			Night sweats	寝汗		N	TE			N	None	Recovered
			Nausea	悪心	2	N	TE	2	1	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	3	2	Y	None	Recovered
			Diarrhoea	下痢	2	N	TE	28	19	Y	None	Recovered
			Diarrhoea	下痢	2	N	TE	28	16	N	None	Recovered
			Bone pain	骨痛	2	N	TE	33	25	N	None	Recovered
			Anaemia	貧血	2	N	TE	56	108	Y	Not applicable	Recovered
			Diarrhoea	下痢	2	N	TE	57	2	N	None	Recovered
			Cough	咳嗽	1	N	TE	83	64	N	None	Recovered
			Anaemia	貧血	2	N	TE	107	57	Y	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	163	39	Y	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	163	39	Y	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	201	22	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	201	103	Y	Not applicable	Ongoing at time of death
			Anaemia	貧血	3	N	TE	222	11	Y	None	Ongoing at time of death
047002	UK	81/M/C	Anaemia	貧血	3	N	TE	2	1	Y	None	Recovered
			Anaemia	貧血	3	N	TE	39	1	Y	None	Recovered
			Anaemia	貧血	3	N	TE	73	1	Y	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	3	N	TE	85		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	2	N	TE	136		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	154	1	N	Not applicable	Death
047003	UK	75/M/C	Urinary tract infection	尿路感染	2	N	TE	14	8	N	None	Recovered with sequelae
			Urinary tract infection	尿路感染	2	N	TE	64	10	N	None	Recovered with sequelae
			Urinary retention	尿閉	3	Y	TE	98	3	N	None	Recovered with sequelae
			Infection	感染	2	N	TE	142	14	N	None	Recovered with sequelae

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	N	TE	155	1	Y	None	Recovered
048001	UK	59/M/C	Decreased appetite	食欲減退	1	N	TE			N	None	Recovered
			Anaemia	貧血	1	N	Pre	-35	71	N	None	Recovered
			Constipation	便秘	2	N	Pre	-12	11	N	None	Recovered
			Musculoskeletal pain	筋骨格痛	3	Y	Pre	-4	12	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	3	1	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	6	1	N	None	Recovered
			Bone pain	骨痛	2	N	TE	8	97	N	None	Ongoing at time of death
			Hypocalcaemia	低カルシウム血症	2	N	TE	29	6	N	None	Recovered
			Vomiting	嘔吐	3	N	TE	33	1	N	None	Recovered
			Hypocalcaemia	低カルシウム血症	3	Y	TE	34	4	N	None	Recovered
			Anaemia	貧血	2	N	TE	36	34	N	None	Recovered
			Hypocalcaemia	低カルシウム血症	2	N	TE	37	21	N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE	58	6	N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE	58	13	N	None	Recovered
			Constipation	便秘	2	N	TE	62	24	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	62	1	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	62	1	N	None	Recovered
			Decreased appetite	食欲減退	2	N	TE	62	17	N	None	Recovered
			Lower respiratory tract infection	下気道感染	3	Y	TE	63	3	N	None	Recovered
			Depression	うつ病	2	N	TE	70		N	None	Ongoing at time of death
			Lymphadenopathy	リンパ節症	1	N	TE	85		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	104	37	N	None	Ongoing at time of death
			Decreased appetite	食欲減退	2	N	TE	113		N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neutropenia	好中球減少症	2	N	TE	129	13	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	134	1	N	None	Recovered
			Bone pain	骨痛	2	N	TE	140		N	None	Ongoing at time of death
			Neutropenia	好中球減少症	3	N	TE	141	15	N	Drug administration postponed	Recovered
			Amnesia	健忘	1	N	TE	141		N	None	Ongoing at time of death
			Headache	頭痛	2	N	TE	141		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	145		N	None	Ongoing at time of death
			Anxiety	不安	2	N	TE	147		N	None	Ongoing at time of death
			Oral candidiasis	口腔カンジダ症	1	N	TE	155		N	None	Ongoing at study termination / withdrawal
048003	UK	60/M/C	Anaemia	貧血	3	N	TE			N	Not applicable	Recovered
			Abdominal distension	腹部膨満	2	N	TE			N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE			N	Not applicable	Recovered
			Oral candidiasis	口腔カンジダ症	1	N	TE			N	Not applicable	Recovered
			Fatigue	疲労	1	N	TE	2	8	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	6	6	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Asthenopia	眼精疲労	1	N	TE	29		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	60		N	None	Ongoing at time of death
			Myalgia	筋痛	2	N	TE	115		N	None	Ongoing at time of death
			Lethargy	嗜眠	1	N	TE	148		N	None	Ongoing at time of death
			Metastases to central nervous system	中枢神経系転移	4	Y	TE	164	19	N	Not applicable	Recovered with sequelae
048004	UK	71/M/C	Diarrhoea	下痢	2	N	TE			N	None	Recovered
			Nausea	悪心	2	N	TE			N	None	Recovered
			Vomiting	嘔吐	2	N	TE			N	None	Recovered
			Constipation	便秘	2	N	Pre	-2	4	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	4	2	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	8	3	N	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	37	107	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	109	3	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	109	3	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	168	16	N	Not applicable	Recovered
			Dyspepsia	消化不良	1	N	TE	169	4	N	Not applicable	Recovered
			Faecal incontinence	便失禁	2	N	TE	194	1	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	195	5	N	Not applicable	Recovered with sequelae
048007	UK	79/M/C	Bone pain	骨痛	2	N	Pre	1	31	N	Drug administration postponed	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	2	N	TE	29		N	None	Recovered
			Bone pain	骨痛	2	N	TE	29		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	31	29	N	Drug administration postponed	Recovered
049002	UK	73/M/C	Lower respiratory tract infection	下気道感染	3	Y	TE	9	11	N	None	Recovered
			Oral candidiasis	口腔カンジダ症	2	N	TE	57	53	Y	None	Recovered
			Paraesthesia	錯感覚	1	N	TE	100	30	N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	Y	TE	109	3	N	Drug administration postponed	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	4	Y	TE	129		N	None	Ongoing at time of death
			Pneumonia	肺炎	4	Y	TE	135	7	N	Drug permanently withdrawn	Death
			Pneumonia	肺炎	5	Y	TE	141	1	N	Drug permanently withdrawn	Death
049007	UK	80/M/C	Nausea	悪心	2	N	TE	3		Y	None	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	3		Y	None	Ongoing at time of death
			Mucosal inflammation	粘膜の炎症	2	N	TE	29		Y	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	29		Y	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	120		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	128		N	None	Ongoing at time of death
			Headache	頭痛	2	N	TE	148	51	N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	176	3	N	Not applicable	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	198		N	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	3	Y	TE	198		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	198	12	N	Not applicable	Death
			Headache	頭痛	4	N	TE	198		N	None	Ongoing at time of death
			Urinary retention	尿閉	2	N	TE	204		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	209	1	N	Not applicable	Death
049008	UK	72/M/C	Decreased appetite	食欲減退	2	N	TE			N	None	Ongoing at time of death
			Lymphoedema	リンパ浮腫	1	N	Pre			N	None	Recovered
			Ear pain	耳痛	1	N	Pre	-7		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre	-3	5	N	None	Recovered
			Fatigue	疲労	2	N	TE	29		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	29	50	Y	None	Recovered
			Constipation	便秘	2	N	TE	40		N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	40	2	N	None	Recovered with sequelae
			Palpitations	動悸	1	N	TE	54	4	N	Not applicable	Recovered
			Depressed mood	抑うつ気分	1	N	TE	54		N	None	Ongoing at time of death
			Vomiting	嘔吐	2	Y	TE	57	6	N	Drug administration postponed	Recovered
			Pyrexia	発熱	1	Y	TE	61	2	N	Drug administration postponed	Recovered
			Nausea	悪心	2	Y	TE	65	6	N	Drug administration postponed	Recovered with sequelae
			Vomiting	嘔吐	2	Y	TE	65	6	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	N	TE	67	1	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	89	1	N	Not applicable	Recovered
			Abdominal pain	腹痛	3	Y	TE	111		N	Not applicable	Ongoing at time of death
			Nausea	悪心	3	Y	TE	111		N	Not applicable	Ongoing at time of death
			Vomiting	嘔吐	3	Y	TE	111		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	111	11	N	Not applicable	Death
			Anaemia	貧血	2	N	TE	113		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	121	1	N	Not applicable	Death
050005	UK	77/M/C	Diarrhoea	下痢	1	N	TE	3	2	N	None	Recovered
			Bone pain	骨痛	3	N	TE	18		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	18	29	N	None	Recovered
			Muscular weakness	筋力低下	1	N	TE	29	26	N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	46		N	None	Recovered
			Muscular weakness	筋力低下	2	N	TE	54	5	N	None	Ongoing at study termination / withdrawal
			Muscular weakness	筋力低下	3	N	TE	58		N	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	2	Y	TE	60	13	N	None	Recovered with sequelae
			Cerebrovascular accident	脳血管発作	4	Y	TE	64	9	N	Drug administration postponed	Recovered with sequelae
			Eye infection	眼感染	2	N	TE	70		N	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	2	N	TE	72	12	N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	82	2	N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	2	Y	TE	83		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	2	Y	TE	83	2	N	None	Recovered
			Spinal cord compression	脊髄圧迫	2	Y	TE	83		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
051003	UK	65/M/C	Bone pain	骨痛	2	N	TE	3		Y	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	5		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	2	N	TE	5		N	None	Ongoing at time of death
			Dysgeusia	味覚異常	1	N	TE	5		Y	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	12		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	42		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	4	Y	TE	42		N	Drug permanently withdrawn	Ongoing at time of death
051007	UK	75/M/C	Bone pain	骨痛	2	N	Pre	-8	59	N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	2	1	Y	None	Recovered
			Bone pain	骨痛	1	N	Pre	51		N	None	Ongoing at time of death
			Dyspepsia	消化不良	1	N	TE	63	25	Y	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspepsia	消化不良	3	N	TE	87	2	Y	None	Ongoing at time of death
			Dyspepsia	消化不良	1	N	TE	88		Y	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	90	80	Y	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	106	26	N	None	Recovered
			Nerve root compression	神経根圧迫	4	Y	TE	119	2	N	Drug administration postponed	Recovered with sequelae
			Night sweats	寝汗	1	N	TE	119	35	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	147		N	Drug administration postponed	Ongoing at time of death
			Night sweats	寝汗	2	N	TE	153		N	None	Ongoing at time of death
			Oedema	浮腫	1	N	TE	159		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	169		Y	None	Ongoing at time of death
			Metastases to central nervous system	中枢神経系転移	2	Y	TE	174		N	Not applicable	Not recovered, but no changes expected
051010	UK	68/M/C	Bone pain	骨痛	2	N	TE	21		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	47		N	None	Not recovered, but no changes expected
			Urinary bladder haemorrhage	膀胱出血	1	N	TE	47	49	N	Drug administration postponed	Not recovered, but no changes expected

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	58		N	None	Ongoing at time of death
			Pilonidal cyst	毛巣嚢胞	2	N	TE	64	65	N	None	Recovered
			Bone pain	骨痛	2	N	TE	83	23	N	None	Recovered
			Urinary bladder haemorrhage	膀胱出血	3	N	TE	95		N	Drug administration postponed	Not recovered, but no changes expected
			Renal failure acute	急性腎不全	3	Y	TE	204	10	N	Not applicable	Recovered with sequelae
051011	UK	77/M/C	Bone pain	骨痛	2	N	TE	2	5	Y	None	Recovered
			Fatigue	疲労	2	N	TE	30	4	N	None	Recovered
			Bone pain	骨痛	2	N	TE	30	2	Y	None	Recovered
			Nausea	悪心	1	N	TE	44		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	44	32	N	None	Recovered
			Bone pain	骨痛	2	N	TE	75	39	N	None	Recovered
			Bile duct obstruction	胆管閉塞	2	Y	TE	166	12	N	Not applicable	Recovered with sequelae
			Bile duct obstruction	胆管閉塞	2	Y	TE	177		N	Not applicable	Not recovered, but no changes expected
			Insomnia	不眠症	1	N	TE	219		N	None	Ongoing at time of death
051012	UK	73/M/C	Decreased appetite	食欲減退	1	N	TE	30		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	108	1	N	None	Death
051021	UK	74/M/C	Gastric ulcer	胃潰瘍	1	N	TE			N	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE			N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pulmonary embolism	肺塞栓症	4	N	TE			N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	8	41	Y	None	Recovered
			Intervertebral disc protrusion	椎間板突出	1	N	TE	8		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	42	7	N	None	Recovered with sequelae
			Anorexia	食欲不振	2	N	TE	94		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	120	211	N	None	Recovered
			Constipation	便秘	2	N	TE	125		N	None	Ongoing at time of death
			Dehydration	脱水	2	Y	TE	125	8	N	None	Recovered
			Helicobacter infection	ヘリコバクター感染	2	N	TE	131	7	N	None	Recovered
054001	Netherlands	75/M/C	Upper respiratory tract infection	上気道感染	1	N	Pre	-15	8	N	Drug administration postponed	Recovered
			Diarrhoea	下痢	1	N	TE	3		Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	57	7	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	63	2	Y	None	Recovered
			Colitis	大腸炎	2	N	TE	86		Y	None	Ongoing at study termination / withdrawal
055002	Netherlands	66/M/C	Lung infection	肺感染	2	N	TE	18	27	N	None	Recovered
			Anorexia	食欲不振	2	N	TE	54		Y	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	54		Y	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	59		Y	None	Ongoing at time of death
			Drug intolerance	薬物不耐性	4	Y	TE	71	3	N	None	Recovered with sequelae
			Pulmonary embolism	肺塞栓症	4	Y	TE	71		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	74	1	N	None	Death
060002	Spain	84/M/C	Anorexia	食欲不振	2	N	TE	29		N	None	Ongoing at time of death
			Cardiac failure	心不全	3	N	TE	100		N	None	Ongoing at study termination / withdrawal
			Dyspnoea	呼吸困難	2	N	TE	100		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	101	31	N	Not applicable	Ongoing at time of death
			Bronchitis	気管支炎	2	N	TE	107	2	N	None	Recovered
			Renal failure	腎不全	2	N	TE	107	3	N	None	Recovered
			Bronchitis	気管支炎	3	Y	TE	108		N	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	N	TE	109	5	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	113	11	Y	None	Ongoing at time of death
			Hyperuricaemia	高尿酸血症	1	N	TE	113		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	123		Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	129	1	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	131		N	Not applicable	Ongoing at time of death
			Death	死亡	5	Y	TE	137	1	N	Not applicable	Death
060003	Spain	85/M/C	Bone pain	骨痛	3	N	TE	31	26	N	None	Ongoing at time of death
			Weight decreased	体重減少	2	N	TE	56	6	N	None	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	2	N	TE	56	11	N	None	Recovered
			Bone pain	骨痛	2	N	TE	56		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	57		N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	61		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	111	1	N	Not applicable	Death
060007	Spain	79/M/C	Nausea	悪心	1	N	Pre	-20	28	N	None	Recovered
			Anorexia	食欲不振	2	N	Pre	-20		N	None	Ongoing at time of death
			Haematuria	血尿	2	N	TE	5		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	6	4	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	6	12	N	Drug permanently withdrawn	Death
			Pyrexia	発熱	1	N	TE	7	2	N	None	Recovered
			Respiratory tract infection	気道感染	2	N	TE	7		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	3	N	TE	8		N	None	Ongoing at time of death
			Asthenia	無力症	1	N	TE	12	2	N	None	Ongoing at time of death
			Asthenia	無力症	3	N	TE	13		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	17	1	N	Drug permanently withdrawn	Death
060010	Spain	75/M/C	Pruritus	そう痒症	1	N	TE	1	37	N	None	Recovered
			Anaemia	貧血	1	N	TE	29	2	Y	None	Recovered
			Cholestasis	胆汁うっ滞	3	Y	TE	29	9	N	Drug permanently withdrawn	Recovered
			Hyperbilirubinaemia	高ビリルビン血症	3	N	TE	29	3	N	None	Recovered
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	3	N	TE	29	3	N	-	
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	29	3	N	-	
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	TE	29	60	N	None	Not recovered, but no changes expected
			Pollakiuria	頻尿	1	N	TE	29	29	N	None	Recovered
			Anaemia	貧血	1	N	TE	31	80	Y	None	Recovered
			Hyperbilirubinaemia	高ビリルビン血症	2	N	TE	31	6	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2	N	TE	31	6	N	-	
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	TE	31	3	N	-	
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1	N	TE	33	22	N	-	
			Hyperbilirubinaemia	高ビリルビン血症	1	N	TE	36	19	N	None	Recovered
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	1	N	TE	36	19	N	-	
			Cholestasis	胆汁うっ滞	1	N	TE	37	35	N	None	Recovered
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2	N	TE	54	18	N	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	TE	54	18	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	57	57	N	None	Recovered
			Cholestasis	胆汁うっ滞	3	Y	TE	71	3	N	Not applicable	Recovered
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	1	N	TE	71	34	N	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1	N	TE	71	40	N	None	Recovered
			Cholestasis	胆汁うっ滞	1	N	TE	73	30	N	None	Recovered
			Hyperbilirubinaemia	高ビリルビン血症	2	N	TE	88	17	N	None	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	4	N	TE	88	23	N	None	Not recovered, but no changes expected
			Chromaturia	着色尿	1	N	TE	88	26	N	None	Recovered
			Cholestasis	胆汁うっ滞	3	Y	TE	102	3	N	Not applicable	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hyperbilirubinaemia	高ビリルビン血症	3	N	TE	104	7	N	None	Recovered
			Hyperbilirubinaemia	高ビリルビン血症	1	N	TE	110	13	N	None	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	TE	110		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	122	41	Y	None	Recovered
063002	Spain	64/M/C	Dizziness	浮動性めまい	1	N	Pre			N	None	Recovered
			Respiratory tract infection	気道感染	2	N	TE	16	9	N	None	Recovered
			Muscle spasms	筋痙縮	1	N	TE	29	29	N	None	Recovered
			Discomfort	不快感	1	N	TE	57	3	Y	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	143	29	N	None	Recovered
			Gastroenteritis	胃腸炎	2	Y	TE	183	4	N	Not applicable	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	226	34	N	Not applicable	Recovered
063004	Spain	74/M/C	Abdominal pain upper	上腹部痛	1	N	TE	32	55	N	None	Recovered
			Somnolence	傾眠	2	N	TE	32	55	N	None	Recovered
			Anaemia	貧血	3	N	TE	58	29	N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	86		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	86	29	N	Not applicable	Ongoing at time of death
			Asthenia	無力症	1	N	TE	86		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	86		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	114		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	128	8	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	135	1	N	Drug permanently withdrawn	Death
070003	Spain	74/M/C	Constipation	便秘	2	N	TE	57	29	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	85	50	N	None	Recovered
			Dyspepsia	消化不良	1	N	TE	85	50	N	None	Recovered
			Nausea	悪心	2	N	TE	85	50	Y	None	Recovered
			Anorexia	食欲不振	2	N	TE	85	50	N	None	Recovered
			Cardiac failure	心不全	3	Y	TE	105	15	N	Drug administration postponed	Recovered
			Renal failure	腎不全	3	Y	TE	105	3	N	Drug administration postponed	Recovered
			Constipation	便秘	1	N	TE	218	29	N	None	Recovered
071006	Spain	76/M/C	Oedema peripheral	末梢性浮腫	1	N	Pre	1	29	N	None	Recovered
			Constipation	便秘	2	Y	TE	35	19	N	None	Recovered
			Asthenia	無力症	2	Y	TE	35	19	N	None	Recovered
			Anorexia	食欲不振	2	Y	TE	35	19	N	None	Recovered
			Renal failure	腎不全	2	Y	TE	52	2	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	80	37	N	None	Recovered
			Bone pain	骨痛	2	N	TE	199	155	N	Not applicable	Recovered
			Headache	頭痛	2	N	TE	199	59	N	None	Recovered
075001	Italy	59/M/C	Strangury	有痛性排尿困難		N	TE	2	2	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	2	N	TE	14	28	N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	33	10	Y	Drug administration postponed	Recovered
			Vomiting	嘔吐	1	N	TE	33	10	Y	Drug administration postponed	Recovered
			Anorexia	食欲不振	1	N	TE	33	10	Y	Drug administration postponed	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	41		N	None	Ongoing at time of death
			Strangury	有痛性排尿困難	2	N	TE	78	1	N	None	Recovered
			Death	死亡	5	Y	TE	93	1	N	None	Death
078001	Italy	76/M/C	Constipation	便秘	1	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE			N	None	Recovered
			Pyrexia	発熱	1	N	TE			N	None	Recovered
			Confusional state	錯乱状態	1	N	TE			N	None	Recovered
			Hyperhidrosis	多汗症	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE	2	11	Y	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	38	21	N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	58	21	N	None	Ongoing at time of death
			Asthenia	無力症	2	N	TE	78	37	Y	None	Recovered
			Pyrexia	発熱	1	N	TE	78	29	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	78		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	78	37	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	127	14	N	None	Ongoing at time of death
			Depression	うつ病	2	N	TE	127		N	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	141		N	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	147	2	Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	Y	TE	147	2	Y	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	149	14	Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	Y	TE	149	11	Y	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	1	Y	TE	163		Y	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	163	15	N	Not applicable	Death
085004	Israel	61/M/C	Asthenia	無力症	1	N	Pre	-4	1	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	Pre	1	30	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	10	3	N	None	Recovered
			Pyrexia	発熱	1	N	TE	36	8	N	None	Recovered
			Arthralgia	関節痛	1	N	TE	100	16	N	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	2	N	TE	115		N	None	Not recovered, but no changes expected

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE	148		N	None	Not recovered, but no changes expected
			Anaemia	貧血	3	N	TE	167	3	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	2	Y	TE	167	4	N	Not applicable	Recovered with sequelae
087002	Israel	69/M/C	Dysgeusia	味覚異常	1	N	TE	29	28	Y	None	Recovered
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	2	N	TE	29	13	N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	33		N	None	Ongoing at study termination / withdrawal
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	3	N	TE	41		N	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	3	Y	TE	44	2	N	None	Recovered with sequelae
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	44	68	N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Haematoma	血腫	1	N	TE	44		N	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	3	N	TE	45		N	None	Ongoing at study termination / withdrawal
			Oral candidiasis	口腔カンジダ症	1	N	TE	56	36	N	None	Recovered
			Blood urea increased	血中尿素増加	1	N	TE	56		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	56	36	N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	3	N	TE	91		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	91		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	91		N	None	Ongoing at study termination / withdrawal
			Decubitus ulcer	褥瘡性潰瘍	3	N	TE	111		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
093002	Slovakia	81/M/C	Anaemia	貧血	2	N	TE	29	48	N	-	
			Nausea	悪心	2	N	TE	29	85	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	29	6	Y	None	Recovered
			Constipation	便秘	1	N	TE	56	58	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	56	4	Y	None	Recovered
			Anaemia	貧血	3	N	TE	76	10	N	-	
			Bone pain	骨痛	3	Y	TE	76	8	N	None	Recovered with sequelae
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	76		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	85	29	N	-	
			Diarrhoea	下痢	2	N	TE	85	5	Y	None	Recovered
			Anaemia	貧血	2	N	TE	113	31	N	Drug administration postponed	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	143	5	N	Drug administration postponed	Recovered
			Bronchopneumonia	気管支肺炎	3	N	TE	150		N	None	Ongoing at time of death
			Cardiopulmonary failure	心肺不全	5	Y	TE	160	1	N	Not applicable	Death
096002	Slovakia	84/M/C	Anaemia	貧血	1	N	TE	58	29	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	86	112	Y	Not applicable	Recovered
			Haematuria	血尿	1	N	TE	90	9	N	None	Recovered
			Anaemia	貧血	3	Y	TE	197	4	Y	Not applicable	Recovered
097002	Slovakia	73/M/C	Pyrexia	発熱	1	N	TE	50	3	N	None	Recovered
			Pyrexia	発熱	1	N	TE	59	8	N	None	Recovered
			Pyrexia	発熱	1	N	TE	59	8	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	85	57	N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	107	15	N	None	Recovered
			Fatigue	疲労	3	Y	TE	107	15	Y	None	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	2	N	TE	107		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	107	15	N	None	Recovered with sequelae
			Vomiting	嘔吐	1	N	TE	113	5	Y	None	Recovered
			Anaemia	貧血	1	N	TE	141	22	N	Not applicable	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	2	N	TE	141		N	None	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	162	7	N	Not applicable	Recovered
			Fatigue	疲労	3	Y	TE	162	7	Y	Not applicable	Recovered with sequelae
			Anorexia	食欲不振	3	Y	TE	162	7	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	1	N	TE	168		N	Not applicable	Ongoing at time of death
			Fatigue	疲労	2	N	TE	168		Y	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	168		N	Not applicable	Ongoing at time of death
097006	Slovakia	73/M/C	Fatigue	疲労	2	N	Pre	1	10	N	None	Recovered
			Mixed incontinence	混合性尿失禁	3	N	Pre	1		N	None	Ongoing at study termination / withdrawal
			Spinal column stenosis	脊柱管狭窄症	4	Y	TE	2	17	N	None	Recovered with sequelae
			Fatigue	疲労	3	N	TE	10	161	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	15	14	N	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	28		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	86	85	Y	None	Recovered
			Weight decreased	体重減少	1	N	TE	113	29	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	113	58	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	113	62	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	141	30	N	None	Recovered
			Fatigue	疲労	1	N	TE	170	57	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
099002	Slovakia	69/M/C	Nausea	悪心	1	N	Pre	-3	32	N	None	Recovered
			Bone pain	骨痛	1	N	Pre	-3	32	N	None	Recovered
			Nausea	悪心	1	N	Pre	29	35	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	57	58	N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	57	2	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	79		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	85		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	102	68	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	105	7	N	None	Recovered
			Urinary tract infection	尿路感染	1	N	TE	106	8	N	None	Recovered
			Anaemia	貧血	1	N	TE	107	63	N	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	2	N	TE	114		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	169		N	None	Ongoing at study termination / withdrawal
			Hypocalcaemia	低カルシウム血症	1	N	TE	169		N	None	Ongoing at study termination / withdrawal
			Hypophosphataemia	低リン酸血症	2	N	TE	169	64	N	None	Recovered
			Bone pain	骨痛	2	N	TE	207	2	N	Not applicable	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	Y	TE	208	14	N	Not applicable	Recovered
103001	Hong Kong	74/M/A	Hypoaesthesia	感覚鈍麻	1	N	Pre	-6	22	N	None	Recovered
			Fatigue	疲労	1	N	TE	5		Y	None	Ongoing at study termination / withdrawal
			Neutropenia	好中球減少症	2	N	TE	12	37	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	12	2	N	None	Recovered
			Abdominal distension	腹部膨満	1	N	TE	13	61	Y	None	Recovered
			Abdominal pain	腹痛	1	N	TE	13	17	Y	None	Recovered
			Headache	頭痛	1	N	TE	14	27	N	None	Recovered
			Constipation	便秘	1	N	TE	25		Y	None	Ongoing at study termination / withdrawal
			Abdominal pain	腹痛	2	N	TE	29	28	Y	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	40	5	N	None	Recovered
			Intentional overdose	企図的過量投与	4	Y	TE	48	7	N	Not applicable	Recovered
			Hypoalbuminaemia	低アルブミン血症	1	N	TE	48	64	N	None	Recovered
			Depression	うつ病	4	Y	TE	48	26	N	Not applicable	Recovered with sequelae
			Intentional self-injury	故意の自傷行為	4	Y	TE	48	7	N	Not applicable	Recovered
			Intentional self-injury	故意の自傷行為	2	Y	TE	48	7	N	Not applicable	Recovered
			Depression	うつ病	2	N	TE	54		N	Not applicable	Ongoing at study termination / withdrawal
			Rash	発疹	1	N	TE	59	24	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
103002	Hong Kong	75/M/A	Constipation	便秘	1	N	TE	28	30	N	None	Ongoing at study termination / withdrawal
			Constipation	便秘	2	N	TE	57		N	None	Ongoing at study termination / withdrawal
			Tinea pedis	足部白癬	1	N	TE	105		N	None	Ongoing at study termination / withdrawal
			Dysuria	排尿困難	1	N	TE	147	36	N	None	Recovered
			Cough	咳嗽	1	N	TE	167	10	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	194	3	N	None	Recovered
			Lower respiratory tract infection	下気道感染	3	Y	TE	196	4	N	Not applicable	Recovered
104005	Hong Kong	73/M/A	Constipation	便秘	1	N	TE	1	29	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	64	2	Y	None	Recovered
			Pneumonia	肺炎	2	N	TE	87		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	87	18	N	Drug permanently withdrawn	Death
			Spinal cord compression	脊髄圧迫	5	Y	TE	104	1	N	Drug permanently withdrawn	Death
106002	Hong Kong	76/M/A	Hypoaesthesia	感覚鈍麻	1	N	TE	29	57	N	None	Recovered
			Pathological fracture	病的骨折	2	N	TE	85		N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	1	N	TE	113	3	N	None	Recovered
			Sleep disorder	睡眠障害	1	N	TE	113	29	N	None	Recovered
			Constipation	便秘	1	N	TE	141	29	Y	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cough	咳嗽	1	N	TE	169		N	None	Ongoing at time of death
			Haemophilus infection	ヘモフィルス感染	2	N	TE	178	14	N	None	Recovered
			Cardiac failure congestive	うっ血性心不全	3	Y	TE	221	26	N	Not applicable	Recovered
			Musculoskeletal pain	筋骨格痛	3	Y	TE	221	26	N	Not applicable	Recovered
			Insomnia	不眠症	2	N	TE	221	3	N	None	Recovered
106005	Hong Kong	79/M/A	Decreased appetite	食欲減退	1	N	TE	29	85	Y	None	Recovered
			Dysuria	排尿困難	1	N	TE	29		N	None	Ongoing at time of death
			Nocturia	夜間頻尿	2	N	TE	29	57	N	None	Recovered
			Anaemia	貧血	3	Y	TE	113	3	Y	Drug administration postponed	Recovered with sequelae
			Constipation	便秘	2	N	TE	113	29	N	None	Recovered
			Sleep disorder	睡眠障害	1	N	TE	113	3	N	None	Recovered
			Spinal compression fracture	脊椎圧迫骨折	3	N	TE	115		N	None	Ongoing at time of death
			Sepsis	敗血症	3	Y	TE	155		N	Not applicable	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	3	N	TE	156		N	Not applicable	Ongoing at time of death
			Haematuria	血尿	3	Y	TE	159		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	165	1	N	Not applicable	Death
106007	Hong Kong	61/M/A	Nerve root compression	神経根圧迫	3	Y	Pre	-17	18	N	Not applicable	Recovered
			Constipation	便秘	1	N	TE	57	29	Y	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hypoaesthesia	感覚鈍麻	1	N	TE	113		N	None	Not recovered, but no changes expected
			Lymphadenopathy	リンパ節症	3	N	TE	225	64	N	None	Recovered
106011	Hong Kong	79/M/A	Decreased appetite	食欲減退	1	N	TE	29	29	N	None	Recovered
			Abdominal pain upper	上腹部痛	1	N	TE	57	29	N	None	Recovered
			Liver function test abnormal	肝機能検査異常	3	Y	TE	57	13	N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	218	1	N	Not applicable	Death
106016	Hong Kong	75/M/A	Constipation	便秘	2	N	TE	29	126	Y	None	Recovered
			Dyspepsia	消化不良	2	N	TE	29	84	N	None	Recovered
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	3	Y	TE	41	3	N	None	Recovered
			Cough	咳嗽	1	N	TE	41	150	N	None	Recovered
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	1	N	TE	57	29	N	None	Recovered
			Headache	頭痛	1	N	TE	127	36	N	None	Recovered
			Dry skin	皮膚乾燥	2	N	TE	127	28	N	None	Recovered
130004	Canada	82/M/C	Hip fracture	股関節部骨折	3	Y	TE	32		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
133002	Poland	78/M/C	Pyrexia	発熱	1	N	TE	3	14	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	3	6	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	8	44	Y	None	Recovered
			Pathological fracture	病的骨折	2	Y	TE	43		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	51	53	Y	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	2	N	TE	72	34	N	None	Recovered
			Fatigue	疲労	3	N	TE	88	26	N	Drug permanently withdrawn	Ongoing at time of death
			Fatigue	疲労	4	N	TE	113		N	Drug permanently withdrawn	Ongoing at time of death
			Weight decreased	体重減少	2	N	TE	113		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	162	1	N	Not applicable	Death
133003	Poland	77/M/C	Arthralgia	関節痛	2	N	TE	3	3	Y	None	Recovered
			Neutropenia	好中球減少症	3	N	TE	56	9	Y	Drug administration postponed	Recovered
			Anaemia	貧血	3	Y	TE	65	2	Y	None	Recovered
			Anaemia	貧血	2	N	TE	85	5	Y	Drug permanently withdrawn	Recovered
			Anaemia	貧血	3	Y	TE	89	5	Y	Drug permanently withdrawn	Recovered
			Neutropenia	好中球減少症	3	N	TE	89	5	Y	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	89	2	Y	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	3	N	TE	90		Y	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fibrin D dimer increased	フィブリンDダイマー増加	2	N	TE	99		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	4	Y	TE	130	2	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	TE	131		N	None	Ongoing at study termination / withdrawal
133005	Poland	62/M/C	Nausea	悪心	1	N	TE			Y	None	Recovered
			Paraparesis	不全対麻痺	3	Y	TE	14		N	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	141		N	None	Ongoing at study termination / withdrawal
133006	Poland	53/M/C	Bone pain	骨痛	2	N	TE	2	10	Y	None	Recovered
			Hypertension	高血圧	2	N	TE	29	29	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	50		N	None	Recovered
			Abdominal pain	腹痛	2	N	TE	71		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	140	29	N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	168		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	168		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	184	2	N	Not applicable	Death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	185	1	N	Not applicable	Death
133009	Poland	75/M/C	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2	N	TE	85	29	N	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1	N	TE	85	29	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	141	29	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	198	1	N	Not applicable	Death
133011	Poland	66/M/C	Anaemia	貧血	2	N	Pre	1		N	None	Ongoing at time of death
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	Pre	1		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre	1		N	None	Not recovered, but no changes expected
			Tremor	振戦	4	Y	TE	25	1	Y	None	Recovered
			Confusional state	錯乱状態	4	Y	TE	25		Y	None	Ongoing at time of death
			Death	死亡	5	Y	TE	29	1	Y	None	Death
133012	Poland	67/M/C	Spinal cord compression	脊髄圧迫	3	Y	Pre	-35		N	Drug administration postponed	Ongoing at time of death
			Dyspnoea	呼吸困難	4	Y	TE	2	1	N	None	Death
			Dyspnoea	呼吸困難	5	Y	TE	2	1	N	None	Death
133017	Poland	61/M/C	Hyperthyroidism	甲状腺機能亢進症	1	N	TE	3		N	None	Not recovered, but no changes expected

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Upper gastrointestinal haemorrhage	上部消化管出血	2	Y	TE	3		N	None	Ongoing at study termination / withdrawal
133018	Poland	72/M/C	Diarrhoea	下痢	1	N	TE	39	5	Y	None	Recovered
			Dehydration	脱水	1	N	TE	57	3	N	None	Recovered
			Leukopenia	白血球減少症	3	N	TE	106		Y	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	3	N	TE	106		Y	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	4	Y	TE	106		N	Drug permanently withdrawn	Not recovered, but no changes expected
133020	Poland	76/M/C	Nausea	悪心	3	N	TE	1		Y	None	Not recovered, but no changes expected
			Vomiting	嘔吐	3	N	TE	1		Y	None	Not recovered, but no changes expected
			Dehydration	脱水	3	Y	TE	8	4	Y	Drug permanently withdrawn	Recovered
			Anaemia	貧血	2	N	TE	9	1	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	25		N	None	Ongoing at study termination / withdrawal
			Dehydration	脱水	2	N	TE	36		N	Not applicable	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	2	N	TE	36	1	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
134001	Poland	57/M/C	Paralysis	麻痺	4	Y	Pre	-10		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	20	1	N	None	Death
135003	Poland	62/M/C	Bone pain	骨痛	3	N	TE			N	None	Recovered
			Anaemia	貧血	3	Y	TE	114	3	Y	None	Recovered
			Anaemia	貧血	2	N	TE	115	2	Y	None	Recovered
137006	Poland	71/M/C	Anaemia	貧血	3	Y	TE	139	8	N	Not applicable	Recovered with sequelae
			Urinary tract infection	尿路感染	2	N	TE	157	8	N	Not applicable	Recovered
			Haematuria	血尿	3	Y	TE	197	7	N	Not applicable	Recovered
			Anaemia	貧血	4	Y	TE	203		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	213	1	N	Not applicable	Death
139001	Poland	76/M/C	Anaemia	貧血	1	N	TE	29		N	None	Ongoing at time of death
			Malaise	倦怠感	3	N	TE	29		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	46	1	N	None	Death
139005	Poland	71/M/C	Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre			N	None	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	57	5	Y	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	120	1	N	None	Death
139006	Poland	76/M/C	Oedema peripheral	末梢性浮腫	3	N	TE			N	None	Not recovered, but no changes expected
			Vomiting	嘔吐	2	N	TE	31	3	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	88	5	Y	None	Recovered with sequelae
			Renal failure	腎不全	2	N	TE	119	26	N	None	Ongoing at study termination / withdrawal
			General physical health deterioration	全身健康状態低下	3	N	TE	144		Y	Drug permanently withdrawn	Not recovered, but no changes expected
			Renal failure	腎不全	1	N	TE	144		N	None	Ongoing at study termination / withdrawal
139009	Poland	57/M/C	Pancytopenia	汎血球減少症	3	Y	TE	117	8	Y	Drug administration postponed	Recovered with sequelae
			Leukopenia	白血球減少症	3	Y	TE	172	10	Y	Drug administration postponed	Recovered with sequelae
			Leukopenia	白血球減少症	2	N	TE	181		Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	181	1	Y	None	Ongoing at time of death
139012	Poland	67/M/C	Thrombophlebitis	血栓性静脈炎	2	Y	Pre	-26	12	N	Drug administration postponed	Recovered with sequelae

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombophlebitis	血栓性静脈炎	1	N	Pre	-15		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	29	8	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	29	8	Y	None	Recovered
			Nausea	悪心	1	N	TE	57	8	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	57	8	Y	None	Recovered
			Nausea	悪心	1	N	TE	85	7	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	85	7	Y	None	Recovered
144002	Germany	77/M/C	Hyperthyroidism	甲状腺機能亢進症	1	N	TE			Y	None	Recovered
			Dysgeusia	味覚異常	1	N	TE			Y	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	2	4	Y	None	Recovered
			Fatigue	疲労	2	N	TE	3	3	Y	None	Recovered with sequelae
			Urinary retention	尿閉	1	N	TE	47	37	N	None	Recovered with sequelae
			Benign neoplasm of bladder	膀胱の良性新生物	3	Y	TE	77	7	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	101	4	N	None	Recovered
			Haematuria	血尿	1	N	TE	158	6	N	None	Recovered
			Haematuria	血尿	1	N	TE	216	3	N	None	Recovered
144004	Germany	68/M/C	Pneumonia	肺炎	3	Y	TE	59	6	N	None	Recovered
146001	Germany	70/M/C	Paraesthesia	錯感覚	2	N	TE	73		N	None	Recovered with sequelae
			Herpes zoster	帯状疱疹	2	Y	TE	169	12	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary incontinence	尿失禁	1	N	TE	174		N	Not applicable	Ongoing at study termination / withdrawal
148009	Germany	71/M/C	Nasopharyngitis	鼻咽頭炎	1	N	Pre	-14	15	N	None	Recovered
			Anaemia	貧血	2	N	Pre	1	57	Y	Drug administration postponed	Recovered
			Fatigue	疲労	2	N	TE	8		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	29	4	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	57	4	Y	Drug administration postponed	Recovered
			Anaemia	貧血	1	N	TE	60	31	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	60	1	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	60	2	Y	None	Recovered
			Herpes zoster	帯状疱疹	3	Y	TE	96	12	Y	Drug administration postponed	Recovered
			Anaemia	貧血	2	Y	TE	98	1	Y	None	Recovered
			Anaemia	貧血	4	Y	TE	125	3	Y	Drug administration postponed	Recovered
			Syncope	失神	3	Y	TE	125	1	Y	Drug administration postponed	Recovered
			Pancytopenia	汎血球減少症		N	TE	140		Y	None	Ongoing at time of death
			Metastases to liver	肝転移	3	Y	TE	140	10	N	Drug permanently withdrawn	Death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Epistaxis	鼻出血	2	N	TE	140	1	N	Not applicable	Recovered
			Metastases to liver	肝転移	5	Y	TE	149	1	N	Drug permanently withdrawn	Death
148012	Germany	72/M/C	Acute coronary syndrome	急性冠動脈症候群	3	Y	TE	6	3	N	None	Recovered
			Angina pectoris	狭心症	2	N	TE	76	15	N	None	Recovered
			Angina pectoris	狭心症	3	Y	TE	90	3	N	None	Recovered
			Anaemia	貧血	3	N	TE	141	15	Y	Drug administration postponed	Ongoing at time of death
			Anaemia	貧血	2	N	TE	155		Y	Drug administration postponed	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	155	29	Y	None	Recovered
			Arthralgia	関節痛	2	N	TE	169		N	None	Ongoing at study termination / withdrawal
			Pigmentation disorder	色素沈着障害	1	N	TE	183		N	None	Recovered
148014	Germany	62/M/C	Nausea	悪心	1	N	TE	29	1	Y	None	Recovered
			Ageusia	味覚消失	1	N	TE	29	1	Y	None	Recovered
			Cataract	白内障	3	Y	TE	154	3	N	Not applicable	Recovered
150002	Germany	72/M/C	Nausea	悪心	2	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE			N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	23	4	N	None	Recovered with sequelae

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	26	8	N	None	Recovered with sequelae
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	4	N	TE	29	26	N	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	4	N	TE	29	2	N	None	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	TE	29	2	N	None	Recovered
			Neuralgia	神経痛	2	N	TE	29	5	N	None	Recovered with sequelae
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	30	25	N	None	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	2	N	TE	30	25	N	None	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1	N	TE	54	13	N	None	Recovered
			Nerve root compression	神経根圧迫	2	Y	TE	66	3	N	None	Recovered with sequelae
			Nausea	悪心	2	N	TE	69	11	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	69	11	N	None	Recovered
			Fatigue	疲労	1	N	TE	69	11	N	None	Recovered
			Urinary retention	尿閉	2	Y	TE	69	11	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	177	11	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	178	1	N	None	Recovered
			Headache	頭痛	2	N	TE	180	1	N	None	Recovered
150003	Germany	70/M/C	Nausea	悪心	1	N	TE	72		N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hydronephrosis	水腎症	2	Y	TE	100	2	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	141	5	N	None	Recovered
			Hypercreatininaemia	高クレアチニン血症	2	N	TE	141	16	N	None	Recovered
			Hydronephrosis	水腎症	2	Y	TE	141	6	N	None	Recovered with sequelae
			Anaemia	貧血	3	N	TE	143		N	None	Ongoing at time of death
			Hypercreatininaemia	高クレアチニン血症	1	N	TE	156	32	N	None	Recovered
154001	Germany	65/M/C	Coronary artery disease	冠動脈疾患	3	Y	Pre	-12	3	N	Not applicable	Recovered
			Hypercholesterolaemia	高コレステロール血症	1	N	Pre	-12		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	50	32	N	None	Recovered
			Anaemia	貧血	2	N	TE	59		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	80	75	N	None	Recovered
			Coronary artery disease	冠動脈疾患	2	Y	TE	122	8	N	Not applicable	Recovered
154002	Germany	71/M/C	Nausea	悪心	1	N	Pre			N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Pain	疼痛	3	N	TE			N	None	Ongoing at study termination / withdrawal
			Angina pectoris	狭心症	1	N	TE	1	15	Y	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	1	N	TE	42		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	42		N	None	Ongoing at time of death
			Joint injury	関節損傷	1	N	TE	61	1	N	None	Recovered
			Anaemia	貧血	2	N	TE	85		N	None	Ongoing at study termination / withdrawal
			Gait disturbance	歩行障害	3	N	TE	94		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	123	13	N	Drug administration postponed	Recovered with sequelae
			Facial palsy	顔面神経麻痺	3	N	TE	155	15	N	Drug administration postponed	Ongoing at time of death
			Facial palsy	顔面神経麻痺	3	Y	TE	169	7	N	Drug administration postponed	Ongoing at time of death
			Facial palsy	顔面神経麻痺	2	N	TE	175		N	Drug administration postponed	Ongoing at study termination / withdrawal
154004	Germany	62/M/C	Atrial fibrillation	心房細動	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Renal failure	腎不全	2	N	TE			N	None	Recovered with sequelae
			Cystitis	膀胱炎	1	N	Pre	-3	7	N	None	Recovered
			Nausea	悪心	1	N	TE	2		Y	None	Not recovered, but no changes expected

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE	2		Y	None	Not recovered, but no changes expected
			Abdominal pain upper	上腹部痛	1	N	TE	7	23	Y	None	Recovered
			Abdominal pain	腹痛	1	N	TE	29	56	N	Not applicable	Ongoing at study termination / withdrawal
			Nocturia	夜間頻尿	2	N	TE	57		N	None	Ongoing at time of death
			Acute prerenal failure	急性腎前性腎不全	2	Y	TE	81	4	N	Not applicable	Recovered
			Abdominal pain	腹痛	2	N	TE	84		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	N	TE	85		N	None	Ongoing at time of death
			Peritonitis bacterial	細菌性腹膜炎	3	Y	TE	86	22	N	Drug permanently withdrawn	Recovered
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	107	6	N	Drug permanently withdrawn	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	112		N	Drug permanently withdrawn	Not recovered, but no changes expected
155004	Germany	63/M/C	Vomiting	嘔吐	2	N	TE			Y	None	Recovered
			Vomiting	嘔吐	1	N	TE			Y	None	Recovered
			Depression	うつ病	1	N	Pre	1	217	N	None	Not recovered, but no changes expected
			Constipation	便秘	1	Y	TE	26	3	N	None	Recovered
			Reflux oesophagitis	逆流性食道炎	1	N	TE	32	46	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	32		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	32		N	None	Not recovered, but no changes expected
			Night sweats	寝汗	1	N	TE	32	31	N	None	Recovered
			Reflux oesophagitis	逆流性食道炎	2	N	TE	77	95	N	None	Recovered
			Depression	うつ病	2	N	TE	217		N	None	Not recovered, but no changes expected
157002	Germany	76/M/C	Dyspnoea	呼吸困難	3	Y	Pre	-10	2	N	Not applicable	Recovered
			Anaemia	貧血	2	N	Pre	1	37	Y	None	Recovered with sequelae
			Fatigue	疲労	2	N	TE	5		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	5		Y	None	Ongoing at time of death
			Night sweats	寝汗	1	N	TE	5		Y	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	37	2	Y	None	Recovered with sequelae
			Anaemia	貧血	3	N	TE	38	6	Y	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	43		Y	None	Not recovered, but no changes expected
170004	Brazil	78/M/C	Pathological fracture	病的骨折	3	N	TE	127		N	Drug administration postponed	Ongoing at time of death
			Urinary retention	尿閉	3	N	TE	156	1	N	None	Recovered
			Anaemia	貧血	2	N	TE	211		N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	4	Y	TE	230		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	230	3	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	232	1	N	Drug permanently withdrawn	Death
173009	Brazil	66/M/O	Bone pain	骨痛	2	N	Pre	-9		N	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	4	Y	TE	29	20	N	Drug permanently withdrawn	Death
			General physical health deterioration	全身健康状態低下	5	Y	TE	48	1	N	Drug permanently withdrawn	Death
179001	Brazil	77/M/C	Hypercreatininaemia	高クレアチニン血症	2	N	Pre	1	59	N	None	Ongoing at study termination / withdrawal
			Hypercreatininaemia	高クレアチニン血症	1	N	Pre	59	29	N	None	Ongoing at study termination / withdrawal
			Asthenia	無力症	1	N	TE	69	1	N	None	Recovered
			Hypercreatininaemia	高クレアチニン血症	2	N	Pre	87		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	Y	TE	93	4	N	None	Recovered
			Anaemia	貧血	2	Y	TE	114	3	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Asthenia	無力症	2	Y	TE	126	5	N	Drug administration postponed	Recovered with sequelae
			Fatigue	疲労	3	Y	TE	146	9	N	Drug permanently withdrawn	Recovered
181005	Brazil	74/M/C	Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	Pre	1		N	None	Ongoing at time of death
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	Pre	1		N	None	Ongoing at time of death
			Hypoglycaemia	低血糖症	3	Y	TE	29	2	N	None	Recovered
			Pneumonia	肺炎	2	Y	TE	30	16	N	Not applicable	Death
			Acute pulmonary oedema	急性肺水腫	2	Y	TE	30		N	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	5	Y	TE	45	1	N	Not applicable	Death
201002	Australia	72/M/C	Dysphagia	嚥下障害	2	N	Pre	-7	70	N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	48	46	N	None	Recovered
			Muscle strain	筋挫傷	2	N	TE	49	15	N	None	Recovered
			Dysphagia	嚥下障害	1	N	Pre	63	71	N	None	Ongoing at time of death
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	2	N	TE	93	4	N	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	99	8	N	None	Recovered
			Anaemia	貧血	3	Y	TE	132	9	N	Not applicable	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Supraventricular tachycardia	上室性頻脈	2	Y	TE	132	1	N	Not applicable	Recovered
			Abdominal distension	腹部膨満	3	Y	TE	132	9	N	Not applicable	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	3	N	TE	132		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	132	39	N	Not applicable	Death
			Anxiety	不安	2	N	TE	132		N	Not applicable	Ongoing at time of death
			Dysphagia	嚥下障害	2	N	Pre	133		N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	1	N	TE	137	3	N	Not applicable	Recovered
			Abdominal distension	腹部膨満	2	N	TE	140		N	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	147		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	161		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	170	1	N	Not applicable	Death
203004	Australia	70/M/C	Constipation	便秘	1	N	Pre	-7		N	None	Recovered
			Hypophosphataemia	低リン酸血症	4	N	Pre	-2	29	N	-	
			Lethargy	嗜眠	1	N	TE	4	1	Y	None	Recovered
			Hypophosphataemia	低リン酸血症	3	N	Pre	27	64	N	-	
			Hypomagnesaemia	低マグネシウム血症	1	N	TE	55	36	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	56	1	N	None	Recovered
			Lethargy	嗜眠	1	N	TE	79	69	Y	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cough	咳嗽	1	N	TE	79	15	N	None	Recovered
			Dyspepsia	消化不良	1	N	TE	84	15	N	None	Recovered
			Hypophosphataemia	低リン酸血症	4	N	Pre	90	29	N	-	
			Paraesthesia	錯感覚	1	N	TE	91		N	None	Ongoing at time of death
			Hypophosphataemia	低リン酸血症	3	N	Pre	118	15	N	-	
			Dyspepsia	消化不良	1	N	TE	120		N	None	Recovered
			Hypophosphataemia	低リン酸血症	4	N	Pre	132	6	N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	132	115	N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	132	115	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	133	114	N	Not applicable	Recovered
			Hypophosphataemia	低リン酸血症	4	Y	TE	137	4	N	Not applicable	Recovered
			Hyperparathyroidism	副甲状腺機能亢進症	1	N	TE	139		N	Not applicable	Recovered
			Cachexia	悪液質	2	N	TE	139		N	Not applicable	
			Osteomalacia	骨軟化症	2	N	TE	139		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	146	20	N	Not applicable	Recovered
			Lethargy	嗜眠	2	N	TE	147		Y	None	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	1	N	TE	166		N	Not applicable	Ongoing at time of death
204001	Australia	76/M/C	Dyspnoea	呼吸困難	1	N	Pre	-392	366	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	1	N	TE	1		Y	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	2		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	2		Y	None	Ongoing at study termination / withdrawal
			Chills	悪寒	1	N	TE	6	1	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	8	1	Y	None	Recovered
			Constipation	便秘	1	N	TE	9		Y	None	Ongoing at study termination / withdrawal
			Contusion	挫傷	1	N	TE	10		N	None	Ongoing at study termination / withdrawal
			Gastroenteritis	胃腸炎	4	Y	TE	18	6	Y	None	Recovered with sequelae
			Renal failure acute	急性腎不全	2	Y	TE	18	6	Y	None	Recovered
			Gastroenteritis	胃腸炎	3	N	TE	21	3	Y	None	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	22	2	Y	None	Recovered
			Gastroenteritis	胃腸炎	2	N	TE	23	1	Y	None	Recovered with sequelae
			Bone pain	骨痛	1	N	TE	34		Y	None	Ongoing at time of death
			Mobility decreased	運動性低下	1	N	TE	34		Y	None	Ongoing at time of death
			Tremor	振戦	1	N	TE	34		Y	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	43	26	N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	63	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	68	9	N	Not applicable	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	76		N	Not applicable	Ongoing at study termination / withdrawal
			Anxiety	不安	1	N	TE	79	1	Y	None	Recovered
205004	Australia	82/M/C	Bone pain	骨痛	2	N	TE			Y	None	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	Pre	1		N	None	Ongoing at time of death
			Urinary incontinence	尿失禁	2	N	TE	6		Y	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	33		Y	None	Ongoing at time of death
			Hydrocephalus	水頭症	4	Y	TE	107	20	N	Drug permanently withdrawn	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	127	14	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	140	1	N	Drug permanently withdrawn	Death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
206001	Australia	83/M/C	Meniere's disease	メニエール病	2	N	TE	78	18	Y	Drug administration postponed	Recovered with sequelae
			Deep vein thrombosis	深部静脈血栓症	3	Y	TE	90	6	Y	None	Recovered with sequelae
			Constipation	便秘	1	N	TE	91	4	N	Drug administration postponed	Recovered
209001	Australia	78/M/C	Stomatitis	口内炎	1	N	Pre	-2	17	N	None	Recovered
			Lethargy	嗜眠	1	N	TE	2	105	N	None	Recovered
			Bone pain	骨痛	1	N	TE	29	84	N	None	Recovered
			Fatigue	疲労	3	Y	TE	107	6	N	Drug administration postponed	Recovered
			Bone pain	骨痛	1	N	TE	107	3	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	107	6	N	Drug administration postponed	Recovered
			Nausea	悪心	1	N	TE	108	3	N	Not applicable	Recovered
			Headache	頭痛	1	N	TE	112	1	N	Not applicable	Recovered
			Lethargy	嗜眠	3	N	TE	113		N	Not applicable	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	126	8	N	Not applicable	Recovered
209002	Australia	78/M/C	Bone pain	骨痛	1	N	Pre	1	71	N	None	Recovered
			Rash	発疹	1	N	Pre	1	57	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Decreased appetite	食欲減退	1	N	TE	2		N	None	Ongoing at time of death
			Neutropenia	好中球減少症	3	N	TE	29	42	N	Drug administration postponed	Recovered
			Diarrhoea	下痢	1	N	TE	29	99	N	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	29	29	N	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	57		N	None	Ongoing at time of death
			Lymphadenopathy	リンパ節症	1	N	TE	57		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	84	59	N	None	Recovered
			Hypoalbuminaemia	低アルブミン血症	1	N	TE	98		N	None	Ongoing at time of death
			Pallor	蒼白	2	N	TE	98	33	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	99		N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	99	29	N	None	Recovered
			Neutropenia	好中球減少症	4	N	TE	126	5	N	Drug permanently withdrawn	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	126		N	Not applicable	Ongoing at time of death
			Rectal tenesmus	直腸しぶり	1	N	TE	127		N	Not applicable	Ongoing at study termination / withdrawal
			Crepitations	捻髪音	1	N	TE	127		N	Not applicable	Ongoing at time of death
			Breath sounds abnormal	呼吸音異常	1	N	TE	127		N	Not applicable	Ongoing at time of death
			Wheezing	喘鳴	1	N	TE	127		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neutropenia	好中球減少症	3	N	TE	130	15	N	Drug permanently withdrawn	Recovered
			Anaemia	貧血	2	N	TE	133	13	N	Not applicable	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	137	6	N	Not applicable	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	TE	142	22	N	Not applicable	Ongoing at time of death
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1	N	TE	142	12	N	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	3	Y	TE	143	12	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	153	61	N	Not applicable	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	2	N	TE	153	11	N	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE	155		N	Not applicable	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	TE	163		N	Not applicable	Ongoing at time of death
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	TE	163		N	Not applicable	Ongoing at time of death
209003	Australia	56/M/C	Bone pain	骨痛	1	N	Pre	-22		N	None	Ongoing at time of death
			Oesophagitis	食道炎	1	N	TE	29		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	29		N	None	Ongoing at time of death
			Muscle spasms	筋痙縮	1	N	TE	57		N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	1	N	TE	78		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	78		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	78		N	None	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	85		N	None	Ongoing at time of death
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	1	N	TE	85		N	None	Ongoing at time of death
			Breath sounds abnormal	呼吸音異常	1	N	TE	85		N	None	Ongoing at time of death
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1	N	TE	85		N	None	Ongoing at time of death
			Neuropathy peripheral	末梢性ニューロパチー	1	N	TE	88		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	4	Y	TE	94	16	N	None	Recovered
			Burning sensation	灼熱感	1	N	TE	102	1	N	None	Recovered
			Rash	発疹	1	N	TE	103		N	None	Ongoing at time of death
			Pyrexia	発熱	1	N	TE	108	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	109		N	Not applicable	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	109		N	Not applicable	Ongoing at time of death
			Radiation skin injury	放射線皮膚損傷	1	N	TE	109		N	Not applicable	Ongoing at time of death
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	Y	TE	109	7	N	Drug permanently withdrawn	Recovered
			Anxiety	不安	1	N	TE	109		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	4	N	TE	138		N	Not applicable	Ongoing at time of death
			Ascites	腹水	1	Y	TE	149		N	Not applicable	Ongoing at time of death
			Epistaxis	鼻出血	1	N	TE	149	18	N	Not applicable	Recovered
			Dry skin	皮膚乾燥	1	N	TE	149		N	Not applicable	Ongoing at time of death
			Pruritus	そう痒症	1	N	TE	149		N	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE	153		N	None	Ongoing at time of death
			Rectal haemorrhage	直腸出血	1	N	TE	158		N	Not applicable	Ongoing at time of death
			Pitting oedema	圧痕浮腫	1	N	TE	158		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	158	9	N	Not applicable	Death
			Confusional state	錯乱状態	1	N	TE	158		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	166	1	N	Not applicable	Death
213002	Australia	49/M/O	Cough	咳嗽	1	N	Pre	-10	31	N	None	Recovered
			Musculoskeletal pain	筋骨格痛	3	N	TE	17	2	Y	None	Recovered
			Dyspnoea	呼吸困難	3	N	TE	82		Y	None	Not recovered, but no changes expected
			Abdominal pain	腹痛	2	N	TE	85	3	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	85	1	N	None	Recovered
			Pulmonary haemorrhage	肺出血	1	N	TE	85	1	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	140	29	N	None	Not recovered, but no changes expected

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Rectal haemorrhage	直腸出血	1	N	TE	159		N	None	Not recovered, but no changes expected
			Fatigue	疲労	2	N	TE	161		N	None	Not recovered, but no changes expected
			Headache	頭痛	1	N	TE	161		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	163	9	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	163	9	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	168	28	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	168	3	N	Not applicable	Recovered
			Insomnia	不眠症	1	N	TE	168		N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	195		N	None	Not recovered, but no changes expected
214003	Australia	68/M/C	Rash	発疹	2	N	TE	3	20	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	8	10	N	None	Recovered
			Bone pain	骨痛	3	N	TE	42	16	N	Drug administration postponed	Recovered
			Constipation	便秘	1	N	TE	54	4	N	None	Recovered
			Fatigue	疲労	3	N	TE	58	28	Y	None	Recovered
			Constipation	便秘	1	N	TE	60	3	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	61		Y	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	85	29	N	None	Recovered
			Hydronephrosis	水腎症	3	N	TE	85	36	N	None	Recovered
			Myositis	筋炎	2	N	TE	101	15	N	None	Recovered
			Anaemia	貧血	2	N	TE	122	3	N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Procedural pain	処置による疼痛	3	Y	TE	122	4	N	None	Recovered
			Dysuria	排尿困難	2	N	TE	122	3	N	None	Recovered
			Haematuria	血尿	1	N	TE	122	15	N	None	Recovered
			Anaemia	貧血	1	N	TE	124		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	124	18	Y	Drug permanently withdrawn	Ongoing at time of death
			Nausea	悪心	2	N	TE	124	18	Y	None	Recovered
			Diarrhoea	下痢	2	N	TE	130	8	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	141	61	Y	Drug permanently withdrawn	Ongoing at time of death
230002	UK	66/M/C	Muscle spasms	筋痙縮	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE	28		N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	38	8	Y	None	Recovered
			Anaemia	貧血	2	N	TE	56	29	Y	None	Recovered with sequelae
			Arthralgia	関節痛	2	N	TE	84	86	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	94	6	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	98	44	Y	None	Recovered
230003	UK	73/M/C	Diarrhoea	下痢	1	N	TE			N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	1	N	Pre			N	None	Ongoing at study termination / withdrawal
			Scrotal swelling	陰嚢腫脹	1	N	TE			N	Not applicable	Ongoing at time of death
			Urosepsis	尿路性敗血症	3	Y	Pre	-15	4	N	Drug administration postponed	Recovered
			Hypoglycaemia	低血糖症	4	Y	Pre	-15	1	N	Drug administration postponed	Recovered
			Dizziness	浮動性めまい	1	N	TE	68		N	Not applicable	Recovered
			Rectal discharge	直腸分泌物	1	N	TE	69	10	N	Not applicable	Recovered
			Dysuria	排尿困難	1	N	TE	73		N	Not applicable	Recovered
			Groin pain	鼠径部痛	3	N	TE	75		Y	Not applicable	Recovered
			Nausea	悪心	1	N	TE	83		N	Not applicable	Ongoing at study termination / withdrawal
233001	UK	75/M/C	Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE			Y	None	Recovered
			Bone pain	骨痛	2	N	Pre	-2	33	N	None	Recovered
			Bone pain	骨痛	3	N	TE	85		N	Drug administration postponed	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	85		N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Spinal cord compression	脊髄圧迫	4	Y	TE	103	7	N	Drug administration postponed	Recovered with sequelae
			Atrial fibrillation	心房細動	3	Y	TE	116	2	Y	None	Recovered
			Cardiac failure congestive	うっ血性心不全	3	Y	TE	131		Y	Not applicable	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	N	TE	131	22	N	Not applicable	Recovered
			Hypokalaemia	低カリウム血症	3	N	TE	132	3	N	Not applicable	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	135	3	N	Not applicable	Recovered
233002	UK	70/M/C	Bone pain	骨痛	2	N	Pre	1		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	4	4	Y	None	Recovered
			Productive cough	湿性咳嗽	2	N	TE	4	4	Y	None	Recovered
			Sepsis	敗血症	4	Y	TE	5	11	Y	Drug permanently withdrawn	Recovered
233005	UK	78/M/C	Nausea	悪心	1	N	TE	1	209	N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	29	181	Y	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	29	29	N	None	Recovered
			Anorexia	食欲不振	3	N	TE	29	113	Y	None	Ongoing at time of death
			Dehydration	脱水	3	N	TE	29	4	Y	Drug administration postponed	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malaise	倦怠感	2	Y	TE	32	6	Y	Drug administration postponed	Recovered
			Dehydration	脱水	3	Y	TE	32	6	Y	Drug administration postponed	Recovered
			Dehydration	脱水	2	Y	TE	45	5	Y	Drug administration postponed	Recovered
			Anaemia	貧血	3	Y	TE	53	3	Y	None	Recovered
			Hypertension	高血圧	3	N	TE	85	125	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	134	3	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	136	3	Y	None	Recovered
			Dehydration	脱水	2	N	TE	136	3	Y	None	Recovered
			Dyspnoea	呼吸困難	3	N	TE	136	2	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	141		Y	None	Ongoing at time of death
			Abdominal pain upper	上腹部痛	1	N	TE	167	3	Y	None	Recovered
			Anaemia	貧血	1	Y	TE	168	2	Y	None	Recovered
			Fatigue	疲労	2	N	TE	168		N	None	Ongoing at time of death
			Dehydration	脱水	2	Y	TE	168	2	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	176	3	Y	Not applicable	Recovered
			Cough	咳嗽	2	N	TE	176	3	N	None	Recovered
			Cough	咳嗽	1	N	TE	176	3	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	N	TE	176	3	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	190		Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neutropenia	好中球減少症	2	Y	TE	190		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	Y	TE	190		Y	Not applicable	Ongoing at time of death
			Abdominal pain	腹痛	1	N	TE	190	1	Y	Not applicable	Recovered
			Decreased appetite	食欲減退	3	N	TE	190		N	None	Ongoing at time of death
			Dehydration	脱水	3	Y	TE	190	4	Y	Not applicable	Recovered
			Hyperkalaemia	高カリウム血症	2	N	TE	190	20	Y	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	190		Y	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	190	4	Y	Not applicable	Recovered
			Dizziness	浮動性めまい	2	N	TE	190		N	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	3	Y	TE	209		N	Not applicable	Ongoing at time of death
			Bronchopneumonia	気管支肺炎	5	Y	TE	209	1	N	Not applicable	Death
			Dehydration	脱水	3	Y	TE	209		Y	Not applicable	Ongoing at time of death
			Agitation	激越	2	N	TE	209	1	N	None	Ongoing at time of death
240002	USA	68/M/C	Anaemia	貧血	3	N	TE	33	6	Y	Drug administration postponed	Recovered with sequelae

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pneumonia	肺炎	3	Y	TE	33	6	N	Drug administration postponed	Recovered
			Sepsis	敗血症	4	Y	TE	33	6	N	Drug administration postponed	Recovered
			Pleural effusion	胸水	2	N	TE	33	4	N	None	Recovered
			Hypotension	低血圧	3	N	TE	33	1	N	None	Recovered
			Anaemia	貧血	1	N	TE	38	48	Y	None	Recovered with sequelae
			Diarrhoea	下痢	1	N	TE	62		Y	None	Ongoing at time of death
			Muscle spasms	筋痙縮	1	N	TE	72	43	N	None	Recovered
			Anaemia	貧血	2	N	TE	85	97	Y	None	Recovered with sequelae
			Nausea	悪心	1	N	TE	114	3	N	None	Recovered
			Fatigue	疲労	2	N	TE	114		Y	None	Ongoing at time of death
			Haematuria	血尿	1	N	TE	133	7	N	None	Recovered
			Leukopenia	白血球減少症	2	N	TE	139		Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	1	N	TE	139		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	139		Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	140		N	None	Ongoing at time of death
			Contusion	挫傷	1	N	TE	140		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	140		N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE	170		N	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	180	3	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	3	Y	TE	180	6	Y	Not applicable	Recovered
			Urinary tract infection	尿路感染	1	N	TE	180	11	N	Not applicable	Recovered
			Bone pain	骨痛	3	N	TE	180	6	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	180	62	N	Not applicable	Death
			Haematuria	血尿	2	Y	TE	180	6	Y	Not applicable	Recovered
			Urinary retention	尿閉	2	Y	TE	180	6	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	N	TE	180	24	N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	181	2	Y	None	Recovered with sequelae
			Dyspnoea	呼吸困難	1	N	TE	181	5	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	182	50	Y	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	194		N	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	199	5	Y	Not applicable	Ongoing at time of death
			Abdominal pain	腹痛	2	N	TE	199	11	N	Not applicable	Recovered
			Diarrhoea	下痢	1	N	TE	199	11	N	Not applicable	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	2	N	TE	199	11	N	Not applicable	Recovered
			Vomiting	嘔吐	2	N	TE	199	11	N	Not applicable	Recovered
			Asthenia	無力症	2	N	TE	199		N	Not applicable	Ongoing at time of death
			Arthralgia	関節痛	1	N	TE	199	11	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	199	11	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	N	TE	199	5	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	203		Y	Not applicable	Ongoing at time of death
			Skin laceration	皮膚裂傷	2	N	TE	205		N	Not applicable	Ongoing at time of death
			Haemorrhoids	痔核	1	N	TE	210	6	N	Not applicable	Recovered
			Convulsion	痙攣	2	N	TE	223	1	N	Not applicable	Recovered
			Subcutaneous abscess	皮下組織膿瘍	2	N	TE	227		N	Not applicable	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	229		N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	231		Y	Not applicable	Ongoing at time of death
			Urinary retention	尿閉	2	N	TE	240	1	Y	Not applicable	Recovered
			Salivary hypersecretion	流涎過多	1	N	TE	241		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	241	1	N	Not applicable	Death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Confusional state	錯乱状態	3	N	TE	241		N	Not applicable	Ongoing at time of death
240006	USA	75/M/C	Constipation	便秘	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	Pre	-7	100	N	None	Recovered
			Cardiac murmur	心雑音	1	N	Pre	-2	35	N	None	Recovered
			Bone pain	骨痛	1	N	TE	31	63	N	None	Recovered
			Contusion	挫傷	1	N	TE	33		N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	3	N	TE	47	11	Y	None	Recovered
			Abdominal pain upper	上腹部痛	1	N	TE	64	25	N	None	Recovered
			Fatigue	疲労	1	N	TE	64		Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	64	60	N	None	Recovered
			Weight increased	体重増加	1	N	TE	64		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	64	25	N	Drug administration postponed	Recovered
			Muscular weakness	筋力低下	1	N	TE	64		N	None	Ongoing at time of death
			Bone pain	骨痛	4	Y	TE	88	6	N	Drug administration postponed	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	88	115	N	Drug permanently withdrawn	Recovered
			Anaemia	貧血	2	N	TE	109	33	Y	Not applicable	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	2	N	TE	110	87	Y	Not applicable	Recovered
			Asthenia	無力症	2	N	TE	110		N	Not applicable	Ongoing at time of death
			Depression	うつ病	2	N	TE	110		N	Not applicable	Ongoing at time of death
			Fluid intake reduced	水分摂取量減少	2	N	TE	116	8	N	Not applicable	Recovered
			Cough	咳嗽	1	N	TE	118	17	N	None	Recovered
			Hypotension	低血圧	2	N	TE	120	55	N	Not applicable	Recovered
			Anorexia	食欲不振	2	N	TE	124		Y	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	145	203	N	Drug permanently withdrawn	Death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
001014	Norway	67/M/C	Bone pain	骨痛	3	N	TE			N	None	Recovered
			Insomnia	不眠症	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	2	N	TE	39	4	Y	None	Recovered
			Nausea	悪心	2	N	TE	48	2	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	48	2	Y	None	Recovered
			Somnolence	傾眠	3	Y	TE	49	5	N	None	Recovered
			Depression	うつ病	2	N	TE	52		N	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	57	85	Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	85	29	Y	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	136		Y	None	Ongoing at study termination / withdrawal
			Confusional state	錯乱状態	1	N	TE	136		Y	None	Ongoing at study termination / withdrawal
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	2	N	TE	141	36	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	141	36	Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	141	6	Y	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	Y	TE	146	6	Y	Not applicable	Recovered with sequelae

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	1	N	TE	176		Y	None	Ongoing at study termination / withdrawal
001015	Norway	65/M/C	Anaemia	貧血	2	N	Pre	1	85	Y	None	Not recovered, but no changes expected
			Bronchitis	気管支炎	2	Y	TE	38	9	N	None	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1	N	TE	57	46	Y	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	57	36	Y	None	Not recovered, but no changes expected
			Hyperhidrosis	多汗症	2	N	TE	57		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	3	N	TE	85	8	Y	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	92		Y	None	Not recovered, but no changes expected
			Weight decreased	体重減少	2	N	TE	92		Y	None	Not recovered, but no changes expected
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	2	N	TE	102		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	102	18	N	Drug permanently withdrawn	Recovered with sequelae
			Nausea	悪心	2	N	TE	113	7	N	None	Recovered
			Anxiety	不安	1	N	TE	113		N	None	Not recovered, but no changes expected
			Depression	うつ病	1	N	TE	113		N	None	Not recovered, but no changes expected

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
001020	Norway	69/M/C	Atrial flutter	心房粗動	2	Y	TE	2	6	Y	Drug permanently withdrawn	Recovered
			Anxiety	不安	1	N	TE	2		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	Y	TE	54	16	N	Drug permanently withdrawn	Recovered with sequelae
001022	Norway	72/M/C	Paresis anal sphincter	肛門括約筋不全麻痺	1	N	TE	43	12	N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Paresis anal sphincter	肛門括約筋不全麻痺	2	N	TE	54	8	N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Paresis anal sphincter	肛門括約筋不全麻痺	3	N	TE	61		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Gait disturbance	歩行障害	3	Y	TE	61		N	Not applicable	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	Y	TE	61	3	N	Drug permanently withdrawn	Recovered with sequelae
			Urinary incontinence	尿失禁	4	N	TE	61		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	N	TE	63		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
001027	Norway	83/M/C	Paresis anal sphincter	肛門括約筋不全麻痺	1	N	TE	52		Y	None	Ongoing at study termination / withdrawal
			Polyneuropathy	多発ニューロパチー	4	Y	TE	52	2	Y	None	Recovered with sequelae
			Urinary incontinence	尿失禁	2	N	TE	52		Y	None	Ongoing at study termination / withdrawal
			Polyneuropathy	多発ニューロパチー	4	N	TE	53		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	63		N	None	Ongoing at study termination / withdrawal
001028	Norway	85/M/C	Fatigue	疲労	2	N	TE	62	29	Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	90		Y	Not applicable	Ongoing at study termination / withdrawal
			Fatigue	疲労	3	N	TE	90		Y	None	Ongoing at study termination / withdrawal
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	90		Y	None	Ongoing at study termination / withdrawal
			Dehydration	脱水	2	Y	TE	90		Y	Not applicable	Ongoing at study termination / withdrawal
001030	Norway	66/M/C	Nausea	悪心	1	N	TE	5	2	Y	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	1	N	TE	6	1	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	28	20	Y	None	Recovered
			Nausea	悪心	2	N	TE	33	2	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	34	1	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	53		N	None	Ongoing at study termination / withdrawal
			Metastases to bone	骨転移	2	N	TE	85		N	Drug administration postponed	Ongoing at study termination / withdrawal
			Confusional state	錯乱状態	4	Y	TE	90	17	N	Drug permanently withdrawn	Recovered with sequelae
			Peroneal nerve palsy	腓骨神経麻痺	1	N	TE	99		N	None	Ongoing at study termination / withdrawal
002004	Norway	81/M/C	Anorexia	食欲不振	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	1	54	N	None	Ongoing at time of death
			Dizziness	浮動性めまい	2	N	Pre	1		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	54	9	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	57		Y	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	57		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	62		N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Left ventricular dysfunction	左室機能不全	5	Y	TE	68	1	N	None	Death
002011	Norway	69/M/C	Oral fungal infection	口腔真菌感染	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Dysuria	排尿困難	2	N	TE	49	10	N	None	Recovered
			Dysuria	排尿困難	2	N	TE	83	10	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	93	16	Y	None	Recovered
			Sepsis	敗血症	3	Y	TE	99	10	N	None	Recovered
			Sepsis	敗血症	2	N	TE	108	8	N	Not applicable	Recovered
002014	Norway	76/M/C	Abdominal pain	腹痛	1	N	TE	1	4	Y	None	Recovered
			Arthralgia	関節痛	1	N	TE	1	4	Y	None	Recovered
			Abdominal pain	腹痛	1	N	TE	2	4	N	None	Recovered
			Arthralgia	関節痛	1	N	TE	2	4	N	None	Recovered
			Anaemia	貧血	2	N	TE	29	3	Y	None	Recovered
			Arthralgia	関節痛	1	N	TE	57	3	Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	1	N	TE	57	3	Y	None	Recovered
			Arthralgia	関節痛	1	N	TE	58	3	N	None	Recovered
			Musculoskeletal pain	筋骨格痛	1	N	TE	58	3	N	None	Recovered
			Chills	悪寒	2	N	TE	81	1	N	None	Recovered
			Anaemia	貧血	3	N	TE	85	3	Y	Drug administration postponed	Recovered
			Bone pain	骨痛	3	Y	TE	100	5	N	None	Recovered
			Bone pain	骨痛	2	N	TE	104		N	Drug administration postponed	Not recovered, but no changes expected
			Spinal cord compression	脊髄圧迫	3	Y	TE	118	12	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
002015	Norway	83/M/C	Oral candidiasis	口腔カンジダ症	2	N	TE			N	Not applicable	Ongoing at time of death
			Cough	咳嗽	2	N	TE			N	Not applicable	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	37	14	N	None	Recovered
			Conjunctivitis	結膜炎	2	N	TE	50	7	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	100	30	N	Drug permanently withdrawn	Death
			Cerebral haemorrhage	脳出血	2	Y	TE	100		Y	Drug permanently withdrawn	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	100	19	N	Not applicable	Recovered with sequelae
003003	Norway	77/M/C	Fatigue	疲労	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	15		Y	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	23	3	N	None	Recovered
			Nausea	悪心	3	Y	TE	25	12	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	25	12	N	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	56	11	Y	None	Recovered
			Spinal cord compression	脊髄圧迫	2	N	TE	56	3	N	None	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	3	Y	TE	58	21	N	None	Recovered with sequelae

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary tract infection	尿路感染	3	N	TE	73		N	Not applicable	Ongoing at study termination / withdrawal
003010	Norway	69/M/C	Nausea	悪心	1	N	TE	1	6	Y	None	Recovered
			Joint range of motion decreased	関節運動範囲減少	2	N	TE	1	6	Y	None	Recovered
			Bone pain	骨痛	3	Y	TE	161	21	N	Not applicable	Recovered
003011	Norway	72/M/C	Insomnia	不眠症	1	N	TE	97		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	107	3	N	None	Recovered
			Vomiting	嘔吐	3	Y	TE	109	12	N	None	Recovered
			Pneumonia	肺炎	2	N	TE	109	16	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	112		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	112	16	N	None	Recovered
			Nausea	悪心	2	N	TE	120	32	Y	None	Recovered
			Pneumonia	肺炎	2	Y	TE	124	4	N	None	Recovered
			Urticaria	蕁麻疹	1	N	TE	127	57	N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	146		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	151	3	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	173	11	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	3	N	TE	175	9	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	TE	181	29	Y	Not applicable	Not recovered, but no changes expected

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Stomatitis	口内炎	2	N	TE	190	3	N	Not applicable	Recovered
			Stomatitis	口内炎	1	N	TE	192	9	N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	209	7	Y	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	215		Y	Not applicable	Not recovered, but no changes expected
003013	Norway	59/M/C	Depression	うつ病	3	N	Pre	-340		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	Pre	-2	11	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	9		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	9	9	N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	Y	TE	17		N	None	Ongoing at study termination / withdrawal
			Urinary retention	尿閉	2	N	TE	17		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	21	1	N	Not applicable	Recovered
			Urinary tract infection	尿路感染	4	N	TE	24		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pathological fracture	病的骨折	4	Y	TE	24		N	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	1	N	TE	25	3	N	None	Ongoing at time of death
			Nausea	悪心	3	N	TE	25		N	Not applicable	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	2	N	TE	27		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	29		N	Drug permanently withdrawn	Ongoing at time of death
			Anxiety	不安	2	N	TE	31		N	Not applicable	Ongoing at study termination / withdrawal
004002	Norway	60/M/C	Anorexia	食欲不振	2	N	Pre	1		N	None	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	9	3	N	None	Recovered
			Vomiting	嘔吐	3	Y	TE	11	10	N	None	Recovered
			Hallucination	幻覚	2	N	TE	12	8	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	20		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	33	2	N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	58		N	Drug administration postponed	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	58	6	N	None	Recovered
			Anaemia	貧血	2	N	TE	83	11	Y	None	Recovered
			Bone pain	骨痛	4	Y	TE	104	4	N	Not applicable	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Eye infection	眼感染	2	N	TE	107		N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	107		N	Not applicable	Ongoing at time of death
005003	Norway	44/M/C	Bone pain	骨痛	2	N	TE	86	58	N	None	Recovered
			Weight decreased	体重減少	3	N	TE	113		N	None	Not recovered, but no changes expected
			Lymphadenopathy	リンパ節症	1	N	TE	172		N	None	Recovered
			Bone pain	骨痛	2	N	TE	202	4	N	Not applicable	Recovered
			Bone pain	骨痛	2	Y	TE	205	9	N	Not applicable	Recovered
			Oral candidiasis	口腔カンジダ症	1	N	TE	206	15	N	Not applicable	Recovered
			Anaemia	貧血	2	N	Post	352	6	Y	Not applicable	Recovered with sequelae
006002	Norway	73/M/C	Pain	疼痛	1	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE	56	27	N	None	Recovered
			Parosmia	嗅覚錯誤	1	N	TE	56		N	None	Recovered
			Anorexia	食欲不振	1	N	TE	82		N	None	Not recovered, but no changes expected
			Food poisoning	食中毒	2	Y	TE	102	5	N	None	Recovered
006003	Norway	73/M/C	Nausea	悪心	1	N	TE	56		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	56	41	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	96	5	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
006012	Norway	81/M/C	Constipation	便秘	2	N	Pre	-1		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	28	18	N	None	Recovered
			Glaucoma	緑内障	3	Y	TE	41		Y	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	45		Y	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	Y	TE	52		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	57	3	N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	N	TE	59		N	None	Ongoing at study termination / withdrawal
006013	Norway	83/M/C	Dizziness	浮動性めまい	1	N	TE			N	Not applicable	Recovered
			Fatigue	疲労	1	N	TE	18	1	N	None	Recovered
			Back pain	背部痛	1	N	TE	18	1	N	None	Recovered
			Bone pain	骨痛	2	N	TE	28	29	N	None	Recovered
			Fatigue	疲労	2	N	TE	56		N	None	Not recovered, but no changes expected
			Pathological fracture	病的骨折	2	Y	TE	137	19	N	Drug administration postponed	Recovered with sequelae
006014	Norway	81/M/C	Anorexia	食欲不振	2	N	TE	29		Y	None	Not recovered, but no changes expected

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	57	80	N	None	Recovered
			Cystitis	膀胱炎	2	N	TE	101	5	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	101	55	N	Drug administration postponed	Recovered
			Pneumonia	肺炎	3	N	TE	106	10	N	Drug administration postponed	Recovered
			Cystitis	膀胱炎	2	N	TE	159	8	N	None	Recovered
			Dyspnoea	呼吸困難	3	Y	TE	159	6	N	Drug administration postponed	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	175	10	N	Not applicable	Recovered with sequelae
			Cystitis	膀胱炎	2	N	TE	177	9	N	None	Recovered
			Bone pain	骨痛	1	Y	TE	184	2	N	Not applicable	Recovered with sequelae
			Death	死亡	5	Y	TE	205	1	N	Not applicable	Death
006019	Norway	70/M/C	Nausea	悪心	1	N	TE			Y	None	Not recovered, but no changes expected
			Musculoskeletal pain	筋骨格痛	1	N	Pre	-1	10	N	None	Recovered
			Nausea	悪心	1	N	TE	2	26	Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	2	N	TE	9	4	N	None	Recovered
			Bone pain	骨痛	2	N	TE	36	15	N	None	Recovered
			Bone pain	骨痛	2	N	TE	70	8	N	None	Recovered
			Constipation	便秘	2	N	TE	75	95	N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	84	29	Y	Drug administration postponed	Recovered with sequelae

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	1	N	TE	84	57	N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	99	8	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	99	8	N	None	Recovered
			Anaemia	貧血	3	Y	TE	112	2	Y	Drug administration postponed	Recovered with sequelae
			Anaemia	貧血	2	N	TE	113	57	Y	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	131	6	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	140		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	140		N	None	Not recovered, but no changes expected
			Anaemia	貧血	3	Y	TE	169	2	Y	Not applicable	Recovered with sequelae
			Constipation	便秘	1	N	TE	169		N	None	Not recovered, but no changes expected
			Fatigue	疲労	2	N	TE	169	3	N	None	Recovered
			Pyrexia	発熱	1	N	TE	169	2	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	N	TE	169	3	Y	None	Recovered
			Anaemia	貧血	2	N	TE	170	2	Y	-	
			Bone pain	骨痛	2	N	TE	170	56	N	None	Recovered
			Anaemia	貧血	1	N	TE	171	33	Y	-	
			Pyrexia	発熱	2	Y	TE	202	7	Y	Not applicable	Recovered
			Arthralgia	関節痛	2	Y	TE	202	7	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	203	3	Y	-	
			Fatigue	疲労	2	N	TE	203	6	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	205	36	Y	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	240	8	Y	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	1	N	TE	247		Y	Not applicable	Not recovered, but no changes expected
006029	Norway	77/M/C	Diarrhoea	下痢	1	N	TE	2	5	Y	None	Recovered
			Fatigue	疲労	1	N	TE	2	5	N	None	Recovered
			Anaemia	貧血	2	N	TE	35	39	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	56		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	68	12	N	None	Recovered with sequelae
			Dysphagia	嚥下障害	2	N	TE	69	5	N	None	Recovered
			Pyrexia	発熱	1	N	TE	69	2	Y	None	Recovered
			Infection	感染	3	N	TE	69	10	N	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	3	N	TE	69	9	N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	72	4	N	None	Recovered
			Anaemia	貧血	1	N	TE	73		N	None	Ongoing at time of death
			Psoriasis	乾癬	2	N	TE	75		N	None	Ongoing at time of death
			Urinary retention	尿閉	2	N	TE	76	1	N	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	1	N	TE	77		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	79		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	4	Y	TE	96	3	N	Not applicable	Death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	5	Y	TE	98	1	N	Not applicable	Death
006045	Norway	63/M/C	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2	N	Pre	-1	63	N	None	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1	N	Pre	-1	91	N	None	Recovered
			Fatigue	疲労	2	N	TE	8	83	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	20	2	N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	21	70	N	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	TE	28	35	N	None	Recovered
007003	Norway	65/M/C	Pleural effusion	胸水	2	Y	TE	1	11	N	None	Recovered
			Pneumonia	肺炎	2	N	TE	26	4	N	Drug administration postponed	Recovered
			Pneumonia	肺炎	3	Y	TE	29	9	N	Drug administration postponed	Recovered
			Bone pain	骨痛	3	N	TE	36		N	None	Ongoing at time of death
			Confusional state	錯乱状態	1	N	TE	53	3	Y	None	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	54		N	None	Ongoing at time of death
			Dizziness	浮動性めまい	1	N	TE	54	2	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pneumonia	肺炎	2	Y	TE	55	19	Y	Drug administration postponed	Recovered
			Confusional state	錯乱状態	2	Y	TE	55	19	Y	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	57	15	N	None	Recovered
			Metastases to meninges	髄膜転移	3	Y	TE	64	30	N	None	Death
			Thrombocytopenia	血小板減少症	4	Y	TE	86		Y	None	Ongoing at time of death
			Metastases to meninges	髄膜転移	5	Y	TE	93	1	N	None	Death
007004	Norway	64/M/C	Bone pain	骨痛	2	N	TE	29	17	N	None	Recovered
			Bone pain	骨痛	1	N	TE	113		N	None	Ongoing at study termination / withdrawal
			Pain in extremity	四肢痛	1	N	TE	113		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	122		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	Y	TE	122	2	N	None	Recovered
			Constipation	便秘	2	Y	TE	126	9	N	None	Recovered
			Nausea	悪心	1	N	TE	126		N	None	Not recovered, but no changes expected
			Hypokalaemia	低カリウム血症	1	N	TE	132	3	N	None	Recovered
007006	Norway	78/M/C	Night sweats	寝汗	2	N	TE			N	None	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	29		N	None	Ongoing at time of death
			Joint stiffness	関節硬直	1	N	TE	57	57	N	None	Recovered
			Influenza	インフルエンザ	1	N	TE	70	4	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	96	60	N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	103		N	None	Ongoing at time of death
			Hyperhidrosis	多汗症	1	N	TE	113	59	N	None	Recovered
			Stomatitis	口内炎	1	N	TE	128	29	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	1	N	TE	155		N	None	Ongoing at time of death
			Fatigue	疲労	3	Y	TE	211	11	N	Not applicable	Recovered with sequelae
007007	Norway	67/M/C	Oedema genital	性器浮腫	2	N	TE			N	None	Not recovered, but no changes expected
			Rash	発疹	1	N	Pre	-7	64	N	None	Not recovered, but no changes expected
			Cardiac murmur	心雑音	1	N	TE	29	29	N	None	Recovered
			Bone pain	骨痛	1	N	TE	39	15	N	None	Recovered
			Rash	発疹	2	N	TE	57		N	None	Not recovered, but no changes expected
			Metastases to skin	皮膚転移	3	N	TE	80		N	None	Not recovered, but no changes expected
			Diarrhoea	下痢	1	N	TE	134	4	N	None	Recovered
			Nausea	悪心	1	N	TE	134	15	N	None	Recovered
			Mucosal inflammation	粘膜の炎症	2	N	TE	141	7	N	None	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	141	18	N	Drug permanently withdrawn	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	145		N	None	Not recovered, but no changes expected
			Hydronephrosis	水腎症	3	Y	TE	148	3	N	Drug permanently withdrawn	Recovered with sequelae

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	151	6	Y	None	Recovered
			Blood urea increased	血中尿素増加	1	N	TE	151		N	Not applicable	Not recovered, but no changes expected
			Hypercreatininaemia	高クレアチニン血症	1	N	TE	151		N	Not applicable	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	157		N	Not applicable	Not recovered, but no changes expected
			Erysipelas	丹毒	1	N	TE	158	9	N	Not applicable	Recovered
007008	Norway	64/M/C	Arthralgia	関節痛	1	N	TE	26	32	N	None	Recovered
			Bone pain	骨痛	1	N	TE	26		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	60	26	N	None	Recovered
			Bone pain	骨痛	2	N	TE	85	36	N	None	Recovered
			Pneumonia	肺炎	2	Y	TE	111	10	N	None	Recovered
			Anaemia	貧血	2	N	TE	112	2	Y	None	Recovered
			Nausea	悪心	1	N	TE	127		N	Not applicable	Not recovered, but no changes expected
			Insomnia	不眠症	1	N	TE	127		N	Not applicable	Not recovered, but no changes expected
008014	Norway	77/M/C	Oedema peripheral	末梢性浮腫	1	N	TE			N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE			N	None	Ongoing at time of death
			Anaemia	貧血	1	N	Pre	1	3	N	-	
			Anaemia	貧血	2	N	TE	3	27	N	-	
			Cystitis	膀胱炎	2	N	TE	3	11	N	None	Recovered
			Myalgia	筋痛	2	Y	TE	3	4	N	None	Recovered
			Anaemia	貧血	1	N	TE	29	42	N	-	

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Respiratory tract infection	気道感染	2	N	TE	48		N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	69	12	N	None	Recovered
			Anaemia	貧血	2	N	TE	70	4	N	None	Ongoing at time of death
			Atrial fibrillation	心房細動	2	N	TE	70	2	N	None	Recovered
			Anaemia	貧血	1	N	TE	73	37	N	None	Ongoing at time of death
			Weight decreased	体重減少	2	N	TE	85		N	None	Ongoing at time of death
			Gastroenteritis norovirus	ノロウイルス性胃腸炎	2	Y	TE	93	5	N	None	Recovered
			Post procedural infection	処置後感染	2	N	TE	93	17	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	109		N	None	Ongoing at time of death
			Post procedural infection	処置後感染	2	Y	TE	109	8	N	Drug administration postponed	Recovered
			Syncope	失神	2	N	TE	110	1	N	None	Recovered
			Syncope	失神	2	N	TE	111	1	N	None	Recovered
			Syncope	失神	2	N	TE	112	1	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	113	3	N	None	Recovered
			Pneumonia	肺炎	2	N	TE	114		N	Drug administration postponed	Recovered
			Dyspnoea	呼吸困難	3	Y	TE	152		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	155	16	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	170	1	N	Not applicable	Death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
009001	Czech Republic	66/M/C	Oedema peripheral	末梢性浮腫	2	N	TE	30		N	None	Not recovered, but no changes expected
			Micturition urgency	尿意切迫	2	N	TE	62	135	N	None	Recovered
			Anaemia	貧血	2	N	TE	183	44	Y	None	Recovered
			Generalised oedema	全身性浮腫	3	N	TE	183	36	Y	Not applicable	Ongoing at time of death
			Cardiac failure	心不全	3	Y	TE	196	23	Y	Not applicable	Recovered with sequelae
010001	Czech Republic	60/M/C	Anaemia	貧血	2	Y	TE	165	5	Y	Not applicable	Recovered
			Bone pain	骨痛	2	Y	TE	165	5	Y	Not applicable	Recovered
			Anaemia	貧血	3	Y	TE	213	4	Y	Not applicable	Recovered
			Anaemia	貧血	3	Y	Post	231	4	Y	Not applicable	Recovered
010003	Czech Republic	70/M/C	Bronchitis	気管支炎	1	N	TE	68	7	N	None	Recovered
			Dermatitis	皮膚炎	1	N	TE	70	27	N	None	Recovered
			Thrombosis	血栓症	2	N	TE	118	52	Y	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	170	9	N	Not applicable	Recovered
010005	Czech Republic	83/M/C	Cachexia	悪液質	5	Y	TE	147	1	N	Not applicable	Death
011003	Czech Republic	63/M/C	Bone pain	骨痛	1	N	TE	2	5	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	37	4	Y	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	78	2	N	None	Recovered
011007	Czech Republic	60/M/C	Anaemia	貧血	1	N	TE	29	29	N	None	Recovered
			Anaemia	貧血	3	Y	TE	57	8	N	None	Recovered
			Anaemia	貧血	1	N	TE	64		N	None	Ongoing at time of death
016001	Czech Republic	72/M/C	Malignant neoplasm progression	悪性新生物進行	3	Y	TE	78	10	N	None	Not recovered, but no changes expected
			Thrombocytopenia	血小板減少症	3	N	TE	84		Y	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	98	3	N	None	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	100	1	N	None	Death
017009	Czech Republic	64/M/C	Spinal cord compression	脊髄圧迫	3	Y	TE	72	21	N	Drug administration postponed	Recovered with sequelae
			Urinary tract infection	尿路感染	2	N	TE	133	7	N	None	Recovered
017010	Czech Republic	69/M/C	Bursitis	滑液包炎	2	Y	TE	37	13	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	52	32	N	None	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	83	1	N	None	Death
017013	Czech Republic	78/M/C	Dyspepsia	消化不良	1	Y	Pre	-17	5	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	1	N	Pre	-1		N	None	Ongoing at time of death
			Cerebral ischaemia	脳虚血	4	Y	TE	85	7	N	None	Death
			Cerebral ischaemia	脳虚血	5	Y	TE	91	1	N	None	Death
017014	Czech Republic	63/M/C	Bone pain	骨痛	2	N	TE	15		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	98	1	N	None	Death
017016	Czech Republic	79/M/C	Urinary tract infection	尿路感染	3	Y	TE	80	6	N	None	Death
			Urinary tract infection	尿路感染	5	Y	TE	85	1	N	None	Death
020001	Sweden	67/M/C	Food poisoning	食中毒	1	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE	46	26	N	Drug administration postponed	Recovered with sequelae
			Bone pain	骨痛	1	N	TE	56	157	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	71	16	N	Drug administration postponed	Recovered with sequelae
			Gastritis	胃炎	1	N	TE	72		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	72		Y	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	1	N	TE	72	106	N	Drug administration postponed	Not recovered, but no changes expected
			Thrombophlebitis	血栓性静脈炎	2	N	TE	77	10	N	None	Recovered
			Dry mouth	口内乾燥	1	N	TE	84		N	None	Not recovered, but no changes expected

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary tract infection	尿路感染	1	N	TE	88	16	N	None	Recovered
			Increased upper airway secretion	上気道分泌増加	2	N	TE	122		N	None	Not recovered, but no changes expected
			Spinal cord compression	脊髄圧迫	2	N	TE	177		N	Drug administration postponed	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	212	49	N	None	Recovered
			Dysphagia	嚥下障害	2	N	TE	239	22	N	None	Recovered
020003	Sweden	71/M/C	Hypoaesthesia	感覚鈍麻	1	N	Pre	-1	1	N	None	Recovered
			Sinus tachycardia	洞性頻脈	1	N	TE	2	4	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	2	4	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	2	78	Y	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	26	9	N	None	Recovered
			Fatigue	疲労	2	N	TE	61		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	64	47	N	None	Recovered
			Headache	頭痛	1	N	TE	64	47	N	None	Recovered
			Anaemia	貧血	2	Y	TE	77	12	Y	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	3	Y	TE	77	12	Y	Drug permanently withdrawn	Recovered with sequelae
			Nausea	悪心	2	N	TE	77		N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	80		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	88		Y	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	2	N	TE	88		Y	Drug permanently withdrawn	Not recovered, but no changes expected
020010	Sweden	63/M/C	Constipation	便秘	1	N	TE			N	None	Ongoing at time of death
			Pathological fracture	病的骨折	2	N	TE			N	Drug permanently withdrawn	Ongoing at time of death
			Hypotension	低血圧	1	N	Pre	1		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	29		Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	29		Y	Drug permanently withdrawn	Ongoing at time of death
			Pathological fracture	病的骨折	3	N	TE	29		N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	30	7	N	Drug permanently withdrawn	Recovered
			Bone pain	骨痛	2	N	TE	36		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
021001	Sweden	65/M/C	Anorexia	食欲不振	1	N	TE			N	None	Ongoing at time of death
			Gastritis	胃炎	2	N	Pre	-1	65	N	None	Recovered
			Pain	疼痛	1	N	TE	2	2	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	17	28	N	None	Recovered
			Pyrexia	発熱	1	N	TE	33	2	Y	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Infection	感染	3	Y	TE	52	4	N	Drug administration postponed	Recovered
			Infection	感染	1	N	TE	55	11	N	Drug administration postponed	Recovered
			Pyrexia	発熱	1	N	TE	101	7	Y	None	Recovered
			Procedural pain	処置による疼痛	2	Y	TE	103	2	N	None	Recovered
			Abdominal pain	腹痛	1	N	TE	108	1	N	None	Recovered
			Pyrexia	発熱	1	N	TE	108	1	N	None	Recovered
			Bone pain	骨痛	2	N	TE	110	9	N	None	Recovered
			Bone pain	骨痛	2	N	TE	126		N	None	Ongoing at time of death
			Abdominal pain	腹痛	1	N	TE	130	26	N	None	Recovered
			Hypercreatininaemia	高クレアチニン血症	2	N	TE	148	44	N	None	Recovered
			Bone pain	骨痛	2	N	TE	157	5	N	None	Recovered
			Pyrexia	発熱	2	N	TE	165	2	N	None	Recovered
			Bone pain	骨痛	1	N	TE	165	2	N	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	171	3	N	Not applicable	Recovered
			Pain	疼痛	2	N	TE	174	2	N	None	Recovered
			Pyrexia	発熱	1	N	TE	174	2	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	179	6	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	3	N	TE	179	19	N	Not applicable	Recovered
			Bone pain	骨痛	4	N	TE	194	46	N	Not applicable	Recovered
			Pyrexia	発熱	1	N	TE	196	2	N	Not applicable	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	201		N	Not applicable	Not recovered, but no changes expected
			Muscle spasms	筋痙縮	1	N	TE	205		N	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	209	5	N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	224		N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	224		N	None	Ongoing at time of death
022002	Sweden	64/M/C	Fatigue	疲労	1	N	TE	29	66	N	None	Recovered
			Bone pain	骨痛	2	N	TE	57	32	N	None	Recovered
			Bone pain	骨痛	2	N	TE	81	32	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	117	5	N	None	Recovered
			Diarrhoea	下痢	3	Y	TE	121	2	N	None	Recovered
			Nephrolithiasis	腎結石症	1	N	TE	168	8	N	Not applicable	Recovered
			Dizziness	浮動性めまい	1	N	TE	200		N	Not applicable	Recovered
022003	Sweden	78/M/C	Anaemia	貧血	1	N	TE	22	92	N	None	Recovered
			Bone pain	骨痛	2	N	TE	27	146	N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	33	1	N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	51	1	N	None	Recovered
			Cognitive disorder	認知障害	1	N	TE	140		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	175	1	N	None	Recovered
			Infection	感染	2	Y	TE	203	6	N	Not applicable	Recovered
022005	Sweden	62/M/C	Dizziness	浮動性めまい	1	N	TE			N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	2	Y	TE	17	7	N	None	Recovered
			Vomiting	嘔吐	2	Y	TE	17	7	N	None	Recovered
			Dehydration	脱水	2	Y	TE	17	7	N	None	Recovered
			Bone pain	骨痛	2	N	TE	18	12	N	None	Recovered
			Fatigue	疲労	2	Y	TE	37	2	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	57		Y	None	Ongoing at time of death
			Sepsis	敗血症	4	Y	TE	57	5	N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	84	53	N	Not applicable	Death
			Anaemia	貧血	3	N	TE	85	14	N	None	Recovered with sequelae
			Anaemia	貧血	3	Y	TE	98	14	N	None	Recovered with sequelae
			Constipation	便秘	3	Y	TE	99	13	N	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	99	13	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	113	2	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	136	1	N	Not applicable	Death
022008	Sweden	67/M/C	Fatigue	疲労	1	N	TE	29		N	None	Ongoing at time of death
			Haematuria	血尿	1	Y	TE	60	2	N	None	Recovered
			Haematuria	血尿	2	N	TE	61	49	N	None	Recovered
			Haematuria	血尿	2	N	TE	61	49	N	None	Recovered
			Bone pain	骨痛	3	N	TE	88	9	N	None	Recovered with sequelae

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	116	1	N	None	Recovered
023002	Sweden	79/M/C	Bone pain	骨痛	2	N	TE	2	27	N	None	Recovered
			Fall	転倒・転落	1	N	TE	42	1	N	None	Recovered
			Amnesia	健忘	2	N	TE	42		N	None	Ongoing at time of death
			Balance disorder	平衡障害	3	N	TE	42		N	None	Ongoing at time of death
			Urinary incontinence	尿失禁	1	N	TE	42		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	56	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	85	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	113	2	Y	None	Recovered
			Fatigue	疲労	1	N	TE	131		N	None	Ongoing at time of death
			Post-traumatic pain	外傷後疼痛	2	N	TE	168		N	None	Ongoing at time of death
			Hydrocephalus	水頭症	2	Y	TE	168	62	N	Not applicable	Recovered with sequelae
			Dizziness	浮動性めまい	1	N	TE	169		N	None	Ongoing at time of death
			Urinary retention	尿閉	1	N	TE	169		N	None	Ongoing at time of death
			Insomnia	不眠症	2	N	TE	170		N	None	Ongoing at time of death
			Erythema	紅斑	1	N	TE	171	4	N	None	Recovered
			Constipation	便秘	1	N	TE	172		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	172		N	None	Ongoing at time of death
			Medical device pain	医療機器による疼痛	1	N	TE	173	2	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
024003	Sweden	71/M/C	Upper respiratory tract infection	上気道感染	2	N	TE	36	8	N	None	Recovered
			Anaemia	貧血	2	N	TE	56	30	N	None	Recovered
			Neutropenia	好中球減少症	2	N	TE	84	8	Y	Drug administration postponed	Recovered
			Neutropenia	好中球減少症	3	Y	TE	112		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	119	1	Y	Not applicable	Recovered
			Dry mouth	口内乾燥	2	N	TE	141	35	N	None	Recovered
			Infection	感染	2	N	TE	141		N	Not applicable	Ongoing at study termination / withdrawal
024005	Sweden	69/M/C	Anaemia	貧血	2	N	TE	57	3	Y	None	Recovered
			Infection	感染	2	N	TE	103	11	N	None	Recovered
			Anaemia	貧血	1	N	TE	113	2	Y	None	Recovered
			General physical health deterioration	全身健康状態低下	3	N	TE	113		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	113	23	N	None	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	135	1	N	None	Death
024009	Sweden	73/M/C	Pathological fracture	病的骨折	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	11	50	N	None	Recovered
			Arrhythmia	不整脈	1	N	TE	29		N	None	Not recovered, but no changes expected

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Chills	悪寒	1	N	TE	29		Y	None	Recovered
			Oedema	浮腫	3	N	TE	29		N	Not applicable	Ongoing at time of death
			Magnesium deficiency	マグネシウム欠乏	1	N	TE	29	29	N	None	Recovered
			General physical health deterioration	全身健康状態低下	3	N	TE	57		N	None	Not recovered, but no changes expected
			Pathological fracture	病的骨折	2	N	TE	61		N	None	Not recovered, but no changes expected
			Dyspepsia	消化不良	2	N	TE	65		N	None	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	Y	TE	65	15	N	None	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	3	N	TE	66		N	None	Not recovered, but no changes expected
			Metastases to liver	肝転移	2	N	TE	86		N	None	Not recovered, but no changes expected
			Metastases to liver	肝転移	2	N	TE	86		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	91	5	Y	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	92		N	Not applicable	Ongoing at time of death
			Anxiety	不安	2	N	TE	93		N	Not applicable	Ongoing at time of death
			Myocardial infarction	心筋梗塞	3	Y	TE	95		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	97	1	N	Drug permanently withdrawn	Death
024014	Sweden	74/M/C	Dry eye	眼乾燥	1	N	TE	15		N	None	Ongoing at time of death
			Skin infection	皮膚感染	2	N	TE	53	9	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Metastases to bone	骨転移	1	N	TE	53		N	None	Not recovered, but no changes expected
			Micturition urgency	尿意切迫	1	N	TE	53		N	None	Not recovered, but no changes expected
			Hypoaesthesia	感覚鈍麻	2	N	TE	61		N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	81		N	None	Not recovered, but no changes expected
			Dizziness	浮動性めまい	2	N	TE	81	27	N	None	Recovered
			Viral skin infection	皮膚ウイルス感染	2	N	TE	100		N	None	Ongoing at time of death
			Atrial fibrillation	心房細動	2	Y	TE	101	7	N	None	Recovered
			Oral fungal infection	口腔真菌感染	2	N	TE	103		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	126	1	N	Drug permanently withdrawn	Death
024022	Sweden	84/M/C	Constipation	便秘	2	N	TE			N	Not applicable	Recovered
			Pneumonia	肺炎	4	Y	TE			N	Drug permanently withdrawn	Ongoing at time of death
			Hip fracture	股関節部骨折	3	Y	Pre			N	Drug administration postponed	Recovered
			Pulmonary oedema	肺水腫	4	Y	TE			N	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	Y	Pre	-33	14	N	Drug administration postponed	Recovered with sequelae

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary retention	尿閉	2	Y	Pre	-33	14	N	Drug administration postponed	Recovered with sequelae
			Vomiting	嘔吐	3	N	Pre	-18	10	N	Not applicable	Recovered
			Pyrexia	発熱	3	N	Pre	-18	10	N	Not applicable	Recovered
			Dislocation of joint prosthesis	人工骨頭関節脱臼	3	Y	Pre	-18	10	N	Not applicable	Recovered
			Bone pain	骨痛	3	N	Pre	-18	10	N	Not applicable	Recovered
			Pathological fracture	病的骨折	3	Y	TE	6		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	6	43	N	Drug permanently withdrawn	Death
			Sepsis	敗血症	3	Y	TE	15		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	48	1	N	Drug permanently withdrawn	Death
024024	Sweden	82/M/C	Fatigue	疲労	2	N	TE	59	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	112		N	None	Not recovered, but no changes expected
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	132	16	N	Drug permanently withdrawn	Not recovered, but no changes expected
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	148	14	N	Not applicable	Death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	161	1	N	Not applicable	Death
025002	Sweden	64/M/C	Nausea	悪心	1	N	TE	60	149	Y	None	Recovered
			Tremor	振戦	1	N	TE	88		N	None	Ongoing at time of death
			Listeriosis	リステリア症	2	Y	TE	92	26	N	Drug administration postponed	Recovered
			Fatigue	疲労	2	N	TE	155		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Haematuria	血尿	1	N	TE	185		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	204	5	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	208	1	N	Not applicable	Death
026009	Sweden	71/M/C	Constipation	便秘	2	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE			Y	None	Not recovered, but no changes expected
			Nausea	悪心	2	N	TE			Y	None	Not recovered, but no changes expected
			Pathological fracture	病的骨折	2	N	TE			N	Not applicable	Ongoing at time of death
			Nausea	悪心	1	N	TE	1	1	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	3		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	29	1	Y	None	Recovered
			Fibroma	線維腫	1	N	TE	56		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pyrexia	発熱	2	Y	TE	65	4	N	None	Recovered
			Myalgia	筋痛	2	Y	TE	65	5	N	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	68		N	Not applicable	Ongoing at time of death
			Pyrexia	発熱	2	Y	TE	85	27	N	Drug permanently withdrawn	Recovered with sequelae
			Anaemia	貧血	2	N	TE	103	1	N	Not applicable	Recovered
			Pyrexia	発熱	1	N	TE	111		N	Drug permanently withdrawn	Not recovered, but no changes expected
028005	Belgium	70/M/C	Radiculitis	神経根炎	2	N	Pre	-8		N	None	Ongoing at time of death
			Pathological fracture	病的骨折	3	Y	TE	21	3	N	None	Recovered
			Anaemia	貧血	3	N	TE	22	1	N	None	Recovered
			General physical health deterioration	全身健康状態低下	3	Y	TE	26	14	Y	None	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	82	12	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	93	1	N	Drug permanently withdrawn	Death
029001	Belgium	56/M/C	Sciatica	坐骨神経痛	2	N	TE	4		N	None	Ongoing at study termination / withdrawal
			Constipation	便秘	1	N	TE	41		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dysuria	排尿困難	1	N	TE	41	15	N	Drug administration postponed	Ongoing at study termination / withdrawal
			Dysuria	排尿困難	2	N	TE	55		N	Drug administration postponed	Ongoing at study termination / withdrawal
			Urinary retention	尿閉	2	N	TE	62	22	N	Not applicable	Recovered with sequelae
			Urinary retention	尿閉	3	Y	TE	83	4	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	3	N	TE	110		N	Not applicable	Ongoing at study termination / withdrawal
			General physical health deterioration	全身健康状態低下	3	Y	TE	110	44	N	Not applicable	Recovered
			Campylobacter infection	カンピロバクター感染	3	N	TE	110	44	N	Not applicable	Recovered
029002	Belgium	81/M/C	Fatigue	疲労	1	N	TE	41	32	N	None	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	1	N	TE	41	30	N	None	Recovered
			Depression	うつ病	1	N	TE	59		N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	2	N	TE	72		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	105	2	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	106		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	106	12	N	None	Recovered
			Muscular weakness	筋力低下	1	N	TE	109		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	117		N	Not applicable	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	128	31	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	158	1	N	Not applicable	Death
033001	UK	84/M/C	Oedema peripheral	末梢性浮腫	1	N	Pre	1		N	None	Ongoing at time of death
			Lymphadenopathy	リンパ節症	1	N	TE	25		N	None	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	2	N	TE	25		N	None	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	25	14	N	None	Ongoing at time of death
			Muscular weakness	筋力低下	2	N	TE	29		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	29		N	None	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	N	TE	38		N	None	Ongoing at time of death
			Pulmonary embolism	肺塞栓症	5	Y	TE	59	1	N	None	Death
033002	UK	72/M/B	Non-cardiac chest pain	非心臓性胸痛	2	N	TE			N	None	Recovered
			Weight decreased	体重減少	1	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	1	N	TE			N	None	Not recovered, but no changes expected
			Muscular weakness	筋力低下	2	N	TE			N	None	Ongoing at time of death
			Lethargy	嗜眠	2	N	TE			N	None	Not recovered, but no changes expected
			Mood altered	気分変化	1	N	TE			N	None	Not recovered, but no changes expected
			Cough	咳嗽	1	N	TE			N	None	Recovered
			Atrial fibrillation	心房細動	3	Y	Pre	-67	4	N	Not applicable	Recovered
			Urinary tract infection	尿路感染	2	Y	Pre	-67	4	N	Not applicable	Recovered
			Eyelid ptosis	眼瞼下垂	1	N	TE	3	7	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	46	8	N	None	Recovered
			Constipation	便秘	1	N	TE	56		Y	Drug administration postponed	Recovered
			Fatigue	疲労	1	N	TE	59		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	93	8	Y	None	Recovered
			Bone pain	骨痛	2	Y	TE	93	2	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	113		N	None	Ongoing at time of death
033014	UK	73/M/C	Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Pitting oedema	圧痕浮腫	2	N	TE			N	None	Ongoing at time of death
			Weight increased	体重増加	1	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE			Y	None	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	1	N	TE			N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	112		Y	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	112	2	N	None	Recovered
			Nausea	悪心	1	N	TE	177	3	Y	None	Recovered
			Dysphasia	不全失語症	3	N	TE	177	3	N	None	Recovered
			Pleuritic pain	胸膜痛	3	Y	TE	177	3	N	Not applicable	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	184	1	N	Not applicable	Death
033017	UK	80/M/C	Abdominal pain lower	下腹部痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			Y	None	Recovered
			Dysuria	排尿困難	1	N	TE			N	None	Recovered
			Pollakiuria	頻尿	2	N	TE			N	None	Recovered with sequelae
			Pollakiuria	頻尿	2	N	TE			N	None	Recovered
			Urine flow decreased	尿流量減少	2	N	TE			N	None	Not recovered, but no changes expected
			Skin lesion	皮膚病変	1	N	TE			N	None	Not recovered, but no changes expected
			Pulmonary embolism	肺塞栓症	5	Y	TE	124	1	N	None	Death
033025	UK	66/M/C	Fatigue	疲労	2	N	TE			N	None	Not recovered, but no changes expected
			Tooth fracture	歯牙破折	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			Y	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	Pre	-35		Y	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	4	14	Y	None	Recovered
			Anaemia	貧血	2	N	TE	29	64	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	85	2	Y	None	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE	88		N	None	Recovered
			Anaemia	貧血	3	N	TE	116	19	Y	None	Recovered
			Anaemia	貧血	2	N	TE	134	29	Y	None	Recovered
034016	UK	66/M/C	Pain	疼痛	3	N	TE	8	4	N	None	Recovered
			Bone pain	骨痛	2	N	TE	8		N	None	Ongoing at time of death
			Pain	疼痛	2	N	TE	11	4	N	None	Recovered
			Lethargy	嗜眠	3	N	TE	11	4	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	14	2	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	22	10	N	None	Recovered
			Bone pain	骨痛	1	N	TE	22	10	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	33	12	N	None	Recovered
			Bone pain	骨痛	2	N	TE	33	10	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	51	3	N	None	Recovered
			Bone pain	骨痛	3	N	TE	54	17	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	61		N	None	Ongoing at time of death
			Pain	疼痛	3	N	TE	69		N	None	Ongoing at time of death
			Dysgeusia	味覚異常	2	N	TE	69	15	Y	None	Recovered
			Lethargy	嗜眠	2	N	TE	69		N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	101		N	None	Ongoing at study termination / withdrawal
			Abdominal pain	腹痛	3	N	TE	140	8	N	None	Recovered
			Constipation	便秘	2	N	TE	141	6	N	None	Recovered
			Pyonephrosis	膿腎症	3	Y	TE	141	18	N	Drug administration postponed	Recovered with sequelae
			Nausea	悪心	1	N	TE	144	14	N	None	Recovered
035011	UK	58/M/C	Bone pain	骨痛	1	N	TE	85	28	N	None	Recovered
			Large intestine perforation	大腸穿孔	3	Y	TE	167		N	Not applicable	Ongoing at study termination / withdrawal
035013	UK	71/M/C	Bone pain	骨痛	3	N	TE	6	24	N	None	Recovered
			Bone pain	骨痛	3	N	TE	28	2	N	None	Recovered
			Nausea	悪心	3	Y	TE	49	8	Y	None	Recovered
			Dehydration	脱水	3	N	TE	49	4	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	49	9	N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	50	1	N	None	Recovered
035015	UK	79/M/C	Vomiting	嘔吐	1	N	TE	58	11	N	None	Recovered
			Pain in extremity	四肢痛	1	N	TE	86	55	Y	None	Recovered
			Confusional state	錯乱状態	1	N	TE	122	4	Y	None	Recovered
			Transient ischaemic attack	一過性脳虚血発作	1	N	TE	160	1	N	None	Recovered
			Bone pain	骨痛	2	N	TE	212	9	N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	220	8	N	Not applicable	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
035017	UK	75/M/C	Diarrhoea	下痢	1	N	TE			Y	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE	106	8	N	None	Recovered
			Constipation	便秘	2	N	TE	127	10	N	None	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	135	7	N	None	Recovered
			Faecal incontinence	便失禁	2	N	TE	169	1	Y	Not applicable	Recovered
			Diarrhoea	下痢	2	N	TE	175		Y	None	Recovered
035022	UK	83/M/C	Bone pain	骨痛	2	N	TE	56	29	N	None	Recovered
			Asthenia	無力症	1	N	TE	66		N	None	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	TE	68	7	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	68	40	N	None	Recovered
			Constipation	便秘	2	N	TE	71		N	None	Ongoing at time of death
			Abdominal pain	腹痛	1	N	TE	77	4	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	77	16	N	None	Recovered
			Haemorrhoids	痔核	1	N	TE	77		N	None	Ongoing at time of death
			Hypoaesthesia facial	顔面感覚鈍麻	2	N	TE	86		N	None	Recovered
			Myalgia	筋痛	2	N	TE	97		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	101	4	N	None	Recovered
			Hypotension	低血圧	1	N	TE	107		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	Post	143	4	Y	Not applicable	Recovered
036003	UK	67/M/C	Dysuria	排尿困難	1	N	Pre			N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Metastases to bone	骨転移	1	N	TE	29		N	None	Not recovered, but no changes expected
			Headache	頭痛	1	N	TE	29	30	N	None	Recovered
			Hypercalcaemia	高カルシウム血症	1	N	TE	58		Y	None	Ongoing at study termination / withdrawal
			Headache	頭痛	2	N	TE	58	123	N	None	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	212	13	N	Not applicable	Recovered
036004	UK	84/M/C	Pulmonary embolism	肺塞栓症	3	Y	TE	32		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
039011	UK	65/M/C	Bone pain	骨痛	3	Y	Pre	-37	3	N	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	1	N	TE	3		N	None	Ongoing at time of death
			Nausea	悪心	3	Y	TE	4	4	Y	None	Recovered
			Dizziness	浮動性めまい	3	N	TE	5	17	Y	None	Ongoing at time of death
			Vomiting	嘔吐	3	N	TE	8		Y	None	Recovered
			Nausea	悪心	3	Y	TE	10		Y	Drug administration postponed	Ongoing at time of death
			Retching	レッチング	3	N	TE	10	12	Y	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	10	12	Y	None	Ongoing at time of death
			Paraesthesia	錯感覚	3	N	TE	10	12	N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Somnolence	傾眠	1	N	TE	12		N	None	Ongoing at time of death
			Somnolence	傾眠	1	N	TE	12		N	None	Ongoing at time of death
			Tachycardia	頻脈	2	N	TE	13	9	N	None	Ongoing at time of death
			Abdominal pain	腹痛	2	N	TE	13	9	N	None	Ongoing at time of death
			Pleural effusion	胸水	2	N	TE	13	9	N	None	Ongoing at time of death
			Pleural effusion	胸水	3	N	TE	14	5	N	Drug administration postponed	Death
			Sepsis	敗血症	2	N	TE	15	7	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	15	7	N	None	Ongoing at time of death
			Rash	発疹	2	N	TE	15	7	N	None	Ongoing at time of death
			Chest pain	胸痛	3	N	TE	17	5	N	None	Ongoing at time of death
			Depressed mood	抑うつ気分	2	N	TE	17	5	N	None	Ongoing at time of death
			Vomiting	嘔吐	3	N	TE	18		N	None	Ongoing at time of death
			Pleural effusion	胸水	4	Y	TE	18	4	N	Drug administration postponed	Death
			Constipation	便秘	3	N	TE	19	3	N	None	Ongoing at time of death
			Abdominal pain lower	下腹部痛	1	N	TE	20	2	N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	3	N	TE	20	2	N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	20	2	N	None	Ongoing at time of death
			Pleural effusion	胸水	5	Y	TE	21	1	N	Drug administration postponed	Death
039020	UK	80/M/C	Bone pain	骨痛	3	N	Pre			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at time of death
			Sleep disorder	睡眠障害	2	N	Pre			N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	N	TE	18		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	1	N	TE	28		N	None	Ongoing at time of death
			Pleural effusion	胸水	2	Y	TE	51	6	N	Drug permanently withdrawn	Recovered
041007	UK	62/M/C	Lymphadenopathy	リンパ節症	1	N	Pre	1		N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	7		Y	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	7		N	None	Ongoing at time of death
			Eyelid function disorder	眼瞼機能障害	2	N	TE	12	19	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vision blurred	霧視	1	N	TE	12		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	29		Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	29		Y	None	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	29		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	60	6	N	None	Death
			Muscular weakness	筋力低下	2	N	TE	61		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	65	1	N	None	Death
042002	UK	64/M/C	Nausea	悪心	1	N	TE			Y	None	Recovered
			Vomiting	嘔吐	1	N	TE			Y	None	Recovered
			Peripheral coldness	末梢冷感	1	N	TE			N	None	Recovered
			Anorexia	食欲不振	1	N	TE			Y	None	Recovered
			Constipation	便秘	1	N	TE	3		Y	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	4	6	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	4	6	N	None	Recovered
			Bone pain	骨痛	2	N	TE	8	22	N	None	Recovered
			Tachycardia	頻脈	1	N	TE	28		N	None	Ongoing at time of death
			Hypotension	低血圧	1	N	TE	55	1	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	57	57	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	57	57	N	None	Recovered
			Spinal cord compression	脊髄圧迫	2	N	TE	58	56	N	None	Recovered with sequelae

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	164	12	N	Not applicable	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	192	1	N	Not applicable	Death
042003	UK	66/M/C	Anaemia	貧血	2	Y	TE	17	2	Y	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	17	7	N	None	Recovered
			Anaemia	貧血	3	N	TE	34	3	N	Not applicable	Recovered
			Cardiac failure congestive	うっ血性心不全	3	Y	TE	34	8	N	None	Death
			Constipation	便秘	2	N	TE	34		N	Not applicable	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	34	4	N	Not applicable	Recovered
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	2	N	TE	34		N	Not applicable	Ongoing at time of death
			Hypokalaemia	低カリウム血症	3	N	TE	35	3	N	Not applicable	Recovered
			Rectal haemorrhage	直腸出血	1	N	TE	37	1	N	Not applicable	Recovered
			Neuropathy peripheral	末梢性ニューロパチー	2	N	TE	38		N	Not applicable	Ongoing at time of death
			Urinary tract obstruction	尿路閉塞	3	N	TE	38		N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	39		N	Not applicable	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	2	Y	TE	39		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	40	2	N	Not applicable	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pneumonia	肺炎	3	N	TE	40		N	Not applicable	Ongoing at time of death
			Confusional state	錯乱状態	1	N	TE	40		N	Not applicable	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	5	Y	TE	41	1	N	None	Death
042004	UK	74/M/C	Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Cough	咳嗽	1	N	TE			N	None	Ongoing at time of death
			Dysphonia	発声障害	1	N	TE			N	None	Ongoing at time of death
			Small intestinal obstruction	小腸閉塞	2	Y	Pre	-35	9	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	3	27	N	None	Recovered
			Epistaxis	鼻出血	1	N	TE	5	1	N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	30	8	N	None	Recovered
			Lethargy	嗜眠	1	N	TE	30	140	Y	None	Ongoing at time of death
			Dysgeusia	味覚異常	2	N	TE	41	3	N	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	45	2	N	None	Recovered
			Pathological fracture	病的骨折	2	Y	TE	55	9	N	None	Recovered
			Nausea	悪心	1	N	TE	56		N	None	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	58	6	Y	None	Recovered
			Eye pain	眼痛	1	N	TE	80	3	N	None	Recovered
			Bone pain	骨痛	1	N	TE	106	1	N	None	Recovered
			Bone pain	骨痛	1	N	TE	112	1	N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	1	N	TE	113		N	None	Ongoing at time of death
			Oral pain	口腔内痛	1	N	TE	119	1	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Palpitations	動悸	1	N	TE	121	1	N	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	141		N	None	Ongoing at time of death
			Contusion	挫傷	1	N	TE	141		N	None	Ongoing at time of death
			Lethargy	嗜眠	2	N	TE	169		Y	None	Ongoing at time of death
			Pleural effusion	胸水	1	N	TE	169		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	198	1	N	Not applicable	Death
042010	UK	61/M/C	Rectal haemorrhage	直腸出血	1	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Malaise	倦怠感	2	Y	Pre	-15	2	N	Not applicable	Recovered
			Venous thrombosis limb	四肢静脈血栓症	2	N	TE	19		N	None	Ongoing at time of death
			Arthritis infective	感染性関節炎	1	N	TE	64		Y	None	Recovered
			Gynaecomastia	女性化乳房	1	N	TE	64		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	152		N	None	Ongoing at time of death
			Neuralgia	神経痛	2	Y	TE	152	10	N	None	Recovered
			Muscle spasms	筋痙縮	1	N	TE	153		N	None	Ongoing at time of death
042024	UK	62/M/C	Fatigue	疲労	1	N	TE			N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Confusional state	錯乱状態	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	1	29	Y	None	Recovered
			Anxiety	不安	1	N	TE	2	28	N	None	Recovered
			Hyperhidrosis	多汗症	2	N	TE	2		N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	8		N	None	Ongoing at time of death
			Pyrexia	発熱	1	N	TE	62	1	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	64		N	None	Ongoing at time of death
			Dysuria	排尿困難	2	N	TE	80	6	N	Not applicable	Recovered
			Vomiting	嘔吐	3	Y	TE	83	6	N	None	Recovered
			Pyrexia	発熱	3	Y	TE	83	6	N	None	Recovered
			Confusional state	錯乱状態	3	Y	TE	83	1	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	99	23	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	121	1	N	Not applicable	Death
042025	UK	57/M/C	Nausea	悪心	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	1	85	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	29	85	N	None	Recovered
			Urinary retention	尿閉	3	Y	TE	51	2	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	52	4	N	None	Recovered
			Bone pain	骨痛	2	N	TE	58	8	Y	None	Recovered
			Fatigue	疲労	1	N	TE	85		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	134	92	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	141		Y	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	142		N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	169	57	N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	169		N	None	Ongoing at time of death
042028	UK	70/M/C	Bone pain	骨痛	2	N	TE	15	155	Y	None	Recovered
			Nocturia	夜間頻尿	1	N	TE	23		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	35	3	N	None	Recovered
			Bone pain	骨痛	1	N	TE	85	57	N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	88	18	Y	None	Recovered
			Viral infection	ウイルス感染	1	N	TE	88	18	N	None	Recovered
			Lethargy	嗜眠	1	N	TE	113		N	None	Ongoing at time of death
045001	UK	74/M/C	Haematuria	血尿	3	Y	TE	6	5	N	None	Recovered
			Haematuria	血尿	3	N	TE	10	26	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	21	20	N	None	Recovered
			Haematuria	血尿	3	Y	TE	35	2	N	None	Recovered
			Hypoalbuminaemia	低アルブミン血症	2	N	TE	56		N	Not applicable	Ongoing at study termination / withdrawal
050001	UK	80/M/C	Anaemia	貧血	3	N	TE			N	Not applicable	Recovered with sequelae

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE			Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Ear infection	耳感染	2	N	TE			N	None	Recovered
			Anorexia	食欲不振	1	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at study termination / withdrawal
			Upper respiratory tract infection	上気道感染	2	N	Pre	-14	8	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	1	29	Y	-	
			Nausea	悪心	2	N	TE	2	2	Y	None	Recovered
			Fatigue	疲労	2	N	TE	8	14	Y	None	Recovered
			Muscular weakness	筋力低下	2	N	TE	8	14	N	None	Recovered
			Myalgia	筋痛	2	N	TE	8	22	N	None	Recovered
			Fatigue	疲労	3	N	TE	21	4	Y	None	Recovered
			Muscular weakness	筋力低下	3	N	TE	21	9	N	None	Recovered
			Fatigue	疲労	1	N	TE	24	37	Y	None	Recovered
			Anaemia	貧血	1	N	TE	29	29	Y	-	
			Nausea	悪心	2	N	TE	30	1	Y	None	Recovered
			Hot flush	ほてり	2	N	TE	30		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	34	1	Y	None	Recovered
			Anaemia	貧血	3	N	TE	57	5	Y	-	
			Anaemia	貧血	1	N	TE	61	12	Y	-	
			Urinary tract infection	尿路感染	2	N	TE	61	6	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary retention	尿閉	3	Y	TE	61	2	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	72	70	Y	-	
			Haemorrhage urinary tract	尿路出血	2	N	TE	80	2	N	None	Recovered
			Urinary retention	尿閉	1	N	TE	84		N	None	Ongoing at study termination / withdrawal
			Urinary retention	尿閉	1	N	TE	84	3	N	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	85	57	N	None	Ongoing at study termination / withdrawal
			Urinary retention	尿閉	2	N	TE	86		N	None	Ongoing at study termination / withdrawal
			Insomnia	不眠症	2	N	TE	101	5	N	None	Recovered
			Fatigue	疲労	3	N	TE	113		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Muscular weakness	筋力低下	2	N	TE	113		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	N	TE	141	9	Y	-	
			Constipation	便秘	1	N	TE	141		Y	Not applicable	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	2	N	TE	141		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Muscular weakness	筋力低下	3	N	TE	141		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	4	N	TE	149	3	Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	151		Y	None	Ongoing at study termination / withdrawal
			Cranial neuropathy	脳ニューロパチー	2	N	TE	155		N	None	Ongoing at time of death
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	2	N	TE	155		N	None	Ongoing at time of death
			Oral candidiasis	口腔カンジダ症	2	N	TE	190		N	None	Ongoing at time of death
			Anaemia	貧血	4	Y	TE	192	5	N	Not applicable	Recovered with sequelae
			Gastric cancer	胃癌	4	Y	TE	192	28	N	Not applicable	Death
			Gastric cancer	胃癌	5	Y	TE	219	1	N	Not applicable	Death
050003	UK	60/M/C	Nausea	悪心	1	N	TE			N	None	Recovered
			Fatigue	疲労	2	N	TE			N	-	
			Fatigue	疲労	3	N	TE			N	-	
			Weight decreased	体重減少	1	N	TE			N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE			N	None	Ongoing at time of death
			Muscular weakness	筋力低下	3	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE			N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	N	TE	6	10	N	-	
			Oedema genital	性器浮腫		N	TE	10		N	None	Ongoing at time of death
			Pharyngolaryngeal pain	咽喉頭疼痛	1	N	TE	13		N	None	Recovered
			Contusion	挫傷	1	N	TE	14		Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	15	9	N	-	
			Constipation	便秘	2	N	TE	16		Y	None	Ongoing at time of death
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE	16		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	18		N	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	19	3	N	-	
			Pollakiuria	頻尿	1	N	TE	19	4	N	None	Recovered
			Fatigue	疲労	3	N	TE	21		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	4	N	TE	23	8	N	-	
			Dysphagia	嚥下障害	2	N	TE	26		N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	1	N	TE	26	3	N	None	Recovered
			Oedema peripheral	末梢性浮腫	3	N	TE	29	2	N	Not applicable	Ongoing at time of death
			Abdominal pain	腹痛	3	N	TE	30	1	N	None	Recovered
			Oedema peripheral	末梢性浮腫	4	N	TE	30		N	Not applicable	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	4	N	TE	30		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	31	1	N	Drug permanently withdrawn	Death
			Agitation	激越	2	N	TE	31	1	N	Not applicable	Recovered
050016	UK	63/M/C	Constipation	便秘	1	N	TE			Y	None	Recovered
			Bone pain	骨痛	3	Y	Pre	-41	3	N	Not applicable	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	3	27	N	None	Recovered
055007	Netherlands	62/M/C	Confusional state	錯乱状態	2	Y	Pre	-13	2	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	8		N	Not applicable	Ongoing at time of death
			Nausea	悪心	2	N	TE	8		N	Not applicable	Ongoing at time of death
			Intertrigo	間擦疹	1	N	TE	8		Y	Not applicable	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	35	2	N	None	Recovered
			Anaemia	貧血	3	N	TE	36		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	85	1	N	Not applicable	Death
060008	Spain	63/M/C	Thrombocytopenia	血小板減少症	1	N	TE	29		Y	None	Ongoing at study termination / withdrawal
			Asthenia	無力症	2	N	TE	29	8	N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	2	N	TE	29	8	N	None	Recovered
			Asthenia	無力症	1	N	TE	36		N	None	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	1	N	TE	36	64	N	None	Recovered
			Anaemia	貧血	2	N	TE	57	43	N	None	Recovered
			Hypocalcaemia	低カルシウム血症	1	N	TE	57	43	N	None	Recovered
			Bone pain	骨痛	2	N	TE	85	39	N	None	Recovered
			Anaemia	貧血	1	N	TE	99	22	N	None	Recovered
			Cushingoid	クッシング様	2	N	TE	99	22	N	None	Recovered
			Pupils unequal	瞳孔不同	1	N	TE	99	25	N	None	Recovered
			Aphasia	失語症	2	N	TE	119	2	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	120	2	N	None	Recovered
			Eyelid ptosis	眼瞼下垂	2	N	TE	120	4	N	None	Recovered
			Pyrexia	発熱	1	N	TE	120	1	N	None	Recovered
			Aphasia	失語症	3	Y	TE	120	10	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	N	TE	121	2	N	None	Recovered
			Anaemia	貧血	1	N	TE	122	6	N	None	Recovered
			Hypertension	高血圧	1	N	TE	123	3	N	None	Ongoing at study termination / withdrawal
			Hypertension	高血圧	2	N	TE	125		N	None	Ongoing at study termination / withdrawal
			Arthralgia	関節痛	3	N	TE	134		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
060009	Spain	66/M/C	Asthenia	無力症	1	N	Pre	1	28	Y	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	Pre	1	116	N	None	Ongoing at time of death
			Hypophosphataemia	低リン酸血症	3	N	Pre	1	28	N	None	Recovered
			Nausea	悪心	1	N	TE	25	92	Y	None	Recovered
			Anaemia	貧血	2	N	TE	28	76	Y	-	
			Asthenia	無力症	2	N	TE	28	135	Y	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	28	61	N	None	Recovered
			Hypocalcaemia	低カルシウム血症	2	N	TE	28	5	N	-	
			Hypophosphataemia	低リン酸血症	2	N	Pre	28	61	N	None	Recovered
			Hypocalcaemia	低カルシウム血症	1	N	TE	32	120	N	-	
			Constipation	便秘	1	N	TE	57	32	N	None	Recovered
			Gastritis	胃炎	2	N	TE	88	29	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	88	149	N	None	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	101	3	N	None	Recovered
			Anaemia	貧血	3	N	TE	103	2	Y	-	
			Diarrhoea	下痢	1	Y	TE	103	2	N	None	Recovered
			Anaemia	貧血	1	N	TE	104	10	Y	-	
			Anaemia	貧血	2	N	TE	113	23	Y	-	
			Anorexia	食欲不振	1	N	Pre	116	54	N	None	Ongoing at time of death
			Asthenia	無力症	2	N	TE	131	11	N	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	131	11	N	None	Recovered
			Anaemia	貧血	1	N	TE	135	1	Y	-	
			Anaemia	貧血	2	N	TE	135	17	Y	-	
			Diarrhoea	下痢	3	N	TE	140		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	141	22	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Acute myocardial infarction	急性心筋梗塞	4	Y	TE	143	5	N	Not applicable	Recovered
			Dysarthria	構語障害	2	N	TE	150	13	N	None	Recovered
			Facial paresis	顔面不全麻痺	2	N	TE	150	13	N	None	Recovered
			Anaemia	貧血	3	N	TE	151	11	Y	None	Ongoing at time of death
			Hypocalcaemia	低カルシウム血症	2	N	TE	151	19	N	-	
			Anaemia	貧血	2	N	TE	161		Y	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	162	36	N	None	Recovered
			Asthenia	無力症	3	N	TE	162		Y	None	Ongoing at time of death
			Facial paresis	顔面不全麻痺	1	N	TE	162	61	N	None	Recovered
			Anorexia	食欲不振	2	N	Pre	169		N	None	Ongoing at time of death
			Hypocalcaemia	低カルシウム血症	1	N	TE	169	64	N	None	Ongoing at time of death
062004	Spain	81/M/C	Oedema peripheral	末梢性浮腫	2	N	Pre	1	57	N	None	Recovered
			Bone pain	骨痛	1	N	TE	28	29	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	56		N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	78	2	N	None	Recovered
			Vomiting	嘔吐	1	Y	TE	80	5	N	Not applicable	Recovered
			Fatigue	疲労	1	N	TE	81	84	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	81	84	N	None	Recovered
			Anorexia	食欲不振	3	N	TE	81	32	N	Not applicable	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hypocalcaemia	低カルシウム血症	2	N	TE	81		N	Not applicable	Ongoing at time of death
063003	Spain	66/M/C	Spinal cord compression	脊髄圧迫	2	Y	TE	30	20	N	Drug permanently withdrawn	Recovered
070002	Spain	55/M/C	Anaemia	貧血	1	N	TE			Y	Not applicable	Recovered
			Bone pain	骨痛	2	N	Pre	1	85	N	Drug permanently withdrawn	Ongoing at time of death
			Nausea	悪心	2	N	TE	8	8	Y	None	Recovered
			Anorexia	食欲不振	2	N	TE	8	8	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	85	29	N	Drug permanently withdrawn	Ongoing at time of death
			Bone pain	骨痛	4	N	TE	113	112	N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	147	7	N	Not applicable	Recovered
071002	Spain	65/M/C	Bone pain	骨痛	3	N	Pre	-9	9	N	None	Recovered
			Bone pain	骨痛	2	N	Pre	-1	58	N	None	Recovered
			Dizziness	浮動性めまい	2	N	TE	28	2	N	None	Recovered
			Anxiety	不安	1	N	TE	28		N	None	Not recovered, but no changes expected
			Depression	うつ病	1	N	TE	28		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	57		N	None	Not recovered, but no changes expected

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Spinal cord compression	脊髄圧迫	3	Y	TE	221	15	N	Not applicable	Recovered
071008	Spain	70/M/C	Rectal tenesmus	直腸しぶり	2	N	TE			N	None	Recovered with sequelae
			Dysuria	排尿困難	2	N	TE			N	None	Recovered with sequelae
			Dysaesthesia	異常感覚	2	N	Pre	-20	21	N	None	Recovered
			Bone pain	骨痛	2	N	Pre	1	93	N	None	Not recovered, but no changes expected
			Urinary retention	尿閉	2	Y	TE	89	14	N	Drug permanently withdrawn	Recovered
			Pyrexia	発熱	2	N	TE	91	8	N	Drug permanently withdrawn	Recovered
			Bone pain	骨痛	3	N	TE	93	46	N	None	Not recovered, but no changes expected
			Spinal cord compression	脊髄圧迫	3	Y	TE	97	6	N	None	Recovered
072001	Spain	78/M/C	Fatigue	疲労	1	N	Pre			N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	10		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	21	7	N	None	Recovered
			Cardiac failure	心不全	4	Y	TE	31	5	N	None	Death
			Cardiac failure	心不全	5	Y	TE	35	1	N	None	Death
080001	Italy	73/M/C	Nausea	悪心	1	N	TE			Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE			Y	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	130	9	N	None	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	138	1	N	None	Death
084002	Israel	63/M/C	Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	TE	27		N	None	Not recovered, but no changes expected
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	2	N	TE	27		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	57		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	Y	TE	72	2	N	None	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	91		N	Drug permanently withdrawn	Not recovered, but no changes expected
			Nausea	悪心	2	N	TE	102	9	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	102	9	N	None	Recovered
			Anaemia	貧血	3	Y	TE	145	6	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	145	6	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	167	5	N	Not applicable	Recovered with sequelae
085001	Israel	58/M/C	Pyrexia	発熱	1	N	TE	31	1	N	None	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	58	7	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	58	7	N	None	Recovered with sequelae
			Pneumonia	肺炎	1	Y	TE	79		N	None	Ongoing at time of death
			Respiratory failure	呼吸不全	4	Y	TE	83	2	N	None	Death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Respiratory failure	呼吸不全	5	Y	TE	84	1	N	None	Death
085003	Israel	74/M/C	Deep vein thrombosis	深部静脈血栓症	2	Y	Pre	-16	3	N	Not applicable	Recovered with sequelae
			Dermatitis contact	接触性皮膚炎	1	N	TE	37	8	N	None	Recovered
			Asthenia	無力症	1	N	TE	49	1	N	None	Recovered
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	55		N	None	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	TE	62		N	None	Ongoing at time of death
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	3	N	TE	62		N	None	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	TE	63	11	N	None	Recovered
			Rectal haemorrhage	直腸出血	2	Y	TE	82	4	N	None	Recovered
			Haematuria	血尿	2	Y	TE	82	4	N	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	90		N	None	Ongoing at time of death
			Tremor	振戦	2	N	TE	90		N	None	Ongoing at time of death
			Hypochromic anaemia	低色素性貧血	2	N	TE	96		N	None	Ongoing at time of death
			Localised oedema	限局性浮腫	1	N	TE	104		N	None	Ongoing at time of death
			Lobar pneumonia	大葉性肺炎	3	Y	TE	104	8	N	Drug permanently withdrawn	Death
			General physical health deterioration	全身健康状態低下	3	Y	TE	107		N	Drug permanently withdrawn	Ongoing at time of death
			Urosepsis	尿路性敗血症	3	Y	TE	107		N	Drug permanently withdrawn	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Lobar pneumonia	大葉性肺炎	5	Y	TE	111	1	N	Drug permanently withdrawn	Death
086002	Israel	70/M/C	Bone pain	骨痛	2	N	Pre	1	30	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	30		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	58	3	N	Drug administration postponed	Recovered with sequelae
			Dysuria	排尿困難	2	N	TE	58	9	N	Drug administration postponed	Recovered
093001	Slovakia	72/M/C	Anaemia	貧血	2	N	Pre	-13	14	N	None	Recovered
			Constipation	便秘	1	N	Pre	-13	57	N	None	Recovered with sequelae
			Hyperbilirubinaemia	高ビリルビン血症	2	Y	Pre	-13	5	N	Not applicable	Recovered with sequelae
			Weight decreased	体重減少	2	Y	Pre	-13	5	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	N	Pre	-13	5	N	Not applicable	Recovered with sequelae
			Hyperbilirubinaemia	高ビリルビン血症	2	N	Pre	-9	3	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	1	N	Pre	-9	10	N	None	Recovered with sequelae
			Hyperbilirubinaemia	高ビリルビン血症	2	Y	Pre	-7	7	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	Y	TE	1	40	N	None	Recovered with sequelae

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	TE	35		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	35		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	35		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	44		N	None	Ongoing at time of death
			Constipation	便秘	2	Y	TE	44	11	N	None	Recovered with sequelae
			Bone pain	骨痛	2	Y	TE	44	11	N	None	Recovered with sequelae
			Pneumonia	肺炎	4	Y	TE	75		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	90	1	N	None	Death
095001	Slovakia	75/M/C	Bone pain	骨痛	4	N	TE	3	8	Y	Drug administration postponed	Recovered
			Bone pain	骨痛	2	N	TE	10	26	Y	Drug administration postponed	Recovered
			Bone pain	骨痛	3	N	TE	14	61	Y	Drug administration postponed	Recovered
			Nausea	悪心	1	N	TE	20	64	N	None	Recovered
			Fatigue	疲労	2	N	TE	20	118	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	35	40	Y	Drug administration postponed	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	83		Y	Not applicable	Ongoing at time of death
			Cardiopulmonary failure	心肺不全	4	Y	Post	235	13	Y	Not applicable	Death
			Cardiopulmonary failure	心肺不全	5	Y	Post	247	1	Y	Not applicable	Death
097001	Slovakia	70/M/C	Anaemia	貧血	2	N	Pre	1		N	None	Ongoing at time of death
			Sudden death	突然死	5	Y	TE	9	1	N	None	Death
097004	Slovakia	80/M/C	Fatigue	疲労	3	N	TE	3		N	None	Ongoing at time of death
			Cerebral ischaemia	脳虚血	4	Y	TE	3	36	N	Drug administration postponed	Recovered with sequelae
			Micturition disorder	排尿異常	2	N	TE	112		N	None	Ongoing at time of death
			Constipation	便秘	3	N	TE	114		N	None	Ongoing at time of death
			Diarrhoea	下痢	3	Y	TE	143	29	Y	Drug permanently withdrawn	Recovered
			Vomiting	嘔吐	3	Y	TE	143	29	Y	Drug permanently withdrawn	Recovered
			Pyrexia	発熱	3	Y	TE	143	29	N	Drug permanently withdrawn	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	143	29	N	Drug permanently withdrawn	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Disorientation	失見当識	3	N	TE	143	29	N	Not applicable	Recovered
			Cardiopulmonary failure	心肺不全	5	Y	TE	176	1	N	Not applicable	Death
097007	Slovakia	70/M/C	Bone pain	骨痛	2	N	Pre	-9	38	N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	2	56	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	29	84	N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	29	112	N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	57	56	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	112	9	Y	None	Recovered
			Anorexia	食欲不振	2	N	TE	112		N	None	Ongoing at time of death
			Sleep disorder	睡眠障害	1	N	TE	112	49	N	None	Recovered
			Mixed incontinence	混合性尿失禁	3	N	TE	112		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	120		Y	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	140		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	Pre	140		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	160	1	N	Not applicable	Death
097010	Slovakia	80/M/C	Nausea	悪心	1	N	TE	2	56	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	2		Y	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	1	N	TE	29	58	N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	64	6	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	64	6	N	None	Recovered
			Nausea	悪心	1	N	TE	86	91	Y	None	Recovered
			Fatigue	疲労	3	Y	TE	86	5	Y	Drug administration postponed	Recovered with sequelae
			Weight decreased	体重減少	2	N	TE	86		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	90	68	Y	None	Recovered with sequelae
			Vomiting	嘔吐	2	N	TE	152	6	Y	None	Recovered
			Anaemia	貧血	2	N	TE	157	5	Y	None	Recovered
			Fatigue	疲労	3	Y	TE	157	5	Y	None	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	206	1	N	Not applicable	Death
105003	Hong Kong	75/M/A	Cough	咳嗽	1	N	TE	4	5	N	None	Recovered
			Pharyngolaryngeal pain	咽喉頭疼痛	1	N	TE	4	5	N	None	Recovered
			Rhinorrhoea	鼻漏	1	N	TE	4	5	N	None	Recovered
			Pruritus	そう痒症	1	N	TE	8	22	N	None	Recovered
			Chromaturia	着色尿	1	N	TE	22		N	None	Ongoing at time of death
			Cough	咳嗽	1	N	TE	32	9	N	None	Recovered
			Productive cough	湿性咳嗽	1	N	TE	32	15	N	None	Recovered
			Pharyngolaryngeal pain	咽喉頭疼痛	1	N	TE	33	14	N	None	Recovered
			Rhinorrhoea	鼻漏	1	N	TE	33	8	N	None	Recovered
			Oedema	浮腫	1	N	TE	66	8	N	None	Recovered
			Rash pruritic	そう痒性皮疹	1	N	TE	66	7	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Gastrooesophageal reflux disease	胃食道逆流性疾患	1	N	TE	71		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	71	8	N	None	Recovered
			Bone pain	骨痛	1	N	TE	85	47	N	None	Ongoing at time of death
			Chest discomfort	胸部不快感	1	N	TE	98	8	N	None	Recovered
			Pruritus	そう痒症	1	N	TE	98		N	None	Ongoing at time of death
			Pharyngolaryngeal pain	咽喉頭疼痛	1	N	TE	99	13	N	None	Recovered
			Cough	咳嗽	1	N	TE	105	7	N	None	Recovered
			Productive cough	湿性咳嗽	1	N	TE	107	5	N	None	Recovered
			Bone pain	骨痛	2	N	TE	131		N	None	Ongoing at time of death
			Bone pain	骨痛	2	Y	TE	131	50	N	Drug administration postponed	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	131		N	None	Ongoing at time of death
106001	Hong Kong	62/M/A	Bone pain	骨痛	2	N	TE	57	57	N	None	Recovered
			Urogenital disorder	尿生殖器障害	2	N	TE	57		N	None	Not recovered, but no changes expected
			Haematuria	血尿	1	N	TE	98	44	N	None	Recovered
			Hypersensitivity	過敏症	2	N	TE	101	5	N	None	Recovered
			Pharyngolaryngeal pain	咽喉頭疼痛	2	N	TE	101	5	N	None	Recovered
			Cough	咳嗽	2	N	TE	105	6	N	None	Recovered
			Nasal discomfort	鼻部不快感	2	N	TE	105	6	N	None	Recovered
			Rhinorrhoea	鼻漏	2	N	TE	105	6	N	None	Recovered
			Hyponatraemia	低ナトリウム血症	3	N	TE	113	9	N	None	Recovered
			Cystitis	膀胱炎	3	Y	TE	115	11	N	None	Recovered
			Urinary bladder haemorrhage	膀胱出血	3	Y	TE	115	11	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary retention	尿閉	3	Y	TE	115	11	N	None	Recovered
			Hyponatraemia	低ナトリウム血症	1	N	TE	121	21	N	None	Recovered
			Constipation	便秘	2	N	TE	141	28	N	None	Recovered
			Nausea	悪心	2	N	TE	141	28	N	None	Recovered
			Hyponatraemia	低ナトリウム血症	3	N	TE	141	28	N	None	Recovered
106012	Hong Kong	75/M/A	Cystitis	膀胱炎	2	N	TE	7	7	N	None	Recovered
			Anaemia	貧血	2	Y	TE	29	2	Y	None	Recovered
			Constipation	便秘	1	N	TE	29	29	Y	None	Recovered
			Faeces discoloured	変色便	1	N	TE	29	29	N	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	29	29	N	None	Recovered
			Anaemia	貧血	3	Y	TE	57	3	Y	Drug administration postponed	Recovered
			Hyperkalaemia	高カリウム血症	1	N	TE	57	23	N	None	Recovered
			Haematuria	血尿	1	N	TE	57	23	N	None	Recovered
			Gastroduodenal ulcer	胃十二指腸潰瘍	1	N	TE	73		N	None	Ongoing at time of death
			Haemorrhoids	痔核	1	N	TE	73	7	N	None	Recovered
			Muscular weakness	筋力低下	2	N	TE	77		N	None	Ongoing at time of death
			Sepsis	敗血症	2	N	TE	79	20	N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	79		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	79		N	Drug permanently withdrawn	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	2	N	TE	80		N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Convulsion	痙攣	2	N	TE	85		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	4	Y	TE	90		N	Not applicable	Ongoing at time of death
			Pyrexia	発熱	2	N	TE	91	4	N	Not applicable	Recovered
			Diabetes mellitus	糖尿病	2	N	TE	91	16	N	Not applicable	Recovered
			Anxiety	不安	2	N	TE	94	13	N	Not applicable	Recovered
			Metastases to bone	骨転移	5	Y	TE	106	1	N	Not applicable	Death
128005	Canada	86/M/C	Bone pain	骨痛	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Musculoskeletal chest pain	筋骨格系胸痛	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Musculoskeletal pain	筋骨格痛	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Cough	咳嗽	1	N	Pre			N	None	Recovered
			Fatigue	疲労	1	N	TE	2	3	Y	None	Recovered
			Decreased appetite	食欲減退	2	N	TE	92	8	N	None	Recovered
			Atrial fibrillation	心房細動	3	Y	TE	121	3	N	Drug permanently withdrawn	Recovered
			Left ventricular failure	左室不全	3	Y	TE	121	3	N	Drug permanently withdrawn	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	1	N	TE	121	11	N	None	Recovered
			Pleural effusion	胸水	2	N	TE	162	8	N	Not applicable	Recovered
133010	Poland	74/M/C	General physical health deterioration	全身健康状態低下	4	Y	TE			N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	12		N	None	Ongoing at study termination / withdrawal
133013	Poland	69/M/C	Fatigue	疲労	3	Y	TE	29	11	N	Drug permanently withdrawn	Recovered
			Fatigue	疲労	2	N	TE	39	20	N	Not applicable	Recovered
133021	Poland	70/M/C	Bone pain	骨痛	2	N	TE	15	8	Y	None	Recovered
			Device dislocation	医療機器位置異常	1	Y	TE	77	3	N	None	Recovered
			Anaemia	貧血	3	Y	TE	171	2	N	Drug administration postponed	Recovered
			Fatigue	疲労	4	Y	TE	171		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Haematuria	血尿	2	N	TE	179		N	Not applicable	Not recovered, but no changes expected
133022	Poland	84/M/C	General physical health deterioration	全身健康状態低下	4	N	TE	77		N	None	Not recovered, but no changes expected

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	3	Y	TE	77	8	N	Drug permanently withdrawn	Death
			Dyspnoea	呼吸困難	5	Y	TE	84	1	N	Drug permanently withdrawn	Death
133025	Poland	66/M/C	Decubitus ulcer	褥瘡性潰瘍	3	N	TE			N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Arteriovenous graft site haemorrhage	動静脈グラフト部位出血	2	Y	Pre	-11	7	N	Not applicable	Recovered
			Paraplegia	対麻痺	3	Y	TE	48		N	Drug administration postponed	Not recovered, but no changes expected
			Insomnia	不眠症	1	N	TE	51		N	None	Ongoing at study termination / withdrawal
			Pyrexia	発熱	2	N	TE	118	10	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	118		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	Y	TE	157	6	N	Drug administration postponed	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	157		N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	2	N	TE	159	2	N	None	Recovered
133029	Poland	56/M/C	Nausea	悪心	1	N	TE	2	2	Y	None	Recovered
			Asthenia	無力症	2	N	TE	2	3	Y	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary retention	尿閉	2	N	TE	53	4	N	None	Recovered
			Subileus	亜イレウス	3	Y	TE	63	5	Y	Drug administration postponed	Recovered
			Renal failure	腎不全	3	Y	TE	82	10	N	Drug permanently withdrawn	Death
			Renal failure	腎不全	5	Y	TE	91	1	N	Drug permanently withdrawn	Death
135005	Poland	65/M/C	Cerebral ischaemia	脳虚血	4	Y	TE	128	8	N	Drug administration postponed	Recovered with sequelae
137001	Poland	84/M/C	Peripheral motor neuropathy	末梢性運動ニューロパチー	3	Y	TE	16	10	N	Drug permanently withdrawn	Recovered with sequelae
			Muscular weakness	筋力低下	2	N	TE	25		N	Not applicable	Ongoing at time of death
137008	Poland	60/M/C	Bone pain	骨痛	2	Y	TE	101	13	N	None	Recovered
139002	Poland	71/M/C	Bone pain	骨痛	2	N	TE	117	47	N	None	Recovered
			Nausea	悪心	2	N	TE	217		N	Not applicable	Recovered
			Vomiting	嘔吐	2	N	TE	217		N	Not applicable	Recovered
			Dizziness	浮動性めまい	2	N	TE	217		N	Not applicable	Recovered
			Dysphasia	不全失語症	3	N	TE	217		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Ischaemic stroke	虚血性脳卒中	3	Y	TE	217	13	N	Not applicable	Recovered with sequelae
141002	Poland	60/M/C	Haematuria	血尿	2	Y	TE	10	27	N	None	Recovered
			Haematuria	血尿	3	Y	TE	40	11	N	None	Recovered with sequelae
			Haematuria	血尿	2	N	TE	50		N	None	Not recovered, but no changes expected
			Hydronephrosis	水腎症	2	Y	TE	56	5	N	Drug administration postponed	Recovered with sequelae
			Anaemia	貧血	3	Y	TE	90	3	N	None	Recovered with sequelae
			Thrombocytopenia	血小板減少症	2	N	TE	92		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	2	N	TE	92		N	None	Ongoing at study termination / withdrawal
			Dyspnoea	呼吸困難	3	Y	TE	95	5	N	Not applicable	Death
			Dyspnoea	呼吸困難	5	Y	TE	99	1	N	Not applicable	Death
148005	Germany	63/M/C	Nausea	悪心	1	N	TE	27	1	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	57	38	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	57	29	Y	None	Recovered
			Nausea	悪心	1	N	TE	59	5	Y	None	Recovered
			Fatigue	疲労	2	N	TE	64		Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	85	1	Y	None	Recovered
			Anaemia	貧血	1	Y	TE	94	2	Y	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	112		N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	114	4	Y	None	Recovered
			Nausea	悪心	1	N	TE	114	4	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	114	4	Y	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	129	1	N	None	Death
148007	Germany	62/M/C	Anaemia	貧血	1	N	TE			N	Not applicable	Recovered
			Oesophageal pain	食道痛	1	N	Pre			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	Pre	-3	10	Y	-	
			Diarrhoea	下痢	1	N	TE	3	1	Y	None	Recovered
			Nausea	悪心	2	N	TE	3	2	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	3	6	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	3	5	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	3		Y	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	4	29	Y	None	Recovered
			Bone pain	骨痛	1	N	Pre	7	45	Y	-	
			Bone pain	骨痛	1	N	TE	7		Y	None	Recovered
			Lymphadenopathy	リンパ節症	2	N	TE	13	40	N	None	
			Bone pain	骨痛	2	N	Pre	51	7	Y	-	
			Lymphadenopathy	リンパ節症	3	N	TE	52	7	N	None	
			Bone pain	骨痛	1	N	Pre	57	2	Y	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	58		N	None	
			Bone pain	骨痛	2	N	Pre	58	2	Y	None	Recovered
			Bone pain	骨痛	1	N	Pre	59		Y	None	Recovered
			Abdominal pain upper	上腹部痛	2	N	TE	67	37	N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Diarrhoea	下痢	1	N	TE	102	2	Y	None	Recovered
			Abdominal pain upper	上腹部痛	1	N	TE	103		N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	111	1	Y	None	Recovered
			Diarrhoea	下痢	3	Y	TE	162	12	N	Not applicable	Recovered
			Nausea	悪心	3	Y	TE	162	12	N	Not applicable	Recovered
			Vomiting	嘔吐	3	Y	TE	162	12	N	Not applicable	Recovered
			Weight decreased	体重減少	2	N	TE	162	91	N	Not applicable	Recovered
148015	Germany	68/M/C	Migraine with aura	前兆を伴う片頭痛	2	N	TE	3	3	Y	None	Recovered
			Metastases to lymph nodes	リンパ節転移	2	N	TE	15	115	N	None	Recovered with sequelae
			Anorexia	食欲不振	1	N	TE	113	56	Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	113	119	Y	None	Recovered
			Metastases to lymph nodes	リンパ節転移	3	Y	TE	129	2	N	None	Recovered with sequelae
			Metastases to lymph nodes	リンパ節転移	3	N	TE	130	101	N	None	Not recovered, but no changes expected
149004	Germany	65/M/C	Bone pain	骨痛	2	N	Pre	-7	37	N	None	Recovered
			Vomiting	嘔吐	2	N	Pre	-1	1	N	None	Recovered
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE	1	1	Y	None	Recovered
			Vertigo	回転性めまい	1	N	TE	15		N	None	Not recovered, but no changes expected

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE	31	1	Y	None	Recovered
			Anaemia	貧血	1	N	TE	51	16	Y	None	Recovered
			Depression	うつ病	1	N	TE	64		N	None	Not recovered, but no changes expected
			Hypertension	高血圧	2	N	TE	64		N	None	Not recovered, but no changes expected
			Nausea	悪心	2	N	TE	66	2	N	None	Recovered
			Bone pain	骨痛	1	N	TE	66	7	N	None	Recovered
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE	66	1	Y	None	Recovered
			Tooth infection	歯感染	1	N	TE	89	4	N	None	Recovered
			Constipation	便秘	1	N	TE	98		N	None	Ongoing at study termination / withdrawal
			Insomnia	不眠症	1	N	TE	99	10	N	None	Recovered
			Hyperhidrosis	多汗症	2	N	TE	129		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	149	3	N	None	Recovered
			Bone pain	骨痛	1	N	TE	220	19	N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	238	5	N	Not applicable	Recovered
149005	Germany	73/M/C	Bone pain	骨痛	1	N	TE	13	31	Y	None	Recovered
			Abdominal pain	腹痛	1	N	TE	31	13	Y	None	Recovered
			Nausea	悪心	1	N	TE	64	3	N	None	Recovered
			Fatigue	疲労	1	N	TE	64	5	N	Drug permanently withdrawn	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	64		N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	1	N	TE	64	28	N	-	
			Insomnia	不眠症	1	N	TE	64	4	N	None	Recovered
			Fatigue	疲労	2	N	TE	68	13	N	Drug permanently withdrawn	Ongoing at time of death
			Fatigue	疲労	3	N	TE	80		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	91	24	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	114	2	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	115	1	N	Not applicable	Death
149006	Germany	60/M/C	Bone pain	骨痛	1	N	TE	63	29	Y	None	Recovered with sequelae
			Urine flow decreased	尿流量減少	1	N	TE	65	7	N	None	Recovered
			Insomnia	不眠症	1	N	TE	77		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	91	123	Y	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	113	3	Y	Drug administration postponed	Recovered
			Haematuria	血尿	1	N	TE	125	1	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	133	4	Y	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	133	39	N	Not applicable	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	133		N	None	Ongoing at study termination / withdrawal
			Monoparesis	不全単麻痺	1	N	TE	133	18	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	134		N	Not applicable	Not recovered, but no changes expected
			Monoparesis	不全単麻痺	3	Y	TE	150		N	Not applicable	Ongoing at time of death
			Monoparesis	不全単麻痺	3	N	TE	150	29	N	Not applicable	Recovered
			Pleural effusion	胸水	1	N	TE	150		N	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	163	5	Y	Not applicable	Recovered
			Stomatitis radiation	放射線口内炎	2	N	TE	168	4	N	Not applicable	Recovered
			Stomatitis radiation	放射線口内炎	1	N	TE	171	8	N	Not applicable	Recovered
			Dysaesthesia	異常感覚	1	N	TE	171		N	Not applicable	Not recovered, but no changes expected
			Thrombocytopenia	血小板減少症	2	N	TE	178	29	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	TE	183	11	Y	Not applicable	Recovered
			Ureteric obstruction	尿管閉塞	1	N	TE	190		N	Not applicable	Not recovered, but no changes expected
			Gastritis	胃炎	3	Y	TE	191	11	N	Not applicable	Recovered
			General physical health deterioration	全身健康状態低下	3	Y	TE	191	11	N	Not applicable	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
151002	Germany	69/M/C	Vomiting	嘔吐	1	N	TE	5	12	N	None	Recovered
			VIth nerve paralysis	第６脳神経麻痺	2	N	TE	7	30	N	None	Recovered
			Hypotension	低血圧	2	N	TE	16	7	N	None	Recovered
			Metastases to soft tissue	軟部組織転移	3	N	TE	19		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	22		N	None	Ongoing at study termination / withdrawal
			Pain in jaw	顎痛	2	N	TE	22	91	N	None	Ongoing at study termination / withdrawal
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	TE	29	28	N	None	Ongoing at study termination / withdrawal
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	56	81	N	None	Ongoing at study termination / withdrawal
			Visual disturbance	視覚障害	3	N	TE	92	8	N	None	Ongoing at study termination / withdrawal
			Visual disturbance	視覚障害	4	N	TE	99		N	None	Ongoing at study termination / withdrawal
			Pain in jaw	顎痛	3	N	TE	112	43	N	None	Ongoing at study termination / withdrawal
			Urinary retention	尿閉	3	Y	TE	129	5	N	Not applicable	Recovered with sequelae
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	TE	136		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	137	4	N	Not applicable	Recovered
			Pain in jaw	顎痛	2	N	TE	154		N	None	Ongoing at study termination / withdrawal
			Abscess jaw	顎膿瘍	3	Y	TE	163	22	N	Not applicable	Recovered with sequelae
155006	Germany	70/M/C	Chills	悪寒	1	N	Pre			N	None	Recovered
			Nausea	悪心	1	N	TE	2		N	None	Not recovered, but no changes expected
			Device related infection	医療機器関連感染	3	Y	TE	92	25	N	Drug administration postponed	Recovered with sequelae
			Bone pain	骨痛	3	N	TE	175		N	Not applicable	Ongoing at study termination / withdrawal
155007	Germany	63/M/C	Metastases to bone	骨転移	3	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	Pre	-10		N	None	Not recovered, but no changes expected
			Benign urinary tract neoplasm	尿路の良性新生物	2	Y	TE	73	6	N	None	Recovered
			Metastases to liver	肝転移	2	N	TE	163		N	None	Not recovered, but no changes expected
172001	Brazil	75/M/C	Fatigue	疲労	2	N	TE	31		N	None	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	1	N	TE	31	29	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	36	4	N	None	Recovered
			Nasal congestion	鼻閉	1	N	TE	38	22	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cachexia	悪液質	3	N	TE	59		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	86	2	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	86	28	N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	87		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	113		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	212	1	N	Not applicable	Death
174003	Brazil	71/M/A	Weight decreased	体重減少	1	N	Pre	1	76	N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	4	15	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	41	17	N	None	Recovered
			Bone pain	骨痛	3	N	TE	41	4	N	None	Recovered
			Bone pain	骨痛	3	N	TE	41	17	N	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	2	N	TE	44		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	44	14	N	None	Recovered
			Constipation	便秘	2	N	TE	48	10	N	None	Recovered
			Nausea	悪心	2	N	TE	51	7	N	None	Recovered
			Bone pain	骨痛	2	N	TE	57		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	57		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	57		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	63	28	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	1	N	TE	63	156	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	76	116	N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	99	43	N	None	Recovered
			Bone pain	骨痛	1	N	TE	105	1	N	None	Recovered
			Anaemia	貧血	3	N	TE	106	29	Y	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	106	29	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	134		Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	162	30	Y	None	Recovered
			Weight decreased	体重減少	3	N	TE	191		N	None	Ongoing at time of death
			Pneumonia	肺炎		N	TE	225		N	Not applicable	Ongoing at time of death
179005	Brazil	77/M/C	Monoparesis	不全単麻痺	1	N	Pre			N	Not applicable	Ongoing at study termination / withdrawal
			Urinary tract infection	尿路感染	3	Y	Pre	-67	9	N	Not applicable	Recovered
			Neutropenia	好中球減少症	3	N	TE	31	33	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	42		N	Not applicable	Recovered
			Asthenia	無力症	1	N	TE	42		N	Not applicable	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	1	N	TE	42	22	N	Not applicable	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Diarrhoea	下痢	1	N	TE	44		N	Not applicable	Recovered
			Gait disturbance	歩行障害	1	N	TE	63		N	Not applicable	Lost to follow-up
			Neutropenia	好中球減少症	3	N	TE	78	14	N	Not applicable	Recovered
181006	Brazil	75/M/B	Sepsis	敗血症	4	Y	TE	146	11	N	None	Death
			Hypernatraemia	高ナトリウム血症	4	N	TE	146		N	Drug administration postponed	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	146		N	None	Ongoing at time of death
			Renal failure acute	急性腎不全	4	N	TE	146		N	Drug permanently withdrawn	Ongoing at time of death
			Respiratory failure	呼吸不全	4	N	TE	146		N	Drug permanently withdrawn	Ongoing at time of death
			Sepsis	敗血症	5	Y	TE	156	1	N	None	Death
200002	Australia	57/M/C	Arthralgia	関節痛	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			N	None	Recovered
			Osteoarthritis	骨関節炎	1	N	Pre			N	None	Recovered
			Synovial cyst	滑液嚢腫	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Non-cardiac chest pain	非心臓性胸痛	3	Y	Pre	-17	3	N	None	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	57	57	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	1	N	TE	92		N	None	Ongoing at study termination / withdrawal
			Constipation	便秘	1	N	TE	94	6	N	Not applicable	Recovered
			Insomnia	不眠症	1	N	TE	95		N	Not applicable	Recovered
			Dizziness	浮動性めまい	1	N	TE	99	1	N	Not applicable	Recovered
202003	Australia	64/M/C	Nausea	悪心	2	N	TE	11	18	N	None	Recovered
			Bone pain	骨痛	3	N	TE	11	2	Y	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	57	7	N	Not applicable	Recovered
			Diplopia	複視	1	N	TE	104	21	N	Not applicable	Recovered
207002	Australia	81/M/C	Anorexia	食欲不振	2	N	TE			N	None	Lost to follow-up
			Urinary incontinence	尿失禁	2	N	TE			N	None	Lost to follow-up
			Oedema peripheral	末梢性浮腫	1	N	TE	58		N	None	Lost to follow-up
			Swelling face	顔面腫脹	1	N	TE	58		N	None	Lost to follow-up
			Faecal incontinence	便失禁	1	N	TE	104		N	None	Ongoing at time of death
			Dementia	認知症	3	Y	TE	104	7	N	Drug permanently withdrawn	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	137	1	N	Not applicable	Death
212001	Australia	81/M/C	Thrombocytopenia	血小板減少症	1	N	TE	30	50	N	None	Recovered
			Atrial fibrillation	心房細動	2	Y	TE	38	11	N	None	Recovered

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Abdominal pain	腹痛	3	N	TE	59	8	N	Drug administration postponed	Recovered
			Nausea	悪心	3	N	TE	59		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	59	21	N	Drug administration postponed	Recovered
			Bone pain	骨痛	2	N	TE	59		N	Drug administration postponed	Ongoing at time of death
			Dyspnoea	呼吸困難	3	N	TE	59	21	N	Drug administration postponed	Recovered
233003	UK	61/M/C	Anorexia	食欲不振	1	N	Pre	-13	22	N	None	Recovered with sequelae
			Fatigue	疲労	2	N	Pre	1	163	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre	1	29	N	None	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	29	36	Y	None	Recovered
			Bone pain	骨痛	2	N	Pre	29	36	N	None	Ongoing at time of death
			Ageusia	味覚消失	2	N	TE	29	36	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	58	4	N	None	Recovered
			Constipation	便秘	2	N	TE	60		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	64	25	N	None	Recovered
			Bone pain	骨痛	3	N	Pre	64		N	None	Ongoing at time of death

表 2.7.4.7- 3 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、中間解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Muscular weakness	筋力低下	3	N	TE	64		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	92	17	N	None	Recovered
			Tachycardia	頻脈	1	N	TE	92		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	92		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	104	60	N	None	Recovered
			Anaemia	貧血	3	Y	TE	135	3	N	Drug administration postponed	Recovered
			Asthenia	無力症	3	N	TE	135	3	Y	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	138		N	Drug administration postponed	Ongoing at study termination / withdrawal
			Dysarthria	構語障害	1	N	TE	145		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	3	N	TE	152	12	N	None	Death
			Cardiac failure	心不全	4	Y	TE	152		N	Drug permanently withdrawn	Ongoing at time of death
			Pleural effusion	胸水	2	N	TE	152		N	Not applicable	Ongoing at time of death
			Nausea	悪心	2	N	TE	159	5	N	Not applicable	Ongoing at time of death
			Anaemia	貧血	5	Y	TE	163	1	N	None	Death

Sex is identified as: M = Male.

Race is identified as: A = Asian, B = Black, C = Caucasian, O = Other.

The unit for "Age" is years.

Phase is identified as: Pre = Pre-Treatment, TE = Treatment-Emergent, Post = Post-Treatment

Source: 5.3.5.1.3 BC1-06_J-table 1/Table 1.4/1

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
001003	Norway	67/M/C	Nausea	悪心	1	N	TE	23	1	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	23	1	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	28	29	Y	None	Not recovered, but no changes expected
			Nausea	悪心	2	N	TE	31	12	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	31	12	Y	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	35	11	Y	None	Recovered
			Nausea	悪心	2	N	TE	56	8	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	56	8	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	56		Y	None	Not recovered, but no changes expected
			Weight decreased	体重減少	2	N	TE	84		Y	None	Not recovered, but no changes expected
			Nausea	悪心	2	N	TE	87	8	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	87	8	Y	None	Recovered
			Nausea	悪心	2	N	TE	114	40	Y	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	2	N	TE	114	40	Y	Not applicable	Recovered with sequelae
			Pathological fracture	病的骨折	2	N	TE	115		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	Y	TE	127	15	N	None	Recovered
			Nausea	悪心	3	Y	TE	153	6	Y	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	3	Y	TE	153	6	Y	Not applicable	Recovered with sequelae
			Nausea	悪心	2	N	TE	158	17	Y	None	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	174	5	Y	Not applicable	Recovered with sequelae

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	3	Y	TE	174	5	Y	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	3	Y	TE	174	5	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	3	N	TE	174	5	Y	Not applicable	Ongoing at study termination / withdrawal
			Infection	感染	1	Y	TE	174	5	Y	Not applicable	Recovered
			Bone pain	骨痛	2	Y	TE	174	5	Y	Not applicable	Recovered
			Nausea	悪心	2	N	TE	178		Y	None	Ongoing at study termination / withdrawal
			General physical health deterioration	全身健康状態低下	2	N	TE	178		Y	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	Y	TE	192	2	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	197	14	Y	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	2	Y	TE	197	14	N	Not applicable	Recovered with sequelae
			Infection	感染	2	Y	TE	197	14	N	Not applicable	Recovered
001012	Norway	52/M/C	Bone pain	骨痛	2	Y	TE	105	2	N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	106		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	Y	TE	141	4	N	Not applicable	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	2	N	TE	166	57	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	Y	TE	184	3	N	Not applicable	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	TE	222		N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	2	N	TE	222		N	Not applicable	Not recovered, but no changes expected
001019	Norway	70/M/C	Ankle fracture	足関節部骨折	2	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE	118	56	Y	None	Recovered
			Chest pain	胸痛	2	Y	TE	133	2	Y	None	Recovered
			Anaemia	貧血	2	N	TE	145	63	Y	Not applicable	Recovered with sequelae
			Dysgeusia	味覚異常	2	N	TE	145	29	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	207	4	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	TE	210		Y	Not applicable	Ongoing at study termination / withdrawal
001021	Norway	66/M/C	Lung infection	肺感染	2	Y	Pre	-13	5	N	Not applicable	Recovered
			Anaemia	貧血	2	N	Pre	1		Y	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	57	1	Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dizziness	浮動性めまい	1	N	TE	57		Y	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	112	6	Y	None	Recovered
			Nausea	悪心	2	N	TE	148		Y	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	148		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	156		Y	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	2	N	TE	183		Y	None	Ongoing at study termination / withdrawal
001023	Norway	62/M/C	Bone pain	骨痛	2	N	Pre	1		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	29		Y	None	Ongoing at study termination / withdrawal
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	57		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	TE	57		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	57		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	57	19	N	Drug permanently withdrawn	Death
			Metastases to liver	肝転移	3	Y	TE	57		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	75	1	N	Drug permanently withdrawn	Death
001025	Norway	77/M/C	Bone pain	骨痛	2	Y	Pre	-14	2	N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	57	16	N	None	Recovered
			Nausea	悪心	2	N	TE	69		Y	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	2	N	TE	85		Y	None	Ongoing at study termination / withdrawal
001029	Norway	66/M/C	Diarrhoea	下痢	1	N	TE	3	8	Y	None	Recovered
			Nausea	悪心	2	N	TE	3	4	Y	None	Recovered
			Fatigue	疲労	1	N	TE	57		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	57		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	87	7	Y	Drug administration postponed	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	90	4	Y	Drug administration postponed	Recovered
			Nausea	悪心	2	N	TE	90	4	Y	Drug administration postponed	Recovered
			Dehydration	脱水	2	Y	TE	90	4	Y	Drug administration postponed	Recovered
			Weight decreased	体重減少	2	N	TE	106	29	Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	Y	TE	134	2	Y	Drug permanently withdrawn	Recovered with sequelae
			Leukopenia	白血球減少症	2	Y	TE	134		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	3	Y	TE	134		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	3	N	TE	134		Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	135		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
001035	Norway	75/M/C	Anaemia	貧血	2	N	TE	3	8	Y	None	Recovered
			Nausea	悪心	2	N	TE	3	8	Y	None	Recovered
			Infection	感染	2	Y	TE	3	8	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pathological fracture	病的骨折	3	Y	TE	66	12	N	None	Recovered with sequelae
			Mobility decreased	運動性低下	2	N	TE	77		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	85		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	Y	TE	141	10	Y	Drug administration postponed	Recovered with sequelae
			Medical device complication	医療機器合併症	3	Y	TE	141	10	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	Y	TE	156	10	Y	Drug administration postponed	Recovered with sequelae
			Urinary tract infection	尿路感染	3	Y	TE	156	10	Y	Drug administration postponed	Recovered
			Urinary retention	尿閉	3	Y	TE	189		N	Drug permanently withdrawn	Ongoing at time of death
001041	Norway	63/M/C	Bone pain	骨痛	1	N	TE	29	71	Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	85	29	Y	Drug permanently withdrawn	Recovered with sequelae
			Pyrexia	発熱	2	N	TE	85	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	99		Y	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Diarrhoea	下痢	1	N	TE	107	5	Y	None	Recovered
			Pneumonia	肺炎	2	N	TE	111	17	N	None	Recovered
			Anaemia	貧血	1	N	TE	113	32	Y	Drug permanently withdrawn	Recovered with sequelae
			Weight decreased	体重減少	2	N	TE	113		Y	None	Ongoing at study termination / withdrawal
			Dehydration	脱水	3	Y	TE	115	8	Y	None	Recovered
			Tumour associated fever	腫瘍熱	1	N	TE	115		N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	141	4	Y	Drug permanently withdrawn	Recovered with sequelae
			Metastases to lung	肺転移	3	N	TE	141		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Cough	咳嗽	1	N	TE	141		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	Y	TE	144	6	Y	Drug permanently withdrawn	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	2	Y	TE	144	6	Y	Drug permanently withdrawn	Recovered with sequelae
			Dehydration	脱水	2	Y	TE	144	6	Y	Drug permanently withdrawn	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	149		Y	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
002006	Norway	66/M/C	Bone pain	骨痛	2	N	Pre			N	None	Ongoing at study termination / withdrawal
			Urinary tract infection	尿路感染	3	N	TE	10	10	N	None	Recovered
			Anaemia	貧血	2	N	TE	29	34	N	None	Recovered
			Bone pain	骨痛	1	N	Pre	29	29	N	None	Ongoing at study termination / withdrawal
			Ascites	腹水	1	N	TE	57	6	N	None	Recovered
			Bone pain	骨痛	2	N	Pre	57		N	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	Y	TE	62	18	N	Drug permanently withdrawn	Recovered with sequelae
			Fungal infection	真菌感染	2	N	TE	76	5	N	None	Recovered
			Anxiety	不安	2	N	TE	77		N	None	Not recovered, but no changes expected
			Sepsis	敗血症	4	Y	TE	79	5	N	Not applicable	Death
			Anaemia	貧血	2	N	TE	81	2	N	None	Recovered
			Sepsis	敗血症	5	Y	TE	83	1	N	Not applicable	Death
002008	Norway	69/M/C	Nausea	悪心	1	N	TE	29	3	N	None	Recovered
			Nausea	悪心	1	N	TE	34		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	105	21	N	None	Recovered
			Constipation	便秘	1	N	TE	120		Y	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	125	5	N	None	Recovered
			Hyperglycaemia	高血糖	4	Y	TE	159	4	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	161	3	N	Not applicable	Recovered
			Ascites	腹水	1	N	TE	176		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	183	2	N	Not applicable	Recovered
			Infection	感染	2	N	TE	183	3	N	Not applicable	Recovered
			Infection	感染	3	Y	TE	185	5	N	Not applicable	Recovered
			Anaemia	貧血	4	Y	TE	216	2	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	4	Y	TE	216		Y	Not applicable	Ongoing at time of death
002009	Norway	73/M/C	Diarrhoea	下痢	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	2	N	TE	2	3	Y	None	Recovered
			Osteoporosis	骨粗鬆症	3	Y	TE	39	6	N	None	Recovered with sequelae
			Atrial fibrillation	心房細動	2	N	TE	71	2	N	None	Recovered
			Pneumonia	肺炎	2	N	TE	71	14	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	71	14	N	None	Recovered with sequelae
			Urinary retention	尿閉	2	N	TE	71	14	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oral infection	口腔感染	2	N	TE	79	5	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	79	2	N	None	Recovered
			Bone pain	骨痛	3	N	TE	113		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	132	47	N	None	Recovered with sequelae
			Constipation	便秘	2	N	TE	225		N	None	Not recovered, but no changes expected
002013	Norway	69/M/C	Vision blurred	霧視	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	2	5	Y	None	Recovered
			Metastases to skin	皮膚転移	1	N	TE	57		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	85		N	None	Ongoing at study termination / withdrawal
			Metastases to soft tissue	軟部組織転移	1	N	TE	86		N	None	Ongoing at time of death
			Cerebral haemorrhage	脳出血	3	Y	TE	100	38	Y	Drug permanently withdrawn	Death
			Anaemia	貧血	2	N	TE	110		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	111		Y	Not applicable	Ongoing at time of death
			Cerebral haemorrhage	脳出血	5	Y	TE	137	1	Y	Drug permanently withdrawn	Death
002017	Norway	79/M/C	Nausea	悪心	1	N	TE	4	2	Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	2	N	TE	28	4	Y	None	Recovered
			Dizziness	浮動性めまい	2	N	TE	28	4	Y	None	Recovered
			Localised infection	限局性感染	2	N	TE	54	116	N	None	Recovered
			Nausea	悪心	2	N	TE	57	4	Y	None	Recovered
			Dizziness	浮動性めまい	2	N	TE	57	4	Y	None	Recovered
			Wound	創傷	2	N	TE	68	122	N	None	Recovered
			Supraventricular tachycardia	上室性頻脈	3	Y	TE	176	7	N	Not applicable	Recovered
			Urinary tract infection	尿路感染	2	N	TE	177	7	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	N	TE	178	4	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	205	10	N	None	Recovered
			Atrial flutter	心房粗動	2	Y	TE	230	4	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	N	TE	230	3	N	Not applicable	Recovered
003001	Norway	64/M/C	Dizziness	浮動性めまい	1	N	TE			Y	None	Ongoing at study termination / withdrawal
			Constipation	便秘	1	N	TE	1	21	Y	None	Recovered
			Nausea	悪心	1	N	TE	2	82	Y	None	Recovered
			Insomnia	不眠症	2	N	TE	2		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	8	18	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	28	98	N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	Y	TE	84		Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Leukopenia	白血球減少症	1	N	TE	84		Y	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	1	N	TE	84		Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	N	TE	112	2	Y	Drug administration postponed	Recovered
			Neutropenia	好中球減少症	3	Y	TE	112	3	Y	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	112		Y	Drug administration postponed	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	125	52	Y	Drug permanently withdrawn	Recovered with sequelae
			Leukopenia	白血球減少症	1	N	TE	125		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	1	N	TE	125		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	3	N	TE	125		N	None	Ongoing at study termination / withdrawal
			Pyrexia	発熱	2	N	TE	131	5	Y	Not applicable	Recovered
003005	Norway	58/M/C	Spinal cord compression	脊髄圧迫	2	N	TE			N	Not applicable	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nasopharyngitis	鼻咽頭炎	2	N	Pre	-1	9	N	None	Recovered
			Bone pain	骨痛	1	N	Pre	-1	9	N	None	Recovered
			Nausea	悪心	1	N	TE	29	30	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	64	84	Y	None	Recovered
			Nausea	悪心	1	N	TE	87	33	Y	None	Recovered
			Anaemia	貧血	2	N	TE	119	123	Y	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	1	N	TE	119		Y	None	Ongoing at study termination / withdrawal
			Muscular weakness	筋力低下	2	N	TE	147		N	None	Ongoing at study termination / withdrawal
			Pneumonia	肺炎	3	Y	TE	187	3	N	Not applicable	Recovered
			Pneumonia	肺炎	1	N	TE	189	25	N	Not applicable	Recovered with sequelae
			Pleural effusion	胸水	3	N	TE	209	5	N	Not applicable	Recovered with sequelae
			Hypovitaminosis	ビタミン欠乏症	1	N	TE	211		N	Not applicable	Ongoing at time of death
			Pleural effusion	胸水	3	Y	TE	213	6	N	Not applicable	Recovered with sequelae
			Insomnia	不眠症	1	N	TE	221		N	Not applicable	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	221		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	1	N	TE	241		Y	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
003007	Norway	51/M/C	Anxiety	不安	1	N	Pre			N	None	Ongoing at study termination / withdrawal
			Radiation associated pain	放射線関連痛	2	N	TE	17	4	N	None	Recovered
			Hypoaesthesia	感覚鈍麻	2	N	TE	20	123	N	None	Recovered with sequelae
			Radiation associated pain	放射線関連痛	3	N	TE	32	55	N	None	Ongoing at study termination / withdrawal
			Radiation associated pain	放射線関連痛	2	N	TE	86		N	None	Ongoing at study termination / withdrawal
			Hypoaesthesia	感覚鈍麻	1	N	TE	86	60	N	None	Recovered
			Neuralgia	神経痛	1	N	TE	86	29	N	None	Recovered
			Micturition urgency	尿意切迫	2	N	TE	144	2	N	Not applicable	Recovered
			Micturition urgency	尿意切迫	1	Y	TE	145	5	N	Not applicable	Recovered
			Hydronephrosis	水腎症	3	N	TE	195	39	N	Not applicable	Recovered
003014	Norway	55/M/C	Diarrhoea	下痢	1	N	TE	1		Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	27	86	Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	2	N	TE	126	49	N	Not applicable	Recovered with sequelae
			Nausea	悪心	2	N	TE	140	5	N	None	Recovered
			Nausea	悪心	3	N	TE	144	5	N	None	Recovered
			Nausea	悪心	1	N	TE	148	25	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	174	1	N	Not applicable	Recovered
			Musculoskeletal pain	筋骨格痛	3	Y	TE	174	21	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Insomnia	不眠症	2	N	TE	174		N	Not applicable	Ongoing at time of death
			Tooth extraction	抜歯	2	N	TE	176	1	N	Not applicable	Recovered
			Thrombosis	血栓症	3	N	TE	187		N	Not applicable	Not recovered, but no changes expected
			Musculoskeletal pain	筋骨格痛	3	Y	TE	201	17	N	Not applicable	Recovered with sequelae
			Depression	うつ病	2	N	TE	209		N	Not applicable	Ongoing at study termination / withdrawal
003015	Norway	72/M/C	Constipation	便秘	2	N				N	None	Recovered
			Oral candidiasis	口腔カンジダ症	1	N	TE	15	43	N	None	Recovered
			Sinus tachycardia	洞性頻脈	3	N	TE	57	29	N	None	Not recovered, but no changes expected
			Rib fracture	肋骨骨折	2	Y	TE	82	4	N	None	Recovered with sequelae
			Sinus tachycardia	洞性頻脈	1	N	TE	85		N	None	Not recovered, but no changes expected
			Herpes zoster	帯状疱疹	3	N	TE	98	9	N	None	Recovered
			Herpes zoster	帯状疱疹	1	N	TE	106	36	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	141		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	1	N	TE	160	9	N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	168	9	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	168	9	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cough	咳嗽	1	N	TE	176		N	Not applicable	Ongoing at study termination / withdrawal
003016	Norway	77/M/C	Spinal compression fracture	脊椎圧迫骨折	1	N	TE	95	5	N	None	Recovered
			Constipation	便秘	3	Y	TE	99	2	Y	None	Recovered
			Nausea	悪心	2	N	TE	99	49	N	None	Recovered
			Spinal compression fracture	脊椎圧迫骨折	3	Y	TE	99	7	N	None	Recovered
			Insomnia	不眠症	1	N	TE	99		N	None	Not recovered, but no changes expected
			Constipation	便秘	1	N	TE	100	1	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	105	38	N	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	142	6	N	None	Recovered with sequelae
			Osteoporosis	骨粗鬆症	2	N	TE	143		N	Not applicable	Not recovered, but no changes expected
			Musculoskeletal pain	筋骨格痛	1	N	TE	147		N	None	
			Constipation	便秘	2	N	TE	197		N	Not applicable	Ongoing at study termination / withdrawal
003017	Norway	63/M/C	Nausea	悪心	1	N	TE	4	54	Y	None	Recovered
			Constipation	便秘	2	N	TE	10	48	Y	None	Recovered
			Hyperchlorhydria	胃酸過多	1	N	TE	29		Y	None	Ongoing at study termination / withdrawal
			Constipation	便秘	3	N	TE	57	110	Y	None	Recovered
			Nausea	悪心	2	N	TE	57	110	Y	None	Recovered
			Fatigue	疲労	2	N	TE	84	83	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Musculoskeletal pain	筋骨格痛	2	N	TE	84	23	N	None	Recovered with sequelae
			Cystitis	膀胱炎	2	N	TE	106	11	N	None	Recovered
			Musculoskeletal pain	筋骨格痛	2	Y	TE	106	4	N	None	Recovered with sequelae
			Musculoskeletal pain	筋骨格痛	2	N	TE	109	4	N	None	Recovered
			Musculoskeletal pain	筋骨格痛	3	Y	TE	112	8	N	None	Recovered
			Depression	うつ病	2	N	TE	112	50	N	None	Recovered
			Nausea	悪心	1	N	TE	116	4	Y	None	Recovered
			Anaemia	貧血	2	N	TE	137	1	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	166		N	None	Ongoing at study termination / withdrawal
			Femoral neck fracture	大腿骨頚部骨折	3	Y	TE	191	7	N	Not applicable	Recovered
003018	Norway	71/M/C	Constipation	便秘	2	N	TE			N	Not applicable	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	2	N	TE	2	134	N	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	1	N	TE	57	102	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	116	57	N	Not applicable	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	3	N	TE	135	24	N	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	2	N	TE	147	72	N	Not applicable	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	3	Y	TE	158	5	N	Not applicable	Recovered with sequelae
			Pelvic pain	骨盤痛	3	N	TE	162		Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	2	N	TE	172		N	Not applicable	Ongoing at time of death
			Weight decreased	体重減少	3	N	TE	172		N	Not applicable	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	3	Y	TE	172	38	N	Not applicable	Recovered with sequelae
			Gastric ulcer	胃潰瘍	3	N	TE	181		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	187	1	Y	Not applicable	Recovered
			Depression	うつ病	3	N	TE	208		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	218	1	N	Not applicable	Death
004001	Norway	60/M/C	Dysgeusia	味覚異常	1	N	TE	2	28	Y	None	Recovered
			Anaemia	貧血	1	N	TE	92	24	Y	None	Recovered
			Anaemia	貧血	1	N	TE	92	24	Y	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	92	113	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	120		Y	None	Ongoing at time of death
			Respiratory tract infection viral	ウイルス性気道感染	2	N	TE	134	11	N	None	Recovered
			Anaemia	貧血	2	N	TE	144		Y	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	2	N	TE	148	37	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	148	12	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	148	12	Y	None	Recovered with sequelae

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pancytopenia	汎血球減少症	3	N	TE	155	5	Y	Not applicable	Recovered with sequelae
			Pancytopenia	汎血球減少症	3	Y	TE	159	11	Y	Not applicable	Recovered with sequelae
			Oedema	浮腫	2	Y	TE	159	11	Y	Not applicable	Recovered with sequelae
			Dyspnoea	呼吸困難	3	Y	TE	159	11	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	Y	TE	159	11	Y	Not applicable	Recovered with sequelae
			Pancytopenia	汎血球減少症	2	N	TE	169	16	Y	Not applicable	Recovered with sequelae
			Dyspnoea	呼吸困難	2	N	TE	169	16	Y	Not applicable	Recovered
			Pleural effusion	胸水	1	N	TE	170	15	Y	Not applicable	Recovered
			Pancytopenia	汎血球減少症	3	Y	TE	184	15	Y	Not applicable	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	3	Y	TE	184	15	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	Y	TE	184	15	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	Y	TE	184	15	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	198	7	Y	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	198	7	Y	Not applicable	Recovered with sequelae
			Pancytopenia	汎血球減少症	4	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	204		Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	3	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	3	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Pleural effusion	胸水	2	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Renal failure	腎不全	5	Y	TE	208	1	N	Not applicable	Death
005002	Norway	75/M/C	Bone pain	骨痛	1	N	TE			N	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	85		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	162	36	N	Not applicable	Recovered
			Pneumonia	肺炎	3	Y	TE	169	15	N	Not applicable	Recovered
			Atrial fibrillation	心房細動	2	Y	TE	180	1	N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	197	7	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	198	6	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	1	N	TE	203		Y	Not applicable	Ongoing at time of death
			Pulmonary embolism	肺塞栓症	4	Y	TE	222	5	Y	Not applicable	Death
			Pulmonary embolism	肺塞栓症	5	Y	TE	226	1	Y	Not applicable	Death
006001	Norway	76/M/C	Bone pain	骨痛	2	N	TE	75	20	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	82	13	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary tract infection	尿路感染	3	Y	TE	82	13	N	Drug administration postponed	Recovered
			Bone pain	骨痛	3	N	TE	113	27	N	None	Recovered
			Renal failure	腎不全	3	Y	TE	113	8	N	None	Recovered
			Reflux gastritis	逆流性胃炎	1	N	TE	114		N	None	Recovered
			Anaemia	貧血	2	N	TE	167	2	N	Not applicable	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	167	86	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	167	3	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	1	N	TE	168		N	Not applicable	Ongoing at time of death
			Hypomagnesaemia	低マグネシウム血症	2	N	TE	191	62	N	None	Not recovered, but no changes expected
			Hypomagnesaemia	低マグネシウム血症	1	N	TE	252		N	None	Not recovered, but no changes expected
006004	Norway	53/M/C	Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE			Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	2	15	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	2	4	Y	None	Recovered
			Nausea	悪心	2	N	TE	15	68	Y	None	Recovered
			Anorexia	食欲不振	2	N	TE	56		N	None	Not recovered, but no changes expected
			Insomnia	不眠症	2	N	TE	166		N	None	Not recovered, but no changes expected
			Upper respiratory tract infection	上気道感染	2	Y	TE	180	10	N	Not applicable	Recovered
			Oesophagitis	食道炎	2	N	TE	217		N	Not applicable	Not recovered, but no changes expected

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
006005	Norway	72/M/C	Diarrhoea	下痢	1	N	TE	3	1	Y	None	Recovered
			Pyrexia	発熱	2	Y	TE	22	7	N	None	Recovered
			Dehydration	脱水	2	Y	TE	22	7	N	None	Recovered
			Vomiting	嘔吐	1	Y	TE	38	1	N	None	Recovered
			Pyrexia	発熱	2	Y	TE	38	1	Y	None	Recovered
			Dehydration	脱水	2	Y	TE	38	6	Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	2	Y	TE	38	6	N	None	Recovered
			Vomiting	嘔吐	2	Y	TE	62	11	Y	None	Recovered
			Dehydration	脱水	2	Y	TE	62	11	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	62	11	N	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	85	15	N	None	Recovered with sequelae
			Dyspepsia	消化不良	2	N	TE	86		N	None	Ongoing at time of death
			Depression	うつ病	2	N	TE	99		N	None	Ongoing at time of death
			Pneumonia	肺炎	3	Y	TE	176	2	N	Not applicable	Death
			Bone pain	骨痛	3	Y	TE	176		N	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	5	Y	TE	177	1	N	Not applicable	Death
006008	Norway	70/M/C	Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	Pre	-1	29	N	None	Ongoing at time of death
			Hydronephrosis	水腎症	3	Y	Pre	-1	3	N	None	Recovered
			Constipation	便秘	2	N	TE	2	25	Y	None	Recovered
			Nausea	悪心	1	N	TE	2	6	Y	None	Recovered
			Fatigue	疲労	2	N	TE	2	6	N	None	Recovered
			Hyperhidrosis	多汗症	2	N	TE	2	6	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	17	11	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	Pre	28		N	None	Ongoing at time of death
			Small intestinal obstruction	小腸閉塞	3	Y	TE	55	3	N	Drug administration postponed	Recovered
			Death	死亡	5	Y	TE	60	1	N	Drug permanently withdrawn	Death
006009	Norway	75/M/C	Dizziness	浮動性めまい	1	N	TE			N	None	Recovered
			Diarrhoea	下痢	1	N	TE	2	1	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	2	2	Y	None	Recovered
			Fatigue	疲労	3	Y	TE	16	9	Y	None	Recovered
			Dehydration	脱水	2	N	TE	19	6	Y	None	Recovered
			Influenza	インフルエンザ	1	N	TE	43	8	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	73	12	Y	None	Recovered
			Nausea	悪心	1	N	TE	84	37	N	None	Recovered
			Fatigue	疲労	2	N	TE	84		Y	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	84	29	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	84	29	Y	None	Ongoing at study termination / withdrawal
			Mood altered	気分変化	1	N	TE	84		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	107		N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	112	5	Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	2	N	TE	112		Y	None	Ongoing at study termination / withdrawal
			Cachexia	悪液質	2	N	TE	112		N	Not applicable	Ongoing at study termination / withdrawal
006011	Norway	68/M/C	Weight decreased	体重減少	2	N	TE	2		Y	None	Not recovered, but no changes expected
			Diarrhoea	下痢	1	N	TE	8	10	N	None	Recovered
			Nausea	悪心	1	N	TE	8	10	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	8	10	N	None	Recovered
			Bone pain	骨痛	2	N	TE	28	29	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	36	10	N	None	Recovered
			Nausea	悪心	1	N	TE	36	10	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	36	10	N	None	Recovered
			Bone pain	骨痛	2	N	TE	103	6	N	None	Recovered
			Nausea	悪心	1	N	TE	114	27	Y	None	Recovered
			Fatigue	疲労	1	N	TE	114		Y	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	114	27	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	140	16	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	Y	TE	155	13	N	Not applicable	Recovered with sequelae
			Nausea	悪心	2	N	TE	157	11	N	None	Recovered
			Anaemia	貧血	2	N	TE	225		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	225	64	N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	225	4	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	4	N	TE	288		N	Not applicable	Ongoing at time of death
006016	Norway	59/M/C	Thrombocytopenia	血小板減少症	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	92	8	N	None	Recovered
			Venous thrombosis	静脈血栓症	2	N	TE	105		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	132		N	None	Ongoing at time of death
			Prostatic haemorrhage	前立腺出血	3	Y	TE	132	29	N	Drug administration postponed	Recovered
			Bone pain	骨痛	2	N	TE	141		N	None	Ongoing at time of death
			Catheter related infection	カテーテル関連感染	3	Y	TE	166		N	Drug permanently withdrawn	Recovered
006017	Norway	59/M/C	Nausea	悪心	1	N	TE	10	3	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	10	1	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	10	75	N	None	Recovered
			Bone pain	骨痛	2	N	TE	10	75	N	None	Recovered
			Anaemia	貧血	3	Y	TE	84	6	Y	-	
			Thrombocytopenia	血小板減少症	4	Y	TE	84	58	Y	Drug permanently withdrawn	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	84		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	Y	TE	89	3	Y	-	
			Anaemia	貧血	2	Y	TE	91	8	Y	-	

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	98	13	Y	-	
			Anaemia	貧血	2	Y	TE	110	2	Y	-	
			Anaemia	貧血	3	Y	TE	111	2	Y	-	
			Anaemia	貧血	2	Y	TE	112	2	Y	-	
			Anaemia	貧血	1	Y	TE	113	2	Y	-	
			Cerebral haemorrhage	脳出血	2	Y	TE	113		Y	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	114	19	Y	-	
			Anaemia	貧血	1	Y	TE	132	3	Y	-	
			Anaemia	貧血	2	Y	TE	134	2	Y	-	
			Anaemia	貧血	1	Y	TE	135	2	Y	-	
			Anaemia	貧血	2	Y	TE	136	3	Y	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	1	Y	TE	138	3	Y	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	140		Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	Y	TE	141	2	Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	Y	TE	142		Y	Drug permanently withdrawn	Ongoing at time of death
006018	Norway	62/M/C	Pyrexia	発熱	2	N	TE	25	2	Y	None	Recovered
			Pyrexia	発熱	1	N	TE	26	2	Y	None	Recovered
			Weight decreased	体重減少	1	N	TE	33	29	N	None	Not recovered, but no changes expected
			Nausea	悪心	2	N	TE	37	2	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	2	N	TE	37	2	N	None	Recovered
			Pyrexia	発熱	2	Y	TE	37	8	Y	None	Recovered
			Anaemia	貧血	2	N	TE	40	3	Y	None	Recovered
			Nausea	悪心	2	N	TE	48	29	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	48	2	N	None	Recovered
			Pyrexia	発熱	2	Y	TE	49	21	Y	None	Recovered
			Anaemia	貧血	2	N	TE	59	2	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	61		N	None	Not recovered, but no changes expected
			Pyrexia	発熱	2	Y	TE	76	2	Y	None	Recovered with sequelae
			Dyspnoea	呼吸困難	1	N	TE	76	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	89	2	N	None	Recovered
			Bone pain	骨痛	2	N	TE	89	26	N	None	Recovered
			Anaemia	貧血	2	N	TE	114	20	N	-	
			Pyrexia	発熱	2	N	TE	114	4	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	114	7	N	None	Recovered
			Pyrexia	発熱	2	N	TE	120		Y	None	Recovered
			Spinal cord compression	脊髄圧迫	2	Y	TE	132	7	N	None	Recovered
			Anaemia	貧血	1	N	TE	133	1	N	-	
			Anaemia	貧血	2	N	TE	133	9	N	-	
			Anaemia	貧血	1	N	TE	141	28	N	-	
			Anaemia	貧血	2	N	TE	168	9	N	-	
			Leukopenia	白血球減少症	2	N	TE	168	15	N	None	Recovered
			Neutropenia	好中球減少症	1	N	TE	168	14	N	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	168	31	N	None	Recovered
			Anaemia	貧血	1	N	TE	176	7	N	-	
			Anorexia	食欲不振	1	N	TE	176	14	N	None	Recovered
			Bone pain	骨痛	2	N	TE	176	14	N	None	Recovered
			Bone pain	骨痛	2	N	TE	176	54	N	None	Recovered
			Diplopia	複視	2	N	TE	177	53	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	181	10	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	TE	182	8	N	-	
			Leukopenia	白血球減少症	1	N	TE	182	8	N	None	Recovered
			Pyrexia	発熱	2	N	TE	182	1	Y	None	Recovered
			Pyrexia	発熱	1	N	TE	182	5	Y	None	Recovered
			Anaemia	貧血	1	N	TE	189	10	N	-	
			Leukopenia	白血球減少症	3	N	TE	189	41	N	None	Recovered
			Neutropenia	好中球減少症	2	N	TE	189	10	N	None	Recovered
			Bone pain	骨痛	1	N	TE	190	40	N	None	Recovered
			Anaemia	貧血	2	N	TE	198	35	N	None	Not recovered, but no changes expected
			Neutropenia	好中球減少症	3	N	TE	198	32	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	198	32	N	None	Recovered
			Diplopia	複視	1	N	TE	229		N	None	Recovered
			Anaemia	貧血	1	N	TE	232		N	None	Not recovered, but no changes expected
006020	Norway	77/M/C	Nausea	悪心	1	N	TE			N	None	Recovered
			Anorexia	食欲不振	1	N	TE	28	134	N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	64	36	N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	2	N	TE	99		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	161		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	198	22	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	TE	205	6	N	Not applicable	Not recovered, but no changes expected

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	210		N	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	219		N	None	Not recovered, but no changes expected
			Constipation	便秘	2	N	TE	232	3	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	232	4	N	Not applicable	Recovered with sequelae
006024	Norway	67/M/C	Gastrointestinal pain	消化器痛	3	Y	Pre	-9	2	N	None	Recovered
			Constipation	便秘	2	N	Pre	-1	29	N	None	Recovered
			Fatigue	疲労	2	N	TE	28	92	N	None	Recovered
			Arthralgia	関節痛	1	N	TE	91	29	N	None	Not recovered, but no changes expected
			Paraesthesia	錯感覚	1	N	TE	91	29	N	None	Recovered
			Arthralgia	関節痛	2	N	TE	119	36	N	None	Not recovered, but no changes expected
			Arthralgia	関節痛	1	N	TE	154		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	182	64	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	245		N	None	Not recovered, but no changes expected
006026	Norway	71/M/C	Nausea	悪心	1	N	TE			Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	2	8	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	55	10	N	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	64	11	N	None	Recovered with sequelae

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	70	3	Y	-	Ongoing at study termination / withdrawal
			Insomnia	不眠症	2	N	TE	71		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	72		Y	-	Ongoing at study termination / withdrawal
			Accidental overdose	偶発的過量投与	2	Y	TE	75	2	N	None	Recovered
			Infection	感染	3	N	TE	87		N	Not applicable	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	Y	TE	87		N	None	Ongoing at study termination / withdrawal
			Confusional state	錯乱状態	2	N	TE	87		N	None	Ongoing at study termination / withdrawal
006030	Norway	64/M/C	Insomnia	不眠症	1	N	TE			N	None	Lost to follow-up
			Spinal cord compression	脊髄圧迫	3	Y	TE	12	7	N	Drug administration postponed	Recovered
			Weight decreased	体重減少	2	N	TE	47	57	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	62	14	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	103	29	N	None	Recovered
			Bone pain	骨痛	1	N	TE	103		Y	None	Ongoing at study termination / withdrawal
			Leukopenia	白血球減少症	2	N	TE	131	29	Y	None	Recovered
			Neutropenia	好中球減少症	2	N	TE	131	29	Y	None	Recovered
			Leukopenia	白血球減少症	1	N	TE	159	92	Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neutropenia	好中球減少症	1	N	TE	159	31	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	159		Y	None	Ongoing at study termination / withdrawal
			Metastases to central nervous system	中枢神経系転移	3	Y	TE	184	27	N	Not applicable	Recovered with sequelae
			Nausea	悪心	2	N	TE	195		N	Not applicable	Recovered
			Vomiting	嘔吐	2	N	TE	195		N	Not applicable	Recovered
			Dysarthria	構語障害	2	N	TE	195	16	N	Not applicable	Recovered
006032	Norway	77/M/C	Musculoskeletal pain	筋骨格痛	1	Y	Pre	-5	2	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	N	Pre	-1	29	N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	28		N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	1	N	TE	30	62	N	None	Recovered
			Nausea	悪心	1	N	TE	31	4	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	31	4	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	91		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	91	65	N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	92	64	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	119	37	N	None	Recovered
			Urinary retention	尿閉	2	N	TE	119		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	155		N	None	Ongoing at time of death
006036	Norway	76/M/C	Patella fracture	膝蓋骨骨折	2	Y	TE	12	2	N	None	Recovered with sequelae
			Patella fracture	膝蓋骨骨折	2	N	TE	13	16	N	None	Recovered
			Anaemia	貧血	1	N	TE	28	85	N	-	
			Neutropenia	好中球減少症	1	N	TE	28	113	N	None	Recovered
			Nausea	悪心	2	N	TE	28	29	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	28	57	N	None	Recovered
			Anorexia	食欲不振	2	N	TE	28	85	N	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	56		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	56	85	N	None	Recovered with sequelae
			Oedema genital	性器浮腫	2	N	TE	80	5	N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	84	57	N	None	Recovered
			Oedema genital	性器浮腫	1	N	TE	84	57	N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	112	72	N	-	
			Nausea	悪心	1	N	TE	140		N	None	Ongoing at time of death
			Localised oedema	限局性浮腫	1	N	TE	140	18	N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	140	18	N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	140		N	None	Ongoing at time of death
			Oedema genital	性器浮腫	2	N	TE	140		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Lymphadenopathy mediastinal	縦隔リンパ節腫脹	2	N	TE	154		N	None	Ongoing at time of death
			Metastases to lung	肺転移	2	N	TE	154		N	None	Ongoing at time of death
			Localised oedema	限局性浮腫	2	N	TE	157		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	157		N	None	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	TE	170	8	N	None	Recovered
			Anaemia	貧血	1	N	TE	183	15	N	-	
			Pleural effusion	胸水	2	N	TE	196	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	197	5	N	-	
			Haematuria	血尿	3	Y	TE	197	21	N	Not applicable	Recovered
			Pneumonia	肺炎	2	N	TE	200	19	N	None	Recovered
			Anaemia	貧血	1	N	TE	201	2	N	-	
			Anaemia	貧血	2	N	TE	202	2	N	-	
			Anaemia	貧血	1	N	TE	203	4	N	-	
			Anaemia	貧血	2	N	TE	206	3	N	-	
			Anaemia	貧血	1	N	TE	208	5	N	-	
			Anaemia	貧血	2	N	TE	212	2	N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	213		N	None	Ongoing at time of death
006038	Norway	60/M/C	Bone pain	骨痛	3	Y	Pre	-46	3	N	Not applicable	Recovered
			Pyelonephritis	腎盂腎炎	3	Y	TE	61	10	N	None	Recovered
			Constipation	便秘	2	N	TE	63		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	64	2	N	-	

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	65	13	N	-	
			Anaemia	貧血	2	N	TE	77	28	N	-	
			Vomiting	嘔吐	2	N	TE	77	3	Y	None	Recovered
			General physical health deterioration	全身健康状態低下	3	Y	TE	77	16	N	Drug administration postponed	Recovered with sequelae
			Infection	感染	3	Y	TE	77	16	N	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	78	18	N	Not applicable	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	78	18	N	None	Recovered with sequelae
			Pyrexia	発熱	1	N	TE	79	8	Y	None	Recovered
			Pyrexia	発熱	2	N	TE	86	2	Y	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	90		N	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	2	N	TE	95	7	N	Not applicable	Ongoing at study termination / withdrawal
			Pyrexia	発熱	1	N	TE	95	3	Y	None	Recovered
			Bone pain	骨痛	3	Y	TE	95	11	N	None	Recovered with sequelae
			Pyrexia	発熱	2	N	TE	97	4	Y	None	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	101		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	N	TE	104		N	Not applicable	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	105		N	None	Ongoing at study termination / withdrawal
006039	Norway	72/M/C	Nausea	悪心	1	N	TE	2	8	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	72	36	N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	82	26	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	99	34	N	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	2	N	TE	99		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	111	11	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	111	11	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	111	11	N	None	Recovered
			Constipation	便秘	2	N	TE	131	7	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	N	TE	131		N	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	Y	TE	131		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Urinary retention	尿閉	2	N	TE	131		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	N	TE	132	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	133	9	N	None	Recovered
006040	Norway	72/M/C	Pain	疼痛	1	N	Pre	-1	29	N	None	Recovered
			Bone pain	骨痛	2	N	TE	84	14	N	None	Recovered with sequelae

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	97	4	N	None	Recovered with sequelae
			Insomnia	不眠症	2	N	TE	97		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	98	5	N	None	Recovered
			Bone pain	骨痛	2	N	TE	99	9	Y	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	102	5	N	None	Recovered
			Vomiting	嘔吐	2	Y	TE	102	10	N	None	Recovered
			Infection	感染	3	N	TE	102	6	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	105	7	N	None	Recovered
			Nausea	悪心	1	N	TE	106	6	N	None	Recovered
			Infection	感染	2	N	TE	107	3	N	None	Recovered
			Bone pain	骨痛	1	N	TE	107		Y	None	Ongoing at study termination / withdrawal
			Infection	感染	1	N	TE	109	3	N	None	Recovered
			Nausea	悪心	2	N	TE	117	5	Y	None	Recovered
			Vomiting	嘔吐	2	Y	TE	117	8	N	None	Recovered
			Infection	感染	3	N	TE	117	5	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	119		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	121	9	Y	None	Recovered
			Infection	感染	2	N	TE	121	11	Y	None	Recovered
			Duodenitis	十二指腸炎	1	N	TE	124		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	129	3	Y	None	Recovered
			Vomiting	嘔吐	2	Y	TE	129	3	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	2	N	TE	136		Y	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	3	Y	TE	136		N	None	Ongoing at study termination / withdrawal
			Infection	感染	2	N	TE	136		N	None	Ongoing at study termination / withdrawal
			Hypomagnesaemia	低マグネシウム血症	1	N	TE	138		N	None	Ongoing at study termination / withdrawal
			Constipation	便秘	2	N	TE	140		Y	None	Ongoing at study termination / withdrawal
			Pulmonary oedema	肺水腫	2	N	TE	141	3	N	None	Recovered
006041	Norway	56/M/C	Nausea	悪心	1	N	TE	1	8	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	8	161	Y	None	Recovered
			Nausea	悪心	1	N	TE	29	19	Y	None	Recovered
			Nausea	悪心	1	N	TE	65	14	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	65	14	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	98	71	Y	None	Recovered
			Nausea	悪心	1	N	TE	99	4	Y	None	Recovered
			Pneumonia	肺炎	2	Y	TE	104	6	N	None	Recovered
			Nausea	悪心	1	N	TE	135	59	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	135	35	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	169	25	Y	None	Recovered
			Pyrexia	発熱	1	N	TE	173	4	Y	Not applicable	Recovered
			Infection	感染	2	Y	TE	173	8	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	173	4	N	Not applicable	Recovered
			Leukopenia	白血球減少症	2	N	TE	176	21	Y	Not applicable	Recovered
			Neutropenia	好中球減少症	1	N	TE	177	2	Y	Not applicable	Recovered
			Neutropenia	好中球減少症	2	N	TE	178	19	Y	Not applicable	Recovered
			Leukopenia	白血球減少症	1	N	TE	196	48	Y	Not applicable	Recovered
			Neutropenia	好中球減少症	1	N	TE	196	48	Y	Not applicable	Recovered
			Pyrexia	発熱	1	N	TE	243	4	N	Not applicable	Recovered
			Infection	感染	3	Y	TE	243	38	N	Not applicable	Recovered
			Cough	咳嗽	1	N	TE	243	4	N	Not applicable	Recovered
			Hypotension	低血圧	2	N	TE	243	1	N	Not applicable	Recovered
006046	Norway	76/M/C	Dizziness	浮動性めまい	1	N	TE			N	Not applicable	Recovered
			Anaemia	貧血	1	N	Pre	-1	59	N	None	
			Bone pain	骨痛	1	N	TE	28	57	N	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	56	3	Y	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	58	5	N	None	
			Leukopenia	白血球減少症	2	N	TE	58	3	Y	None	Recovered
			Nausea	悪心	2	N	TE	58	3	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	58	2	Y	None	Recovered
			Pyrexia	発熱	3	Y	TE	58	3	Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pyrexia	発熱	1	N	TE	58	2	N	None	Recovered
			Dyspnoea	呼吸困難	2	Y	TE	58	3	Y	None	Recovered with sequelae
			Cardiomegaly	心拡大	2	N	TE	59	39	N	None	Recovered
			Leukopenia	白血球減少症	3	N	TE	60	3	Y	None	Recovered
			Neutropenia	好中球減少症	3	Y	TE	60	3	Y	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	60	25	N	None	Recovered
			Anaemia	貧血	1	N	TE	62	126	N	None	
			Leukopenia	白血球減少症	1	N	TE	62	23	Y	None	Recovered
			Hypertension	高血圧	2	N	TE	97	77	N	None	Recovered
			Anaemia	貧血	2	N	TE	187	2	N	-	
			Abdominal pain	腹痛	3	Y	TE	187	4	N	Not applicable	Recovered
			Diarrhoea	下痢	2	N	TE	187	3	N	Not applicable	Recovered
			Rectal haemorrhage	直腸出血	2	N	TE	187	4	N	Not applicable	Recovered
			Vomiting	嘔吐	2	N	TE	187	3	N	Not applicable	Recovered
			Chills	悪寒	2	N	TE	187	3	N	Not applicable	Recovered
			Anaemia	貧血	1	N	TE	188	1	N	-	
			Anaemia	貧血	2	N	TE	188	2	N	-	
			Infection	感染	2	N	TE	188	3	N	Not applicable	Recovered
			Anaemia	貧血	1	N	TE	189		N	Not applicable	Not recovered, but no changes expected
			Diarrhoea	下痢	1	N	TE	189	2	N	Not applicable	Recovered
			Pyrexia	発熱	2	N	TE	193	4	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Infection	感染	3	Y	TE	193	19	N	Not applicable	Recovered
			Pyrexia	発熱	1	N	TE	196	3	N	Not applicable	Recovered
			Pyrexia	発熱	2	N	TE	202		N	Not applicable	Recovered
006047	Norway	73/M/C	Nausea	悪心	1	N	TE	2	23	N	None	Recovered
			Nausea	悪心	1	N	TE	28	21	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	55	22	Y	-	
			Nausea	悪心	1	N	TE	57	27	Y	None	Recovered
			Nerve root compression	神経根圧迫	3	Y	TE	76	6	N	None	Recovered
			Bone pain	骨痛	1	N	TE	81		N	None	Not recovered, but no changes expected
			Oedema peripheral	末梢性浮腫	1	N	TE	111		N	None	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	1	N	TE	111	57	N	None	Recovered
			Epigastric discomfort	心窩部不快感	1	N	TE	167	43	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	167	43	Y	Not applicable	Recovered
006052	Norway	73/M/C	Constipation	便秘	2	N	TE	14	2	N	None	Recovered
			Hydronephrosis	水腎症	3	Y	TE	14	5	N	None	Recovered
			Urinary retention	尿閉	2	N	TE	27	1	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	70	6	N	None	Recovered
			Nausea	悪心	2	N	TE	70	4	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	70	4	N	None	Recovered
			Pyrexia	発熱	1	N	TE	70	4	N	None	Recovered
			Sepsis	敗血症	3	Y	TE	70	6	N	None	Recovered
			Anaemia	貧血	2	N	TE	71	2	Y	None	
			Thrombocytopenia	血小板減少症	1	N	TE	71	3	Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hypokalaemia	低カリウム血症	1	N	TE	71	4	N	None	Recovered
			Anaemia	貧血	1	N	TE	72	40	Y	None	
			Weight decreased	体重減少	2	N	TE	83	29	N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	111	29	Y	None	
			Thrombocytopenia	血小板減少症	1	N	TE	111	85	N	None	Not recovered, but no changes expected
			Oedema peripheral	末梢性浮腫	1	N	TE	111	83	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	111	29	N	None	Not recovered, but no changes expected
			Urinary retention	尿閉	3	Y	TE	131	4	N	None	Recovered
			Anaemia	貧血	1	N	TE	139	28	Y	None	
			Weight decreased	体重減少	2	N	TE	139		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	166	28	Y	None	
			Bone pain	骨痛	1	N	TE	167	21	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	187	18	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	3	N	TE	193	3	Y	None	
			Leukopenia	白血球減少症	3	N	TE	193	3	Y	Not applicable	Recovered
			Neutropenia	好中球減少症	2	N	TE	193	3	Y	Not applicable	Recovered
			Chills	悪寒	2	N	TE	193	1	N	Not applicable	Recovered
			Fatigue	疲労	3	N	TE	193	2	N	Not applicable	Not recovered, but no changes expected
			Pyrexia	発熱	3	N	TE	193	1	N	Not applicable	Recovered
			Pyrexia	発熱	2	N	TE	193	5	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urosepsis	尿路性敗血症	3	Y	TE	193	12	N	Not applicable	Recovered
			Fatigue	疲労	2	N	TE	194		N	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	195	3	N	Not applicable	Not recovered, but no changes expected
			Leukopenia	白血球減少症	1	N	TE	195	3	Y	Not applicable	Recovered
			Neutropenia	好中球減少症	1	N	TE	195	3	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	195	11	N	None	Not recovered, but no changes expected
			Anaemia	貧血	1	N	TE	197		N	Not applicable	Not recovered, but no changes expected
			Pyrexia	発熱	1	N	TE	197		N	Not applicable	Recovered
			Bone pain	骨痛	2	Y	TE	204	5	N	Not applicable	Recovered with sequelae
			Thrombocytopenia	血小板減少症	1	N	TE	205		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	208		N	Not applicable	Not recovered, but no changes expected
006055	Norway	63/M/C	Petechiae	点状出血	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Nerve root compression	神経根圧迫	3	Y	Pre	-33	4	N	None	Recovered
			Groin pain	鼠径部痛	2	N	Pre	-2	3	N	None	Recovered
			Nerve root compression	神経根圧迫	3	Y	TE	1	4	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	1	4	N	None	Recovered
			Pyrexia	発熱	1	N	TE	23	3	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	3	Y	TE	24	4	N	None	Recovered with sequelae
			Hypoalbuminaemia	低アルブミン血症	2	N	TE	24	4	N	None	Ongoing at study termination / withdrawal
			Hypoaesthesia	感覚鈍麻	1	N	TE	24		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	27	8	N	None	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	2	N	TE	27	8	N	None	Ongoing at study termination / withdrawal
			Hypoalbuminaemia	低アルブミン血症	1	N	TE	27		N	None	Ongoing at study termination / withdrawal
			Cardiac failure	心不全	2	N	TE	28		N	None	Ongoing at study termination / withdrawal
			Pyrexia	発熱	1	N	TE	28	2	N	None	Recovered
			Pneumonia	肺炎	3	Y	TE	28	6	N	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	28	7	N	None	Recovered
			Pleural effusion	胸水	2	N	TE	28	7	N	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	30	3	N	None	Recovered
			Pulmonary hypertension	肺高血圧症	2	N	TE	32		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	34	5	N	None	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	1	N	TE	34		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	38	31	N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	52	18	N	None	Ongoing at study termination / withdrawal
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	Y	TE	52	3	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	53	11	N	None	Recovered
			Thrombocytopenia	血小板減少症	4	Y	TE	66	2	Y	Drug administration postponed	Recovered with sequelae
			Hypokalaemia	低カリウム血症	1	N	TE	66		N	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	Y	TE	66		N	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	3	N	TE	67	4	N	None	Ongoing at study termination / withdrawal
			Urinary tract infection	尿路感染	1	N	TE	67		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	N	TE	68		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	69		N	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	3	N	TE	70		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	4	N	TE	70	1	N	None	Ongoing at study termination / withdrawal
			General physical health deterioration	全身健康状態低下	3	N	TE	71		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	84	1	N	Not applicable	Death
008001	Norway	66/M/C	Haemorrhoids	痔核	1	N	TE			N	None	Recovered
			Decreased appetite	食欲減退	2	N	TE			N	None	Ongoing at time of death
			Depressed mood	抑うつ気分	2	N	TE			N	None	Ongoing at time of death
			Pathological fracture	病的骨折	3	Y	Pre	-48	14	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	Pre	-26	15	Y	-	
			Post procedural infection	処置後感染	3	Y	Pre	-26	29	N	Drug administration postponed	Recovered
			Nausea	悪心	1	N	Pre	-20	77	N	None	Recovered
			Vomiting	嘔吐	1	N	Pre	-20	77	N	None	Recovered
			Anaemia	貧血	1	N	Pre	-12	4	Y	-	
			Anaemia	貧血	2	N	Pre	-9	86	Y	-	
			Soft tissue infection	軟部組織感染	2	N	TE	3		N	None	Recovered
			Nausea	悪心	2	N	TE	57	14	N	None	Recovered
			Fatigue	疲労	2	N	TE	57		N	None	Ongoing at time of death
			Nausea	悪心	2	Y	TE	70	11	N	None	Recovered
			Anaemia	貧血	1	N	Pre	77	51	Y	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	86	7	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	92		N	Not applicable	Ongoing at time of death
			Pyrexia	発熱	2	N	TE	112	1	N	None	Recovered
			Anaemia	貧血	2	N	Pre	127		Y	None	Ongoing at time of death
008003	Norway	79/M/C	Nausea	悪心	2	N	Pre	1	25	N	None	Recovered
			Nausea	悪心	2	Y	TE	25	4	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	25		N	None	Ongoing at time of death
			Hypercalcaemia	高カルシウム血症	1	N	TE	25	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	27	2	Y	None	Recovered
			Nausea	悪心	2	N	TE	28		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	35	25	N	Drug permanently withdrawn	Recovered
			Dehydration	脱水	2	N	TE	51		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	59	1	N	Not applicable	Death
008007	Norway	62/M/C	Fatigue	疲労	1	N	TE			N	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE			N	Not applicable	Recovered
			Anaemia	貧血	1	N	Pre	1	85	Y	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	21	78	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	85	16	Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	98		N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	98	13	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	99	1	N	Not applicable	Recovered
			Anaemia	貧血	1	N	TE	100		Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	106		N	Not applicable	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	106	1	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	110		N	Not applicable	Ongoing at time of death
			Infection	感染	3	Y	TE	112	6	N	Not applicable	Recovered
008008	Norway	74/M/C	Anorexia	食欲不振	1	N	TE			Y	None	Not recovered, but no changes expected
			Fatigue	疲労	2	N	Pre	-1		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	1		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	29	40	Y	None	Recovered
			Anorexia	食欲不振	2	N	TE	29		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	3	Y	TE	68	1	Y	None	Recovered
			Anaemia	貧血	2	N	TE	68	78	Y	-	
			Atrial fibrillation	心房細動	3	N	TE	68	1	Y	None	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	131	38	Y	-	

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Leukopenia	白血球減少症	2	N	TE	141	14	Y	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	145	1	Y	-	
			Anaemia	貧血	2	N	TE	145	16	Y	-	
			Leukopenia	白血球減少症	1	N	TE	154	7	Y	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	160	7	Y	-	
			Leukopenia	白血球減少症	2	N	TE	160	35	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	166	18	Y	-	
			Thrombocytopenia	血小板減少症	4	N	TE	168	7	Y	-	
			General physical health deterioration	全身健康状態低下	2	Y	TE	168	2	Y	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	169		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	174	28	Y	-	
			Anaemia	貧血	3	N	TE	183	7	Y	-	
			Anaemia	貧血	2	N	TE	189	13	Y	-	
			Anaemia	貧血	1	N	TE	201	8	Y	-	
			Thrombocytopenia	血小板減少症	4	N	TE	201	39	Y	-	
			Anaemia	貧血	2	N	TE	208	31	Y	-	
			Leukopenia	白血球減少症	3	N	Post	236	2	Y	-	
			Leukopenia	白血球減少症	2	N	Post	237	17	Y	-	
			Anaemia	貧血	1	N	TE	238	2	Y	-	
			Anaemia	貧血	2	N	TE	239	15	Y	-	
			Thrombocytopenia	血小板減少症	3	N	TE	239	7	Y	-	
			Thrombocytopenia	血小板減少症	4	N	TE	245	16	Y	-	
			Anaemia	貧血	1	N	TE	253	5	Y	-	
			Leukopenia	白血球減少症	3	N	Post	253	11	Y	-	
			Anaemia	貧血	2	N	TE	257	2	Y	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	258	13	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	260	3	Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	262		Y	Drug permanently withdrawn	Ongoing at time of death
			Leukopenia	白血球減少症	4	N	Post	263	5	Y	Not applicable	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	Post	267	4	Y	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	270		Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	Post	270		Y	Not applicable	Ongoing at time of death
008011	Norway	69/M/C	Nausea	悪心	1	N	TE			N	None	Recovered
			Vomiting	嘔吐	1	N	TE			N	None	Recovered
			Fatigue	疲労	1	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE	2	2	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	2	2	N	None	Recovered
			Tendonitis	腱炎	2	N	TE	35		N	None	Recovered
			Constipation	便秘	1	N	TE	37		N	None	Recovered
			Nausea	悪心	1	N	TE	37	5	N	None	Recovered
			Musculoskeletal stiffness	筋骨格硬直	2	N	TE	99	15	N	None	Recovered
			Pharyngitis	咽頭炎	1	N	TE	138	3	N	None	Recovered
			Pathological fracture	病的骨折	2	N	TE	149		N	Not applicable	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	149	9	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Spinal cord compression	脊髄圧迫	2	N	TE	157	10	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	166	6	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	167	22	N	None	Recovered
			Spinal cord compression	脊髄圧迫	3	N	TE	171	42	N	Not applicable	Ongoing at time of death
			Subileus	亜イレウス	2	Y	TE	181	4	N	Not applicable	Recovered
			Oesophageal pain	食道痛	1	N	TE	198	1	N	Not applicable	Recovered
			Cystitis	膀胱炎	1	N	TE	201	11	N	Not applicable	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	212	1	N	Not applicable	Death
008013	Norway	77/M/C	Weight decreased	体重減少	2	N	TE	15		Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	1	N	TE	29		N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	29	50	N	None	Recovered
			Nausea	悪心	1	N	TE	57	22	N	None	Recovered
			Pathological fracture	病的骨折	2	N	TE	73		N	None	Not recovered, but no changes expected
			Atrial fibrillation	心房細動	3	Y	TE	221	5	N	Not applicable	Recovered
008015	Norway	63/M/C	Vomiting	嘔吐	1	N	TE			N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	2	N	TE			N	None	Not recovered, but no changes expected
			Diarrhoea	下痢	1	N	TE	1	9	Y	None	Recovered
			Nausea	悪心	1	N	TE	1	9	Y	None	Recovered
			Skin laceration	皮膚裂傷	2	N	TE	28	1	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	29		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	74	45	N	None	Not recovered, but no changes expected
			Constipation	便秘	2	N	TE	114		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	116	3	N	None	Recovered
			Nausea	悪心	2	N	TE	117	29	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	118	8	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	125		N	None	Not recovered, but no changes expected
			Nausea	悪心	3	Y	TE	145	10	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	154		N	Not applicable	Not recovered, but no changes expected
			Urinary retention	尿閉	1	N	TE	180	1	N	Not applicable	Recovered
010008	Czech Republic	75/M/C	Viral infection	ウイルス感染	1	N	TE	84	8	N	None	Recovered
			Anaemia	貧血	3	N	TE	91	13	N	Drug permanently withdrawn	Recovered with sequelae
			Leukopenia	白血球減少症	2	N	TE	91	127	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	98	52	N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	2	N	TE	98	21	N	Not applicable	Recovered
			Anaemia	貧血	3	Y	TE	103	12	N	Drug permanently withdrawn	Recovered with sequelae

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	114	266	N	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	149	69	N	None	Recovered
011006	Czech Republic	68/M/C	Diarrhoea	下痢	1	N	TE	2	11	Y	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	150	256	Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	Y	TE	405		Y	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	4	Y	Post	405	2	Y	Not applicable	Death
			Pneumonia	肺炎	5	Y	Post	406	1	Y	Not applicable	Death
012001	Czech Republic	60/M/C	Blood testosterone abnormal	血中テストステロン異常	1	Y	Pre	-35	4	N	None	Recovered
			Anaemia	貧血	3	Y	TE	169	2	Y	Not applicable	Recovered
017003	Czech Republic	80/M/C	Cachexia	悪液質	4	Y	TE	115	10	N	None	Death
			Pneumonitis	肺臓炎	3	N	TE	115		N	None	Ongoing at time of death
			Cachexia	悪液質	5	Y	TE	124	1	N	None	Death
017004	Czech Republic	83/M/C	Angina pectoris	狭心症	3	Y	TE	105	15	N	None	Recovered with sequelae
			Depression	うつ病	2	N	TE	105	8	N	Drug administration postponed	Recovered
			Angina pectoris	狭心症	2	N	TE	119	184	N	None	Death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hypokalaemia	低カリウム血症	1	N	TE	119		N	None	Not recovered, but no changes expected
			Angina pectoris	狭心症	5	Y	TE	302	1	N	None	Death
017005	Czech Republic	80/M/C	Anaemia	貧血	4	Y	TE	168	7	N	Not applicable	Recovered
			Anorexia	食欲不振	1	N	TE	174		N	None	Not recovered, but no changes expected
017007	Czech Republic	80/M/C	Malignant neoplasm progression	悪性新生物進行	4	Y	TE	178	3	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	180	1	N	Not applicable	Death
017017	Czech Republic	77/M/C	General physical health deterioration	全身健康状態低下	4	Y	TE	151	2	N	Not applicable	Death
			General physical health deterioration	全身健康状態低下	5	Y	TE	152	1	N	Not applicable	Death
017018	Czech Republic	76/M/C	Bone pain	骨痛	1	Y	Pre	-61	10	N	None	Recovered
			Myocardial ischaemia	心筋虚血	4	Y	TE	146		N	Not applicable	Ongoing at time of death
			Myocardial infarction	心筋梗塞	5	Y	TE	154	1	N	Not applicable	Death
017027	Czech Republic	60/M/C	Anaemia	貧血	2	N	TE	79	43	N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	116	6	N	Drug permanently withdrawn	Death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	121	1	N	Drug permanently withdrawn	Death
017030	Czech Republic	86/M/C	Leukopenia	白血球減少症			TE			N	None	Recovered
			Anaemia	貧血	2	N	Pre	1		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	28		N	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	Y	TE	50	8	N	None	Recovered
			Thrombocytopenia	血小板減少症	3	Y	TE	50	8	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	Y	TE	57		N	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	5	Y	TE	59	1	N	None	Death
017031	Czech Republic	71/M/C	Duodenal ulcer	十二指腸潰瘍	2	Y	TE	155	6	N	Not applicable	Recovered
			Intervertebral disc disorder	椎間板障害	2	N	TE	202	16	N	Not applicable	Not recovered, but no changes expected
			Intervertebral disc disorder	椎間板障害	3	N	TE	217		N	Not applicable	Not recovered, but no changes expected
017032	Czech Republic	57/M/C	Malignant neoplasm progression	悪性新生物進行	5	Y	TE	97	1	N	None	Death
018004	Czech Republic	62/M/C	Bone pain	骨痛	2	N	TE	19	18	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	1	N	TE	19		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Gastritis	胃炎	1	Y	TE	127	4	N	None	Recovered
			Pancytopenia	汎血球減少症	4	Y	TE	169	44	Y	Not applicable	Recovered
			Gastritis	胃炎	1	N	TE	169		N	None	Ongoing at time of death
			Metastases to central nervous system	中枢神経系転移	3	N	TE	178		N	None	Ongoing at time of death
020005	Sweden	71/M/C	Anorexia	食欲不振	2	N	TE			N	None	Ongoing at time of death
			Micturition urgency	尿意切迫	2	N	Pre			N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	1	4	Y	None	Recovered
			Fatigue	疲労	2	N	TE	1		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	1		Y	None	Not recovered, but no changes expected
			Musculoskeletal pain	筋骨格痛	1	N	TE	1	4	Y	None	Recovered
			Haematuria	血尿	2	N	TE	11		N	None	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	17	3	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	33	5	Y	None	Recovered
			Constipation	便秘	3	N	TE	39		N	None	Ongoing at study termination / withdrawal
			Chills	悪寒	1	N	TE	54		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	Y	TE	75	14	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	91	22	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	112	1	N	Drug permanently withdrawn	Death
020015	Sweden	74/M/C	Nausea	悪心	1	N	Pre			N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE			N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	N	TE			Y	None	Ongoing at time of death
			Myalgia	筋痛	1	N	Pre			N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE			Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	19		Y	None	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	3	Y	TE	28	15	Y	Drug administration postponed	Recovered with sequelae
			Constipation	便秘	2	N	TE	28		Y	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	28	15	Y	None	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	1	N	TE	42		Y	None	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE	42		Y	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	106	5	N	Drug permanently withdrawn	Death
021002	Sweden	63/M/C	Vomiting	嘔吐	1	N	TE	2	49	N	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	26	10	N	None	Recovered
			Cough	咳嗽	1	N	TE	26		N	None	Recovered
			Nausea	悪心	2	N	TE	30	21	N	None	Recovered
			Erosive duodenitis	びらん性十二指腸炎	3	Y	TE	32	6	Y	None	Recovered
			Erosive duodenitis	びらん性十二指腸炎	2	N	TE	38	16	Y	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	44		N	None	Ongoing at time of death
			Nausea	悪心	3	Y	TE	50	4	N	None	Recovered
			Vomiting	嘔吐	3	Y	TE	50	4	N	None	Recovered
			Anorexia	食欲不振	3	Y	TE	50	4	N	None	Recovered
			Dehydration	脱水	3	Y	TE	50	4	N	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	50	4	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	57	29	N	None	Recovered
			Anxiety	不安	1	N	TE	57		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	63	79	N	None	Recovered
			Bone pain	骨痛	2	N	TE	96	5	N	None	Recovered
			Bone pain	骨痛	2	N	TE	100	42	N	None	Recovered
			Abdominal pain	腹痛	2	N	TE	130	32	N	None	Recovered
			Nausea	悪心	2	N	TE	130	32	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	147	15	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	204	6	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	209	4	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	3	N	TE	210		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	210	3	N	Not applicable	Recovered with sequelae
			Hypoaesthesia	感覚鈍麻	2	N	TE	210		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	212		N	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	213	42	N	None	Recovered
021003	Sweden	63/M/C	Bone pain	骨痛	2	N	Pre	-10	40	N	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	Pre	-7	5	N	None	Recovered
			Weight decreased	体重減少	3	N	Pre	-2		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	Pre	-2	149	N	None	Recovered
			Nausea	悪心	1	N	TE	1		N	None	Recovered
			Paraesthesia	錯感覚	1	N	Pre	1		N	None	Recovered
			Fatigue	疲労	2	N	TE	15	42	N	None	Recovered
			Diarrhoea	下痢	2	Y	TE	29	5	N	None	Recovered
			Myasthenia gravis	重症筋無力症	2	N	TE	29	442	N	None	Recovered
			Myasthenia gravis	重症筋無力症	1	N	TE	29	29	N	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	29		N	None	Recovered
			Pyrexia	発熱	2	Y	TE	44	13	Y	None	Recovered
			Headache	頭痛	1	N	TE	44	11	N	None	Recovered
			Dysphagia	嚥下障害	1	N	TE	57	57	N	None	Recovered
			Pyrexia	発熱	1	N	TE	59	3	N	None	Recovered
			Myalgia	筋痛	1	N	TE	66	4	N	None	Recovered
			Bone pain	骨痛	2	N	TE	72		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	138	12	N	None	Recovered
			Respiratory tract infection	気道感染	1	N	TE	142	12	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	2	N	TE	216	82	N	Not applicable	Recovered
022004	Sweden	84/M/C	Weight decreased	体重減少	1	N	TE	25	151	N	None	Recovered
			Increased upper airway secretion	上気道分泌増加	1	N	TE	98	15	N	None	Recovered
			Nausea	悪心	1	N	TE	101	75	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	116	60	N	None	Recovered with sequelae
			Cystitis	膀胱炎	2	N	TE	141	35	N	None	Recovered
			Sternal fracture	胸骨骨折	2	Y	TE	190	7	N	Not applicable	Recovered
			Anaemia	貧血	1	N	TE	226		N	None	Not recovered, but no changes expected
022009	Sweden	75/M/C	Fatigue	疲労	1	N	TE	116		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	116		N	None	Not recovered, but no changes expected
			Spinal cord compression	脊髄圧迫	3	N	TE	176	67	N	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	178	7	N	Not applicable	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	2	N	TE	242	137	N	Not applicable	Not recovered, but no changes expected
			Spinal cord compression	脊髄圧迫	3	N	TE	378		N	Not applicable	Not recovered, but no changes expected
023003	Sweden	57/M/C	Anorexia	食欲不振	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Haematuria	血尿	2	N	Pre	-7		N	None	Ongoing at time of death
			Cushing's syndrome	クッシング症候群	1	N	TE	29		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	149	82	N	None	Recovered
			Bacterial sepsis	細菌性敗血症	4	Y	TE	149	21	Y	Not applicable	Recovered with sequelae
			Renal failure	腎不全	1	N	TE	150	3	N	None	Recovered
			Oral candidiasis	口腔カンジダ症	2	N	TE	151	18	N	None	Recovered
			Fatigue	疲労	2	N	TE	155		N	None	Ongoing at time of death
024007	Sweden	63/M/C	Insomnia	不眠症	1	N	Pre	-2		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	Pre	-1		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	1	2	Y	None	Recovered
			Cystitis	膀胱炎	2	N	TE	30	41	N	None	Recovered
			Oedema	浮腫	2	N	TE	63	106	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	75		N	None	Not recovered, but no changes expected
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	114		N	None	Not recovered, but no changes expected
			Erysipelas	丹毒	2	N	TE	128		N	None	Recovered
			Thrombophlebitis	血栓性静脈炎	1	N	TE	128		N	None	Recovered
			Bone pain	骨痛	3	Y	TE	138		N	None	Ongoing at time of death
			Metastases to liver	肝転移	3	N	TE	141	28	N	Not applicable	Death
			Anaemia	貧血	2	N	TE	158	4	Y	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Metastases to liver	肝転移	5	Y	TE	168	1	N	Not applicable	Death
024010	Sweden	75/M/C	Anaemia	貧血	2	N	TE			N	Not applicable	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	Y	Pre	1	12	N	None	Recovered with sequelae
			Pathological fracture	病的骨折	2	N	TE	5	145	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	31		Y	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	59		N	None	Not recovered, but no changes expected
			Rash	発疹	1	N	TE	66	84	N	None	Recovered
			Abdominal pain upper	上腹部痛	2	N	TE	78	38	N	None	Recovered
			Anaemia	貧血	1	N	TE	114	37	Y	None	Recovered
			Nausea	悪心	2	N	TE	131		N	None	Recovered
			Oedema genital	性器浮腫	1	N	TE	150		N	None	Not recovered, but no changes expected
			Metastases to central nervous system	中枢神経系転移	3	N	TE	198		N	None	Not recovered, but no changes expected
			Pathological fracture	病的骨折	3	N	TE	213		N	None	Not recovered, but no changes expected
024011	Sweden	87/M/C	Diarrhoea	下痢	1	N	Pre	-5	2	N	None	Recovered
			Anaemia	貧血	2	N	Pre	-1	30	N	None	Recovered
			Bone pain	骨痛	3	N	Pre	-1	30	N	None	Recovered
			Dysgeusia	味覚異常	1	N	Pre	1		N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	49		N	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	2	N	TE	60		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	63	18	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	Y	TE	82	11	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	91		N	None	Ongoing at study termination / withdrawal
			Dry mouth	口内乾燥	1	N	TE	91		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	135		N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	2	N	TE	135		N	None	Ongoing at study termination / withdrawal
024016	Sweden	73/M/C	Injury	損傷	3	Y	TE			N	-	Recovered with sequelae
			Post-traumatic pain	外傷後疼痛	3	Y	TE			N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	3	N	TE			N	None	Not recovered, but no changes expected
			Fatigue	疲労	1	N	TE	29		N	None	Not recovered, but no changes expected
			Cushingoid	クッシング様	2	N	TE	57		N	None	Not recovered, but no changes expected
			Oedema peripheral	末梢性浮腫	2	N	TE	57		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	113	29	N	None	Recovered
024017	Sweden	73/M/C	Bone pain	骨痛	2	N	TE	34		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	64	27	Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	64		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	117	30	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	204	1	N	Not applicable	Death
024023	Sweden	81/M/C	Bone pain	骨痛	2	Y	TE	16	2	N	None	Recovered
			Bone pain	骨痛	3	N	TE	28		N	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	2	N	TE	29		N	None	Ongoing at study termination / withdrawal
			Rash	発疹	2	N	TE	29		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	57		N	None	Ongoing at study termination / withdrawal
025001	Sweden	66/M/C	Pyrexia	発熱	2	N	TE			N	Not applicable	Recovered
			Cough	咳嗽	1	N	TE			N	Not applicable	Recovered
			Arrhythmia	不整脈	1	N	Pre	-1		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	4	6	N	None	Recovered
			Anaemia	貧血	3	Y	TE	57	4	Y	Drug permanently withdrawn	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	2	Y	TE	57	4	Y	None	Recovered with sequelae
			Dyspnoea	呼吸困難	2	N	TE	57	4	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	59	39	N	Not applicable	Recovered
			Polyneuropathy	多発ニューロパチー	2	N	TE	94		N	Not applicable	Not recovered, but no changes expected
025004	Sweden	63/M/C	Fatigue	疲労	1	N	TE	31	-1	Y	None	Recovered
			Upper respiratory tract infection bacterial	細菌性上気道感染	1	N	TE	48	12	N	None	Recovered
			Haematuria	血尿	3	Y	TE	82		N	Drug administration postponed	Ongoing at time of death
			Cardiac failure	心不全	4	Y	TE	90	2	N	Drug permanently withdrawn	Death
			Cardiac failure	心不全	5	Y	TE	91	1	N	Drug permanently withdrawn	Death
025012	Sweden	74/M/C	Vomiting	嘔吐	2	N	TE	53	1	N	None	Recovered
			Hydronephrosis	水腎症	2	Y	TE	172	7	N	Not applicable	Recovered
			Hypercreatininaemia	高クレアチニン血症	2	N	TE	175		N	None	Ongoing at time of death
			Ureteric obstruction	尿管閉塞	3	N	TE	175		N	Not applicable	Not recovered, but no changes expected
025013	Sweden	71/M/C	Dry mouth	口内乾燥	1	N	TE			N	None	Recovered
			Increased bronchial secretion	気管支分泌増加	1	N	TE			N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	Pre	1		N	None	Ongoing at study termination / withdrawal
			Pyrexia	発熱	1	N	TE	79	12	N	None	Recovered
			Leukopenia	白血球減少症	2	N	TE	102	104	N	None	Recovered
			Anaemia	貧血	2	N	TE	121		N	None	Ongoing at time of death
			Infection	感染	2	N	TE	137	2	N	Drug administration postponed	Recovered
			Infection	感染	3	Y	TE	138	4	N	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	148	29	N	Drug administration postponed	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	176	57	N	Drug administration postponed	Ongoing at time of death
			Pyrexia	発熱	2	Y	TE	185	6	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	4	N	TE	232		N	Drug administration postponed	Ongoing at time of death
025014	Sweden	82/M/C	Haematuria	血尿	2	N	Pre			N	None	Recovered
			Fatigue	疲労	3	N	TE	29		N	Drug permanently withdrawn	Ongoing at time of death
			Hepatic failure	肝不全	3	Y	TE	29	9	N	Drug permanently withdrawn	Death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	Y	TE	29		N	Drug permanently withdrawn	Ongoing at time of death
			Hepatic failure	肝不全	5	Y	TE	37	1	N	Drug permanently withdrawn	Death
025015	Sweden	72/M/C	Fatigue	疲労	2	N	TE	57		N	None	Ongoing at study termination / withdrawal
			Lymphadenopathy	リンパ節症	2	N	TE	62		N	None	Ongoing at time of death
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	TE	62		N	None	Ongoing at study termination / withdrawal
			Metastases to liver	肝転移	5	Y	TE	88	1	N	Not applicable	Death
025020	Sweden	61/M/C	Bone pain	骨痛	2	Y	TE	42	3	N	None	Recovered
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE	70	71	N	None	Recovered
			Bone pain	骨痛	1	N	TE	127		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	132	8	N	None	Recovered
			Sepsis	敗血症	4	Y	TE	160	11	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	4	Y	TE	160	14	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	166		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	220	1	N	Not applicable	Death
025022	Sweden	61/M/C	Anorexia	食欲不振	1	N	TE			N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	25	2	Y	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	30	9	Y	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	3	N	TE	30	9	Y	None	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	TE	30	9	Y	None	Recovered
			Chills	悪寒	1	N	TE	32		N	None	Ongoing at study termination / withdrawal
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	2	N	TE	38	20	Y	None	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	2	N	TE	38	20	Y	None	Recovered
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	2	N	TE	38	20	N	None	Recovered
			Bone pain	骨痛	2	N	TE	42	44	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	85	7	N	Drug administration postponed	Recovered
			Bone pain	骨痛	1	N	TE	86	64	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	91	30	N	Drug administration postponed	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	149		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	150		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	177		Y	Not applicable	Ongoing at time of death
			Nausea	悪心	2	N	TE	177	3	N	Not applicable	Recovered
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	177	3	N	Not applicable	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	179		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	233	8	Y	Not applicable	
026001	Sweden	78/M/C	Bone pain	骨痛	3	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	3		N	None	Not recovered, but no changes expected
			Haematuria	血尿	1	N	TE	106	4	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	114		N	None	Ongoing at time of death
			Dehydration	脱水	2	Y	TE	117	12	N	None	Recovered
			Confusional state	錯乱状態	2	Y	TE	117	12	N	None	Recovered with sequelae
			Urinary retention	尿閉	2	N	TE	118		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	137	2	N	Drug permanently withdrawn	Death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	138	1	N	Drug permanently withdrawn	Death
026002	Sweden	66/M/C	Oesophageal spasm	食道痙攣	1	N	TE			N	None	Recovered
			Bone pain	骨痛	3	Y	Pre	-2	8	N	Not applicable	Recovered with sequelae
			Polyneuropathy	多発ニューロパチー	1	Y	TE	91	4	N	None	Recovered with sequelae
			Faecal incontinence	便失禁	3	Y	TE	108	8	N	None	Recovered with sequelae
			Hyperglycaemia	高血糖	3	Y	TE	108	8	N	None	Recovered with sequelae
			Urinary incontinence	尿失禁	3	Y	TE	108	8	N	None	Recovered with sequelae
			Pancytopenia	汎血球減少症	2	N	TE	124	6	N	Drug permanently withdrawn	Ongoing at time of death
			Fall	転倒・転落	3	Y	TE	124		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	124	13	N	None	Death
			Urinary retention	尿閉	2	N	TE	124		N	Not applicable	Ongoing at time of death
			Mouth ulceration	口腔内潰瘍形成	2	N	TE	125		N	Not applicable	Ongoing at time of death
			Pancytopenia	汎血球減少症	3	Y	TE	129		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	136	1	N	None	Death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
026003	Sweden	55/M/C	Nausea	悪心	1	N	TE			Y	None	Not recovered, but no changes expected
			Fatigue	疲労	1	N	TE			N	None	Not recovered, but no changes expected
			Pneumonia	肺炎	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			Y	None	Not recovered, but no changes expected
			Sciatica	坐骨神経痛	2	N	TE			N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	2	2	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	2	2	Y	None	Recovered
			Nausea	悪心	1	N	TE	31	2	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	31	2	Y	None	Recovered
			Anorexia	食欲不振	2	N	TE	116	119	N	None	Recovered
			Anaemia	貧血	2	N	TE	197		Y	None	
			General physical health deterioration	全身健康状態低下	2	Y	TE	219	5	N	Not applicable	Recovered
			Pneumonia	肺炎	3	Y	TE	219	15	N	Not applicable	Recovered
			Compression fracture	圧迫骨折	1	N	TE	220		N	Not applicable	Not recovered, but no changes expected
026005	Sweden	66/M/C	Lymphadenopathy	リンパ節症	1	N	Pre			N	Not applicable	Ongoing at time of death
			Toothache	歯痛	1	N	TE			N	None	Recovered
			Dizziness	浮動性めまい	1	N	TE			N	Not applicable	Recovered
			Insomnia	不眠症	2	N	Pre	1		N	Not applicable	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	TE	109		N	None	Not recovered, but no changes expected

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	1	N	TE	127		N	None	Ongoing at time of death
			Hydronephrosis	水腎症	3	Y	TE	136	5	N	None	Recovered with sequelae
			Weight decreased	体重減少	1	N	TE	147		N	Not applicable	Ongoing at time of death
			Anxiety	不安	2	N	TE	147		N	None	Ongoing at time of death
			Hyponatraemia	低ナトリウム血症	1	N	TE	161	26	N	None	Recovered
			Depression	うつ病	2	N	TE	161		N	None	Recovered with sequelae
			Rectal haemorrhage	直腸出血	3	Y	TE	167	4	N	Not applicable	Recovered
			General physical health deterioration	全身健康状態低下	1	Y	TE	167	4	N	Not applicable	Recovered
			Lymphadenopathy	リンパ節症	2	N	TE	171		N	Not applicable	Ongoing at time of death
			Oral fungal infection	口腔真菌感染	1	N	TE	186		N	Not applicable	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	186	6	N	Not applicable	Recovered
			Dehydration	脱水	2	Y	TE	199	3	N	Not applicable	Recovered
			Bone pain	骨痛	2	Y	TE	199	3	N	Not applicable	Recovered
026007	Sweden	66/M/C	Nausea	悪心	1	N	TE			Y	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE			Y	Not applicable	Recovered
			Upper respiratory tract infection	上気道感染	1	N	TE			N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary tract infection	尿路感染	2	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			N	None	Recovered
			Stent occlusion	ステント閉塞	2	Y	Pre	-10	5	N	None	Recovered
			Herpes zoster	帯状疱疹	2	N	TE	6	10	N	None	Recovered
			Lymphadenopathy	リンパ節症	2	N	TE	119	43	N	None	Recovered with sequelae
026010	Sweden	66/M/C	Bone pain	骨痛	2	N	TE	3	4	Y	None	Recovered
			Anaemia	貧血	2	N	TE	170		Y	None	Not recovered, but no changes expected
			Convulsion	痙攣	4	Y	TE	193	3	N	Not applicable	Recovered with sequelae
			Metastases to nervous system	神経系転移	2	N	TE	195		N	Not applicable	Ongoing at time of death
026016	Sweden	72/M/C	Fatigue	疲労	1	N	TE			N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Nocturia	夜間頻尿	1	N	TE			N	None	Ongoing at time of death
			Hyperhidrosis	多汗症	2	N	TE			N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	2	11	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	2	11	Y	None	Recovered
			Anaemia	貧血	2	N	TE	29		Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	68		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	3	Y	TE	83	24	Y	Drug permanently withdrawn	Recovered with sequelae
			Thrombocytopenia	血小板減少症	3	N	TE	83	25	Y	Not applicable	Ongoing at time of death
			Mucosal inflammation	粘膜の炎症	2	N	TE	83	18	N	None	Recovered
			Pneumonia	肺炎	3	Y	TE	83	24	N	Drug administration postponed	Recovered
			Petechiae	点状出血	2	N	TE	83		N	None	Ongoing at time of death
			Epistaxis	鼻出血	1	N	TE	84	1	N	None	Recovered
			Thrombocytopenia	血小板減少症	4	N	TE	107		Y	Not applicable	Ongoing at time of death
027001	Sweden	72/M/C	Dry mouth	口内乾燥	1	N	TE	29	204	Y	None	Recovered
			Fatigue	疲労	1	N	TE	29	204	Y	None	Recovered with sequelae
			Anorexia	食欲不振	2	N	TE	29	141	Y	None	Recovered
			Arthralgia	関節痛	2	N	TE	29	56	N	None	Not recovered, but no changes expected
			Arthralgia	関節痛	1	N	TE	84		N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	113	120	Y	None	Recovered
			Circulatory collapse	循環虚脱	4	Y	TE	176	9	N	Not applicable	Recovered
028001	Belgium	63/M/C	Bone pain	骨痛	2	N	Pre	-102	103	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	Pre	1		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			General physical health deterioration	全身健康状態低下	2	N	TE	18	103	Y	None	Recovered with sequelae
			Sinus tachycardia	洞性頻脈	1	N	TE	26	73	N	None	Recovered
			Hepatic function abnormal	肝機能異常	2	N	TE	28		N	None	Ongoing at time of death
			Jaundice	黄疸	3	N	TE	28	10	N	None	Recovered
			Jaundice	黄疸	1	N	TE	37	48	N	None	Recovered
			Hypotension	低血圧	2	N	TE	37	62	N	None	Recovered
			Anaemia	貧血	2	N	TE	56	29	Y	Drug permanently withdrawn	Recovered with sequelae
			Leukopenia	白血球減少症	1	N	TE	56	29	Y	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	56	29	Y	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	56	29	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	56	65	N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	56	29	N	None	Recovered with sequelae
			Dyspnoea	呼吸困難	2	N	TE	72	13	N	None	Recovered with sequelae
			Vomiting	嘔吐	2	N	TE	77	8	N	None	Recovered
			Anaemia	貧血	4	Y	TE	84	15	Y	Drug permanently withdrawn	Recovered with sequelae
			Leukopenia	白血球減少症	2	N	TE	84	49	Y	None	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	84	15	Y	None	Ongoing at time of death
			Vomiting	嘔吐	1	Y	TE	84	2	N	None	Recovered
			Anorexia	食欲不振	1	Y	TE	84	2	N	None	Recovered with sequelae

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	2	Y	TE	84	2	N	None	Recovered with sequelae
			Anorexia	食欲不振	1	N	TE	85		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	98	23	Y	Not applicable	Recovered with sequelae
			Thrombocytopenia	血小板減少症	4	N	TE	98		Y	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	120	2	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	3	Y	TE	120	2	Y	Not applicable	Recovered with sequelae
			Weight decreased	体重減少	2	N	TE	120		N	None	Ongoing at time of death
			Cough	咳嗽	1	N	TE	120		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	121	12	Y	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	2	N	TE	121	12	Y	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	132		Y	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	3	Y	TE	132	4	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	2	N	TE	135	8	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	3	Y	TE	142	2	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	2	N	TE	143	10	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	3	Y	TE	152	4	Y	Not applicable	Recovered with sequelae

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			General physical health deterioration	全身健康状態低下	2	N	Post	155		Y	Not applicable	Ongoing at time of death
028002	Belgium	72/M/C	General physical health deterioration	全身健康状態低下	2	Y	Pre	-9	19	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	Y	Pre	-9	19	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	3	N	Pre	-1	2	N	None	Recovered
			Anal ulcer	肛門潰瘍	2	N	Pre	-1	88	N	None	Recovered
			General physical health deterioration	全身健康状態低下	1	N	Pre	10		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	Pre	10		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	3	Y	TE	29	7	Y	Drug administration postponed	Recovered
			Weight decreased	体重減少	2	N	TE	29	28	N	None	Recovered
			Anorexia	食欲不振	3	N	TE	56	28	N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	56		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	Y	TE	83		Y	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	3	Y	TE	83	24	N	Drug permanently withdrawn	Death
			Anorexia	食欲不振	1	N	TE	83		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	87	20	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	91		N	Drug permanently withdrawn	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Insomnia	不眠症	1	N	TE	105		N	Not applicable	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	5	Y	TE	106	1	N	Drug permanently withdrawn	Death
028003	Belgium	83/M/C	Nausea	悪心	1	N	TE	2	1	Y	None	Recovered
			Fatigue	疲労	1	N	TE	29		N	None	Ongoing at time of death
			Skin irritation	皮膚刺激	2	N	TE	50	15	N	None	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	55		Y	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	4	Y	TE	55		N	None	Ongoing at time of death
			Renal failure	腎不全	4	Y	TE	55		N	Drug permanently withdrawn	Ongoing at time of death
			Pulmonary oedema	肺水腫	4	Y	TE	55		N	None	Ongoing at time of death
			Multi-organ failure	多臓器不全	4	Y	TE	59	6	N	None	Death
			Multi-organ failure	多臓器不全	5	Y	TE	64	1	N	None	Death
028004	Belgium	84/M/C	Transient ischaemic attack	一過性脳虚血発作	2	Y	Pre	-13	55	N	Not applicable	Recovered
			Urinary retention	尿閉	2	N	Pre	-7	6	N	None	Recovered
			Pruritus	そう痒症	1	N	TE	8	7	N	None	Recovered with sequelae
			Pruritus	そう痒症	1	N	TE	8	27	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	14	48	N	None	Recovered
			Urinary tract infection	尿路感染	1	N	TE	28	29	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Confusional state	錯乱状態	1	N	TE	30		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	51		N	None	Ongoing at time of death
			Hypercholesterolaemia	高コレステロール血症	2	N	TE	51		N	None	Ongoing at time of death
			Inguinal hernia	鼠径ヘルニア	1	N	TE	55	14	N	None	Recovered
			Bone pain	骨痛	3	N	TE	57		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	93	1	N	Not applicable	Death
028007	Belgium	65/M/C	Fatigue	疲労	1	N	TE	28		Y	None	Ongoing at study termination / withdrawal
			Feeling cold	冷感	1	N	TE	28	36	Y	None	Recovered
			Pallor	蒼白	1	N	TE	28		Y	None	Ongoing at study termination / withdrawal
			Pyrexia	発熱	2	N	TE	50	6	N	None	Recovered
			Urinary retention	尿閉	3	Y	TE	50	2	N	None	Recovered with sequelae
			Anaemia	貧血	3	N	TE	55	9	Y	None	Recovered with sequelae
			Pleurisy	胸膜炎	2	N	TE	56	23	N	None	Recovered
			Anaemia	貧血	2	N	TE	63		Y	None	Ongoing at study termination / withdrawal
			Tachycardia	頻脈	2	N	TE	91	15	N	None	Recovered
			Pleural effusion	胸水	2	N	TE	167	15	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Paraesthesia	錯感覚	2	N	TE	168		N	None	Ongoing at study termination / withdrawal
			Lymphangiosis carcinomatosa	癌性リンパ管症	4	Y	TE	181	19	N	Not applicable	Recovered with sequelae
			Pleural effusion	胸水	4	Y	TE	181	2	N	Not applicable	Recovered
			Lymphangiosis carcinomatosa	癌性リンパ管症	4	N	TE	199	5	N	Not applicable	Recovered with sequelae
			Lymphangiosis carcinomatosa	癌性リンパ管症	5	Y	TE	203	1	N	Not applicable	Death
033005	UK	83/M/C	Bone pain	骨痛	1	N	TE	1	3	Y	None	Recovered
			Myocardial infarction	心筋梗塞	4	Y	TE	82	3	N	None	Death
			Myocardial infarction	心筋梗塞	5	Y	TE	84	1	N	None	Death
033006	UK	76/M/C	Bone pain	骨痛	2	N	TE			N	None	Not recovered, but no changes expected
			Constipation	便秘	3	Y	TE	77	10	N	Drug administration postponed	Recovered
			Cellulitis	蜂巣炎	3	Y	TE	77	10	N	Drug administration postponed	Recovered
			Pneumonia	肺炎	3	Y	TE	89		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Pathological fracture	病的骨折	3	Y	TE	89		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
033011	UK	84/M/C	Abdominal distension	腹部膨満	2	N	TE			N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	1	N	TE			Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE			N	None	Recovered with sequelae
			Contusion	挫傷	1	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Balance disorder	平衡障害	1	N	TE			N	None	Not recovered, but no changes expected
			Hallucination	幻覚	1	N	TE			N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	2	N	TE			N	None	Not recovered, but no changes expected
			Orthostatic hypotension	起立性低血圧	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	71	43	N	None	Recovered with sequelae
			Haematemesis	吐血	3	Y	TE	195	5	N	Not applicable	Recovered
			Hyperaesthesia	知覚過敏	2	N	TE	214		N	None	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	214		N	None	Ongoing at time of death
033012	UK	72/M/C	Constipation	便秘	2	N	TE			N	None	Recovered
			Mouth ulceration	口腔内潰瘍形成	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Mobility decreased	運動性低下	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Dizziness	浮動性めまい	2	N	TE	11	1	N	None	Recovered
			Dizziness	浮動性めまい	2	N	TE	47	1	N	None	Recovered
			Bone pain	骨痛	3	N	TE	55		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	106	16	N	Drug administration postponed	Recovered
			Hypokalaemia	低カリウム血症	3	N	TE	111	3	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	142		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	144	15	N	None	Recovered with sequelae
			Nausea	悪心	1	N	TE	158		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	158	8	N	None	Recovered with sequelae
033019	UK	71/M/C	Oedema peripheral	末梢性浮腫	1	N	TE			N	None	Not recovered, but no changes expected
			Spinal compression fracture	脊椎圧迫骨折	2	N	TE			Y	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Not recovered, but no changes expected
			Paraesthesia	錯感覚	1	N	TE			N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	2	N	Pre			N	None	Not recovered, but no changes expected
			Pleuritic pain	胸膜痛	1	N	TE			N	None	Recovered
			Spinal cord compression	脊髄圧迫	3	N	Pre	-6	13	N	None	Recovered
			Anaemia	貧血	1	N	TE	2	181	Y	None	Not recovered, but no changes expected

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Deep vein thrombosis	深部静脈血栓症	2	Y	TE	26	4	N	Drug administration postponed	Recovered with sequelae
			Deep vein thrombosis	深部静脈血栓症	1	N	TE	29		N	Drug administration postponed	Recovered with sequelae
			Deep vein thrombosis	深部静脈血栓症	1	N	TE	29		N	None	Not recovered, but no changes expected
			Pulmonary embolism	肺塞栓症	3	Y	TE	59	79	N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	3	N	TE	169		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	182	65	Y	None	Recovered
033022	UK	82/M/C	Constipation	便秘	2	N	TE			N	None	Recovered
			Nausea	悪心	2	N	TE			N	None	Recovered
			Vomiting	嘔吐	2	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			N	Drug permanently withdrawn	Recovered with sequelae
			Bone pain	骨痛	3	N	TE	77	15	N	Drug permanently withdrawn	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	77	15	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	91		N	Not applicable	Ongoing at time of death
033023	UK	69/M/C	Post-traumatic pain	外傷後疼痛	2	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	Pre			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at time of death
			Muscular weakness	筋力低下	3	N	TE			N	None	Ongoing at time of death
			Pathological fracture	病的骨折	2	N	TE			N	None	Not recovered, but no changes expected
			Constipation	便秘	1	N	Pre	-673	882	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	28		N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	85	65	N	None	Recovered with sequelae
			Pathological fracture	病的骨折	3	Y	TE	149	20	Y	Drug administration postponed	Recovered
			Mobility decreased	運動性低下	2	N	TE	168	42	N	None	Ongoing at time of death
			Pathological fracture	病的骨折	2	N	TE	168		Y	None	Not recovered, but no changes expected
			Paraesthesia	錯感覚	1	Y	TE	175	5	N	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	178	7	N	None	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	178	32	N	None	Ongoing at time of death
			Upper limb fracture	上肢骨折	3	Y	TE	202		Y	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	5	Y	TE	209	1	N	Not applicable	Death
033027	UK	58/M/C	Diarrhoea	下痢	1	N	TE			Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	1	N	TE			Y	None	Recovered
			Gingival infection	歯肉感染	1	N	TE			N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			N	None	Not recovered, but no changes expected
			Pain in jaw	顎痛	1	N	TE			Y	None	Recovered
			Hypoaesthesia	感覚鈍麻	1	N	TE			N	None	Not recovered, but no changes expected
			Depression	うつ病	1	N	TE			N	None	Not recovered, but no changes expected
			Palpitations	動悸	2	N	TE	40	1	N	None	Recovered
			Dyspepsia	消化不良	2	N	TE	40		N	None	Ongoing at time of death
			Hyperhidrosis	多汗症	2	N	TE	40	1	N	None	Recovered
			Vomiting	嘔吐	3	Y	TE	44	3	N	None	Recovered
			Nausea	悪心	1	N	TE	57		N	None	Recovered
			Diarrhoea	下痢	1	N	TE	60	10	Y	None	Recovered
			Osteonecrosis	骨壊死	2	N	TE	100		Y	None	Not recovered, but no changes expected
			Defaecation urgency	便意切迫	3	N	TE	120	1	Y	None	Recovered
			Defaecation urgency	便意切迫	3	N	TE	120	2	Y	None	Recovered
			Faecal incontinence	便失禁	3	N	TE	120	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	193		N	None	Recovered
			Diarrhoea	下痢	3	Y	TE	196	8	N	Not applicable	Recovered
			Vomiting	嘔吐	3	Y	TE	196	8	N	Not applicable	Recovered
			Intervertebral disc degeneration	椎間板変性症	3	Y	TE	196	8	N	Not applicable	Recovered
			Paraesthesia	錯感覚	2	N	TE	196	8	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
034004	UK	63/M/C	Nausea	悪心	1	N	TE	8		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	8		Y	None	Ongoing at time of death
			Oral candidiasis	口腔カンジダ症	1	N	TE	8		N	None	Ongoing at time of death
			Dizziness	浮動性めまい	1	N	TE	8		N	None	Ongoing at time of death
			Cerebral ischaemia	脳虚血	4	Y	TE	43	5	N	None	Recovered with sequelae
			Anorexia	食欲不振	3	N	TE	53		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	92	9	N	Not applicable	Recovered
			Diarrhoea	下痢	3	N	TE	95	6	Y	Not applicable	Recovered
			Vomiting	嘔吐	3	N	TE	95	6	N	Not applicable	Recovered
			Anaemia	貧血	4	N	TE	98	2	N	Not applicable	Recovered
			Bone marrow failure	骨髄機能不全	4	Y	TE	98	9	N	Not applicable	Death
			Sinus tachycardia	洞性頻脈	1	N	TE	98		N	Not applicable	Ongoing at time of death
			Confusional state	錯乱状態	3	N	TE	98	2	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	98	2	N	Not applicable	Recovered
			Rash	発疹	2	N	TE	98		N	None	Ongoing at time of death
			Haematemesis	吐血	3	N	TE	99	2	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oesophagitis	食道炎	2	N	TE	99		N	Not applicable	Ongoing at time of death
			Bone marrow failure	骨髄機能不全	5	Y	TE	106	1	N	Not applicable	Death
034017	UK	83/M/C	Rash	発疹	1	N	TE			N	None	Recovered
			Vision blurred	霧視	3	N	TE	25	2	N	None	Ongoing at time of death
			Vision blurred	霧視	2	N	TE	26		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	42	57	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	42	57	N	None	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	2	N	TE	42		N	None	Ongoing at time of death
			Oral candidiasis	口腔カンジダ症	2	N	TE	70	29	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	95	1	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	98		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	114		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
035006	UK	62/M/C	Fatigue	疲労	1	N	Pre	-22	23	N	None	Recovered
			Conjunctivitis	結膜炎	1	N	TE	13	15	N	None	Recovered
			Polyneuropathy	多発ニューロパチー	1	N	TE	27	28	N	None	Recovered
			Paresis cranial nerve	脳神経不全麻痺	3	Y	TE	30		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	84	35	N	None	Recovered
			Constipation	便秘	1	N	TE	85		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oral candidiasis	口腔カンジダ症	2	N	TE	86		N	None	Recovered
			Respiratory tract infection	気道感染	1	N	TE	86		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	87		N	None	Ongoing at time of death
			Urinary tract obstruction	尿路閉塞	2	N	TE	101		N	None	Recovered with sequelae
			Decreased appetite	食欲減退	1	N	TE	111	2	N	None	Recovered
035016	UK	62/M/C	Diarrhoea	下痢	2	N	TE	3	11	N	None	Recovered
			Nausea	悪心	2	N	TE	3	11	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	109	9	N	None	Recovered
			Constipation	便秘	1	N	TE	111	8	N	None	Recovered
			Oral candidiasis	口腔カンジダ症	2	N	TE	112	42	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	112	7	N	Drug administration postponed	Recovered
			Dyspepsia	消化不良	1	N	TE	113	3	N	None	Recovered
			Nausea	悪心	1	N	TE	113	3	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	113		N	None	Recovered
			Bone pain	骨痛	3	N	TE	118	36	N	None	Not recovered, but no changes expected
			Diarrhoea	下痢	3	Y	TE	150	4	Y	Not applicable	Recovered
			Vomiting	嘔吐	3	Y	TE	150	4	Y	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	153		N	None	Not recovered, but no changes expected
			Diarrhoea	下痢	3	Y	Post	337	10	Y	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
035019	UK	67/M/C	Nausea	悪心	2	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	Pre	1	4	Y	None	Recovered
			Bone pain	骨痛	2	Y	TE	106	5	N	None	Recovered with sequelae
			Urinary tract infection	尿路感染	1	N	TE	128	11	N	None	Recovered
			Constipation	便秘	1	N	TE	132	5	N	None	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	152	6	Y	Not applicable	Recovered
			Nausea	悪心	1	N	TE	158	46	N	Not applicable	Recovered
			Fatigue	疲労	1	N	TE	163		N	Not applicable	Not recovered, but no changes expected
035023	UK	70/M/C	Fatigue	疲労	1	N	TE	66		Y	None	Not recovered, but no changes expected
			Fatigue	疲労	2	N	TE	66		Y	None	Not recovered, but no changes expected
			Dyspepsia	消化不良	2	N	TE	70		N	None	Not recovered, but no changes expected
			Decreased appetite	食欲減退	2	N	TE	70		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	84		Y	None	Not recovered, but no changes expected
			Gastrointestinal haemorrhage	胃腸出血	3	Y	TE	94	8	N	None	Recovered
			Electrocardiogram QT prolonged	心電図ＱＴ延長	1	N	TE	105		N	Not applicable	Not recovered, but no changes expected
			Clostridium difficile colitis	クロストリジウム・ディフィシレ大腸炎	2	Y	TE	110	9	N	Not applicable	Recovered
			Clostridium difficile colitis	クロストリジウム・ディフィシレ大腸炎	1	N	TE	150	9	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
035027	UK	68/M/C	Decreased appetite	食欲減退	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	1	3	Y	None	Recovered
			Constipation	便秘	2	N	TE	44		Y	None	Ongoing at time of death
			Intestinal obstruction	腸閉塞	4	Y	TE	54	2	Y	None	Death
			Intestinal obstruction	腸閉塞	5	Y	TE	55	1	Y	None	Death
035028	UK	70/M/C	Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Recovered
			Urine flow decreased	尿流量減少	1	N	TE	11	19	N	None	Recovered
			Bone pain	骨痛	2	N	TE	29		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	44	18	N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	44		N	None	Recovered
			Constipation	便秘	2	Y	TE	66	6	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	71	79	N	Not applicable	Death
			Constipation	便秘	1	N	TE	72	42	N	None	Recovered
			Anaemia	貧血	2	N	TE	141		Y	None	Ongoing at time of death
			Confusional state	錯乱状態	3	Y	TE	150	11	N	Not applicable	Death
			Confusional state	錯乱状態	5	Y	TE	160	1	N	Not applicable	Death
035031	UK	63/M/C	Pollakiuria	頻尿	1	N	TE	2	2	Y	None	Recovered
			Sepsis	敗血症	4	Y	TE	50	19	N	Drug permanently withdrawn	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	4	Y	TE	50	24	N	Drug permanently withdrawn	Recovered
			Haematuria	血尿	3	N	TE	50		N	Not applicable	Not recovered, but no changes expected
			Herpes zoster	帯状疱疹	2	N	TE	86	6	N	Not applicable	Recovered
			Renal impairment	腎機能障害	2	N	TE	86	5	N	Not applicable	Recovered
035033	UK	63/M/C	Angina pectoris	狭心症	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			N	None	Ongoing at time of death
			Blood urea increased	血中尿素増加	1	N	TE	41	57	N	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	87	1	N	None	Recovered
			Constipation	便秘	2	N	TE	159	3	N	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	202	1	N	None	Recovered
			Myocardial ischaemia	心筋虚血	4	Y	TE	203	3	N	Not applicable	Recovered
036001	UK	82/M/C	Bone pain	骨痛	1	N	TE	43		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	56	8	N	None	Recovered
			Bone pain	骨痛	4	Y	TE	63	11	N	None	Recovered
			Arrhythmia	不整脈	3	Y	TE	111	16	N	None	Recovered
			Anaemia	貧血	2	N	TE	149		Y	Not applicable	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	149		N	None	Ongoing at study termination / withdrawal
036005	UK	63/M/C	Dysphagia	嚥下障害	1	N	Pre			N	None	Ongoing at study termination / withdrawal
			Dizziness	浮動性めまい	1	N	TE			N	None	Recovered
			Diarrhoea	下痢	2	N	TE	24	6	N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE	24		N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	3	N	TE	36	28	Y	None	Recovered
			Disturbance in attention	注意力障害	1	N	TE	63		N	None	Ongoing at study termination / withdrawal
			Tremor	振戦	2	N	TE	63		N	None	Not recovered, but no changes expected
			Hyperhidrosis	多汗症	1	N	TE	63		N	None	Ongoing at study termination / withdrawal
			Wheezing	喘鳴	2	N	TE	91		N	None	Not recovered, but no changes expected
			Lower respiratory tract infection	下気道感染	2	N	TE	182		N	None	Ongoing at study termination / withdrawal
			Pneumonia	肺炎	3	Y	TE	182		N	Not applicable	Recovered with sequelae
			Pneumonia	肺炎	3	Y	TE	205	14	N	Not applicable	Recovered
037007	UK	72/M/C	Constipation	便秘	1	N	TE			Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	1	N	TE			N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE			N	None	Recovered
			Muscle spasms	筋痙縮	2	N	TE			N	None	Not recovered, but no changes expected
			Hypertension	高血圧	1	N	TE			Y	None	Not recovered, but no changes expected
			Diarrhoea	下痢	3	N	TE	2	3	Y	None	Recovered
			Nausea	悪心	1	N	TE	2	8	Y	None	Recovered
			Fatigue	疲労	1	N	TE	2	7	Y	None	Recovered
			Influenza	インフルエンザ	2	N	TE	11	8	Y	None	Recovered
			Cough	咳嗽	1	N	TE	18	12	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	54	4	Y	None	Recovered
			Chills	悪寒	1	N	TE	54	1	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	54	10	N	None	Recovered
			Cough	咳嗽	1	N	TE	64	9	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	68	3	Y	None	Recovered
			Urge incontinence	切迫性尿失禁	1	N	TE	68	1	N	None	Recovered
			Nausea	悪心	1	Y	TE	72	1	Y	None	Recovered
			Vomiting	嘔吐	1	Y	TE	72	1	Y	None	Recovered
			Hydronephrosis	水腎症	3	Y	TE	72	12	N	None	Recovered with sequelae
			Renal failure	腎不全	3	Y	TE	72	4	N	Drug administration postponed	Recovered with sequelae
			Renal failure	腎不全	2	N	TE	75		N	None	Not recovered, but no changes expected
			Catheter related infection	カテーテル関連感染	2	N	TE	152	40	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	160	3	N	None	Recovered
			Gynaecomastia	女性化乳房	1	N	TE	162	30	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
037008	UK	81/M/C	Mobility decreased	運動性低下	2	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	2	1	N	None	Recovered
			Musculoskeletal pain	筋骨格痛	1	N	TE	2	1	N	None	Recovered
			Constipation	便秘	1	N	TE	63		N	None	Not recovered, but no changes expected
			Eye infection	眼感染	2	N	TE	99	19	N	None	Recovered
			Gastritis	胃炎	2	N	TE	221	3	N	Not applicable	Recovered
			Gastritis	胃炎	3	Y	TE	223	2	N	Not applicable	Recovered
037012	UK	67/M/C	Abdominal pain	腹痛	1	N	TE			N	None	Not recovered, but no changes expected
			Hiatus hernia	裂孔ヘルニア	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			N	None	Recovered
			Pain in jaw	顎痛	1	N	TE			N	None	Ongoing at time of death
			Deep vein thrombosis	深部静脈血栓症	3	N	TE			Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	28	2	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	113		N	None	Ongoing at time of death
			Osteoarthritis	骨関節炎	1	N	TE	163		N	None	Not recovered, but no changes expected
			Dyspnoea exertional	労作性呼吸困難	1	N	TE	171		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	198		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Head injury	頭部損傷	3	N	TE	212	1	N	None	Recovered with sequelae
			Disseminated intravascular coagulation	播種性血管内凝固	3	N	TE	214		N	None	Not recovered, but no changes expected
			Thrombocytopenia	血小板減少症	3	Y	TE	214		N	Not applicable	Ongoing at time of death
			Extradural haematoma	硬膜外血腫	5	Y	TE	214	1	N	Not applicable	Death
037013	UK	70/M/C	Anorexia	食欲不振	1	N	TE			Y	None	Recovered
			Dysarthria	構語障害	1	N	TE			N	None	Not recovered, but no changes expected
			Non-cardiac chest pain	非心臓性胸痛	1	N	TE	3	8	N	None	Recovered
			Non-cardiac chest pain	非心臓性胸痛	2	N	TE	10	24	N	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	19	6	N	None	Recovered
			Bursitis infective	感染性滑液包炎	1	N	TE	30	8	N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	30		N	None	Not recovered, but no changes expected
			Bursitis infective	感染性滑液包炎	2	Y	TE	37	3	N	None	Recovered
			Nausea	悪心	1	N	TE	46	4	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	48	2	Y	None	Recovered
			Lethargy	嗜眠	1	N	TE	59		Y	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	61	4	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	118	9	Y	None	Recovered
			Rectal haemorrhage	直腸出血	1	N	TE	118	1	Y	None	Recovered
			Nausea	悪心	1	N	TE	141		Y	None	Not recovered, but no changes expected
			Diarrhoea	下痢	1	N	TE	143	3	Y	None	Recovered
			Anaemia	貧血	3	N	TE	190	44	Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
038003	UK	80/M/C	Vomiting	嘔吐	3	N	TE	1	2	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	2	7	Y	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	4	4	N	None	Recovered
			Haematuria	血尿	2	N	TE	4	6	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	8	2	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	16	6	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	28	2	Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	2	N	TE	28		Y	None	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	29	2	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	35	2	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	56		N	None	Ongoing at time of death
			Muscular weakness	筋力低下	4	Y	TE	56		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	57	2	Y	None	Recovered
039005	UK	72/M/C	Constipation	便秘	3	N	TE	4	38	N	None	Recovered
			Nausea	悪心	3	N	TE	13	29	N	None	Recovered
			Nausea	悪心	3	N	TE	35	7	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	35		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	N	TE	35	8	N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	42	1	N	None	Death
039007	UK	68/M/C	Bone pain	骨痛	1	N	Pre			N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	Y	Pre	-23	2	N	Drug administration postponed	Recovered
			Decreased appetite	食欲減退	1	N	Pre	-11		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	-11		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	-11	5	N	None	Recovered
			Nausea	悪心	1	N	Pre	-4		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	Pre	-4		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	4	23	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	27		Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	29	36	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	60		Y	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	70	1	N	None	Recovered
			Anaemia	貧血	2	N	TE	92		Y	Drug administration postponed	Ongoing at time of death
			Joint injury	関節損傷	2	N	TE	94		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	95		Y	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	118	2	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	180	2	Y	Not applicable	Recovered
			Skin lesion	皮膚病変	3	N	TE	183		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	214	1	N	Not applicable	Death
039012	UK	82/M/C	Anaemia	貧血	3	N	TE			N	None	Recovered
			Hyperchlorhydria	胃酸過多	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	2	N	Pre	-2	26	N	None	Recovered
			Hypoaesthesia	感覚鈍麻	2	N	Pre	-2		N	None	Ongoing at study termination / withdrawal
			Hypoaesthesia	感覚鈍麻	2	N	TE	8		N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	2	N	TE	8		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	24		N	None	Ongoing at time of death
			Pathological fracture	病的骨折	3	Y	TE	35	33	N	Drug administration postponed	Recovered
			Nausea	悪心	2	N	TE	71	86	Y	None	Ongoing at time of death
			Dry mouth	口内乾燥	3	N	TE	87	70	N	None	Ongoing at time of death
			Back injury	背部損傷	3	N	TE	91	66	N	None	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	125		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	156	1	N	None	Death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
039015	UK	79/M/C	Abdominal distension	腹部膨満	2	N	TE			N	None	Recovered
			Nausea	悪心	2	N	TE			Y	None	Recovered
			Fatigue	疲労	3	N	TE			N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	Pre	1	85	N	None	Recovered
			Bone pain	骨痛	2	N	Pre	1	85	N	None	Recovered
			Bone pain	骨痛	2	N	Pre	1	111	N	None	Recovered
			Incontinence	失禁	2	N	Pre	1	85	N	None	Recovered
			Decreased appetite	食欲減退	2	N	TE	29		N	None	Ongoing at study termination / withdrawal
			Haematuria	血尿	3	Y	TE	85	7	N	Drug administration postponed	Recovered
			Cystitis radiation	放射線性膀胱炎	3	Y	TE	93	5	N	Drug administration postponed	Recovered
			Cystitis radiation	放射線性膀胱炎	2	N	TE	97		N	None	Recovered
			Urinary tract infection	尿路感染	3	N	TE	146	18	N	None	Recovered
			Urinary tract infection	尿路感染	3	N	TE	167		N	None	Recovered
			Oesophageal obstruction	食道閉塞症	3	N	TE	176		N	None	Ongoing at study termination / withdrawal
			Hyperchlorhydria	胃酸過多	2	N	TE	179		N	None	Ongoing at time of death
039016	UK	69/M/C	Fatigue	疲労	2	N	TE			Y	None	Recovered
			Cellulitis	蜂巣炎	3	N	Pre			N	None	Recovered
			Rhinitis	鼻炎	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	Pre			N	None	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	7	9	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	3	N	TE	25	296	N	None	Recovered
			Dyspnoea	呼吸困難	2	N	TE	146		N	None	Not recovered, but no changes expected
039025	UK	78/M/C	Asthenia	無力症	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	Pre	1	57	N	None	Recovered
			Bone pain	骨痛	2	N	Pre	1	29	N	None	Recovered
			Bone pain	骨痛	2	N	TE	83		N	None	Ongoing at time of death
			Metastases to central nervous system	中枢神経系転移	3	Y	TE	109		N	Drug permanently withdrawn	Ongoing at time of death
			Dysphasia	不全失語症	2	N	TE	109		N	None	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	113		N	Not applicable	Ongoing at time of death
039027	UK	74/M/C	Nausea	悪心	2	N	TE	1		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	1		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	2	N	Pre	1		N	None	Ongoing at time of death
			Dizziness	浮動性めまい	2	N	TE	1		N	None	Ongoing at time of death
			Headache	頭痛	1	N	TE	1		N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	1	N	TE	1		N	None	Ongoing at time of death
			Dehydration	脱水	3	Y	TE	8	7	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	18	20	N	Drug administration postponed	Death
			Renal failure	腎不全	3	Y	TE	18	1	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	N	TE	19	4	N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	37	1	N	Drug administration postponed	Death
040004	UK	67/M/C	Nausea	悪心	1	N	Pre			N	None	Recovered
			Vomiting	嘔吐	1	N	Pre			N	None	Recovered
			Upper respiratory tract infection	上気道感染	2	N	TE	29	8	N	None	Recovered
			Nausea	悪心	2	Y	TE	70	2	Y	None	Recovered
			Vomiting	嘔吐	2	Y	TE	70	2	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	105		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	142		Y	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	1	N	TE	142		Y	None	Ongoing at study termination / withdrawal
040005	UK	67/M/C	Bone pain	骨痛	3	N	TE			N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Diarrhoea	下痢	1	N	TE	2	3	Y	None	Recovered
			Malaise	倦怠感	2	N	TE	2	3	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	2		N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	29	4	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	29	4	N	None	Recovered
			Lower respiratory tract infection	下気道感染	3	N	TE	49	13	N	None	Recovered
			Anaemia	貧血	2	N	TE	57	56	Y	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	68	60	N	Drug permanently withdrawn	Death
			Anaemia	貧血	3	Y	TE	112	3	Y	None	Recovered
			Fatigue	疲労	3	Y	TE	112	3	Y	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	N	TE	114		Y	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	2	N	TE	114		Y	Not applicable	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	127	1	N	Drug permanently withdrawn	Death
040007	UK	68/M/C	Breast tenderness	乳房圧痛	1	N	Pre			N	None	Recovered
			Breast tenderness	乳房圧痛	1	N	TE			Y	None	Recovered
			Nausea	悪心	1	N	TE	4	16	Y	None	Recovered
			Fatigue	疲労	1	N	TE	4	16	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	67	29	Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	84	2	N	None	Recovered
			Fatigue	疲労	2	N	TE	132		N	None	Ongoing at study termination / withdrawal
			Dyspnoea	呼吸困難	1	N	TE	132		N	None	Ongoing at study termination / withdrawal
			Joint swelling	関節腫脹	1	N	TE	139		N	None	Ongoing at study termination / withdrawal
040008	UK	75/M/C	Bone pain	骨痛	2	N	Pre	-10	8	N	None	Recovered
			Headache	頭痛	1	N	Pre	-10	8	N	None	Recovered
			Nausea	悪心	2	N	Pre	-8	40	N	None	Recovered
			Anorexia	食欲不振	2	N	Pre	-8	5	N	None	Recovered
			Vomiting	嘔吐	1	N	Pre	-5	1	N	None	Recovered
			Fatigue	疲労	1	N	Pre	-5		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	Pre	1	79	N	None	Recovered
			Bone pain	骨痛	1	N	Pre	1	79	N	None	Recovered
			Bone pain	骨痛	1	N	Pre	1	79	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	33	30	Y	None	Recovered
			Dyspepsia	消化不良	2	N	TE	67		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	72	1	N	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	85	30	Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	3	N	TE	114		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Mouth haemorrhage	口腔内出血	3	Y	TE	135		Y	Not applicable	Ongoing at study termination / withdrawal
041001	UK	56/M/C	Pulmonary embolism	肺塞栓症	4	Y	Pre	-39	8	N	Not applicable	Recovered with sequelae
			Intertrigo	間擦疹	2	N	Pre	-33	30	N	None	Recovered
			Nausea	悪心	1	N	Pre	1	57	N	None	Recovered
			Decreased appetite	食欲減退	1	N	Pre	1	113	N	None	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	2	4	Y	None	Recovered
			Fatigue	疲労	1	N	TE	2	15	N	None	Recovered
			Bone pain	骨痛	2	N	TE	2	112	Y	None	Recovered
			Weight decreased	体重減少	1	N	TE	29	85	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	46	96	N	None	Recovered
			Pain in extremity	四肢痛	2	N	TE	46		N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	57	203	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	57		N	None	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	3	Y	TE	81	5	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	113		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	3	N	TE	113	57	N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	141	8	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	148	21	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	168		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	169		N	None	Ongoing at time of death
			Night sweats	寝汗	2	N	TE	192		N	None	Ongoing at time of death
			Oral candidiasis	口腔カンジダ症	2	N	TE	202		N	None	Ongoing at time of death
			Abdominal pain upper	上腹部痛	1	N	TE	223		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	223		N	None	Ongoing at time of death
041003	UK	59/M/C	Dry mouth	口内乾燥	1	N	TE			N	None	Ongoing at time of death
			Abdominal distension	腹部膨満	1	N	Pre	-13	52	N	None	Recovered
			Bone pain	骨痛	3	N	Pre	-13	4	N	None	Recovered
			Joint swelling	関節腫脹	1	N	Pre	-13		N	None	Ongoing at time of death
			Hot flush	ほてり	1	N	Pre	-13		N	None	Ongoing at time of death
			Pitting oedema	圧痕浮腫	1	N	Pre	1	39	N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	1	N	Pre	1		N	None	Ongoing at time of death
			Lethargy	嗜眠	2	N	TE	2	52	Y	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	4	50	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	30	140	N	None	Recovered
			Insomnia	不眠症	1	N	TE	30	124	N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Depressed mood	抑うつ気分	1	N	TE	42		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	43	15	Y	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	43	69	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	44	126	N	None	Recovered
			Pain in jaw	顎痛	1	N	TE	44	4	N	None	Recovered
			Bone pain	骨痛	2	N	TE	50	8	N	None	Recovered
			Lethargy	嗜眠	3	N	TE	53		Y	None	Ongoing at time of death
			Musculoskeletal stiffness	筋骨格硬直	1	N	TE	55	57	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	57	55	N	None	Ongoing at time of death
			Ligament injury	靭帯損傷	2	N	TE	74	38	N	None	Recovered
			Lower limb fracture	下肢骨折	2	N	TE	74		N	None	Ongoing at time of death
			Dysgeusia	味覚異常	1	N	TE	83		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	103	3	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	105	2	Y	None	Recovered
			Oral herpes	口腔ヘルペス	2	N	TE	107		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	111	16	Y	-	
			Weight decreased	体重減少	2	N	TE	111		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	2	N	TE	111	59	N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	124	1	Y	None	Recovered
			Anaemia	貧血	2	N	TE	126	12	Y	-	
			Vomiting	嘔吐	1	N	TE	126	1	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	129	1	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	136	1	Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	N	TE	137	5	Y	-	
			Anaemia	貧血	2	N	TE	141		Y	None	Ongoing at time of death
			Insomnia	不眠症	2	N	TE	153		N	None	Ongoing at time of death
			Restless legs syndrome	下肢静止不能症候群	2	N	TE	165		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	169		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	169	50	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	218		N	None	Ongoing at time of death
			Epistaxis	鼻出血	1	N	TE	218		N	None	Ongoing at time of death
041005	UK	76/M/C	Bone pain	骨痛	2	N	TE	7	191	N	None	Not recovered, but no changes expected
			Defaecation urgency	便意切迫	1	N	TE	8	21	Y	None	Recovered
			Frequent bowel movements	排便回数増加	1	N	TE	8	21	Y	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	78	5	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	80	1	Y	None	Recovered
			Pathological fracture	病的骨折	2	Y	TE	118	51	N	None	Recovered
			Bone pain	骨痛	3	N	TE	197		N	None	Not recovered, but no changes expected
			Musculoskeletal stiffness	筋骨格硬直	1	N	TE	197		N	None	Not recovered, but no changes expected
			Pain in extremity	四肢痛	1	N	TE	197		N	None	Not recovered, but no changes expected
			Soft tissue infection	軟部組織感染	2	N	TE	222		N	None	Not recovered, but no changes expected

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
041006	UK	64/M/C	Lower respiratory tract infection	下気道感染	2	Y	Pre	-65	8	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	2	2	Y	None	Recovered
			Contusion	挫傷	1	N	TE	39	110	N	None	Recovered
			Joint sprain	関節捻挫	1	N	TE	39	110	N	None	Recovered
			Skin laceration	皮膚裂傷	1	N	TE	39	110	N	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	60	7	N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	Y	TE	66	20	N	None	Recovered
			Therapeutic agent toxicity	治療薬毒性	4	Y	TE	73	1	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	92	6	Y	None	Recovered
			Bone pain	骨痛	3	Y	TE	100	17	N	None	Recovered
			Bone pain	骨痛	3	N	TE	116	2	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	117	25	N	None	Recovered
			Bone pain	骨痛	2	N	TE	141		N	None	Not recovered, but no changes expected
041008	UK	74/M/C	Anaemia	貧血	2	N	Pre	1	29	N	Drug administration postponed	Recovered
			Nausea	悪心	2	N	TE	1	3	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	1	3	N	None	Recovered
			Anaemia	貧血	2	Y	TE	29	4	N	Drug administration postponed	Recovered
			Acute myocardial infarction	急性心筋梗塞	4	Y	TE	29	4	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	32	19	N	Drug administration postponed	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Lower respiratory tract infection	下気道感染	2	N	TE	35	13	N	None	Recovered
			Anaemia	貧血	3	Y	TE	50	4	N	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	50	3	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	52		N	None	Ongoing at time of death
			Anaemia	貧血		Y	TE	76		N	Drug administration postponed	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	5	Y	TE	79	1	N	None	Death
041011	UK	58/M/C	Oral candidiasis	口腔カンジダ症	2	N	Pre	1		N	None	Recovered
			Metastases to bone	骨転移	2	N	TE	27	6	N	None	Recovered
			Anaemia	貧血	2	N	TE	29	84	Y	None	Ongoing at time of death
			Metastases to bone	骨転移	2	Y	TE	32	18	N	None	Recovered
			Metastases to bone	骨転移	2	N	TE	49		N	None	Not recovered, but no changes expected
			Oedema peripheral	末梢性浮腫	2	N	TE	57	57	N	None	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	3	Y	TE	63	6	N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	63	6	N	Drug administration postponed	Recovered
			Diabetes mellitus	糖尿病	2	N	TE	71	56	N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	2	N	TE	84	58	Y	Drug administration postponed	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	85	79	N	Drug permanently withdrawn	Death
			Anaemia	貧血	1	N	TE	112	30	Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	113	38	N	None	Ongoing at time of death
			Memory impairment	記憶障害	1	N	TE	113		N	None	Ongoing at time of death
			Rales	ラ音	1	N	TE	113		N	None	Ongoing at time of death
			Dizziness postural	体位性めまい	2	N	TE	116		N	None	Ongoing at time of death
			Diabetes mellitus	糖尿病	1	N	TE	126		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	141		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	141	5	Y	Drug administration postponed	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	145		Y	Drug administration postponed	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	Y	TE	150		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	163	1	N	Drug permanently withdrawn	Death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
041012	UK	62/M/C	Nausea	悪心	1	N	TE			N	None	Recovered
			Ingrowing nail	嵌入爪	2	N	Pre			N	Not applicable	Recovered
			Lower respiratory tract infection	下気道感染	2	N	Pre	-2		N	None	Recovered
			Bone pain	骨痛	2	N	TE	1	5	Y	None	Recovered
			Nightmare	悪夢	2	N	TE	1	20	N	None	Recovered
			Skin odour abnormal	皮膚異常臭	2	N	TE	1	57	Y	None	Recovered
			Nail infection	爪感染	2	N	TE	5	1	N	None	Recovered
			Anaemia	貧血	2	N	TE	29	29	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	29	3	Y	None	Recovered
			Fatigue	疲労	2	N	TE	40		Y	None	Not recovered, but no changes expected
			Insomnia	不眠症	2	N	TE	40	176	N	None	Recovered
			Anaemia	貧血	1	N	TE	57	29	Y	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	1	N	TE	57	57	Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	61	4	Y	None	Recovered
			Dry skin	皮膚乾燥	2	N	TE	80	154	N	None	Recovered
			Skin exfoliation	皮膚剥脱	2	N	TE	80	153	N	None	Recovered
			Anaemia	貧血	2	N	TE	85	85	Y	None	Recovered
			Nasopharyngitis	鼻咽頭炎	2	N	TE	110	32	N	None	Recovered
			Odynophagia	嚥下痛	1	N	TE	113	6	N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	2	N	TE	113		Y	None	Not recovered, but no changes expected
			Pharyngolaryngeal pain	咽喉頭疼痛	2	N	TE	113	6	N	None	Recovered
			Oral candidiasis	口腔カンジダ症	2	Y	TE	118	2	N	None	Recovered
			Oral candidiasis	口腔カンジダ症	1	N	TE	119	7	N	None	Recovered
			Pain of skin	皮膚疼痛	1	N	TE	120	113	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	133	2	N	None	Recovered
			Stomach discomfort	胃不快感	2	N	TE	148	22	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Decreased appetite	食欲減退	2	N	TE	148	17	N	Not applicable	Recovered
			Oral candidiasis	口腔カンジダ症	2	N	TE	154		N	Not applicable	Recovered
			Decreased appetite	食欲減退	1	N	TE	164	53	N	Not applicable	Recovered
			Anaemia	貧血	3	Y	TE	169	2	Y	Not applicable	Recovered
			Leukopenia	白血球減少症	3	N	TE	169		N	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	1	N	TE	169	21	Y	Not applicable	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	169		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	N	TE	170	11	Y	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	180	16	Y	Not applicable	Not recovered, but no changes expected
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	189	13	N	Not applicable	Recovered
			Anaemia	貧血	1	N	TE	195		Y	Not applicable	Not recovered, but no changes expected
042015	UK	72/M/C	Increased appetite	食欲亢進	1	N	TE			N	None	Recovered
			Somnolence	傾眠	2	N	TE			N	None	Recovered
			Diplopia	複視	3	N	TE	14	10	Y	None	Recovered
			Balance disorder	平衡障害	1	N	TE	14	10	N	None	Recovered
			Confusional state	錯乱状態	3	N	TE	14	10	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	15	15	Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Lower respiratory tract infection	下気道感染	1	N	TE	53	6	N	None	Recovered
			Agitation	激越	2	N	TE	114	2	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	115	1	N	None	Death
			Increased bronchial secretion	気管支分泌増加	2	N	TE	115	1	N	None	Recovered
042020	UK	73/M/C	Aphthous stomatitis	アフタ性口内炎	1	N	TE			N	None	Recovered
			Diarrhoea	下痢	1	N	TE	4	6	Y	None	Recovered
			Decreased appetite	食欲減退	2	N	TE	4	150	N	None	Ongoing at time of death
			Lethargy	嗜眠	2	N	TE	4	146	N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	23		N	None	Ongoing at time of death
			Radius fracture	橈骨骨折	3	N	TE	48	33	N	None	Recovered
			Bone pain	骨痛	2	N	TE	63		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	67	122	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	89	71	N	None	Recovered
			Melaena	メレナ	1	N	TE	99		N	None	Ongoing at time of death
			Haematuria	血尿	1	Y	TE	125	2	N	None	Recovered
			Haematuria	血尿	2	N	TE	140	4	N	Drug administration postponed	Recovered
			Haematuria	血尿	2	Y	TE	143	2	N	Drug administration postponed	Recovered
			Lethargy	嗜眠	1	N	TE	149		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Decreased appetite	食欲減退	1	N	TE	153		N	None	Ongoing at time of death
			Renal tubular necrosis	腎尿細管壊死	3	Y	TE	210	89	N	Not applicable	Recovered
042030	UK	61/M/C	Proctalgia	肛門周囲痛	2	N	TE			N	None	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	TE			N	None	Ongoing at time of death
			Depressed mood	抑うつ気分	1	N	TE			N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	1		N	None	
			Vomiting	嘔吐	1	N	TE	1		N	None	Recovered
			Bone pain	骨痛	1	N	TE	2	28	Y	None	Recovered
			Haematuria	血尿	3	Y	TE	12	5	N	None	Recovered
			Constipation	便秘	1	N	TE	29	39	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	52		N	None	Recovered
			Renal failure acute	急性腎不全	3	Y	TE	52	8	N	Drug administration postponed	Recovered
			Hypotension	低血圧	2	N	TE	52		N	None	Recovered
			Constipation	便秘	3	Y	TE	67	6	N	Drug administration postponed	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	132	3	N	None	Recovered
			Deep vein thrombosis	深部静脈血栓症	2	N	TE	177		N	Drug permanently withdrawn	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Diarrhoea	下痢	2	N	TE	207		N	None	Ongoing at time of death
042034	UK	75/M/C	Oedema peripheral	末梢性浮腫	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	141		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	141		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	172	1	N	Not applicable	Death
042041	UK	80/M/C	Fatigue	疲労	2	N	TE			N	None	Recovered
			Cauda equina syndrome	馬尾症候群	3	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	5		Y	None	Recovered
			Urinary incontinence	尿失禁	1	N	TE	29	115	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	41	22	N	Drug administration postponed	Recovered with sequelae
			Bone pain	骨痛	3	N	TE	42	93	N	None	Recovered
			Pathological fracture	病的骨折	2	N	TE	62	73	N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	84	6	N	None	Recovered
			Cellulitis	蜂巣炎	2	N	TE	85	7	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	85	59	N	None	Recovered
			Bone pain	骨痛	2	N	TE	87		N	None	Ongoing at time of death
			Urine flow decreased	尿流量減少	1	N	TE	127	17	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	134	57	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Haematuria	血尿	1	N	TE	142		N	Not applicable	Ongoing at time of death
			Dysarthria	構語障害	2	Y	TE	143	9	N	None	Recovered
			Aggression	攻撃性	2	Y	TE	143	5	N	None	Recovered
			Confusional state	錯乱状態	2	Y	TE	143	9	N	None	Recovered
			Urinary retention	尿閉	2	Y	TE	143	5	N	None	Recovered with sequelae
			Confusional state	錯乱状態	1	N	TE	151	40	N	None	Recovered
			Urinary retention	尿閉	3	N	TE	151		N	Not applicable	Ongoing at time of death
043003	UK	64/M/C	Anaemia	貧血	1	N	Pre	-5	99	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	1	29	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	1	6	Y	None	Recovered
			Mouth ulceration	口腔内潰瘍形成	2	N	TE	73	29	N	None	Recovered
			Bone pain	骨痛	2	N	TE	75	6	N	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	96	6	N	None	Recovered
			Bone pain	骨痛	2	N	TE	96		Y	None	Not recovered, but no changes expected
			Lower respiratory tract infection	下気道感染	3	Y	TE	101	3	N	None	Recovered
			Metastases to central nervous system	中枢神経系転移	4	Y	TE	121	9	N	Drug permanently withdrawn	Recovered
			Fatigue	疲労	1	N	TE	175	6	Y	None	Recovered
043005	UK	66/M/C	Bone pain	骨痛	2	N	Pre	-5	29	N	Not applicable	Recovered
			Myalgia	筋痛	1	N	TE	52	29	N	None	Recovered
			Myalgia	筋痛	1	N	TE	52	29	N	None	Recovered
			Fatigue	疲労	1	N	TE	108	42	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Myalgia	筋痛	1	N	TE	148		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	216	3	N	Not applicable	Recovered
043007	UK	60/M/A	Urinary retention	尿閉	2	N	TE			N	Not applicable	Recovered
			Diarrhoea	下痢	2	N	TE	1		Y	None	Recovered
			Fatigue	疲労	1	N	TE	1		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	Pre	1	9	N	None	Recovered
			Bone pain	骨痛	2	N	TE	29	1	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	47	3	Y	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	85	29	N	None	Recovered
			Skin nodule	皮膚小結節	1	N	TE	85	29	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	94	4	Y	None	Recovered
			Cough	咳嗽	1	N	TE	94	7	Y	None	Recovered
			Skin discolouration	皮膚変色	1	N	TE	107		Y	None	Recovered
			Bone pain	骨痛	1	N	TE	113		N	None	Not recovered, but no changes expected
			Dysuria	排尿困難	3	N	TE	122		N	None	Recovered with sequelae
			Urinary retention	尿閉	3	Y	TE	152	4	N	Not applicable	Recovered
			Micturition disorder	排尿異常	2	N	TE	156		N	Not applicable	Not recovered, but no changes expected
			Vertigo	回転性めまい	2	N	TE	198	41	N	None	Recovered
			Bone pain	骨痛	2	N	TE	198		N	None	Not recovered, but no changes expected
043011	UK	77/M/A	Vision blurred	霧視	1	N	TE			N	None	Recovered
			Diarrhoea	下痢	1	N	TE			Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Paraesthesia	錯感覚	1	N	TE			N	None	Not recovered, but no changes expected
			Fatigue	疲労	2	N	TE	1		Y	None	Not recovered, but no changes expected
			Hypocalcaemia	低カルシウム血症	2	N	TE	10		N	None	Not recovered, but no changes expected
			Dizziness	浮動性めまい	2	Y	TE	36	2	N	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	56	29	N	None	Recovered
			Dizziness	浮動性めまい	2	N	TE	84	6	N	None	Recovered
			Skin discolouration	皮膚変色	1	N	TE	86		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	2	Y	TE	88	2	Y	None	Recovered
			Vertigo	回転性めまい	1	N	TE	106	3	N	None	Recovered
			Fatigue	疲労	3	N	TE	120		Y	None	Not recovered, but no changes expected
043012	UK	55/M/C	Diarrhoea	下痢	1	N	TE			Y	None	Recovered
			Nocturia	夜間頻尿	1	N	TE			N	None	Not recovered, but no changes expected
			Myalgia	筋痛	1	N	Pre	-6	64	N	None	Recovered
			Paraesthesia	錯感覚	1	N	TE	30	29	Y	None	Recovered
			Abdominal pain	腹痛	1	N	TE	86		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	135	14	N	None	Recovered
			Hydronephrosis	水腎症	3	Y	TE	135	14	N	None	Recovered
			Renal failure acute	急性腎不全	3	Y	TE	135	14	N	Drug permanently withdrawn	Recovered
			Nausea	悪心	2	N	TE	137		N	None	Recovered
			Pulmonary embolism	肺塞栓症	4	Y	TE	142	7	N	Drug permanently withdrawn	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	2	N	TE	173		N	Not applicable	Recovered
044004	UK	76/M/C	Vomiting	嘔吐	1	N	TE			Y	None	
			Haematuria	血尿	1	N	TE			N	None	Recovered
			Ataxia	運動失調	2	N	TE	23		N	None	
			Speech disorder	会話障害	3	N	TE	23	29	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	23		N	None	
			Deafness	難聴	2	N	TE	51		N	None	
			Tinnitus	耳鳴	2	N	TE	51		N	None	
			Fatigue	疲労	1	N	TE	71		Y	None	
			Radiation skin injury	放射線皮膚損傷	1	N	TE	71		N	None	
			Arthralgia	関節痛	2	N	TE	71		Y	None	
			Alopecia	脱毛症	1	N	TE	71		N	None	
			Faecal incontinence	便失禁	1	N	TE	75	1	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	76	1	N	None	Recovered
			Urinary tract infection	尿路感染	1	N	TE	76		N	None	Recovered
			Aphasia	失語症	3	Y	TE	76	4	N	None	Recovered
			Bone pain	骨痛	1	N	TE	78	2	N	None	Recovered
			Bone pain	骨痛	1	N	TE	99		Y	None	
			Bone pain	骨痛	2	N	TE	121		N	None	Not recovered, but no changes expected
			Confusional state	錯乱状態	2	N	TE	121	15	N	None	Recovered
			Mobility decreased	運動性低下	2	N	TE	135		N	None	Ongoing at time of death
			Haematuria	血尿	2	N	TE	154	88	N	Not applicable	Recovered
			Mania	躁病	2	N	TE	159		N	None	Ongoing at study termination / withdrawal
			Haematuria	血尿	2	Y	TE	227	14	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary retention	尿閉	3	Y	TE	227	15	N	Not applicable	Recovered with sequelae
044005	UK	76/M/C	Cardiac failure congestive	うっ血性心不全	4	N	TE			N	Drug administration postponed	Death
			Fatigue	疲労	2	N	TE			Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	7	1	Y	None	Recovered
			Left ventricular dysfunction	左室機能不全	3	N	TE	54	73	N	Drug administration postponed	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	54	73	N	Drug administration postponed	Ongoing at time of death
			Dyspnoea	呼吸困難	3	N	TE	54	17	N	Drug administration postponed	Ongoing at time of death
			Troponin T increased	トロポニンＴ増加	4	N	TE	57	70	N	Drug administration postponed	Ongoing at time of death
			Pleural effusion	胸水	2	N	TE	57	70	N	Drug administration postponed	Ongoing at time of death
			Pulmonary embolism	肺塞栓症	3	Y	TE	57	3	N	Drug permanently withdrawn	Recovered with sequelae
			Pulmonary oedema	肺水腫	1	N	TE	58	69	N	Drug administration postponed	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	2	N	TE	70	57	N	Drug administration postponed	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	5	Y	TE	126	1	N	Drug administration postponed	Death
044009	UK	67/M/C	Diarrhoea	下痢	1	N	TE			Y	None	Recovered
			Bone pain	骨痛	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Haematuria	血尿	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	2		Y	None	Recovered
			Pelvic pain	骨盤痛	2	N	TE	56		N	None	Recovered
			Deep vein thrombosis	深部静脈血栓症	3	Y	TE	107	8	N	Drug administration postponed	Recovered
			Intestinal perforation	腸管穿孔	4	Y	TE	167	10	N	Drug administration postponed	Recovered
			Anorexia	食欲不振	2	Y	TE	167	10	N	Drug administration postponed	Recovered
			Dehydration	脱水	3	Y	TE	167	10	N	Drug administration postponed	Recovered
			Deep vein thrombosis	深部静脈血栓症	3	Y	TE	167	11	N	Drug permanently withdrawn	Recovered with sequelae

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pathological fracture	病的骨折	2	Y	TE	173	5	N	Drug administration postponed	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	173		N	Drug permanently withdrawn	Not recovered, but no changes expected
			Cellulitis	蜂巣炎	3	Y	TE	200	7	N	Not applicable	Recovered
045009	UK	57/M/C	Neutropenia	好中球減少症	4	N	TE	154	15	Y	Drug administration postponed	Recovered
			Bone pain	骨痛	2	N	TE	169	37	Y	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	176	31	N	Not applicable	Recovered
046002	UK	78/M/C	Urinary tract infection	尿路感染	2	N	TE			N	None	Recovered
			Urinary incontinence	尿失禁	1	N	TE			N	None	Recovered
			Anaemia	貧血	2	N	Post	250	138	Y	Not applicable	Recovered
			Anaemia	貧血	3	Y	Post	387	2	Y	Not applicable	Recovered
046004	UK	64/M/C	Nausea	悪心		N	TE			Y	None	Recovered
			Vomiting	嘔吐		N	TE			Y	None	Recovered
			Bone pain	骨痛	3	N	TE			Y	None	Ongoing at study termination / withdrawal
			Night sweats	寝汗		N	TE			N	None	Recovered
			Nausea	悪心	2	N	TE	2	1	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	3	2	Y	None	Recovered
			Diarrhoea	下痢	2	N	TE	28	19	Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Diarrhoea	下痢	2	N	TE	28	16	N	None	Recovered
			Bone pain	骨痛	2	N	TE	33	25	N	None	Recovered
			Anaemia	貧血	2	N	TE	56	108	Y	Not applicable	Recovered
			Diarrhoea	下痢	2	N	TE	57	2	N	None	Recovered
			Cough	咳嗽	1	N	TE	83	64	N	None	Recovered
			Anaemia	貧血	2	N	TE	107	57	Y	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	163	39	Y	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	163	39	Y	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	201	22	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	201	103	Y	Not applicable	Ongoing at time of death
			Anaemia	貧血	3	N	TE	222	11	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	232	3	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	234	18	Y	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	251	14	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	264	31	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	294	10	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	303	21	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	303	76	Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	N	TE	323	8	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	330	30	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	359	20	Y	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	378	9	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	378	77	Y	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	386		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	Post	454	23	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	Post	476		Y	None	Ongoing at time of death
047002	UK	81/M/C	Anaemia	貧血	3	N	TE	2	1	Y	None	Recovered
			Anaemia	貧血	3	N	TE	39	1	Y	None	Recovered
			Anaemia	貧血	3	N	TE	73	1	Y	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	3	N	TE	85		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	2	N	TE	136		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	154	1	N	Not applicable	Death
047003	UK	75/M/C	Urinary tract infection	尿路感染	2	N	TE	14	8	N	None	Recovered with sequelae

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary tract infection	尿路感染	2	N	TE	64	10	N	None	Recovered with sequelae
			Urinary retention	尿閉	3	Y	TE	98	3	N	None	Recovered with sequelae
			Infection	感染	2	N	TE	142	14	N	None	Recovered with sequelae
			Anaemia	貧血	3	N	TE	155	1	Y	None	Recovered
048001	UK	59/M/C	Decreased appetite	食欲減退	1	N	TE			N	None	Recovered
			Anaemia	貧血	1	N	Pre	-35	71	N	None	Recovered
			Constipation	便秘	2	N	Pre	-12	11	N	None	Recovered
			Musculoskeletal pain	筋骨格痛	3	Y	Pre	-4	12	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	3	1	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	6	1	N	None	Recovered
			Bone pain	骨痛	2	N	TE	8	97	N	None	Ongoing at time of death
			Hypocalcaemia	低カルシウム血症	2	N	TE	29	6	N	None	Recovered
			Vomiting	嘔吐	3	N	TE	33	1	N	None	Recovered
			Hypocalcaemia	低カルシウム血症	3	Y	TE	34	4	N	None	Recovered
			Anaemia	貧血	2	N	TE	36	34	N	None	Recovered
			Hypocalcaemia	低カルシウム血症	2	N	TE	37	21	N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE	58	6	N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE	58	13	N	None	Recovered
			Constipation	便秘	2	N	TE	62	24	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	62	1	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	62	1	N	None	Recovered
			Decreased appetite	食欲減退	2	N	TE	62	17	N	None	Recovered
			Lower respiratory tract infection	下気道感染	3	Y	TE	63	3	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Depression	うつ病	2	N	TE	70		N	None	Ongoing at time of death
			Lymphadenopathy	リンパ節症	1	N	TE	85		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	104	37	N	None	Ongoing at time of death
			Decreased appetite	食欲減退	2	N	TE	113		N	None	Recovered
			Neutropenia	好中球減少症	2	N	TE	129	13	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	134	1	N	None	Recovered
			Bone pain	骨痛	2	N	TE	140		N	None	Ongoing at time of death
			Neutropenia	好中球減少症	3	N	TE	141	15	N	Drug administration postponed	Recovered
			Amnesia	健忘	1	N	TE	141		N	None	Ongoing at time of death
			Headache	頭痛	2	N	TE	141		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	145		N	None	Ongoing at time of death
			Anxiety	不安	2	N	TE	147		N	None	Ongoing at time of death
			Oral candidiasis	口腔カンジダ症	1	N	TE	155		N	None	Ongoing at study termination / withdrawal
048003	UK	60/M/C	Anaemia	貧血	3	N	TE			N	Not applicable	Recovered
			Abdominal distension	腹部膨満	2	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	1	N	TE			N	Not applicable	Recovered
			Oral candidiasis	口腔カンジダ症	1	N	TE			N	Not applicable	Recovered
			Fatigue	疲労	1	N	TE	2	8	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	6	6	N	None	Recovered
			Asthenopia	眼精疲労	1	N	TE	29		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	60		N	None	Ongoing at time of death
			Myalgia	筋痛	2	N	TE	115		N	None	Ongoing at time of death
			Lethargy	嗜眠	1	N	TE	148		N	None	Ongoing at time of death
			Metastases to central nervous system	中枢神経系転移	4	Y	TE	164	19	N	Not applicable	Recovered with sequelae
048004	UK	71/M/C	Diarrhoea	下痢	2	N	TE			N	None	Recovered
			Nausea	悪心	2	N	TE			N	None	Recovered
			Vomiting	嘔吐	2	N	TE			N	None	Recovered
			Constipation	便秘	2	N	Pre	-2	4	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	4	2	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	8	3	N	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	37	107	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	109	3	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	109	3	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	168	16	N	Not applicable	Recovered
			Dyspepsia	消化不良	1	N	TE	169	4	N	Not applicable	Recovered
			Faecal incontinence	便失禁	2	N	TE	194	1	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Spinal cord compression	脊髄圧迫	3	Y	TE	195	5	N	Not applicable	Recovered with sequelae
048007	UK	79/M/C	Bone pain	骨痛	2	N	Pre	1	31	N	Drug administration postponed	Recovered
			Constipation	便秘	2	N	TE	29		N	None	Recovered
			Bone pain	骨痛	2	N	TE	29		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	31	29	N	Drug administration postponed	Recovered
048010	UK	77/M/C	Decreased appetite	食欲減退	1	N	TE	4	2	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	6	3	N	None	Recovered
			Hot flush	ほてり	1	N	TE	6		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	8	62	N	-	
			Nausea	悪心	1	N	TE	25	4	N	None	Recovered
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2	N	TE	29	29	Y	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	TE	29	29	Y	None	Recovered
			Nail avulsion	爪裂離	2	N	TE	52		N	None	Recovered with sequelae
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	3	N	TE	57	29	Y	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	57	29	Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	69	144	N	Not applicable	Recovered
			Constipation	便秘	1	N	TE	70		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	72		N	None	Ongoing at time of death
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2	N	TE	85	29	Y	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	TE	85	29	Y	None	Recovered
			Paraesthesia	錯感覚	1	N	TE	127		N	None	Ongoing at time of death
			Bone pain	骨痛	2	Y	TE	212	8	N	Not applicable	Recovered
			Urinary incontinence	尿失禁	2	N	TE	212	8	N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	219		N	Not applicable	Ongoing at time of death
049002	UK	73/M/C	Lower respiratory tract infection	下気道感染	3	Y	TE	9	11	N	None	Recovered
			Oral candidiasis	口腔カンジダ症	2	N	TE	57	53	Y	None	Recovered
			Paraesthesia	錯感覚	1	N	TE	100	30	N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	Y	TE	109	3	N	Drug administration postponed	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	4	Y	TE	129		N	None	Ongoing at time of death
			Pneumonia	肺炎	4	Y	TE	135	7	N	Drug permanently withdrawn	Death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pneumonia	肺炎	5	Y	TE	141	1	N	Drug permanently withdrawn	Death
049007	UK	80/M/C	Nausea	悪心	2	N	TE	3		Y	None	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	3		Y	None	Ongoing at time of death
			Mucosal inflammation	粘膜の炎症	2	N	TE	29		Y	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	29		Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	120		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	128		N	None	Ongoing at time of death
			Headache	頭痛	2	N	TE	148	51	N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	176	3	N	Not applicable	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	198		N	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	3	Y	TE	198		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	198	12	N	Not applicable	Death
			Headache	頭痛	4	N	TE	198		N	None	Ongoing at time of death
			Urinary retention	尿閉	2	N	TE	204		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	209	1	N	Not applicable	Death
049008	UK	72/M/C	Decreased appetite	食欲減退	2	N	TE			N	None	Ongoing at time of death
			Lymphoedema	リンパ浮腫	1	N	Pre			N	None	Recovered
			Ear pain	耳痛	1	N	Pre	-7		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre	-3	5	N	None	Recovered
			Fatigue	疲労	2	N	TE	29		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	29	50	Y	None	Recovered
			Constipation	便秘	2	N	TE	40		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	40	2	N	None	Recovered with sequelae
			Palpitations	動悸	1	N	TE	54	4	N	Not applicable	Recovered
			Depressed mood	抑うつ気分	1	N	TE	54		N	None	Ongoing at time of death
			Vomiting	嘔吐	2	Y	TE	57	6	N	Drug administration postponed	Recovered
			Pyrexia	発熱	1	Y	TE	61	2	N	Drug administration postponed	Recovered
			Nausea	悪心	2	Y	TE	65	6	N	Drug administration postponed	Recovered with sequelae
			Vomiting	嘔吐	2	Y	TE	65	6	N	Drug administration postponed	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	N	TE	67	1	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	89	1	N	Not applicable	Recovered
			Abdominal pain	腹痛	3	Y	TE	111		N	Not applicable	Ongoing at time of death
			Nausea	悪心	3	Y	TE	111		N	Not applicable	Ongoing at time of death
			Vomiting	嘔吐	3	Y	TE	111		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	111	11	N	Not applicable	Death
			Anaemia	貧血	2	N	TE	113		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	121	1	N	Not applicable	Death
050005	UK	77/M/C	Diarrhoea	下痢	1	N	TE	3	2	N	None	Recovered
			Bone pain	骨痛	3	N	TE	18		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	18	29	N	None	Recovered
			Muscular weakness	筋力低下	1	N	TE	29	26	N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	46		N	None	Recovered
			Muscular weakness	筋力低下	2	N	TE	54	5	N	None	Ongoing at study termination / withdrawal
			Muscular weakness	筋力低下	3	N	TE	58		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Spinal cord compression	脊髄圧迫	2	Y	TE	60	13	N	None	Recovered with sequelae
			Cerebrovascular accident	脳血管発作	4	Y	TE	64	9	N	Drug administration postponed	Recovered with sequelae
			Eye infection	眼感染	2	N	TE	70		N	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	2	N	TE	72	12	N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	82	2	N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	Y	TE	83		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	2	Y	TE	83	2	N	None	Recovered
			Spinal cord compression	脊髄圧迫	2	Y	TE	83		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
050019	UK	70/M/C	Urine output increased	尿量増加	1	N	TE			N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Night sweats	寝汗	1	N	TE			N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dehydration	脱水	2	Y	Pre	-6	2	N	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	1	N	TE	55	3	N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	55	3	N	None	Recovered
			Infection	感染	3	Y	TE	60	3	N	None	Recovered with sequelae
			Gout	痛風	2	N	TE	74	14	N	None	Recovered
			Bone pain	骨痛	1	N	TE	99		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	113		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE	141		N	None	Ongoing at time of death
			Transient ischaemic attack	一過性脳虚血発作	2	Y	TE	189	4	N	Not applicable	Recovered
			Confusional state	錯乱状態	3	Y	TE	195	9	N	Not applicable	Recovered
			Urinary retention	尿閉	2	N	TE	195	6	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	196	4	N	Not applicable	Recovered
			Rash	発疹	1	N	TE	200	89	N	Not applicable	Recovered
051003	UK	65/M/C	Bone pain	骨痛	2	N	TE	3		Y	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	5		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	2	N	TE	5		N	None	Ongoing at time of death
			Dysgeusia	味覚異常	1	N	TE	5		Y	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	1	N	TE	12		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	42		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	4	Y	TE	42		N	Drug permanently withdrawn	Ongoing at time of death
051007	UK	75/M/C	Bone pain	骨痛	2	N	Pre	-8	59	N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	2	1	Y	None	Recovered
			Bone pain	骨痛	1	N	Pre	51		N	None	Ongoing at time of death
			Dyspepsia	消化不良	1	N	TE	63	25	Y	None	Ongoing at time of death
			Dyspepsia	消化不良	3	N	TE	87	2	Y	None	Ongoing at time of death
			Dyspepsia	消化不良	1	N	TE	88		Y	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	90	80	Y	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	106	26	N	None	Recovered
			Nerve root compression	神経根圧迫	4	Y	TE	119	2	N	Drug administration postponed	Recovered with sequelae
			Night sweats	寝汗	1	N	TE	119	35	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	147		N	Drug administration postponed	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Night sweats	寝汗	2	N	TE	153		N	None	Ongoing at time of death
			Oedema	浮腫	1	N	TE	159		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	169		Y	None	Ongoing at time of death
			Metastases to central nervous system	中枢神経系転移	2	Y	TE	174		N	Not applicable	Not recovered, but no changes expected
051010	UK	68/M/C	Bone pain	骨痛	2	N	TE	21		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	47		N	None	Not recovered, but no changes expected
			Urinary bladder haemorrhage	膀胱出血	1	N	TE	47	49	N	Drug administration postponed	Not recovered, but no changes expected
			Fatigue	疲労	2	N	TE	58		N	None	Ongoing at time of death
			Pilonidal cyst	毛巣嚢胞	2	N	TE	64	65	N	None	Recovered
			Bone pain	骨痛	2	N	TE	83	23	N	None	Recovered
			Urinary bladder haemorrhage	膀胱出血	3	N	TE	95		N	Drug administration postponed	Not recovered, but no changes expected
			Renal failure acute	急性腎不全	3	Y	TE	204	10	N	Not applicable	Recovered with sequelae
051011	UK	77/M/C	Bone pain	骨痛	2	N	TE	2	5	Y	None	Recovered
			Fatigue	疲労	2	N	TE	30	4	N	None	Recovered
			Bone pain	骨痛	2	N	TE	30	2	Y	None	Recovered
			Nausea	悪心	1	N	TE	44		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	44	32	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	75	39	N	None	Recovered
			Bile duct obstruction	胆管閉塞	2	Y	TE	166	12	N	Not applicable	Recovered with sequelae
			Bile duct obstruction	胆管閉塞	2	Y	TE	177		N	Not applicable	Not recovered, but no changes expected
			Insomnia	不眠症	1	N	TE	219		N	None	Ongoing at time of death
051012	UK	73/M/C	Decreased appetite	食欲減退	1	N	TE	30		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	108	1	N	None	Death
051021	UK	74/M/C	Gastric ulcer	胃潰瘍	1	N	TE			N	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE			N	None	Recovered
			Pulmonary embolism	肺塞栓症	4	N	TE			N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	8	41	Y	None	Recovered
			Intervertebral disc protrusion	椎間板突出	1	N	TE	8		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	42	7	N	None	Recovered with sequelae
			Anorexia	食欲不振	2	N	TE	94		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	120	211	N	None	Recovered
			Constipation	便秘	2	N	TE	125		N	None	Ongoing at time of death
			Dehydration	脱水	2	Y	TE	125	8	N	None	Recovered
			Helicobacter infection	ヘリコバクター感染	2	N	TE	131	7	N	None	Recovered
053002	Netherlands	79/M/C	Balance disorder	平衡障害	1	N	TE			N	None	Not recovered, but no changes expected

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	Pre	-9	19	N	None	Recovered
			Fatigue	疲労	2	N	TE	1	224	Y	None	Recovered with sequelae
			Nausea	悪心	2	N	TE	2	6	Y	None	Recovered
			Nausea	悪心	1	N	TE	7	232	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	7	1	Y	None	Recovered
			Increased tendency to bruise	挫傷発生の増加傾向	1	N	TE	29		Y	None	Not recovered, but no changes expected
			Gastrointestinal pain	消化器痛	1	N	TE	113	1	N	None	Recovered
			Bone pain	骨痛	2	N	TE	116	54	N	None	Recovered with sequelae
			Eructation	おくび	1	N	TE	149		N	None	Not recovered, but no changes expected
			Vomiting	嘔吐	2	N	TE	149	6	Y	Not applicable	Recovered
			Dizziness postural	体位性めまい	1	N	TE	162		N	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	169		N	None	Not recovered, but no changes expected
			Thrombocytopenia	血小板減少症	2	N	TE	176		N	Not applicable	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	176		N	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	3	Y	TE	177	2	Y	Not applicable	Recovered with sequelae
			Fatigue	疲労	3	N	TE	224		Y	None	Not recovered, but no changes expected
053004	Netherlands	72/M/C	Bone pain	骨痛	1	N	Pre	-1	4	N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	3	22	Y	None	Recovered with sequelae

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Headache	頭痛	1	N	TE	3	22	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	24		N	None	Not recovered, but no changes expected
			Chills	悪寒	1	N	TE	31	4	Y	None	Recovered
			Pruritus	そう痒症	1	N	TE	31	4	Y	None	Recovered
			Nausea	悪心	2	N	TE	32	3	Y	None	Recovered
			Myalgia	筋痛	1	N	TE	32	3	Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	1	N	TE	38	70	N	None	Recovered
			Bone pain	骨痛	1	N	TE	79	15	N	None	Recovered with sequelae
			Faecal incontinence	便失禁	1	N	TE	81	31	N	None	Not recovered, but no changes expected
			Back pain	背部痛	2	N	TE	93	12	N	None	Recovered
			Back pain	背部痛	3	N	TE	104	38	N	None	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	104		N	None	Not recovered, but no changes expected
			Faecal incontinence	便失禁	2	N	TE	111		N	None	Not recovered, but no changes expected
			Faecal incontinence	便失禁	2	N	TE	111	60	N	None	Recovered
			Gastritis	胃炎	1	N	TE	113	24	N	None	Recovered
			Rash pruritic	そう痒性皮疹	1	N	TE	130	7	Y	None	Recovered
			Nausea	悪心	2	N	TE	141	7	Y	Not applicable	Recovered
			Fatigue	疲労	3	N	TE	141	7	Y	Not applicable	Recovered
			Constipation	便秘	1	N	TE	150	8	N	Not applicable	Recovered
			Radicular syndrome	根症候群	3	Y	TE	150	8	N	Not applicable	Recovered with sequelae
			Haematuria	血尿	1	N	TE	153	5	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Radicular syndrome	根症候群	2	N	TE	157		N	Not applicable	Not recovered, but no changes expected
054001	Netherlands	75/M/C	Upper respiratory tract infection	上気道感染	1	N	Pre	-15	8	N	Drug administration postponed	Recovered
			Diarrhoea	下痢	1	N	TE	3		Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	57	7	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	63	2	Y	None	Recovered
			Colitis	大腸炎	2	N	TE	86		Y	None	Ongoing at study termination / withdrawal
055002	Netherlands	66/M/C	Lung infection	肺感染	2	N	TE	18	27	N	None	Recovered
			Anorexia	食欲不振	2	N	TE	54		Y	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	54		Y	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	59		Y	None	Ongoing at time of death
			Drug intolerance	薬物不耐性	4	Y	TE	71	3	N	None	Recovered with sequelae
			Pulmonary embolism	肺塞栓症	4	Y	TE	71		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	74	1	N	None	Death
060002	Spain	84/M/C	Anorexia	食欲不振	2	N	TE	29		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cardiac failure	心不全	3	N	TE	100		N	None	Ongoing at study termination / withdrawal
			Dyspnoea	呼吸困難	2	N	TE	100		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	101	31	N	Not applicable	Ongoing at time of death
			Bronchitis	気管支炎	2	N	TE	107	2	N	None	Recovered
			Renal failure	腎不全	2	N	TE	107	3	N	None	Recovered
			Bronchitis	気管支炎	3	Y	TE	108		N	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	N	TE	109	5	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	113	11	Y	None	Ongoing at time of death
			Hyperuricaemia	高尿酸血症	1	N	TE	113		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	123		Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	129	1	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	131		N	Not applicable	Ongoing at time of death
			Death	死亡	5	Y	TE	137	1	N	Not applicable	Death
060003	Spain	85/M/C	Bone pain	骨痛	3	N	TE	31	26	N	None	Ongoing at time of death
			Weight decreased	体重減少	2	N	TE	56	6	N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	2	N	TE	56	11	N	None	Recovered
			Bone pain	骨痛	2	N	TE	56		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	57		N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	61		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	111	1	N	Not applicable	Death
060007	Spain	79/M/C	Nausea	悪心	1	N	Pre	-20	28	N	None	Recovered
			Anorexia	食欲不振	2	N	Pre	-20		N	None	Ongoing at time of death
			Haematuria	血尿	2	N	TE	5		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	6	4	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	6	12	N	Drug permanently withdrawn	Death
			Pyrexia	発熱	1	N	TE	7	2	N	None	Recovered
			Respiratory tract infection	気道感染	2	N	TE	7		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	3	N	TE	8		N	None	Ongoing at time of death
			Asthenia	無力症	1	N	TE	12	2	N	None	Ongoing at time of death
			Asthenia	無力症	3	N	TE	13		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	17	1	N	Drug permanently withdrawn	Death
060010	Spain	75/M/C	Pruritus	そう痒症	1	N	TE	1	37	N	None	Recovered
			Anaemia	貧血	1	N	TE	29	2	Y	None	Recovered
			Cholestasis	胆汁うっ滞	3	Y	TE	29	9	N	Drug permanently withdrawn	Recovered
			Hyperbilirubinaemia	高ビリルビン血症	3	N	TE	29	3	N	None	Recovered
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	3	N	TE	29	3	N	-	
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	29	3	N	-	
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	TE	29	60	N	None	Not recovered, but no changes expected
			Pollakiuria	頻尿	1	N	TE	29	29	N	None	Recovered
			Anaemia	貧血	1	N	TE	31	80	Y	None	Recovered
			Hyperbilirubinaemia	高ビリルビン血症	2	N	TE	31	6	N	None	Recovered
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2	N	TE	31	6	N	-	
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	TE	31	3	N	-	
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1	N	TE	33	22	N	-	
			Hyperbilirubinaemia	高ビリルビン血症	1	N	TE	36	19	N	None	Recovered
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	1	N	TE	36	19	N	-	
			Cholestasis	胆汁うっ滞	1	N	TE	37	35	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2	N	TE	54	18	N	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	TE	54	18	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	57	57	N	None	Recovered
			Cholestasis	胆汁うっ滞	3	Y	TE	71	3	N	Not applicable	Recovered
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	1	N	TE	71	34	N	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1	N	TE	71	40	N	None	Recovered
			Cholestasis	胆汁うっ滞	1	N	TE	73	30	N	None	Recovered
			Hyperbilirubinaemia	高ビリルビン血症	2	N	TE	88	17	N	None	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	4	N	TE	88	23	N	None	Not recovered, but no changes expected
			Chromaturia	着色尿	1	N	TE	88	26	N	None	Recovered
			Cholestasis	胆汁うっ滞	3	Y	TE	102	3	N	Not applicable	Recovered
			Hyperbilirubinaemia	高ビリルビン血症	3	N	TE	104	7	N	None	Recovered
			Hyperbilirubinaemia	高ビリルビン血症	1	N	TE	110	13	N	None	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	TE	110		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	122	41	Y	None	Recovered
			Anaemia	貧血	1	N	TE	162	64	Y	None	Recovered
063002	Spain	64/M/C	Dizziness	浮動性めまい	1	N	Pre			N	None	Recovered
			Respiratory tract infection	気道感染	2	N	TE	16	9	N	None	Recovered
			Muscle spasms	筋痙縮	1	N	TE	29	29	N	None	Recovered
			Discomfort	不快感	1	N	TE	57	3	Y	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	143	29	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Gastroenteritis	胃腸炎	2	Y	TE	183	4	N	Not applicable	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	226	34	N	Not applicable	Recovered
063004	Spain	74/M/C	Abdominal pain upper	上腹部痛	1	N	TE	32	55	N	None	Recovered
			Somnolence	傾眠	2	N	TE	32	55	N	None	Recovered
			Anaemia	貧血	3	N	TE	58	29	N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	86		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	86	29	N	Not applicable	Ongoing at time of death
			Asthenia	無力症	1	N	TE	86		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	86		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	114		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	128	8	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	135	1	N	Drug permanently withdrawn	Death
066004	Spain	78/M/C	Asthenia	無力症	1	N	TE	30	58	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	30	28	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	87	27	N	None	Recovered
			Toothache	歯痛	1	N	TE	113	32	N	None	Recovered
			Pancytopenia	汎血球減少症	4	Y	TE	144		Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	2	N	TE	144	44	Y	None	Ongoing at time of death
			Asthenia	無力症	1	N	TE	177	78	N	Not applicable	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	177	51	N	None	Recovered
070003	Spain	74/M/C	Constipation	便秘	2	N	TE	57	29	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	85	50	N	None	Recovered
			Dyspepsia	消化不良	1	N	TE	85	50	N	None	Recovered
			Nausea	悪心	2	N	TE	85	50	Y	None	Recovered
			Anorexia	食欲不振	2	N	TE	85	50	N	None	Recovered
			Cardiac failure	心不全	3	Y	TE	105	15	N	Drug administration postponed	Recovered
			Renal failure	腎不全	3	Y	TE	105	3	N	Drug administration postponed	Recovered
			Constipation	便秘	1	N	TE	218	29	N	None	Recovered
071006	Spain	76/M/C	Oedema peripheral	末梢性浮腫	1	N	Pre	1	29	N	None	Recovered
			Constipation	便秘	2	Y	TE	35	19	N	None	Recovered
			Asthenia	無力症	2	Y	TE	35	19	N	None	Recovered
			Anorexia	食欲不振	2	Y	TE	35	19	N	None	Recovered
			Renal failure	腎不全	2	Y	TE	52	2	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	80	37	N	None	Recovered
			Bone pain	骨痛	2	N	TE	199	155	N	Not applicable	Recovered
			Headache	頭痛	2	N	TE	199	59	N	None	Recovered
074002	Italy	79/M/C	Muscle spasms	筋痙縮	1	N	Pre	-10	11	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	28	8	N	None	Recovered
			Asthenia	無力症	2	N	TE	33	3	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pyrexia	発熱	1	N	TE	33	15	N	Drug administration postponed	Recovered
			Urinary tract infection	尿路感染	2	N	TE	46	39	N	None	Recovered
			Dry skin	皮膚乾燥	1	N	TE	75	10	Y	None	Recovered
			Asthenia	無力症	1	N	TE	84	83	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	131	29	Y	None	Recovered
			Neutropenia	好中球減少症	2	N	TE	131	29	Y	Drug permanently withdrawn	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	131	29	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	159	18	Y	None	Recovered
			Leukopenia	白血球減少症	4	N	TE	159	4	Y	None	Recovered
			Neutropenia	好中球減少症	4	N	TE	159	4	Y	Drug permanently withdrawn	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	159	15	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	162	5	Y	None	Recovered
			Neutropenia	好中球減少症	1	N	TE	162	5	Y	Drug permanently withdrawn	Recovered
			Blood urea increased	血中尿素増加	1	N	TE	162	43	N	None	Recovered
			Asthenia	無力症	2	N	TE	166		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	173	8	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	180	8	Y	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	183	5	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	187	32	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	187	8	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	194	11	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	204	15	Y	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	218	5	Y	None	Recovered
			Thrombocytopenia	血小板減少症	4	N	TE	218	5	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	222	2	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	222	2	Y	None	Ongoing at time of death
			Bone marrow tumour cell infiltration	腫瘍細胞の骨髄浸潤	3	Y	TE	222	37	N	Not applicable	Death
			Anaemia	貧血	3	N	TE	223	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	223	2	Y	None	
			Neutropenia	好中球減少症	1	N	TE	223	5	Y	Not applicable	
			Thrombocytopenia	血小板減少症	4	N	TE	223	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	1	N	TE	224	2	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	225	8	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	225	1	Y	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Leukopenia	白血球減少症	1	N	TE	225	3	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	225	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	227	3	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	2	N	TE	227	3	Y	Not applicable	
			Thrombocytopenia	血小板減少症	4	N	TE	227	4	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	229	2	Y	None	
			Neutropenia	好中球減少症	3	N	TE	229	2	Y	Not applicable	
			Leukopenia	白血球減少症	2	N	TE	230	4	Y	None	
			Neutropenia	好中球減少症	2	N	TE	230	2	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	230	3	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	1	N	TE	231	3	Y	Not applicable	Recovered
			Anaemia	貧血	1	N	TE	232	4	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	232	4	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	233	2	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	2	N	TE	233	2	Y	Not applicable	Recovered
			Leukopenia	白血球減少症	2	N	TE	234	4	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	235	7	Y	None	Recovered
			Neutropenia	好中球減少症	1	N	Post	235	3	Y	-	

表 2.7.4.7- 4　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	3	N	TE	235	2	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	236	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	237	7	Y	None	
			Neutropenia	好中球減少症	2	N	Post	237	2	Y	-	
			Neutropenia	好中球減少症	3	N	Post	238	5	Y	-	
			Thrombocytopenia	血小板減少症	3	N	TE	238	4	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	241	2	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	241	3	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	242	8	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	2	N	Post	242	4	Y	Not applicable	Recovered
			Leukopenia	白血球減少症	2	N	TE	243	3	Y	None	
			Thrombocytopenia	血小板減少症	3	N	TE	243	2	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	244		Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	1	N	TE	245	9	Y	None	
			Anaemia	貧血	1	N	TE	249		Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	253	2	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	1	N	Post	253	4	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	1	N	TE	254	3	Y	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Leukopenia	白血球減少症	3	N	TE	256		Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	2	N	Post	256		Y	None	Ongoing at time of death
			Bone marrow tumour cell infiltration	腫瘍細胞の骨髄浸潤	5	Y	TE	258	1	N	Not applicable	Death
075001	Italy	59/M/C	Strangury	有痛性排尿困難		N	TE	2	2	N	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	14	28	N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	33	10	Y	Drug administration postponed	Recovered
			Vomiting	嘔吐	1	N	TE	33	10	Y	Drug administration postponed	Recovered
			Anorexia	食欲不振	1	N	TE	33	10	Y	Drug administration postponed	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	41		N	None	Ongoing at time of death
			Strangury	有痛性排尿困難	2	N	TE	78	1	N	None	Recovered
			Death	死亡	5	Y	TE	93	1	N	None	Death
078001	Italy	76/M/C	Constipation	便秘	1	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE			N	None	Recovered
			Pyrexia	発熱	1	N	TE			N	None	Recovered
			Confusional state	錯乱状態	1	N	TE			N	None	Recovered
			Hyperhidrosis	多汗症	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE	2	11	Y	None	Recovered with sequelae

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	38	21	N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	58	21	N	None	Ongoing at time of death
			Asthenia	無力症	2	N	TE	78	37	Y	None	Recovered
			Pyrexia	発熱	1	N	TE	78	29	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	78		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	78	37	N	None	Recovered
			Fatigue	疲労	2	N	TE	127	14	N	None	Ongoing at time of death
			Depression	うつ病	2	N	TE	127		N	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	141		N	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	147	2	Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	Y	TE	147	2	Y	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	149	14	Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	Y	TE	149	11	Y	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	1	Y	TE	163		Y	Drug permanently withdrawn	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	163	15	N	Not applicable	Death
078003	Italy	74/M/C	Somnolence	傾眠	2	N	Pre	1		N	None	Ongoing at time of death
			Confusional state	錯乱状態	2	N	Pre	1		N	None	Ongoing at time of death
			Upper limb fracture	上肢骨折	2	N	TE	20	25	N	None	Recovered
			Asthenia	無力症	2	N	TE	49		Y	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	187		N	Not applicable	Ongoing at time of death
			Amnesia	健忘	2	N	TE	198		N	Not applicable	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	3	Y	TE	213	8	N	Not applicable	Death
			General physical health deterioration	全身健康状態低下	5	Y	TE	220	1	N	Not applicable	Death
078006	Italy	77/M/C	Pyrexia	発熱	1	N	TE	39	34	N	None	Recovered
			Pyrexia	発熱	1	N	TE	91	14	N	None	Recovered
			Anaemia	貧血	2	N	TE	104		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	104		Y	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	104	28	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	131	1	N	Drug permanently withdrawn	Death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
080004	Italy	72/M/C	Weight decreased	体重減少	1	N	Pre	-13	13	N	None	Ongoing at time of death
			Weight decreased	体重減少	2	N	Pre	-1		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	Pre	-1	50	N	None	Recovered
			Bone pain	骨痛	3	N	TE	49	85	N	None	Recovered
			Fatigue	疲労	3	N	TE	133		N	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	133		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	161	1	N	Not applicable	Death
085004	Israel	61/M/C	Asthenia	無力症	1	N	Pre	-4	1	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	Pre	1	30	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	10	3	N	None	Recovered
			Pyrexia	発熱	1	N	TE	36	8	N	None	Recovered
			Arthralgia	関節痛	1	N	TE	100	16	N	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	2	N	TE	115		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	148		N	None	Not recovered, but no changes expected
			Anaemia	貧血	3	N	TE	167	3	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	2	Y	TE	167	4	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	TE	220	7	N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	Y	TE	220	7	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	220	7	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oral fungal infection	口腔真菌感染	1	N	TE	222	6	N	Not applicable	Recovered
087002	Israel	69/M/C	Dysgeusia	味覚異常	1	N	TE	29	28	Y	None	Recovered
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	2	N	TE	29	13	N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	33		N	None	Ongoing at study termination / withdrawal
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	3	N	TE	41		N	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	3	Y	TE	44	2	N	None	Recovered with sequelae
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	44	68	N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Haematoma	血腫	1	N	TE	44		N	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	3	N	TE	45		N	None	Ongoing at study termination / withdrawal
			Oral candidiasis	口腔カンジダ症	1	N	TE	56	36	N	None	Recovered
			Blood urea increased	血中尿素増加	1	N	TE	56		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	56	36	N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	3	N	TE	91		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	91		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	91		N	None	Ongoing at study termination / withdrawal
			Decubitus ulcer	褥瘡性潰瘍	3	N	TE	111		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
093002	Slovakia	81/M/C	Anaemia	貧血	2	N	TE	29	48	N	-	
			Nausea	悪心	2	N	TE	29	85	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	29	6	Y	None	Recovered
			Constipation	便秘	1	N	TE	56	58	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	56	4	Y	None	Recovered
			Anaemia	貧血	3	N	TE	76	10	N	-	
			Bone pain	骨痛	3	Y	TE	76	8	N	None	Recovered with sequelae
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	76		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	85	29	N	-	
			Diarrhoea	下痢	2	N	TE	85	5	Y	None	Recovered
			Anaemia	貧血	2	N	TE	113	31	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	Y	TE	143	5	N	Drug administration postponed	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bronchopneumonia	気管支肺炎	3	N	TE	150		N	None	Ongoing at time of death
			Cardiopulmonary failure	心肺不全	5	Y	TE	160	1	N	Not applicable	Death
096002	Slovakia	84/M/C	Anaemia	貧血	1	N	TE	58	29	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	86	112	Y	Not applicable	Recovered
			Haematuria	血尿	1	N	TE	90	9	N	None	Recovered
			Anaemia	貧血	3	Y	TE	197	4	Y	Not applicable	Recovered
097002	Slovakia	73/M/C	Pyrexia	発熱	1	N	TE	50	3	N	None	Recovered
			Pyrexia	発熱	1	N	TE	59	8	N	None	Recovered
			Pyrexia	発熱	1	N	TE	59	8	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	85	57	N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	107	15	N	None	Recovered
			Fatigue	疲労	3	Y	TE	107	15	Y	None	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	2	N	TE	107		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	107	15	N	None	Recovered with sequelae
			Vomiting	嘔吐	1	N	TE	113	5	Y	None	Recovered
			Anaemia	貧血	1	N	TE	141	22	N	Not applicable	Recovered
			Weight decreased	体重減少	2	N	TE	141		N	None	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	162	7	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	3	Y	TE	162	7	Y	Not applicable	Recovered with sequelae
			Anorexia	食欲不振	3	Y	TE	162	7	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	1	N	TE	168		N	Not applicable	Ongoing at time of death
			Fatigue	疲労	2	N	TE	168		Y	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	168		N	Not applicable	Ongoing at time of death
097006	Slovakia	73/M/C	Fatigue	疲労	2	N	Pre	1	10	N	None	Recovered
			Mixed incontinence	混合性尿失禁	3	N	Pre	1		N	None	Ongoing at study termination / withdrawal
			Spinal column stenosis	脊柱管狭窄症	4	Y	TE	2	17	N	None	Recovered with sequelae
			Fatigue	疲労	3	N	TE	10	161	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	15	14	N	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	28		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	86	85	Y	None	Recovered
			Weight decreased	体重減少	1	N	TE	113	29	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	113	58	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	113	62	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	141	30	N	None	Recovered
			Fatigue	疲労	1	N	TE	170	57	N	None	Recovered
097015	Slovakia	75/M/C	Calculus ureteric	尿管結石	3	Y	TE	203	9	N	Not applicable	Recovered
099002	Slovakia	69/M/C	Nausea	悪心	1	N	Pre	-3	32	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	Pre	-3	32	N	None	Recovered
			Nausea	悪心	1	N	Pre	29	35	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	57	58	N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	57	2	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	79		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	85		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	102	68	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	105	7	N	None	Recovered
			Urinary tract infection	尿路感染	1	N	TE	106	8	N	None	Recovered
			Anaemia	貧血	1	N	TE	107	63	N	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	2	N	TE	114		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	169		N	None	Ongoing at study termination / withdrawal
			Hypocalcaemia	低カルシウム血症	1	N	TE	169		N	None	Ongoing at study termination / withdrawal
			Hypophosphataemia	低リン酸血症	2	N	TE	169	64	N	None	Recovered
			Bone pain	骨痛	2	N	TE	207	2	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	Y	TE	208	14	N	Not applicable	Recovered
103001	Hong Kong	74/M/A	Hypoaesthesia	感覚鈍麻	1	N	Pre	-6	22	N	None	Recovered
			Fatigue	疲労	1	N	TE	5		Y	None	Ongoing at study termination / withdrawal
			Neutropenia	好中球減少症	2	N	TE	12	37	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	12	2	N	None	Recovered
			Abdominal distension	腹部膨満	1	N	TE	13	61	Y	None	Recovered
			Abdominal pain	腹痛	1	N	TE	13	17	Y	None	Recovered
			Headache	頭痛	1	N	TE	14	27	N	None	Recovered
			Constipation	便秘	1	N	TE	25		Y	None	Ongoing at study termination / withdrawal
			Abdominal pain	腹痛	2	N	TE	29	28	Y	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	40	5	N	None	Recovered
			Intentional overdose	企図的過量投与	4	Y	TE	48	7	N	Not applicable	Recovered
			Hypoalbuminaemia	低アルブミン血症	1	N	TE	48	64	N	None	Recovered
			Depression	うつ病	4	Y	TE	48	26	N	Not applicable	Recovered with sequelae
			Intentional self-injury	故意の自傷行為	4	Y	TE	48	7	N	Not applicable	Recovered
			Intentional self-injury	故意の自傷行為	2	Y	TE	48	7	N	Not applicable	Recovered
			Depression	うつ病	2	N	TE	54		N	Not applicable	Ongoing at study termination / withdrawal
			Rash	発疹	1	N	TE	59	24	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
103002	Hong Kong	75/M/A	Constipation	便秘	1	N	TE	28	30	N	None	Ongoing at study termination / withdrawal
			Constipation	便秘	2	N	TE	57		N	None	Ongoing at study termination / withdrawal
			Tinea pedis	足部白癬	1	N	TE	105		N	None	Ongoing at study termination / withdrawal
			Dysuria	排尿困難	1	N	TE	147	36	N	None	Recovered
			Cough	咳嗽	1	N	TE	167	10	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	194	3	N	None	Recovered
			Lower respiratory tract infection	下気道感染	3	Y	TE	196	4	N	Not applicable	Recovered
104005	Hong Kong	73/M/A	Constipation	便秘	1	N	TE	1	29	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	64	2	Y	None	Recovered
			Pneumonia	肺炎	2	N	TE	87		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	87	18	N	Drug permanently withdrawn	Death
			Spinal cord compression	脊髄圧迫	5	Y	TE	104	1	N	Drug permanently withdrawn	Death
105004	Hong Kong	70/M/A	Urinary retention	尿閉	2	N	Pre	-14	15	N	Drug administration postponed	Recovered
			Malaise	倦怠感	1	N	TE	2		Y	None	Not recovered, but no changes expected
			Abdominal pain	腹痛	1	N	TE	80	23	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Diarrhoea	下痢	1	N	TE	80	23	N	None	Recovered
			Muscle spasms	筋痙縮	2	N	TE	85		N	None	Not recovered, but no changes expected
			Muscle spasms	筋痙縮	2	N	TE	85		N	None	Not recovered, but no changes expected
			Pyrexia	発熱	1	N	TE	89	11	N	None	Recovered
			Musculoskeletal chest pain	筋骨格系胸痛	2	Y	TE	99	4	N	None	Recovered
			Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	2	N	TE	100	19	N	None	Recovered
			Anaemia	貧血	3	Y	TE	118	2	N	None	Recovered
			Musculoskeletal chest pain	筋骨格系胸痛	2	Y	TE	118	2	N	Drug administration postponed	Recovered with sequelae
			Abdominal pain upper	上腹部痛	2	Y	TE	120	5	N	Drug administration postponed	Recovered
			Faecal incontinence	便失禁	2	Y	TE	120	5	N	Drug administration postponed	Recovered with sequelae
			Musculoskeletal chest pain	筋骨格系胸痛	2	Y	TE	120	5	N	None	Recovered
			Haematuria	血尿	2	Y	TE	120	5	N	Drug administration postponed	Recovered
			Urinary incontinence	尿失禁	2	Y	TE	120	5	N	Drug administration postponed	Recovered with sequelae
			Faecal incontinence	便失禁	2	N	TE	125		N	Drug administration postponed	Not recovered, but no changes expected
			Hearing impaired	聴覚障害	2	N	TE	129		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dizziness	浮動性めまい	1	N	TE	134		N	None	Not recovered, but no changes expected
			Haematuria	血尿	2	N	TE	134	8	N	None	Recovered
			Anaemia	貧血	3	N	TE	141	8	N	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	141		N	Not applicable	Ongoing at study termination / withdrawal
			Cellulitis	蜂巣炎	3	Y	TE	148	10	N	Not applicable	Recovered
			Urinary tract infection	尿路感染	3	N	TE	148	4	N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	2	N	TE	148	3	N	None	Recovered
106002	Hong Kong	76/M/A	Hypoaesthesia	感覚鈍麻	1	N	TE	29	57	N	None	Recovered
			Pathological fracture	病的骨折	2	N	TE	85		N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	1	N	TE	113	3	N	None	Recovered
			Sleep disorder	睡眠障害	1	N	TE	113	29	N	None	Recovered
			Constipation	便秘	1	N	TE	141	29	Y	None	Recovered
			Cough	咳嗽	1	N	TE	169		N	None	Ongoing at time of death
			Haemophilus infection	ヘモフィルス感染	2	N	TE	178	14	N	None	Recovered
			Cardiac failure congestive	うっ血性心不全	3	Y	TE	221	26	N	Not applicable	Recovered
			Musculoskeletal pain	筋骨格痛	3	Y	TE	221	26	N	Not applicable	Recovered
			Insomnia	不眠症	2	N	TE	221	3	N	None	Recovered
106005	Hong Kong	79/M/A	Decreased appetite	食欲減退	1	N	TE	29	85	Y	None	Recovered
			Dysuria	排尿困難	1	N	TE	29		N	None	Ongoing at time of death
			Nocturia	夜間頻尿	2	N	TE	29	57	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	113	3	Y	Drug administration postponed	Recovered with sequelae
			Constipation	便秘	2	N	TE	113	29	N	None	Recovered
			Sleep disorder	睡眠障害	1	N	TE	113	3	N	None	Recovered
			Spinal compression fracture	脊椎圧迫骨折	3	N	TE	115		N	None	Ongoing at time of death
			Sepsis	敗血症	3	Y	TE	155		N	Not applicable	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	3	N	TE	156		N	Not applicable	Ongoing at time of death
			Haematuria	血尿	3	Y	TE	159		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	165	1	N	Not applicable	Death
106007	Hong Kong	61/M/A	Nerve root compression	神経根圧迫	3	Y	Pre	-17	18	N	Not applicable	Recovered
			Constipation	便秘	1	N	TE	57	29	Y	None	Recovered
			Hypoaesthesia	感覚鈍麻	1	N	TE	113		N	None	Not recovered, but no changes expected
			Lymphadenopathy	リンパ節症	3	N	TE	225	64	N	None	Recovered
106011	Hong Kong	79/M/A	Decreased appetite	食欲減退	1	N	TE	29	29	N	None	Recovered
			Abdominal pain upper	上腹部痛	1	N	TE	57	29	N	None	Recovered
			Liver function test abnormal	肝機能検査異常	3	Y	TE	57	13	N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	218	1	N	Not applicable	Death
106016	Hong Kong	75/M/A	Constipation	便秘	2	N	TE	29	126	Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspepsia	消化不良	2	N	TE	29	84	N	None	Recovered
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	3	Y	TE	41	3	N	None	Recovered
			Cough	咳嗽	1	N	TE	41	150	N	None	Recovered
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	1	N	TE	57	29	N	None	Recovered
			Headache	頭痛	1	N	TE	127	36	N	None	Recovered
			Dry skin	皮膚乾燥	2	N	TE	127	28	N	None	Recovered
110002	France	79/M/C	Hypertension	高血圧	2	N	TE			N	None	Recovered
			Somnolence	傾眠	2	N	Pre	-11	4	N	None	Recovered
			Neuralgia	神経痛	3	N	Pre	-5	34	N	None	Recovered
			Depression	うつ病	1	N	Pre	1	141	N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	Y	TE	3	5	Y	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	50	8	N	None	Recovered
			Bone pain	骨痛	3	N	TE	141		N	None	Ongoing at study termination / withdrawal
			Depression	うつ病	2	N	TE	141		N	None	Ongoing at study termination / withdrawal
111001	France	70/M/C	Nausea	悪心	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	2	N	TE			N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Headache	頭痛	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	Pre	1	55	N	Drug administration postponed	Recovered
			Pyrexia	発熱	2	N	TE	9		N	None	Not recovered, but no changes expected
			Anaemia	貧血	3	N	TE	55	4	N	Drug administration postponed	Recovered
			Malnutrition	栄養障害	2	N	TE	56		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	4	N	TE	87	1	N	Drug administration postponed	Recovered
			Lymphopenia	リンパ球減少症	3	N	TE	87	2	N	None	Recovered
			Anaemia	貧血	3	Y	TE	113	1	N	Drug administration postponed	Recovered
			Confusional state	錯乱状態	3	Y	TE	113		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Cerebral haemorrhage	脳出血	3	Y	TE	114		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
111002	France	72/M/C	Abdominal pain upper	上腹部痛	2	N	TE			N	None	Recovered
			Anorexia	食欲不振	2	N	TE	51	195	N	None	Recovered
			Pleural effusion	胸水	2	Y	TE	51	2	N	None	Recovered
			Pleural effusion	胸水	2	Y	TE	65	5	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pulmonary embolism	肺塞栓症	4	Y	TE	120	6	N	None	Recovered
			Deep vein thrombosis	深部静脈血栓症	3	Y	TE	120	6	N	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	146	29	N	None	Recovered
			Dyspnoea	呼吸困難	2	Y	TE	146	4	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	150	96	N	Not applicable	Recovered
			Pleural effusion	胸水	2	N	TE	174	1	N	None	Recovered
			Pleural effusion	胸水	2	Y	TE	218	2	N	Not applicable	Recovered
			Pleural effusion	胸水	1	N	TE	220	26	N	None	Recovered
117008	France	82/M/C	Weight decreased	体重減少	1	N	TE			N	Not applicable	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	Pre	1	29	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	29		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	29		N	None	Ongoing at study termination / withdrawal
			Dementia Alzheimer's type	アルツハイマー型認知症	2	Y	TE	45	11	N	None	Recovered
			Lung infection	肺感染	2	N	TE	60	58	N	Not applicable	Recovered
			Leukocytosis	白血球増加症	1	N	TE	88	5	N	None	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	88		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Asthenia	無力症	1	N	TE	111		N	Not applicable	Ongoing at study termination / withdrawal
129006	Canada	88/M/C	Vomiting	嘔吐	2	N	Pre			N	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	Pre			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre			N	None	Recovered
			Bone pain	骨痛	1	N	Pre			N	Drug administration postponed	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			N	None	Ongoing at time of death
			Headache	頭痛	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE			N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Somnolence	傾眠	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Confusional state	錯乱状態	1	N	TE			N	None	Recovered
			Depression	うつ病	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Dysphonia	発声障害	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	Pre	-8		N	Not applicable	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	Pre	-8	25	N	None	Recovered with sequelae
			Bone pain	骨痛	4	N	TE	29		N	Drug administration postponed	Ongoing at time of death
			Bone pain	骨痛	4	N	TE	29		N	Drug administration postponed	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	4	Y	TE	29		N	Drug permanently withdrawn	Ongoing at time of death
			Confusional state	錯乱状態	2	N	TE	29		N	Drug permanently withdrawn	Ongoing at time of death
			Cough	咳嗽	1	N	TE	29		N	None	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	TE	30		N	None	Ongoing at study termination / withdrawal
			Excoriation	擦過傷	1	N	TE	30		N	Not applicable	Ongoing at time of death
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	31		N	None	Ongoing at time of death
			Herpes simplex	単純ヘルペス	2	N	TE	33		N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	36		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	36		N	Not applicable	Ongoing at time of death
			Dysphagia	嚥下障害	2	N	TE	37		N	Not applicable	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oral candidiasis	口腔カンジダ症	2	N	TE	37		N	Not applicable	Ongoing at study termination / withdrawal
			Oral candidiasis	口腔カンジダ症	2	N	TE	38		N	None	Ongoing at time of death
129007	Canada	81/M/0	Anaemia	貧血			TE			N	Not applicable	Recovered with sequelae
			Abdominal distension	腹部膨満	1	N	TE			N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE			Y	None	Not recovered, but no changes expected
			Weight decreased	体重減少	2	N	Pre	1		N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	2		Y	None	Not recovered, but no changes expected
			Stomatitis	口内炎	1	N	TE	9		N	None	Recovered
			Anaemia	貧血	3	Y	TE	119	3	N	Drug administration postponed	Recovered with sequelae
			Anaemia	貧血	2	N	TE	121	27	N	None	Recovered
			Anaemia	貧血	3	Y	TE	147	4	Y	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	150	26	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	3	Y	TE	175	10	N	Not applicable	Recovered with sequelae
			Thrombocytopenia	血小板減少症	1	N	TE	175	9	N	None	Recovered
			Fall	転倒・転落	1	N	TE	181	1	N	None	Recovered
			Anxiety	不安	1	N	TE	181		N	None	Not recovered, but no changes expected

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	3	N	TE	183	51	N	None	Recovered
130004	Canada	82/M/C	Hip fracture	股関節部骨折	3	Y	TE	32		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
130009	Canada	72/M/C	Diarrhoea	下痢	1	N	TE			Y	None	Recovered
			Fatigue	疲労	2	N	TE			Y	None	Ongoing at study termination / withdrawal
			Decreased appetite	食欲減退	1	N	TE			Y	None	Recovered
			Bone pain	骨痛	1	N	TE			Y	None	Recovered
			Bone pain	骨痛	1	N	TE			Y	None	Recovered
			Anaemia	貧血	2	N	Pre	1	86	Y	-	
			Lymphopenia	リンパ球減少症	3	N	Pre	1	29	N	None	Ongoing at study termination / withdrawal
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	Pre	1	57	N	None	Recovered
			Lymphopenia	リンパ球減少症	2	N	Pre	29	29	N	None	Ongoing at study termination / withdrawal
			Injection site reaction	注射部位反応	1	N	TE	31	3	Y	None	Recovered
			Lymphopenia	リンパ球減少症	3	N	Pre	57		N	None	Ongoing at study termination / withdrawal
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	Pre	57	86	N	None	Recovered
			Gynaecomastia	女性化乳房	2	N	TE	57	114	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	62	1	Y	None	Recovered
			Cough	咳嗽	1	N	TE	65		Y	None	Recovered
			Anaemia	貧血	1	N	Pre	86	29	Y	-	

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	Pre	114	29	Y	-	
			Anaemia	貧血	1	N	Pre	142	29	Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	Pre	170		Y	None	Ongoing at study termination / withdrawal
			Blood urea increased	血中尿素増加	1	N	TE	170		Y	None	Ongoing at study termination / withdrawal
			Hypercreatininaemia	高クレアチニン血症	1	N	TE	170	23	Y	None	Recovered
			Bone pain	骨痛	3	Y	TE	191	7	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	1	N	Post	228	82	Y	None	Recovered
133002	Poland	78/M/C	Pyrexia	発熱	1	N	TE	3	14	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	3	6	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	8	44	Y	None	Recovered
			Pathological fracture	病的骨折	2	Y	TE	43		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	51	53	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	72	34	N	None	Recovered
			Fatigue	疲労	3	N	TE	88	26	N	Drug permanently withdrawn	Ongoing at time of death
			Fatigue	疲労	4	N	TE	113		N	Drug permanently withdrawn	Ongoing at time of death
			Weight decreased	体重減少	2	N	TE	113		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	162	1	N	Not applicable	Death
133003	Poland	77/M/C	Arthralgia	関節痛	2	N	TE	3	3	Y	None	Recovered
			Neutropenia	好中球減少症	3	N	TE	56	9	Y	Drug administration postponed	Recovered
			Anaemia	貧血	3	Y	TE	65	2	Y	None	Recovered
			Anaemia	貧血	2	N	TE	85	5	Y	Drug permanently withdrawn	Recovered
			Anaemia	貧血	3	Y	TE	89	5	Y	Drug permanently withdrawn	Recovered
			Neutropenia	好中球減少症	3	N	TE	89	5	Y	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	89	2	Y	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	3	N	TE	90		Y	None	Ongoing at study termination / withdrawal
			Fibrin D dimer increased	フィブリンDダイマー増加	2	N	TE	99		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	4	Y	TE	130	2	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	TE	131		N	None	Ongoing at study termination / withdrawal
133005	Poland	62/M/C	Nausea	悪心	1	N	TE			Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Paraparesis	不全対麻痺	3	Y	TE	14		N	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	141		N	None	Ongoing at study termination / withdrawal
133006	Poland	53/M/C	Bone pain	骨痛	2	N	TE	2	10	Y	None	Recovered
			Hypertension	高血圧	2	N	TE	29	29	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	50		N	None	Recovered
			Abdominal pain	腹痛	2	N	TE	71		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	140	29	N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	168		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	168		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	184	2	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	185	1	N	Not applicable	Death
133009	Poland	75/M/C	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2	N	TE	85	29	N	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1	N	TE	85	29	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	141	29	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	198	1	N	Not applicable	Death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
133011	Poland	66/M/C	Anaemia	貧血	2	N	Pre	1		N	None	Ongoing at time of death
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	Pre	1		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre	1		N	None	Not recovered, but no changes expected
			Tremor	振戦	4	Y	TE	25	1	Y	None	Recovered
			Confusional state	錯乱状態	4	Y	TE	25		Y	None	Ongoing at time of death
			Death	死亡	5	Y	TE	29	1	Y	None	Death
133012	Poland	67/M/C	Spinal cord compression	脊髄圧迫	3	Y	Pre	-35		N	Drug administration postponed	Ongoing at time of death
			Dyspnoea	呼吸困難	4	Y	TE	2	1	N	None	Death
			Dyspnoea	呼吸困難	5	Y	TE	2	1	N	None	Death
133017	Poland	61/M/C	Hyperthyroidism	甲状腺機能亢進症	1	N	TE	3		N	None	Not recovered, but no changes expected
			Upper gastrointestinal haemorrhage	上部消化管出血	2	Y	TE	3		N	None	Ongoing at study termination / withdrawal
133018	Poland	72/M/C	Diarrhoea	下痢	1	N	TE	39	5	Y	None	Recovered
			Dehydration	脱水	1	N	TE	57	3	N	None	Recovered
			Leukopenia	白血球減少症	3	N	TE	106		Y	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	3	N	TE	106		Y	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	4	Y	TE	106		N	Drug permanently withdrawn	Not recovered, but no changes expected
133020	Poland	76/M/C	Nausea	悪心	3	N	TE	1		Y	None	Not recovered, but no changes expected
			Vomiting	嘔吐	3	N	TE	1		Y	None	Not recovered, but no changes expected
			Dehydration	脱水	3	Y	TE	8	4	Y	Drug permanently withdrawn	Recovered
			Anaemia	貧血	2	N	TE	9	1	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	25		N	None	Ongoing at study termination / withdrawal
			Dehydration	脱水	2	N	TE	36		N	Not applicable	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	2	N	TE	36	1	N	None	Recovered
133026	Poland	50/M/C	Neutropenia	好中球減少症	2	N	TE	57	15	Y	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	57	15	Y	Drug administration postponed	Recovered
			Pollakiuria	頻尿	1	N	TE	99	53	N	None	
			Urinary retention	尿閉	2	N	TE	151	1	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	155		N	None	Recovered
			Haematuria	血尿	2	Y	TE	200	6	N	Not applicable	Recovered
134001	Poland	57/M/C	Paralysis	麻痺	4	Y	Pre	-10		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	20	1	N	None	Death
135003	Poland	62/M/C	Bone pain	骨痛	3	N	TE			N	None	Recovered
			Anaemia	貧血	3	Y	TE	114	3	Y	None	Recovered
			Anaemia	貧血	2	N	TE	115	2	Y	None	Recovered
137006	Poland	71/M/C	Anaemia	貧血	3	Y	TE	139	8	N	Not applicable	Recovered with sequelae
			Urinary tract infection	尿路感染	2	N	TE	157	8	N	Not applicable	Recovered
			Haematuria	血尿	3	Y	TE	197	7	N	Not applicable	Recovered
			Anaemia	貧血	4	Y	TE	203		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	213	1	N	Not applicable	Death
139001	Poland	76/M/C	Anaemia	貧血	1	N	TE	29		N	None	Ongoing at time of death
			Malaise	倦怠感	3	N	TE	29		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	46	1	N	None	Death
139005	Poland	71/M/C	Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre			N	None	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	57	5	Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	120	1	N	None	Death
139006	Poland	76/M/C	Oedema peripheral	末梢性浮腫	3	N	TE			N	None	Not recovered, but no changes expected
			Vomiting	嘔吐	2	N	TE	31	3	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	88	5	Y	None	Recovered with sequelae
			Renal failure	腎不全	2	N	TE	119	26	N	None	Ongoing at study termination / withdrawal
			General physical health deterioration	全身健康状態低下	3	N	TE	144		Y	Drug permanently withdrawn	Not recovered, but no changes expected
			Renal failure	腎不全	1	N	TE	144		N	None	Ongoing at study termination / withdrawal
139009	Poland	57/M/C	Pancytopenia	汎血球減少症	3	Y	TE	117	8	Y	Drug administration postponed	Recovered with sequelae
			Leukopenia	白血球減少症	3	Y	TE	172	10	Y	Drug administration postponed	Recovered with sequelae
			Leukopenia	白血球減少症	2	N	TE	181		Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	181	1	Y	None	Ongoing at time of death
139012	Poland	67/M/C	Thrombophlebitis	血栓性静脈炎	2	Y	Pre	-26	12	N	Drug administration postponed	Recovered with sequelae

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombophlebitis	血栓性静脈炎	1	N	Pre	-15		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	29	8	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	29	8	Y	None	Recovered
			Nausea	悪心	1	N	TE	57	8	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	57	8	Y	None	Recovered
			Nausea	悪心	1	N	TE	85	7	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	85	7	Y	None	Recovered
144002	Germany	77/M/C	Hyperthyroidism	甲状腺機能亢進症	1	N	TE			Y	None	Recovered
			Dysgeusia	味覚異常	1	N	TE			Y	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	2	4	Y	None	Recovered
			Fatigue	疲労	2	N	TE	3	3	Y	None	Recovered with sequelae
			Urinary retention	尿閉	1	N	TE	47	37	N	None	Recovered with sequelae
			Benign neoplasm of bladder	膀胱の良性新生物	3	Y	TE	77	7	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	101	4	N	None	Recovered
			Haematuria	血尿	1	N	TE	158	6	N	None	Recovered
			Haematuria	血尿	1	N	TE	216	3	N	None	Recovered
144004	Germany	68/M/C	Pneumonia	肺炎	3	Y	TE	59	6	N	None	Recovered
146001	Germany	70/M/C	Paraesthesia	錯感覚	2	N	TE	73		N	None	Recovered with sequelae
			Herpes zoster	帯状疱疹	2	Y	TE	169	12	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary incontinence	尿失禁	1	N	TE	174		N	Not applicable	Ongoing at study termination / withdrawal
146004	Germany	77/M/C	Anaemia	貧血	2	N	TE	17	5	N	Drug administration postponed	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	17		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Multi-organ failure	多臓器不全	4	Y	TE	17	12	N	None	Death
			Anaemia	貧血	4	N	TE	21		N	Drug administration postponed	Ongoing at time of death
			Multi-organ failure	多臓器不全	5	Y	TE	28	1	N	None	Death
148009	Germany	71/M/C	Nasopharyngitis	鼻咽頭炎	1	N	Pre	-14	15	N	None	Recovered
			Anaemia	貧血	2	N	Pre	1	57	Y	Drug administration postponed	Recovered
			Fatigue	疲労	2	N	TE	8		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	29	4	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	57	4	Y	Drug administration postponed	Recovered
			Anaemia	貧血	1	N	TE	60	31	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	60	1	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	60	2	Y	None	Recovered
			Herpes zoster	帯状疱疹	3	Y	TE	96	12	Y	Drug administration postponed	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	Y	TE	98	1	Y	None	Recovered
			Anaemia	貧血	4	Y	TE	125	3	Y	Drug administration postponed	Recovered
			Syncope	失神	3	Y	TE	125	1	Y	Drug administration postponed	Recovered
			Pancytopenia	汎血球減少症		N	TE	140		Y	None	Ongoing at time of death
			Metastases to liver	肝転移	3	Y	TE	140	10	N	Drug permanently withdrawn	Death
			Epistaxis	鼻出血	2	N	TE	140	1	N	Not applicable	Recovered
			Metastases to liver	肝転移	5	Y	TE	149	1	N	Drug permanently withdrawn	Death
148012	Germany	72/M/C	Acute coronary syndrome	急性冠動脈症候群	3	Y	TE	6	3	N	None	Recovered
			Angina pectoris	狭心症	2	N	TE	76	15	N	None	Recovered
			Angina pectoris	狭心症	3	Y	TE	90	3	N	None	Recovered
			Anaemia	貧血	3	N	TE	141	15	Y	Drug administration postponed	Ongoing at time of death
			Anaemia	貧血	2	N	TE	155		Y	Drug administration postponed	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	155	29	Y	None	Recovered
			Arthralgia	関節痛	2	N	TE	169		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pigmentation disorder	色素沈着障害	1	N	TE	183		N	None	Recovered
148014	Germany	62/M/C	Nausea	悪心	1	N	TE	29	1	Y	None	Recovered
			Ageusia	味覚消失	1	N	TE	29	1	Y	None	Recovered
			Cataract	白内障	3	Y	TE	154	3	N	Not applicable	Recovered
148019	Germany	65/M/C	Conjunctivitis	結膜炎	2	N	TE	2	8	N	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	29	1	Y	None	Recovered
			Nausea	悪心	1	N	TE	31	4	Y	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	32	1	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	32	1	Y	None	Recovered
			Pleural effusion	胸水	1	N	TE	93		N	None	Ongoing at time of death
			Blood urea increased	血中尿素増加	2	N	TE	109	11	N	None	Recovered
			Blood creatinine increased	血中クレアチニン増加	2	N	TE	113	7	N	None	Recovered
			Hydronephrosis	水腎症	3	Y	TE	113	2	N	None	Recovered
			Dyspnoea	呼吸困難	2	N	TE	113		N	None	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	119	4	N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	119		N	None	Ongoing at time of death
			Blood creatinine increased	血中クレアチニン増加	3	N	TE	119	4	N	None	Recovered
			Blood urea increased	血中尿素増加	3	N	TE	119	4	N	None	Recovered
			Hydronephrosis	水腎症	3	Y	TE	119	4	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	143	1	N	Drug permanently withdrawn	Death
149009	Germany	72/M/C	Bone pain	骨痛	1	N	TE	1	3	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	29	3	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	36	21	Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Insomnia	不眠症	1	N	TE	56		N	None	Not recovered, but no changes expected
			Diarrhoea	下痢	1	N	TE	58	18	Y	None	Recovered
			Anaemia	貧血	1	N	TE	82	2	Y	Drug administration postponed	Recovered
			Bone pain	骨痛	1	N	TE	83	87	Y	None	Recovered with sequelae
			Pancytopenia	汎血球減少症	2	N	TE	140		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	169	27	Y	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	176		Y	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	208	2	Y	Not applicable	Recovered
			Anaemia	貧血	3	N	Post	251	3	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	Post	265	2	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	Post	279	9	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	Post	307	4	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	Post	356	2	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	Post	371	14	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	Post	412	17	Y	Not applicable	Recovered
			Anaemia	貧血	3	N	Post	470	7	Y	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Aplastic anaemia	再生不良性貧血	3	Y	Post	526		Y	Not applicable	Ongoing at time of death
150002	Germany	72/M/C	Nausea	悪心	2	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE			N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	23	4	N	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	26	8	N	None	Recovered with sequelae
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	4	N	TE	29	26	N	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	4	N	TE	29	2	N	None	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	TE	29	2	N	None	Recovered
			Neuralgia	神経痛	2	N	TE	29	5	N	None	Recovered with sequelae
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	30	25	N	None	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	2	N	TE	30	25	N	None	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1	N	TE	54	13	N	None	Recovered
			Nerve root compression	神経根圧迫	2	Y	TE	66	3	N	None	Recovered with sequelae
			Nausea	悪心	2	N	TE	69	11	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	69	11	N	None	Recovered
			Fatigue	疲労	1	N	TE	69	11	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary retention	尿閉	2	Y	TE	69	11	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	177	11	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	178	1	N	None	Recovered
			Headache	頭痛	2	N	TE	180	1	N	None	Recovered
150003	Germany	70/M/C	Nausea	悪心	1	N	TE	72		N	None	Ongoing at time of death
			Hydronephrosis	水腎症	2	Y	TE	100	2	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	141	5	N	None	Recovered
			Hypercreatininaemia	高クレアチニン血症	2	N	TE	141	16	N	None	Recovered
			Hydronephrosis	水腎症	2	Y	TE	141	6	N	None	Recovered with sequelae
			Anaemia	貧血	3	N	TE	143		N	None	Ongoing at time of death
			Hypercreatininaemia	高クレアチニン血症	1	N	TE	156	32	N	None	Recovered
151005	Germany	83/M/C	Diarrhoea	下痢	1	N	TE			N	None	Recovered
			Cystitis	膀胱炎	3	N	TE	44	5	Y	None	Recovered
			Urinary retention	尿閉	3	Y	TE	130	7	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	131		Y	None	Ongoing at time of death
152003	Germany	49/M/C	Nausea	悪心	1	N	TE			N	Not applicable	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE			N	Not applicable	Recovered with sequelae
			Escherichia urinary tract infection	大腸菌性尿路感染	1	N	TE			N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Depression	うつ病	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	1	85	N	Drug administration postponed	Recovered with sequelae
			Productive cough	湿性咳嗽	1	N	TE	22	11	N	None	Recovered
			Injection site swelling	注射部位腫脹	1	N	TE	34		Y	None	Recovered
			Injection site swelling	注射部位腫脹	1	N	TE	58		Y	None	Recovered
			Bone pain	骨痛	3	Y	TE	85	10	N	Drug administration postponed	Recovered with sequelae
			Anaemia	貧血	2	N	TE	115	18	N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	115		N	Not applicable	Recovered with sequelae
			Dehydration	脱水	2	N	TE	115		N	None	Recovered
			Bone pain	骨痛	3	Y	TE	115	18	N	Not applicable	Recovered with sequelae
152004	Germany	75/M/C	Bone pain	骨痛	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	1	N	TE	1		N	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	1	N	TE	79		N	None	Recovered
			Bone pain	骨痛	3	Y	TE	79	14	N	Drug administration postponed	Recovered with sequelae
			Disturbance in attention	注意力障害	1	N	TE	79		N	None	Ongoing at study termination / withdrawal
			Insomnia	不眠症	1	N	TE	79		N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pleural effusion	胸水	1	N	TE	79		N	None	Recovered
			Bone pain	骨痛	2	N	TE	92	37	N	None	Recovered with sequelae
			Pancytopenia	汎血球減少症	2	N	TE	128		N	None	Recovered with sequelae
			Nausea	悪心	1	N	TE	128	8	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	128	8	N	None	Recovered
			Infection	感染	2	N	TE	128	8	N	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	128	8	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	128	8	N	None	Recovered with sequelae
			Pneumonia primary atypical	原発性異型肺炎	3	Y	TE	147	22	N	Drug administration postponed	Recovered with sequelae
			Asthenia	無力症	2	N	TE	161		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
154001	Germany	65/M/C	Coronary artery disease	冠動脈疾患	3	Y	Pre	-12	3	N	Not applicable	Recovered
			Hypercholesterolaemia	高コレステロール血症	1	N	Pre	-12		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	50	32	N	None	Recovered
			Anaemia	貧血	2	N	TE	59		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	80	75	N	None	Recovered
			Coronary artery disease	冠動脈疾患	2	Y	TE	122	8	N	Not applicable	Recovered
154002	Germany	71/M/C	Nausea	悪心	1	N	Pre			N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			General physical health deterioration	全身健康状態低下	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Pain	疼痛	3	N	TE			N	None	Ongoing at study termination / withdrawal
			Angina pectoris	狭心症	1	N	TE	1	15	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	42		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	42		N	None	Ongoing at time of death
			Joint injury	関節損傷	1	N	TE	61	1	N	None	Recovered
			Anaemia	貧血	2	N	TE	85		N	None	Ongoing at study termination / withdrawal
			Gait disturbance	歩行障害	3	N	TE	94		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	123	13	N	Drug administration postponed	Recovered with sequelae
			Facial palsy	顔面神経麻痺	3	N	TE	155	15	N	Drug administration postponed	Ongoing at time of death
			Facial palsy	顔面神経麻痺	3	Y	TE	169	7	N	Drug administration postponed	Ongoing at time of death
			Facial palsy	顔面神経麻痺	2	N	TE	175		N	Drug administration postponed	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
154004	Germany	62/M/C	Atrial fibrillation	心房細動	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Renal failure	腎不全	2	N	TE			N	None	Recovered with sequelae
			Cystitis	膀胱炎	1	N	Pre	-3	7	N	None	Recovered
			Nausea	悪心	1	N	TE	2		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	2		Y	None	Not recovered, but no changes expected
			Abdominal pain upper	上腹部痛	1	N	TE	7	23	Y	None	Recovered
			Abdominal pain	腹痛	1	N	TE	29	56	N	Not applicable	Ongoing at study termination / withdrawal
			Nocturia	夜間頻尿	2	N	TE	57		N	None	Ongoing at time of death
			Acute prerenal failure	急性腎前性腎不全	2	Y	TE	81	4	N	Not applicable	Recovered
			Abdominal pain	腹痛	2	N	TE	84		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	N	TE	85		N	None	Ongoing at time of death
			Peritonitis bacterial	細菌性腹膜炎	3	Y	TE	86	22	N	Drug permanently withdrawn	Recovered
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	107	6	N	Drug permanently withdrawn	Recovered with sequelae

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	112		N	Drug permanently withdrawn	Not recovered, but no changes expected
155004	Germany	63/M/C	Vomiting	嘔吐	2	N	TE			Y	None	Recovered
			Vomiting	嘔吐	1	N	TE			Y	None	Recovered
			Depression	うつ病	1	N	Pre	1	217	N	None	Not recovered, but no changes expected
			Constipation	便秘	1	Y	TE	26	3	N	None	Recovered
			Reflux oesophagitis	逆流性食道炎	1	N	TE	32	46	N	None	Recovered
			Fatigue	疲労	2	N	TE	32		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	32		N	None	Not recovered, but no changes expected
			Night sweats	寝汗	1	N	TE	32	31	N	None	Recovered
			Reflux oesophagitis	逆流性食道炎	2	N	TE	77	95	N	None	Recovered
			Depression	うつ病	2	N	TE	217		N	None	Not recovered, but no changes expected
157002	Germany	76/M/C	General physical health deterioration	全身健康状態低下	2	N	TE			N	None	Not recovered, but no changes expected
			General physical health deterioration	全身健康状態低下	1	N	TE			N	None	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	3	Y	Pre	-10	2	N	Not applicable	Recovered
			Anaemia	貧血	2	N	Pre	1	37	Y	None	Recovered with sequelae
			Fatigue	疲労	2	N	TE	5		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	5		Y	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Night sweats	寝汗	1	N	TE	5		Y	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	37	2	Y	None	Recovered with sequelae
			Anaemia	貧血	3	N	TE	38	6	Y	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	43		Y	None	Not recovered, but no changes expected
170004	Brazil	78/M/C	Pathological fracture	病的骨折	3	N	TE	127		N	Drug administration postponed	Ongoing at time of death
			Urinary retention	尿閉	3	N	TE	156	1	N	None	Recovered
			Anaemia	貧血	2	N	TE	211		N	None	Ongoing at time of death
			Bone pain	骨痛	4	Y	TE	230		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	230	3	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	232	1	N	Drug permanently withdrawn	Death
173008	Brazil	67/M/C	Anaemia	貧血	2	N	Pre	1	33	N	Drug administration postponed	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	Pre	1	63	N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	33	2	N	Drug administration postponed	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	34	30	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	N	TE	63	3	N	Drug administration postponed	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	Pre	63		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	65	83	N	Drug administration postponed	Recovered
			Anorexia	食欲不振	2	N	TE	87	70	N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	147	5	N	Drug administration postponed	Recovered
			Anorexia	食欲不振	3	N	TE	156		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	156		N	None	Ongoing at time of death
			Weight decreased	体重減少	3	N	TE	183		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	3	N	TE	184	11	N	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	184	11	N	None	Ongoing at time of death
			Anaemia	貧血	4	N	TE	194	5	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	194	5	N	None	Ongoing at time of death
			Neutropenia	好中球減少症	4	N	TE	198		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	198		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cerebrovascular accident	脳血管発作	4	Y	TE	198	4	Y	Not applicable	Death
			Cerebrovascular accident	脳血管発作	5	Y	TE	201	1	Y	Not applicable	Death
173009	Brazil	66/M/O	Bone pain	骨痛	2	N	Pre	-9		N	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	4	Y	TE	29	20	N	Drug permanently withdrawn	Death
			General physical health deterioration	全身健康状態低下	5	Y	TE	48	1	N	Drug permanently withdrawn	Death
173011	Brazil	62/M/B	Constipation	便秘	2	N	Pre	-7	13	N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	Pre	-7	8	N	None	Ongoing at time of death
			Arthralgia	関節痛	2	N	Pre	-7		N	None	Ongoing at time of death
			Anorexia	食欲不振	3	N	TE	1		N	None	Ongoing at time of death
			Constipation	便秘	1	N	Pre	6		N	None	Ongoing at time of death
			Anaemia	貧血	4	N	TE	29		N	Drug permanently withdrawn	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	4	Y	TE	30		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
178007	Brazil	71/M/O	Hypercalcaemia	高カルシウム血症	3	N	Pre	1	88	Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neutropenia	好中球減少症	2	N	TE	29	29	Y	Drug administration postponed	Recovered
			Bone pain	骨痛	2	N	TE	48	77	N	None	Ongoing at time of death
			Neutropenia	好中球減少症	3	N	TE	57	4	Y	Drug administration postponed	Recovered
			Neutropenia	好中球減少症	2	N	TE	60	65	Y	Drug administration postponed	Recovered
			Insomnia	不眠症	2	N	TE	78		N	None	Ongoing at time of death
			Pathological fracture	病的骨折	3	Y	TE	121	28	N	Drug administration postponed	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	124		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	124	15	N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	138	25	N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	139	7	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	141	1	N	Not applicable	Recovered
			Anaemia	貧血	3	Y	TE	147	2	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	148		N	Not applicable	Lost to follow-up
			Device dislocation	医療機器位置異常	3	Y	TE	162	3	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Procedural pain	処置による疼痛	3	Y	TE	162	3	N	Not applicable	Recovered
179001	Brazil	77/M/C	Hypercreatininaemia	高クレアチニン血症	2	N	Pre	1	59	N	None	Ongoing at study termination / withdrawal
			Hypercreatininaemia	高クレアチニン血症	1	N	Pre	59	29	N	None	Ongoing at study termination / withdrawal
			Asthenia	無力症	1	N	TE	69	1	N	None	Recovered
			Hypercreatininaemia	高クレアチニン血症	2	N	Pre	87		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	Y	TE	93	4	N	None	Recovered
			Anaemia	貧血	2	Y	TE	114	3	N	None	Recovered
			Asthenia	無力症	2	Y	TE	126	5	N	Drug administration postponed	Recovered with sequelae
			Fatigue	疲労	3	Y	TE	146	9	N	Drug permanently withdrawn	Recovered
179006	Brazil	79/M/C	Nausea	悪心	1	N	Pre	-17	3	N	Not applicable	Recovered
			Cough	咳嗽	1	N	Pre	-6	5	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	34	99	N	None	Recovered
			Arthralgia	関節痛	1	N	TE	132		N	None	Recovered
			Bone pain	骨痛	1	N	TE	159	2	N	None	Recovered
			Myocardial infarction	心筋梗塞	5	Y	TE	244	1	N	Not applicable	Death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
181005	Brazil	74/M/C	Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	Pre	1		N	None	Ongoing at time of death
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	Pre	1		N	None	Ongoing at time of death
			Hypoglycaemia	低血糖症	3	Y	TE	29	2	N	None	Recovered
			Pneumonia	肺炎	2	Y	TE	30	16	N	Not applicable	Death
			Acute pulmonary oedema	急性肺水腫	2	Y	TE	30		N	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	5	Y	TE	45	1	N	Not applicable	Death
181048	Brazil	70/M/C	Thrombosis	血栓症	2	N	Pre	-1		N	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	29		N	None	Ongoing at study termination / withdrawal
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	1	N	TE	141		N	None	Ongoing at study termination / withdrawal
			Constipation	便秘	2	N	TE	158		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	Y	TE	176	5	N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	176	5	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	209		N	Not applicable	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	4	Y	TE	209	23	N	Not applicable	Recovered with sequelae
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1	N	TE	209		N	Not applicable	Ongoing at study termination / withdrawal
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1	N	TE	209		N	Not applicable	Ongoing at study termination / withdrawal
201002	Australia	72/M/C	Dysphagia	嚥下障害	2	N	Pre	-7	70	N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	48	46	N	None	Recovered
			Muscle strain	筋挫傷	2	N	TE	49	15	N	None	Recovered
			Dysphagia	嚥下障害	1	N	Pre	63	71	N	None	Ongoing at time of death
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	2	N	TE	93	4	N	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	99	8	N	None	Recovered
			Anaemia	貧血	3	Y	TE	132	9	N	Not applicable	Recovered
			Supraventricular tachycardia	上室性頻脈	2	Y	TE	132	1	N	Not applicable	Recovered
			Abdominal distension	腹部膨満	3	Y	TE	132	9	N	Not applicable	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	3	N	TE	132		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	132	39	N	Not applicable	Death
			Anxiety	不安	2	N	TE	132		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dysphagia	嚥下障害	2	N	Pre	133		N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	1	N	TE	137	3	N	Not applicable	Recovered
			Abdominal distension	腹部膨満	2	N	TE	140		N	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	147		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	161		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	170	1	N	Not applicable	Death
203004	Australia	70/M/C	Constipation	便秘	1	N	Pre	-7		N	None	Recovered
			Hypophosphataemia	低リン酸血症	4	N	Pre	-2	29	N	-	
			Lethargy	嗜眠	1	N	TE	4	1	Y	None	Recovered
			Hypophosphataemia	低リン酸血症	3	N	Pre	27	64	N	-	
			Hypomagnesaemia	低マグネシウム血症	1	N	TE	55	36	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	56	1	N	None	Recovered
			Lethargy	嗜眠	1	N	TE	79	69	Y	None	Ongoing at study termination / withdrawal
			Cough	咳嗽	1	N	TE	79	15	N	None	Recovered
			Dyspepsia	消化不良	1	N	TE	84	15	N	None	Recovered
			Hypophosphataemia	低リン酸血症	4	N	Pre	90	29	N	-	
			Paraesthesia	錯感覚	1	N	TE	91		N	None	Ongoing at time of death
			Hypophosphataemia	低リン酸血症	3	N	Pre	118	15	N	-	
			Dyspepsia	消化不良	1	N	TE	120		N	None	Recovered
			Hypophosphataemia	低リン酸血症	4	N	Pre	132	6	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	132	115	N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	132	115	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	133	114	N	Not applicable	Recovered
			Hypophosphataemia	低リン酸血症	4	Y	TE	137	4	N	Not applicable	Recovered
			Hyperparathyroidism	副甲状腺機能亢進症	1	N	TE	139		N	Not applicable	Recovered
			Cachexia	悪液質	2	N	TE	139		N	Not applicable	
			Osteomalacia	骨軟化症	2	N	TE	139		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	146	20	N	Not applicable	Recovered
			Lethargy	嗜眠	2	N	TE	147		Y	None	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	1	N	TE	166		N	Not applicable	Ongoing at time of death
203007	Australia	70/M/C	Bone pain	骨痛	2	N	Pre	-7	63	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	Pre	-7	63	N	None	Recovered
			Constipation	便秘	2	Y	Pre	-1	3	N	None	Recovered
			Anorexia	食欲不振	2	N	TE	3		N	None	Ongoing at time of death
			Dysgeusia	味覚異常	1	N	TE	3		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	4	2	Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	28	49	Y	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	28	29	N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	28	83	N	Not applicable	Death
			Fatigue	疲労	2	N	TE	35		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	53	5	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	56	3	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	56	3	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	56	3	N	None	Recovered
			Bone pain	骨痛	1	N	TE	58		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	58		N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	66	8	N	Not applicable	Recovered
			Constipation	便秘	3	Y	TE	73	6	N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	76	3	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	78		Y	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	110	1	N	Not applicable	Death
204001	Australia	76/M/C	Dyspnoea	呼吸困難	1	N	Pre	-392	366	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	1	N	TE	1		Y	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	2		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	2		Y	None	Ongoing at study termination / withdrawal
			Chills	悪寒	1	N	TE	6	1	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	8	1	Y	None	Recovered
			Constipation	便秘	1	N	TE	9		Y	None	Ongoing at study termination / withdrawal
			Contusion	挫傷	1	N	TE	10		N	None	Ongoing at study termination / withdrawal
			Gastroenteritis	胃腸炎	4	Y	TE	18	6	Y	None	Recovered with sequelae
			Renal failure acute	急性腎不全	2	Y	TE	18	6	Y	None	Recovered
			Gastroenteritis	胃腸炎	3	N	TE	21	3	Y	None	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	22	2	Y	None	Recovered
			Gastroenteritis	胃腸炎	2	N	TE	23	1	Y	None	Recovered with sequelae
			Bone pain	骨痛	1	N	TE	34		Y	None	Ongoing at time of death
			Mobility decreased	運動性低下	1	N	TE	34		Y	None	Ongoing at time of death
			Tremor	振戦	1	N	TE	34		Y	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	43	26	N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	63	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	68	9	N	Not applicable	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	76		N	Not applicable	Ongoing at study termination / withdrawal
			Anxiety	不安	1	N	TE	79	1	Y	None	Recovered
			Anxiety	不安	1	N	TE	83	3	Y	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	116	1	N	Drug permanently withdrawn	Death
205004	Australia	82/M/C	Bone pain	骨痛	2	N	TE			Y	None	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	Pre	1		N	None	Ongoing at time of death
			Urinary incontinence	尿失禁	2	N	TE	6		Y	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	33		Y	None	Ongoing at time of death
			Hydrocephalus	水頭症	4	Y	TE	107	20	N	Drug permanently withdrawn	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	127	14	N	Drug permanently withdrawn	Death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	140	1	N	Drug permanently withdrawn	Death
206001	Australia	83/M/C	Meniere's disease	メニエール病	2	N	TE	78	18	Y	Drug administration postponed	Recovered with sequelae
			Deep vein thrombosis	深部静脈血栓症	3	Y	TE	90	6	Y	None	Recovered with sequelae
			Constipation	便秘	1	N	TE	91	4	N	Drug administration postponed	Recovered
			Pollakiuria	頻尿	3	N	TE	189		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	201		N	Not applicable	Ongoing at time of death
			Nausea	悪心	3	N	TE	201		N	Not applicable	Ongoing at time of death
			Pain	疼痛	3	N	TE	201		N	Not applicable	Ongoing at time of death
			Urinary tract infection	尿路感染	3	N	TE	201		N	Not applicable	Ongoing at time of death
			Hydronephrosis	水腎症	3	Y	TE	201		N	Not applicable	Ongoing at time of death
			Fluid overload	水分過負荷	3	N	TE	202		N	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	4	N	TE	202		N	Not applicable	Ongoing at time of death
			Lung consolidation	肺硬化	3	N	TE	202		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	212	1	N	Not applicable	Death
209001	Australia	78/M/C	Stomatitis	口内炎	1	N	Pre	-2	17	N	None	Recovered
			Lethargy	嗜眠	1	N	TE	2	105	N	None	Recovered
			Bone pain	骨痛	1	N	TE	29	84	N	None	Recovered
			Fatigue	疲労	3	Y	TE	107	6	N	Drug administration postponed	Recovered
			Bone pain	骨痛	1	N	TE	107	3	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	107	6	N	Drug administration postponed	Recovered
			Nausea	悪心	1	N	TE	108	3	N	Not applicable	Recovered
			Headache	頭痛	1	N	TE	112	1	N	Not applicable	Recovered
			Lethargy	嗜眠	3	N	TE	113		N	Not applicable	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	126	8	N	Not applicable	Recovered
209002	Australia	78/M/C	Bone pain	骨痛	1	N	Pre	1	71	N	None	Recovered
			Rash	発疹	1	N	Pre	1	57	N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	2		N	None	Ongoing at time of death
			Neutropenia	好中球減少症	3	N	TE	29	42	N	Drug administration postponed	Recovered
			Diarrhoea	下痢	1	N	TE	29	99	N	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	29	29	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Lymphadenopathy	リンパ節症	1	N	TE	57		N	None	Ongoing at time of death
			Lymphadenopathy	リンパ節症	1	N	TE	57		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	84	59	N	None	Recovered
			Hypoalbuminaemia	低アルブミン血症	1	N	TE	98		N	None	Ongoing at time of death
			Pallor	蒼白	2	N	TE	98	33	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	99		N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	99	29	N	None	Recovered
			Neutropenia	好中球減少症	4	N	TE	126	5	N	Drug permanently withdrawn	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	126		N	Not applicable	Ongoing at time of death
			Rectal tenesmus	直腸しぶり	1	N	TE	127		N	Not applicable	Ongoing at study termination / withdrawal
			Crepitations	捻髪音	1	N	TE	127		N	Not applicable	Ongoing at time of death
			Breath sounds abnormal	呼吸音異常	1	N	TE	127		N	Not applicable	Ongoing at time of death
			Wheezing	喘鳴	1	N	TE	127		N	Not applicable	Ongoing at time of death
			Neutropenia	好中球減少症	3	N	TE	130	15	N	Drug permanently withdrawn	Recovered
			Anaemia	貧血	2	N	TE	133	13	N	Not applicable	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	137	6	N	Not applicable	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	TE	142	22	N	Not applicable	Ongoing at time of death
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1	N	TE	142	12	N	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	3	Y	TE	143	12	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	153	61	N	Not applicable	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	2	N	TE	153	11	N	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE	155		N	Not applicable	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	TE	163		N	Not applicable	Ongoing at time of death
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	TE	163		N	Not applicable	Ongoing at time of death
209003	Australia	56/M/C	Bone pain	骨痛	1	N	Pre	-22		N	None	Ongoing at time of death
			Oesophagitis	食道炎	1	N	TE	29		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	29		N	None	Ongoing at time of death
			Muscle spasms	筋痙縮	1	N	TE	57		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	78		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	78		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	78		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	85		N	None	Ongoing at time of death
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	1	N	TE	85		N	None	Ongoing at time of death
			Breath sounds abnormal	呼吸音異常	1	N	TE	85		N	None	Ongoing at time of death
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1	N	TE	85		N	None	Ongoing at time of death
			Neuropathy peripheral	末梢性ニューロパチー	1	N	TE	88		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	4	Y	TE	94	16	N	None	Recovered
			Burning sensation	灼熱感	1	N	TE	102	1	N	None	Recovered
			Rash	発疹	1	N	TE	103		N	None	Ongoing at time of death
			Pyrexia	発熱	1	N	TE	108	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	109		N	Not applicable	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	109		N	Not applicable	Ongoing at time of death
			Radiation skin injury	放射線皮膚損傷	1	N	TE	109		N	Not applicable	Ongoing at time of death
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	Y	TE	109	7	N	Drug permanently withdrawn	Recovered
			Anxiety	不安	1	N	TE	109		N	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	138		N	Not applicable	Ongoing at time of death
			Ascites	腹水	1	Y	TE	149		N	Not applicable	Ongoing at time of death
			Epistaxis	鼻出血	1	N	TE	149	18	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dry skin	皮膚乾燥	1	N	TE	149		N	Not applicable	Ongoing at time of death
			Pruritus	そう痒症	1	N	TE	149		N	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE	153		N	None	Ongoing at time of death
			Rectal haemorrhage	直腸出血	1	N	TE	158		N	Not applicable	Ongoing at time of death
			Pitting oedema	圧痕浮腫	1	N	TE	158		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	158	9	N	Not applicable	Death
			Confusional state	錯乱状態	1	N	TE	158		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	166	1	N	Not applicable	Death
213002	Australia	49/M/O	Cough	咳嗽	1	N	Pre	-10	31	N	None	Recovered
			Musculoskeletal pain	筋骨格痛	3	N	TE	17	2	Y	None	Recovered
			Dyspnoea	呼吸困難	3	N	TE	82		Y	None	Not recovered, but no changes expected
			Abdominal pain	腹痛	2	N	TE	85	3	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	85	1	N	None	Recovered
			Pulmonary haemorrhage	肺出血	1	N	TE	85	1	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	140	29	N	None	Not recovered, but no changes expected
			Rectal haemorrhage	直腸出血	1	N	TE	159		N	None	Not recovered, but no changes expected
			Fatigue	疲労	2	N	TE	161		N	None	Not recovered, but no changes expected
			Headache	頭痛	1	N	TE	161		N	None	Not recovered, but no changes expected

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	1	N	TE	163	9	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	163	9	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	168	28	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	168	3	N	Not applicable	Recovered
			Insomnia	不眠症	1	N	TE	168		N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	195		N	None	Not recovered, but no changes expected
213008	Australia	74/M/C	Bone pain	骨痛	1	N	TE			N	None	Recovered
			Hypotension	低血圧	1	N	TE			N	Not applicable	Recovered
			Hypotension	低血圧	2	N	TE			N	Not applicable	Not recovered, but no changes expected
			Hypotension	低血圧	3	N	TE			N	Not applicable	Not recovered, but no changes expected
			Nausea	悪心	2	N	TE	2	6	Y	None	Recovered
			Fatigue	疲労	1	N	TE	2	6	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	2	10	Y	None	Recovered
			Headache	頭痛	1	N	TE	2	6	Y	None	Recovered
			Constipation	便秘	1	N	TE	4	8	N	None	Recovered
			Nausea	悪心	1	N	TE	7	5	Y	None	Recovered
			Skin laceration	皮膚裂傷	3	Y	TE	25	2	N	None	Recovered
			Hypotension	低血圧	1	N	TE	45	15	N	None	Recovered
			Nausea	悪心	1	N	TE	64	29	Y	None	Recovered
			Fatigue	疲労	1	N	TE	65	8	Y	None	Recovered
			Fatigue	疲労	1	N	TE	92		Y	None	Not recovered, but no changes expected
			Paraesthesia	錯感覚	1	N	TE	92	24	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	1	N	TE	120		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	120		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	146	4	N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	149	28	N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	149		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	176		N	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	176		N	None	Ongoing at study termination / withdrawal
214003	Australia	68/M/C	Rash	発疹	2	N	TE	3	20	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	8	10	N	None	Recovered
			Bone pain	骨痛	3	N	TE	42	16	N	Drug administration postponed	Recovered
			Constipation	便秘	1	N	TE	54	4	N	None	Recovered
			Fatigue	疲労	3	N	TE	58	28	Y	None	Recovered
			Constipation	便秘	1	N	TE	60	3	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	61		Y	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	85	29	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hydronephrosis	水腎症	3	N	TE	85	36	N	None	Recovered
			Myositis	筋炎	2	N	TE	101	15	N	None	Recovered
			Anaemia	貧血	2	N	TE	122	3	N	None	Ongoing at time of death
			Procedural pain	処置による疼痛	3	Y	TE	122	4	N	None	Recovered
			Dysuria	排尿困難	2	N	TE	122	3	N	None	Recovered
			Haematuria	血尿	1	N	TE	122	15	N	None	Recovered
			Anaemia	貧血	1	N	TE	124		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	124	18	Y	Drug permanently withdrawn	Ongoing at time of death
			Nausea	悪心	2	N	TE	124	18	Y	None	Recovered
			Diarrhoea	下痢	2	N	TE	130	8	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	141	61	Y	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	173	5	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	201		Y	Drug permanently withdrawn	Ongoing at time of death
230002	UK	66/M/C	Muscle spasms	筋痙縮	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE	28		N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	38	8	Y	None	Recovered
			Anaemia	貧血	2	N	TE	56	29	Y	None	Recovered with sequelae
			Arthralgia	関節痛	2	N	TE	84	86	N	None	Not recovered, but no changes expected

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	94	6	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	98	44	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	159		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	169	33	Y	None	Recovered
			Hypocalcaemia	低カルシウム血症	1	N	TE	169	79	N	None	Recovered
			Hypophosphataemia	低リン酸血症	4	N	TE	169		Y	None	Not recovered, but no changes expected
			Arthralgia	関節痛	3	N	TE	169		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	169	28	N	Not applicable	Recovered
			Pathological fracture	病的骨折	3	Y	TE	197	9	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	203	15	Y	None	Recovered
			Anaemia	貧血	3	N	TE	245	2	Y	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	245	11	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	1	N	TE	247	6	Y	Not applicable	Recovered
230003	UK	73/M/C	Diarrhoea	下痢	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	1	N	Pre			N	None	Ongoing at study termination / withdrawal
			Scrotal swelling	陰嚢腫脹	1	N	TE			N	Not applicable	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urosepsis	尿路性敗血症	3	Y	Pre	-15	4	N	Drug administration postponed	Recovered
			Hypoglycaemia	低血糖症	4	Y	Pre	-15	1	N	Drug administration postponed	Recovered
			Dizziness	浮動性めまい	1	N	TE	68		N	Not applicable	Recovered
			Rectal discharge	直腸分泌物	1	N	TE	69	10	N	Not applicable	Recovered
			Dysuria	排尿困難	1	N	TE	73		N	Not applicable	Recovered
			Groin pain	鼠径部痛	3	N	TE	75		Y	Not applicable	Recovered
			Nausea	悪心	1	N	TE	83		N	Not applicable	Ongoing at study termination / withdrawal
230005	UK	64/M/C	Bone pain	骨痛	3	N	TE	62		N	None	Not recovered, but no changes expected
			Hypoaesthesia	感覚鈍麻	2	N	TE	62		N	None	Not recovered, but no changes expected
			Pyrexia	発熱	3	N	TE	69	3	N	None	Recovered
			Infection	感染	3	Y	TE	69	3	N	None	Recovered
			Hyperglycaemia	高血糖	4	Y	TE	77	8	N	None	Recovered with sequelae
			Hyperglycaemia	高血糖	2	N	TE	84		Y	None	Ongoing at study termination / withdrawal
233001	UK	75/M/C	Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE			Y	None	Recovered
			Bone pain	骨痛	2	N	Pre	-2	33	N	None	Recovered
			Bone pain	骨痛	3	N	TE	85		N	Drug administration postponed	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	85		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	4	Y	TE	103	7	N	Drug administration postponed	Recovered with sequelae
			Atrial fibrillation	心房細動	3	Y	TE	116	2	Y	None	Recovered
			Cardiac failure congestive	うっ血性心不全	3	Y	TE	131		Y	Not applicable	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	N	TE	131	22	N	Not applicable	Recovered
			Hypokalaemia	低カリウム血症	3	N	TE	132	3	N	Not applicable	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	135	3	N	Not applicable	Recovered
233002	UK	70/M/C	Bone pain	骨痛	2	N	Pre	1		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	4	4	Y	None	Recovered
			Productive cough	湿性咳嗽	2	N	TE	4	4	Y	None	Recovered
			Sepsis	敗血症	4	Y	TE	5	11	Y	Drug permanently withdrawn	Recovered
233005	UK	78/M/C	Nausea	悪心	1	N	TE	1	209	N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	29	181	Y	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	1	N	TE	29	29	N	None	Recovered
			Anorexia	食欲不振	3	N	TE	29	113	Y	None	Ongoing at time of death
			Dehydration	脱水	3	N	TE	29	4	Y	Drug administration postponed	Recovered
			Malaise	倦怠感	2	Y	TE	32	6	Y	Drug administration postponed	Recovered
			Dehydration	脱水	3	Y	TE	32	6	Y	Drug administration postponed	Recovered
			Dehydration	脱水	2	Y	TE	45	5	Y	Drug administration postponed	Recovered
			Anaemia	貧血	3	Y	TE	53	3	Y	None	Recovered
			Hypertension	高血圧	3	N	TE	85	125	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	134	3	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	136	3	Y	None	Recovered
			Dehydration	脱水	2	N	TE	136	3	Y	None	Recovered
			Dyspnoea	呼吸困難	3	N	TE	136	2	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	141		Y	None	Ongoing at time of death
			Abdominal pain upper	上腹部痛	1	N	TE	167	3	Y	None	Recovered
			Anaemia	貧血	1	Y	TE	168	2	Y	None	Recovered
			Fatigue	疲労	2	N	TE	168		N	None	Ongoing at time of death
			Dehydration	脱水	2	Y	TE	168	2	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	176	3	Y	Not applicable	Recovered
			Cough	咳嗽	2	N	TE	176	3	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cough	咳嗽	1	N	TE	176	3	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	N	TE	176	3	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	190		Y	Not applicable	Ongoing at time of death
			Neutropenia	好中球減少症	2	Y	TE	190		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	Y	TE	190		Y	Not applicable	Ongoing at time of death
			Abdominal pain	腹痛	1	N	TE	190	1	Y	Not applicable	Recovered
			Decreased appetite	食欲減退	3	N	TE	190		N	None	Ongoing at time of death
			Dehydration	脱水	3	Y	TE	190	4	Y	Not applicable	Recovered
			Hyperkalaemia	高カリウム血症	2	N	TE	190	20	Y	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	190		Y	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	190	4	Y	Not applicable	Recovered
			Dizziness	浮動性めまい	2	N	TE	190		N	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	3	Y	TE	209		N	Not applicable	Ongoing at time of death
			Bronchopneumonia	気管支肺炎	5	Y	TE	209	1	N	Not applicable	Death
			Dehydration	脱水	3	Y	TE	209		Y	Not applicable	Ongoing at time of death
			Agitation	激越	2	N	TE	209	1	N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
234005	UK	58/M/C	Nausea	悪心	2	N	Pre			N	None	Recovered
			Vomiting	嘔吐	2	N	Pre			Y	None	Recovered
			Anaemia	貧血	2	N	Pre	-1	85	N	None	Recovered with sequelae
			Anaemia	貧血	3	Y	TE	84	4	Y	Drug permanently withdrawn	Recovered
			Pancytopenia	汎血球減少症	3	N	TE	87		Y	None	Ongoing at time of death
			Cerebrovascular accident	脳血管発作	4	Y	TE	94		Y	None	Ongoing at study termination / withdrawal
240002	USA	68/M/C	Anaemia	貧血	3	N	TE	33	6	Y	Drug administration postponed	Recovered with sequelae
			Pneumonia	肺炎	3	Y	TE	33	6	N	Drug administration postponed	Recovered
			Sepsis	敗血症	4	Y	TE	33	6	N	Drug administration postponed	Recovered
			Pleural effusion	胸水	2	N	TE	33	4	N	None	Recovered
			Hypotension	低血圧	3	N	TE	33	1	N	None	Recovered
			Anaemia	貧血	1	N	TE	38	48	Y	None	Recovered with sequelae
			Diarrhoea	下痢	1	N	TE	62		Y	None	Ongoing at time of death
			Muscle spasms	筋痙縮	1	N	TE	72	43	N	None	Recovered
			Anaemia	貧血	2	N	TE	85	97	Y	None	Recovered with sequelae
			Nausea	悪心	1	N	TE	114	3	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	114		Y	None	Ongoing at time of death
			Haematuria	血尿	1	N	TE	133	7	N	None	Recovered
			Leukopenia	白血球減少症	2	N	TE	139		Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	1	N	TE	139		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	139		Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	140		N	None	Ongoing at time of death
			Contusion	挫傷	1	N	TE	140		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	140		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	170		N	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	180	3	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	3	Y	TE	180	6	Y	Not applicable	Recovered
			Urinary tract infection	尿路感染	1	N	TE	180	11	N	Not applicable	Recovered
			Bone pain	骨痛	3	N	TE	180	6	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	180	62	N	Not applicable	Death
			Haematuria	血尿	2	Y	TE	180	6	Y	Not applicable	Recovered
			Urinary retention	尿閉	2	Y	TE	180	6	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	N	TE	180	24	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	N	TE	181	2	Y	None	Recovered with sequelae
			Dyspnoea	呼吸困難	1	N	TE	181	5	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	182	50	Y	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	194		N	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	199	5	Y	Not applicable	Ongoing at time of death
			Abdominal pain	腹痛	2	N	TE	199	11	N	Not applicable	Recovered
			Diarrhoea	下痢	1	N	TE	199	11	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	199	11	N	Not applicable	Recovered
			Vomiting	嘔吐	2	N	TE	199	11	N	Not applicable	Recovered
			Asthenia	無力症	2	N	TE	199		N	Not applicable	Ongoing at time of death
			Arthralgia	関節痛	1	N	TE	199	11	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	199	11	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	N	TE	199	5	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	203		Y	Not applicable	Ongoing at time of death
			Skin laceration	皮膚裂傷	2	N	TE	205		N	Not applicable	Ongoing at time of death
			Haemorrhoids	痔核	1	N	TE	210	6	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Convulsion	痙攣	2	N	TE	223	1	N	Not applicable	Recovered
			Subcutaneous abscess	皮下組織膿瘍	2	N	TE	227		N	Not applicable	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	229		N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	231		Y	Not applicable	Ongoing at time of death
			Urinary retention	尿閉	2	N	TE	240	1	Y	Not applicable	Recovered
			Salivary hypersecretion	流涎過多	1	N	TE	241		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	241	1	N	Not applicable	Death
			Confusional state	錯乱状態	3	N	TE	241		N	Not applicable	Ongoing at time of death
240006	USA	75/M/C	Constipation	便秘	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	Pre	-7	100	N	None	Recovered
			Cardiac murmur	心雑音	1	N	Pre	-2	35	N	None	Recovered
			Bone pain	骨痛	1	N	TE	31	63	N	None	Recovered
			Contusion	挫傷	1	N	TE	33		N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	3	N	TE	47	11	Y	None	Recovered
			Abdominal pain upper	上腹部痛	1	N	TE	64	25	N	None	Recovered
			Fatigue	疲労	1	N	TE	64		Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	64	60	N	None	Recovered
			Weight increased	体重増加	1	N	TE	64		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	64	25	N	Drug administration postponed	Recovered
			Muscular weakness	筋力低下	1	N	TE	64		N	None	Ongoing at time of death
			Bone pain	骨痛	4	Y	TE	88	6	N	Drug administration postponed	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	88	115	N	Drug permanently withdrawn	Recovered
			Anaemia	貧血	2	N	TE	109	33	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	110	87	Y	Not applicable	Recovered
			Asthenia	無力症	2	N	TE	110		N	Not applicable	Ongoing at time of death
			Depression	うつ病	2	N	TE	110		N	Not applicable	Ongoing at time of death
			Fluid intake reduced	水分摂取量減少	2	N	TE	116	8	N	Not applicable	Recovered
			Cough	咳嗽	1	N	TE	118	17	N	None	Recovered
			Hypotension	低血圧	2	N	TE	120	55	N	Not applicable	Recovered
			Anorexia	食欲不振	2	N	TE	124		Y	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	145	203	N	Drug permanently withdrawn	Death
			Spinal cord compression	脊髄圧迫	3	N		202		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	347	1	N	Drug permanently withdrawn	Death
242001	USA	80/M/C	Vomiting	嘔吐	1	N	TE	83	1	N	None	Recovered
			Fatigue	疲労	2	N	TE	83	5	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	83	31	N	Drug administration postponed	Recovered
			Muscular weakness	筋力低下	2	N	TE	83	5	N	Drug administration postponed	Recovered
			Pyrexia	発熱	1	N	TE	85	3	N	Drug administration postponed	Recovered
			Viral infection	ウイルス感染	2	N	TE	85	3	N	Drug administration postponed	Recovered
			Confusional state	錯乱状態	1	N	TE	85	15	N	Drug administration postponed	Recovered
			Fatigue	疲労	1	N	TE	87	13	N	None	Not recovered, but no changes expected
			Pyrexia	発熱	1	N	TE	88	6	N	None	Recovered
			Dyspepsia	消化不良	1	N	TE	89	116	N	None	Recovered
			Eructation	おくび	1	N	TE	89	116	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	99	40	N	Not applicable	Recovered
			Fatigue	疲労	2	N	TE	99		N	None	Not recovered, but no changes expected

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	109	31	N	None	Not recovered, but no changes expected
			Diarrhoea	下痢	1	N	TE	135	7	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	135	4	N	Not applicable	Recovered
			Asthenia	無力症	2	N	TE	137	16	N	Not applicable	Recovered
			Chills	悪寒	1	N	TE	137	2	N	Not applicable	Recovered
			Dehydration	脱水	3	Y	TE	137	5	N	Not applicable	Recovered
			Dizziness	浮動性めまい	1	N	TE	137	2	N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	139	14	N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	147	4	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	150	5	N	Not applicable	Recovered
			Vomiting	嘔吐	2	N	TE	150	5	N	Not applicable	Recovered
			Angina pectoris	狭心症	1	N	TE	152	4	N	Not applicable	Recovered
			Abdominal pain upper	上腹部痛	1	N	TE	152	2	N	Not applicable	Recovered
			Dysphagia	嚥下障害	2	N	TE	152	4	N	Not applicable	Recovered
			Asthenia	無力症	3	N	TE	152	4	N	Not applicable	Recovered
			Skin laceration	皮膚裂傷	1	N	TE	152	11	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dehydration	脱水	3	Y	TE	152	4	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	152		N	None	Not recovered, but no changes expected
			Cough	咳嗽	1	N	TE	152		N	Not applicable	Not recovered, but no changes expected
			Hypoxia	低酸素症	3	N	TE	152	11	N	Not applicable	Recovered
			Hypophosphataemia	低リン酸血症	3	N	TE	154		N	Not applicable	Not recovered, but no changes expected
			Pleural effusion	胸水	2	N	TE	154		N	Not applicable	Not recovered, but no changes expected
			Hypokalaemia	低カリウム血症	1	N	TE	155	50	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	155		N	Not applicable	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	162		N	Not applicable	Not recovered, but no changes expected
253001	USA	72/M/C	Constipation	便秘	1	N	Pre	1	29	N	None	Recovered
			Asthenia	無力症	1	N	Pre	1	13	N	None	Ongoing at time of death
			Micturition frequency decreased	排尿回数減少	1	N	Pre	1	13	N	None	Recovered
			Bone pain	骨痛	2	N	TE	3	11	N	None	Recovered
			Nausea	悪心	1	N	TE	13	29	N	None	Recovered
			Asthenia	無力症	2	N	TE	13	157	N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	13	17	Y	-	
			Anorexia	食欲不振	2	N	TE	13	218	N	None	Recovered
			Hypocalcaemia	低カルシウム血症	1	N	TE	13	31	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	29	141	Y	-	

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment:BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dehydration	脱水	2	N	TE	29	1	N	None	Recovered
			Neck pain	頚部痛	2	N	TE	29	13	N	None	Recovered
			Dizziness	浮動性めまい	2	N	TE	34		Y	None	Ongoing at time of death
			Ventricular extrasystoles	心室性期外収縮	2	N	TE	41	3	N	None	Recovered
			Skin laceration	皮膚裂傷	2	N	TE	41	17	N	None	Recovered
			Bone pain	骨痛	1	N	TE	41	3	N	None	Recovered
			Memory impairment	記憶障害	1	N	TE	41	3	N	None	Recovered
			Syncope	失神	3	Y	TE	41	3	N	None	Recovered
			Hypertension	高血圧	3	N	TE	41		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	42	44	Y	None	Recovered
			Hypocalcaemia	低カルシウム血症	2	N	TE	43	15	N	None	Recovered
			Constipation	便秘	1	N	TE	57	56	N	None	Recovered
			Hypocalcaemia	低カルシウム血症	1	N	TE	57	13	N	None	Recovered
			Ocular hyperaemia	眼充血	1	N	TE	140	7	N	None	Recovered
			Micturition frequency decreased	排尿回数減少	1	N	TE	140	30	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
001014	Norway	67/M/C	Bone pain	骨痛	3	N	TE			N	None	Recovered
			Insomnia	不眠症	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	2	N	TE	39	4	Y	None	Recovered
			Nausea	悪心	2	N	TE	48	2	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	48	2	Y	None	Recovered
			Somnolence	傾眠	3	Y	TE	49	5	N	None	Recovered
			Depression	うつ病	2	N	TE	52		N	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	57	85	Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	85	29	Y	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	136		Y	None	Ongoing at study termination / withdrawal
			Confusional state	錯乱状態	1	N	TE	136		Y	None	Ongoing at study termination / withdrawal
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	2	N	TE	141	36	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	141	36	Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	141	6	Y	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	Y	TE	146	6	Y	Not applicable	Recovered with sequelae

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	1	N	TE	176		Y	None	Ongoing at study termination / withdrawal
001015	Norway	65/M/C	Anaemia	貧血	2	N	Pre	1	85	Y	None	Not recovered, but no changes expected
			Bronchitis	気管支炎	2	Y	TE	38	9	N	None	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1	N	TE	57	46	Y	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	57	36	Y	None	Not recovered, but no changes expected
			Hyperhidrosis	多汗症	2	N	TE	57		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	3	N	TE	85	8	Y	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	92		Y	None	Not recovered, but no changes expected
			Weight decreased	体重減少	2	N	TE	92		Y	None	Not recovered, but no changes expected
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	2	N	TE	102		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	102	18	N	Drug permanently withdrawn	Recovered with sequelae
			Nausea	悪心	2	N	TE	113	7	N	None	Recovered
			Anxiety	不安	1	N	TE	113		N	None	Not recovered, but no changes expected
			Depression	うつ病	1	N	TE	113		N	None	Not recovered, but no changes expected

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
001020	Norway	69/M/C	Atrial flutter	心房粗動	2	Y	TE	2	6	Y	Drug permanently withdrawn	Recovered
			Anxiety	不安	1	N	TE	2		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	Y	TE	54	16	N	Drug permanently withdrawn	Recovered with sequelae
001022	Norway	72/M/C	Paresis anal sphincter	肛門括約筋不全麻痺	1	N	TE	43	12	N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Paresis anal sphincter	肛門括約筋不全麻痺	2	N	TE	54	8	N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Paresis anal sphincter	肛門括約筋不全麻痺	3	N	TE	61		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Gait disturbance	歩行障害	3	Y	TE	61		N	Not applicable	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	Y	TE	61	3	N	Drug permanently withdrawn	Recovered with sequelae
			Urinary incontinence	尿失禁	4	N	TE	61		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	N	TE	63		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
001027	Norway	83/M/C	Paresis anal sphincter	肛門括約筋不全麻痺	1	N	TE	52		Y	None	Ongoing at study termination / withdrawal
			Polyneuropathy	多発ニューロパチー	4	Y	TE	52	2	Y	None	Recovered with sequelae
			Urinary incontinence	尿失禁	2	N	TE	52		Y	None	Ongoing at study termination / withdrawal
			Polyneuropathy	多発ニューロパチー	4	N	TE	53		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	63		N	None	Ongoing at study termination / withdrawal
001028	Norway	85/M/C	Fatigue	疲労	2	N	TE	62	29	Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	90		Y	Not applicable	Ongoing at study termination / withdrawal
			Fatigue	疲労	3	N	TE	90		Y	None	Ongoing at study termination / withdrawal
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	90		Y	None	Ongoing at study termination / withdrawal
			Dehydration	脱水	2	Y	TE	90		Y	Not applicable	Ongoing at study termination / withdrawal
001030	Norway	66/M/C	Nausea	悪心	1	N	TE	5	2	Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	1	N	TE	6	1	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	28	20	Y	None	Recovered
			Nausea	悪心	2	N	TE	33	2	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	34	1	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	53		N	None	Ongoing at study termination / withdrawal
			Metastases to bone	骨転移	2	N	TE	85		N	Drug administration postponed	Ongoing at study termination / withdrawal
			Confusional state	錯乱状態	4	Y	TE	90	17	N	Drug permanently withdrawn	Recovered with sequelae
			Peroneal nerve palsy	腓骨神経麻痺	1	N	TE	99		N	None	Ongoing at study termination / withdrawal
001038	Norway	61/M/C	Diarrhoea	下痢	1	N	TE	4	4	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	4		Y	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	29		Y	Drug administration postponed	Ongoing at study termination / withdrawal
			Urinary tract infection	尿路感染	2	N	TE	31		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	Y	TE	34		Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	Y	TE	34		Y	Drug permanently withdrawn	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Haematuria	血尿	3	Y	TE	34		Y	Drug permanently withdrawn	Ongoing at time of death
002004	Norway	81/M/C	Anorexia	食欲不振	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	1	54	N	None	Ongoing at time of death
			Dizziness	浮動性めまい	2	N	Pre	1		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	54	9	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	57		Y	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	57		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	62		N	None	Ongoing at time of death
			Left ventricular dysfunction	左室機能不全	5	Y	TE	68	1	N	None	Death
002011	Norway	69/M/C	Oral fungal infection	口腔真菌感染	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Dysuria	排尿困難	2	N	TE	49	10	N	None	Recovered
			Dysuria	排尿困難	2	N	TE	83	10	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	93	16	Y	None	Recovered
			Sepsis	敗血症	3	Y	TE	99	10	N	None	Recovered
			Sepsis	敗血症	2	N	TE	108	8	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
002014	Norway	76/M/C	Abdominal pain	腹痛	1	N	TE	1	4	Y	None	Recovered
			Arthralgia	関節痛	1	N	TE	1	4	Y	None	Recovered
			Abdominal pain	腹痛	1	N	TE	2	4	N	None	Recovered
			Arthralgia	関節痛	1	N	TE	2	4	N	None	Recovered
			Anaemia	貧血	2	N	TE	29	3	Y	None	Recovered
			Arthralgia	関節痛	1	N	TE	57	3	Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	1	N	TE	57	3	Y	None	Recovered
			Arthralgia	関節痛	1	N	TE	58	3	N	None	Recovered
			Musculoskeletal pain	筋骨格痛	1	N	TE	58	3	N	None	Recovered
			Chills	悪寒	2	N	TE	81	1	N	None	Recovered
			Anaemia	貧血	3	N	TE	85	3	Y	Drug administration postponed	Recovered
			Bone pain	骨痛	3	Y	TE	100	5	N	None	Recovered
			Bone pain	骨痛	2	N	TE	104		N	Drug administration postponed	Not recovered, but no changes expected
			Spinal cord compression	脊髄圧迫	3	Y	TE	118	12	N	None	Recovered
			Infection	感染	3	Y	TE	133	14	N	Drug administration postponed	Recovered
			Fungal skin infection	皮膚真菌感染	2	N	TE	141	15	N	None	Recovered
002015	Norway	83/M/C	Oral candidiasis	口腔カンジダ症	2	N	TE			N	Not applicable	Ongoing at time of death
			Cough	咳嗽	2	N	TE			N	Not applicable	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	37	14	N	None	Recovered
			Conjunctivitis	結膜炎	2	N	TE	50	7	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	100	30	N	Drug permanently withdrawn	Death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cerebral haemorrhage	脳出血	2	Y	TE	100		Y	Drug permanently withdrawn	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	100	19	N	Not applicable	Recovered with sequelae
			Confusional state	錯乱状態	2	N	TE	127		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	129	1	N	Drug permanently withdrawn	Death
002018	Norway	70/M/C	Bone pain	骨痛	2	N	TE	2	21	Y	None	Recovered
			Stomatitis	口内炎	2	N	TE	22	9	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	22	14	Y	None	Recovered
			Insomnia	不眠症	1	N	TE	22		N	None	Ongoing at study termination / withdrawal
			Constipation	便秘	2	N	TE	29	5	N	None	Recovered
			Bone pain	骨痛	2	N	TE	35		Y	None	Not recovered, but no changes expected
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	44	63	N	None	Ongoing at time of death
			Pneumonia	肺炎	2	N	TE	75		N	Not applicable	Ongoing at study termination / withdrawal
			Metastases to central nervous system	中枢神経系転移	4	Y	TE	79		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	106	1	N	None	Death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
003003	Norway	77/M/C	Fatigue	疲労	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	15		Y	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	23	3	N	None	Recovered
			Nausea	悪心	3	Y	TE	25	12	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	25	12	N	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	56	11	Y	None	Recovered
			Spinal cord compression	脊髄圧迫	2	N	TE	56	3	N	None	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	3	Y	TE	58	21	N	None	Recovered with sequelae
			Urinary tract infection	尿路感染	3	N	TE	73		N	Not applicable	Ongoing at study termination / withdrawal
003010	Norway	69/M/C	Nausea	悪心	1	N	TE	1	6	Y	None	Recovered
			Joint range of motion decreased	関節運動範囲減少	2	N	TE	1	6	Y	None	Recovered
			Bone pain	骨痛	3	Y	TE	161	21	N	Not applicable	Recovered
003011	Norway	72/M/C	Insomnia	不眠症	1	N	TE	97		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	107	3	N	None	Recovered
			Vomiting	嘔吐	3	Y	TE	109	12	N	None	Recovered
			Pneumonia	肺炎	2	N	TE	109	16	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	112		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	112	16	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	2	N	TE	120	32	Y	None	Recovered
			Pneumonia	肺炎	2	Y	TE	124	4	N	None	Recovered
			Urticaria	蕁麻疹	1	N	TE	127	57	N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	146		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	151	3	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	173	11	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	3	N	TE	175	9	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	TE	181	29	Y	Not applicable	Not recovered, but no changes expected
			Stomatitis	口内炎	2	N	TE	190	3	N	Not applicable	Recovered
			Stomatitis	口内炎	1	N	TE	192	9	N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	209	7	Y	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	215		Y	Not applicable	Not recovered, but no changes expected
003013	Norway	59/M/C	Depression	うつ病	3	N	Pre	-340		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	Pre	-2	11	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	9		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	9	9	N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	17		N	None	Ongoing at study termination / withdrawal
			Urinary retention	尿閉	2	N	TE	17		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	21	1	N	Not applicable	Recovered
			Urinary tract infection	尿路感染	4	N	TE	24		N	None	Ongoing at study termination / withdrawal
			Pathological fracture	病的骨折	4	Y	TE	24		N	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	1	N	TE	25	3	N	None	Ongoing at time of death
			Nausea	悪心	3	N	TE	25		N	Not applicable	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	2	N	TE	27		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	29		N	Drug permanently withdrawn	Ongoing at time of death
			Anxiety	不安	2	N	TE	31		N	Not applicable	Ongoing at study termination / withdrawal
004002	Norway	60/M/C	Anorexia	食欲不振	2	N	Pre	1		N	None	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	9	3	N	None	Recovered
			Vomiting	嘔吐	3	Y	TE	11	10	N	None	Recovered
			Hallucination	幻覚	2	N	TE	12	8	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	2	N	TE	20		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	33	2	N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	58		N	Drug administration postponed	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	58	6	N	None	Recovered
			Anaemia	貧血	2	N	TE	83	11	Y	None	Recovered
			Bone pain	骨痛	4	Y	TE	104	4	N	Not applicable	Recovered
			Eye infection	眼感染	2	N	TE	107		N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	107		N	Not applicable	Ongoing at time of death
005003	Norway	44/M/C	Bone pain	骨痛	2	N	TE	86	58	N	None	Recovered
			Weight decreased	体重減少	3	N	TE	113		N	None	Not recovered, but no changes expected
			Lymphadenopathy	リンパ節症	1	N	TE	172		N	None	Recovered
			Bone pain	骨痛	2	N	TE	202	4	N	Not applicable	Recovered
			Bone pain	骨痛	2	Y	TE	205	9	N	Not applicable	Recovered
			Oral candidiasis	口腔カンジダ症	1	N	TE	206	15	N	Not applicable	Recovered
			Anaemia	貧血	2	N	Post	352	6	Y	Not applicable	Recovered with sequelae
006002	Norway	73/M/C	Pain	疼痛	1	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE	56	27	N	None	Recovered
			Parosmia	嗅覚錯誤	1	N	TE	56		N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	1	N	TE	82		N	None	Not recovered, but no changes expected
			Food poisoning	食中毒	2	Y	TE	102	5	N	None	Recovered
006003	Norway	73/M/C	Nausea	悪心	1	N	TE	56		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	56	41	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	96	5	N	None	Recovered
006012	Norway	81/M/C	Constipation	便秘	2	N	Pre	-1		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	28	18	N	None	Recovered
			Glaucoma	緑内障	3	Y	TE	41		Y	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	45		Y	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	Y	TE	52		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	57	3	N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	N	TE	59		N	None	Ongoing at study termination / withdrawal
006013	Norway	83/M/C	Dizziness	浮動性めまい	1	N	TE			N	Not applicable	Recovered
			Fatigue	疲労	1	N	TE	18	1	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Back pain	背部痛	1	N	TE	18	1	N	None	Recovered
			Bone pain	骨痛	2	N	TE	28	29	N	None	Recovered
			Fatigue	疲労	2	N	TE	56		N	None	Not recovered, but no changes expected
			Pathological fracture	病的骨折	2	Y	TE	137	19	N	Drug administration postponed	Recovered with sequelae
006014	Norway	81/M/C	Anorexia	食欲不振	2	N	TE	29		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	57	80	N	None	Recovered
			Cystitis	膀胱炎	2	N	TE	101	5	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	101	55	N	Drug administration postponed	Recovered
			Pneumonia	肺炎	3	N	TE	106	10	N	Drug administration postponed	Recovered
			Cystitis	膀胱炎	2	N	TE	159	8	N	None	Recovered
			Dyspnoea	呼吸困難	3	Y	TE	159	6	N	Drug administration postponed	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	175	10	N	Not applicable	Recovered with sequelae
			Cystitis	膀胱炎	2	N	TE	177	9	N	None	Recovered
			Bone pain	骨痛	1	Y	TE	184	2	N	Not applicable	Recovered with sequelae
			Death	死亡	5	Y	TE	205	1	N	Not applicable	Death
006019	Norway	70/M/C	Nausea	悪心	1	N	TE			Y	None	Not recovered, but no changes expected

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Musculoskeletal pain	筋骨格痛	1	N	Pre	-1	10	N	None	Recovered
			Nausea	悪心	1	N	TE	2	26	Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	2	N	TE	9	4	N	None	Recovered
			Bone pain	骨痛	2	N	TE	36	15	N	None	Recovered
			Bone pain	骨痛	2	N	TE	70	8	N	None	Recovered
			Constipation	便秘	2	N	TE	75	95	N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	84	29	Y	Drug administration postponed	Recovered with sequelae
			Weight decreased	体重減少	1	N	TE	84	57	N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	99	8	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	99	8	N	None	Recovered
			Anaemia	貧血	3	Y	TE	112	2	Y	Drug administration postponed	Recovered with sequelae
			Anaemia	貧血	2	N	TE	113	57	Y	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	131	6	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	140		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	140		N	None	Not recovered, but no changes expected
			Anaemia	貧血	3	Y	TE	169	2	Y	Not applicable	Recovered with sequelae
			Constipation	便秘	1	N	TE	169		N	None	Not recovered, but no changes expected
			Fatigue	疲労	2	N	TE	169	3	N	None	Recovered
			Pyrexia	発熱	1	N	TE	169	2	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	N	TE	169	3	Y	None	Recovered
			Anaemia	貧血	2	N	TE	170	2	Y	-	

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	170	56	N	None	Recovered
			Anaemia	貧血	1	N	TE	171	33	Y	-	
			Pyrexia	発熱	2	Y	TE	202	7	Y	Not applicable	Recovered
			Arthralgia	関節痛	2	Y	TE	202	7	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	203	3	Y	-	
			Fatigue	疲労	2	N	TE	203	6	N	None	Recovered
			Anaemia	貧血	1	N	TE	205	36	Y	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	240	8	Y	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	1	N	TE	247		Y	Not applicable	Not recovered, but no changes expected
006029	Norway	77/M/C	Diarrhoea	下痢	1	N	TE	2	5	Y	None	Recovered
			Fatigue	疲労	1	N	TE	2	5	N	None	Recovered
			Anaemia	貧血	2	N	TE	35	39	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	56		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	68	12	N	None	Recovered with sequelae
			Dysphagia	嚥下障害	2	N	TE	69	5	N	None	Recovered
			Pyrexia	発熱	1	N	TE	69	2	Y	None	Recovered
			Infection	感染	3	N	TE	69	10	N	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	3	N	TE	69	9	N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	72	4	N	None	Recovered
			Anaemia	貧血	1	N	TE	73		N	None	Ongoing at time of death
			Psoriasis	乾癬	2	N	TE	75		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary retention	尿閉	2	N	TE	76	1	N	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	1	N	TE	77		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	79		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	4	Y	TE	96	3	N	Not applicable	Death
			Dyspnoea	呼吸困難	5	Y	TE	98	1	N	Not applicable	Death
006043	Norway	68/M/C	Dysgeusia	味覚異常	1	N	TE	4	61	N	None	Recovered
			Bone pain	骨痛	2	N	TE	64	92	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	99		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	99	85	N	None	Recovered
			Constipation	便秘	1	N	TE	127	100	N	None	Recovered
			Anorexia	食欲不振	2	N	TE	127		N	None	Not recovered, but no changes expected
			Urinary retention	尿閉	2	N	TE	127	1	N	None	Recovered
			Haematuria	血尿	2	Y	TE	128	2	N	None	Recovered
			Bone pain	骨痛	1	N	TE	155	29	N	None	Recovered
006045	Norway	63/M/C	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2	N	Pre	-1	63	N	None	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1	N	Pre	-1	91	N	None	Recovered
			Fatigue	疲労	2	N	TE	8	83	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	20	2	N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	21	70	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	TE	28	35	N	None	Recovered
			Fatigue	疲労	1	N	TE	90	156	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	90	114	N	None	Recovered
			Femoral neck fracture	大腿骨頚部骨折	3	Y	TE	121	7	N	Drug administration postponed	Recovered
			Bone pain	骨痛	2	N	TE	203	43	N	Not applicable	Recovered
			Fatigue	疲労	2	N	TE	245		N	None	Not recovered, but no changes expected
006048	Norway	69/M/C	Cough	咳嗽	1	N	TE			N	Not applicable	Recovered
			Dyspnoea	呼吸困難	1	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	Pre	-1	29	N	None	Not recovered, but no changes expected
			Urinary retention	尿閉	2	Y	TE	10	7	N	None	Recovered
			Musculoskeletal pain	筋骨格痛	2	N	TE	17	82	N	None	Recovered with sequelae
			Bone pain	骨痛	3	N	TE	28	29	N	None	Not recovered, but no changes expected
			Localised oedema	限局性浮腫	1	N	TE	56		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	56		N	None	Not recovered, but no changes expected
			Musculoskeletal pain	筋骨格痛	3	Y	TE	98	5	N	None	Recovered with sequelae
			Musculoskeletal pain	筋骨格痛	2	N	TE	102		N	None	Not recovered, but no changes expected

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neoplasm	新生物	2	N	TE	114		N	None	Not recovered, but no changes expected
			Oedema peripheral	末梢性浮腫	2	Y	TE	170	2	N	Not applicable	Recovered
006051	Norway	86/M/C	Nasopharyngitis	鼻咽頭炎	2	N	TE			N	None	Recovered
			Flushing	潮紅	1	N	TE			Y	None	Recovered
			Bone pain	骨痛	1	N	TE	37	3	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	63		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	63		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	93	4	N	None	Recovered
			Bone pain	骨痛	1	N	TE	120	8	N	None	Recovered
			Bone pain	骨痛	1	N	TE	184	3	N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	194	8	N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	201	2	N	Not applicable	Recovered
007003	Norway	65/M/C	Pleural effusion	胸水	2	Y	TE	1	11	N	None	Recovered
			Pneumonia	肺炎	2	N	TE	26	4	N	Drug administration postponed	Recovered
			Pneumonia	肺炎	3	Y	TE	29	9	N	Drug administration postponed	Recovered
			Bone pain	骨痛	3	N	TE	36		N	None	Ongoing at time of death
			Confusional state	錯乱状態	1	N	TE	53	3	Y	None	Recovered with sequelae

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	54		N	None	Ongoing at time of death
			Dizziness	浮動性めまい	1	N	TE	54	2	N	None	Recovered
			Pneumonia	肺炎	2	Y	TE	55	19	Y	Drug administration postponed	Recovered
			Confusional state	錯乱状態	2	Y	TE	55	19	Y	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	57	15	N	None	Recovered
			Metastases to meninges	髄膜転移	3	Y	TE	64	30	N	None	Death
			Thrombocytopenia	血小板減少症	4	Y	TE	86		Y	None	Ongoing at time of death
			Metastases to meninges	髄膜転移	5	Y	TE	93	1	N	None	Death
007004	Norway	64/M/C	Bone pain	骨痛	2	N	TE	29	17	N	None	Recovered
			Bone pain	骨痛	1	N	TE	113		N	None	Ongoing at study termination / withdrawal
			Pain in extremity	四肢痛	1	N	TE	113		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	122		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	Y	TE	122	2	N	None	Recovered
			Constipation	便秘	2	Y	TE	126	9	N	None	Recovered
			Nausea	悪心	1	N	TE	126		N	None	Not recovered, but no changes expected
			Hypokalaemia	低カリウム血症	1	N	TE	132	3	N	None	Recovered
007006	Norway	78/M/C	Night sweats	寝汗	2	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	29		N	None	Ongoing at time of death
			Joint stiffness	関節硬直	1	N	TE	57	57	N	None	Recovered
			Influenza	インフルエンザ	1	N	TE	70	4	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	96	60	N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	103		N	None	Ongoing at time of death
			Hyperhidrosis	多汗症	1	N	TE	113	59	N	None	Recovered
			Stomatitis	口内炎	1	N	TE	128	29	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	1	N	TE	155		N	None	Ongoing at time of death
			Fatigue	疲労	3	Y	TE	211	11	N	Not applicable	Recovered with sequelae
007007	Norway	67/M/C	Oedema genital	性器浮腫	2	N	TE			N	None	Not recovered, but no changes expected
			Rash	発疹	1	N	Pre	-7	64	N	None	Not recovered, but no changes expected
			Cardiac murmur	心雑音	1	N	TE	29	29	N	None	Recovered
			Bone pain	骨痛	1	N	TE	39	15	N	None	Recovered
			Rash	発疹	2	N	TE	57		N	None	Not recovered, but no changes expected
			Metastases to skin	皮膚転移	3	N	TE	80		N	None	Not recovered, but no changes expected
			Diarrhoea	下痢	1	N	TE	134	4	N	None	Recovered
			Nausea	悪心	1	N	TE	134	15	N	None	Recovered
			Mucosal inflammation	粘膜の炎症	2	N	TE	141	7	N	None	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	141	18	N	Drug permanently withdrawn	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	145		N	None	Not recovered, but no changes expected

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hydronephrosis	水腎症	3	Y	TE	148	3	N	Drug permanently withdrawn	Recovered with sequelae
			Anaemia	貧血	2	N	TE	151	6	Y	None	Recovered
			Blood urea increased	血中尿素増加	1	N	TE	151		N	Not applicable	Not recovered, but no changes expected
			Hypercreatininaemia	高クレアチニン血症	1	N	TE	151		N	Not applicable	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	157		N	Not applicable	Not recovered, but no changes expected
			Erysipelas	丹毒	1	N	TE	158	9	N	Not applicable	Recovered
			Dyspepsia	消化不良	1	N	TE	187		N	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	187		N	Not applicable	Ongoing at time of death
007008	Norway	64/M/C	Arthralgia	関節痛	1	N	TE	26	32	N	None	Recovered
			Bone pain	骨痛	1	N	TE	26		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	60	26	N	None	Recovered
			Bone pain	骨痛	2	N	TE	85	36	N	None	Recovered
			Pneumonia	肺炎	2	Y	TE	111	10	N	None	Recovered
			Anaemia	貧血	2	N	TE	112	2	Y	None	Recovered
			Nausea	悪心	1	N	TE	127		N	Not applicable	Not recovered, but no changes expected
			Insomnia	不眠症	1	N	TE	127		N	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	2	Y	TE	134	10	N	Not applicable	Recovered
			Suicide attempt	自殺企図	4	Y	TE	152	7	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pneumonia aspiration	嚥下性肺炎	1	N	TE	152		N	Not applicable	Recovered
			Anaemia	貧血	3	Y	TE	162	5	N	Not applicable	Recovered
			Tooth infection	歯感染	3	N	TE	162	5	N	Not applicable	Recovered
007009	Norway	67/M/C	Thrombocytopenia	血小板減少症	1	N	Pre	1	2	N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	4	Y	Pre	1		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	2	4	N	None	Ongoing at time of death
			Myocardial infarction	心筋梗塞	2	Y	TE	3	14	N	None	Death
			Hyperglycaemia	高血糖	4	Y	TE	4		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	5	8	N	None	Ongoing at time of death
			Localised oedema	限局性浮腫	1	N	TE	11		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	12		N	None	Ongoing at time of death
			Myocardial infarction	心筋梗塞	5	Y	TE	16	1	N	None	Death
008014	Norway	77/M/C	Oedema peripheral	末梢性浮腫	1	N	TE			N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE			N	None	Ongoing at time of death
			Anaemia	貧血	1	N	Pre	1	3	N	-	
			Anaemia	貧血	2	N	TE	3	27	N	-	
			Cystitis	膀胱炎	2	N	TE	3	11	N	None	Recovered
			Myalgia	筋痛	2	Y	TE	3	4	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	29	42	N	-	
			Respiratory tract infection	気道感染	2	N	TE	48		N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	69	12	N	None	Recovered
			Anaemia	貧血	2	N	TE	70	4	N	None	Ongoing at time of death
			Atrial fibrillation	心房細動	2	N	TE	70	2	N	None	Recovered
			Anaemia	貧血	1	N	TE	73	37	N	None	Ongoing at time of death
			Weight decreased	体重減少	2	N	TE	85		N	None	Ongoing at time of death
			Gastroenteritis norovirus	ノロウイルス性胃腸炎	2	Y	TE	93	5	N	None	Recovered
			Post procedural infection	処置後感染	2	N	TE	93	17	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	109		N	None	Ongoing at time of death
			Post procedural infection	処置後感染	2	Y	TE	109	8	N	Drug administration postponed	Recovered
			Syncope	失神	2	N	TE	110	1	N	None	Recovered
			Syncope	失神	2	N	TE	111	1	N	None	Recovered
			Syncope	失神	2	N	TE	112	1	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	113	3	N	None	Recovered
			Pneumonia	肺炎	2	N	TE	114		N	Drug administration postponed	Recovered
			Dyspnoea	呼吸困難	3	Y	TE	152		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	155	16	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	170	1	N	Not applicable	Death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
009001	Czech Republic	66/M/C	Oedema peripheral	末梢性浮腫	2	N	TE	30		N	None	Not recovered, but no changes expected
			Micturition urgency	尿意切迫	2	N	TE	62	135	N	None	Recovered
			Anaemia	貧血	2	N	TE	183	44	Y	None	Recovered
			Generalised oedema	全身性浮腫	3	N	TE	183	36	Y	Not applicable	Ongoing at time of death
			Cardiac failure	心不全	3	Y	TE	196	23	Y	Not applicable	Recovered with sequelae
010001	Czech Republic	60/M/C	Anaemia	貧血	2	Y	TE	165	5	Y	Not applicable	Recovered
			Bone pain	骨痛	2	Y	TE	165	5	Y	Not applicable	Recovered
			Anaemia	貧血	3	Y	TE	213	4	Y	Not applicable	Recovered
			Anaemia	貧血	3	Y	Post	231	4	Y	Not applicable	Recovered
010003	Czech Republic	70/M/C	Bronchitis	気管支炎	1	N	TE	68	7	N	None	Recovered
			Dermatitis	皮膚炎	1	N	TE	70	27	N	None	Recovered
			Thrombosis	血栓症	2	N	TE	118	52	Y	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	170	9	N	Not applicable	Recovered
010005	Czech Republic	83/M/C	Cachexia	悪液質	5	Y	TE	147	1	N	Not applicable	Death
011003	Czech Republic	63/M/C	Bone pain	骨痛	1	N	TE	2	5	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	37	4	Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	78	2	N	None	Recovered
011007	Czech Republic	60/M/C	Anaemia	貧血	1	N	TE	29	29	N	None	Recovered
			Anaemia	貧血	3	Y	TE	57	8	N	None	Recovered
			Anaemia	貧血	1	N	TE	64		N	None	Ongoing at time of death
016001	Czech Republic	72/M/C	Malignant neoplasm progression	悪性新生物進行	3	Y	TE	78	10	N	None	Not recovered, but no changes expected
			Thrombocytopenia	血小板減少症	3	N	TE	84		Y	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	98	3	N	None	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	100	1	N	None	Death
017009	Czech Republic	64/M/C	Spinal cord compression	脊髄圧迫	3	Y	TE	72	21	N	Drug administration postponed	Recovered with sequelae
			Urinary tract infection	尿路感染	2	N	TE	133	7	N	None	Recovered
017010	Czech Republic	69/M/C	Bursitis	滑液包炎	2	Y	TE	37	13	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	52	32	N	None	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	83	1	N	None	Death
017013	Czech Republic	78/M/C	Dyspepsia	消化不良	1	Y	Pre	-17	5	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	1	N	Pre	-1		N	None	Ongoing at time of death
			Cerebral ischaemia	脳虚血	4	Y	TE	85	7	N	None	Death
			Cerebral ischaemia	脳虚血	5	Y	TE	91	1	N	None	Death
017014	Czech Republic	63/M/C	Bone pain	骨痛	2	N	TE	15		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	98	1	N	None	Death
017016	Czech Republic	79/M/C	Urinary tract infection	尿路感染	3	Y	TE	80	6	N	None	Death
			Urinary tract infection	尿路感染	5	Y	TE	85	1	N	None	Death
017028	Czech Republic	63/M/C	Insomnia	不眠症	1	N	TE	113	29	N	None	Recovered
			Bone pain	骨痛	2	N	TE	141	29	N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	169	64	N	Not applicable	Ongoing at time of death
			Venous thrombosis	静脈血栓症	3	Y	TE	184	8	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	191	42	N	Not applicable	Ongoing at time of death
			Renal failure	腎不全	3	Y	TE	191	42	N	Not applicable	Death
			Staphylococcal infection	ブドウ球菌感染	3	Y	TE	200		N	Not applicable	Ongoing at time of death
			Renal failure	腎不全	5	Y	TE	232	1	N	Not applicable	Death
020001	Sweden	67/M/C	Food poisoning	食中毒	1	N	TE			N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	46	26	N	Drug administration postponed	Recovered with sequelae
			Bone pain	骨痛	1	N	TE	56	157	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	71	16	N	Drug administration postponed	Recovered with sequelae
			Gastritis	胃炎	1	N	TE	72		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	72		Y	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	1	N	TE	72	106	N	Drug administration postponed	Not recovered, but no changes expected
			Thrombophlebitis	血栓性静脈炎	2	N	TE	77	10	N	None	Recovered
			Dry mouth	口内乾燥	1	N	TE	84		N	None	Not recovered, but no changes expected
			Urinary tract infection	尿路感染	1	N	TE	88	16	N	None	Recovered
			Increased upper airway secretion	上気道分泌増加	2	N	TE	122		N	None	Not recovered, but no changes expected
			Spinal cord compression	脊髄圧迫	2	N	TE	177		N	Drug administration postponed	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	212	49	N	None	Recovered
			Dysphagia	嚥下障害	2	N	TE	239	22	N	None	Recovered
020003	Sweden	71/M/C	Hypoaesthesia	感覚鈍麻	1	N	Pre	-1	1	N	None	Recovered
			Sinus tachycardia	洞性頻脈	1	N	TE	2	4	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	2	4	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	2	78	Y	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	26	9	N	None	Recovered
			Fatigue	疲労	2	N	TE	61		N	None	Not recovered, but no changes expected

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE	64	47	N	None	Recovered
			Headache	頭痛	1	N	TE	64	47	N	None	Recovered
			Anaemia	貧血	2	Y	TE	77	12	Y	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	3	Y	TE	77	12	Y	Drug permanently withdrawn	Recovered with sequelae
			Nausea	悪心	2	N	TE	77		N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	80		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	88		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	88		Y	Drug permanently withdrawn	Not recovered, but no changes expected
020010	Sweden	63/M/C	Constipation	便秘	1	N	TE			N	None	Ongoing at time of death
			Pathological fracture	病的骨折	2	N	TE			N	Drug permanently withdrawn	Ongoing at time of death
			Hypotension	低血圧	1	N	Pre	1		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	29		Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	29		Y	Drug permanently withdrawn	Ongoing at time of death
			Pathological fracture	病的骨折	3	N	TE	29		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	30	7	N	Drug permanently withdrawn	Recovered
			Bone pain	骨痛	2	N	TE	36		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
021001	Sweden	65/M/C	Anorexia	食欲不振	1	N	TE			N	None	Ongoing at time of death
			Gastritis	胃炎	2	N	Pre	-1	65	N	None	Recovered
			Pain	疼痛	1	N	TE	2	2	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	17	28	N	None	Recovered
			Pyrexia	発熱	1	N	TE	33	2	Y	None	Recovered
			Infection	感染	3	Y	TE	52	4	N	Drug administration postponed	Recovered
			Infection	感染	1	N	TE	55	11	N	Drug administration postponed	Recovered
			Pyrexia	発熱	1	N	TE	101	7	Y	None	Recovered
			Procedural pain	処置による疼痛	2	Y	TE	103	2	N	None	Recovered
			Abdominal pain	腹痛	1	N	TE	108	1	N	None	Recovered
			Pyrexia	発熱	1	N	TE	108	1	N	None	Recovered
			Bone pain	骨痛	2	N	TE	110	9	N	None	Recovered
			Bone pain	骨痛	2	N	TE	126		N	None	Ongoing at time of death
			Abdominal pain	腹痛	1	N	TE	130	26	N	None	Recovered
			Hypercreatininaemia	高クレアチニン血症	2	N	TE	148	44	N	None	Recovered
			Bone pain	骨痛	2	N	TE	157	5	N	None	Recovered
			Pyrexia	発熱	2	N	TE	165	2	N	None	Recovered
			Bone pain	骨痛	1	N	TE	165	2	N	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	171	3	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pain	疼痛	2	N	TE	174	2	N	None	Recovered
			Pyrexia	発熱	1	N	TE	174	2	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	179	6	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	3	N	TE	179	19	N	Not applicable	Recovered
			Bone pain	骨痛	4	N	TE	194	46	N	Not applicable	Recovered
			Pyrexia	発熱	1	N	TE	196	2	N	Not applicable	Recovered
			Bone pain	骨痛	3	N	TE	201		N	Not applicable	Not recovered, but no changes expected
			Muscle spasms	筋痙縮	1	N	TE	205		N	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	209	5	N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	224		N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	224		N	None	Ongoing at time of death
022002	Sweden	64/M/C	Fatigue	疲労	1	N	TE	29	66	N	None	Recovered
			Bone pain	骨痛	2	N	TE	57	32	N	None	Recovered
			Bone pain	骨痛	2	N	TE	81	32	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	117	5	N	None	Recovered
			Diarrhoea	下痢	3	Y	TE	121	2	N	None	Recovered
			Nephrolithiasis	腎結石症	1	N	TE	168	8	N	Not applicable	Recovered
			Dizziness	浮動性めまい	1	N	TE	200		N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
022003	Sweden	78/M/C	Anaemia	貧血	1	N	TE	22	92	N	None	Recovered
			Bone pain	骨痛	2	N	TE	27	146	N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	33	1	N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	51	1	N	None	Recovered
			Cognitive disorder	認知障害	1	N	TE	140		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	175	1	N	None	Recovered
			Infection	感染	2	Y	TE	203	6	N	Not applicable	Recovered
022005	Sweden	62/M/C	Dizziness	浮動性めまい	1	N	TE			N	None	Recovered
			Nausea	悪心	2	Y	TE	17	7	N	None	Recovered
			Vomiting	嘔吐	2	Y	TE	17	7	N	None	Recovered
			Dehydration	脱水	2	Y	TE	17	7	N	None	Recovered
			Bone pain	骨痛	2	N	TE	18	12	N	None	Recovered
			Fatigue	疲労	2	Y	TE	37	2	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	57		Y	None	Ongoing at time of death
			Sepsis	敗血症	4	Y	TE	57	5	N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	84	53	N	Not applicable	Death
			Anaemia	貧血	3	N	TE	85	14	N	None	Recovered with sequelae
			Anaemia	貧血	3	Y	TE	98	14	N	None	Recovered with sequelae
			Constipation	便秘	3	Y	TE	99	13	N	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	99	13	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	113	2	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	136	1	N	Not applicable	Death
022008	Sweden	67/M/C	Fatigue	疲労	1	N	TE	29		N	None	Ongoing at time of death
			Haematuria	血尿	1	Y	TE	60	2	N	None	Recovered
			Haematuria	血尿	2	N	TE	61	49	N	None	Recovered
			Haematuria	血尿	2	N	TE	61	49	N	None	Recovered
			Bone pain	骨痛	3	N	TE	88	9	N	None	Recovered with sequelae
			Anaemia	貧血	1	N	TE	116	1	N	None	Recovered
022010	Sweden	76/M/C	Rash	発疹	1	N	TE			N	Not applicable	Recovered
			Fatigue	疲労	2	N	TE	32	8	Y	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	32	1	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	46	56	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	59	12	N	Drug permanently withdrawn	Recovered
			Bone pain	骨痛	2	N	TE	60		N	Not applicable	Ongoing at time of death
			Erythema	紅斑	1	N	TE	70	74	N	Not applicable	Recovered
			Diarrhoea	下痢	1	N	TE	77	15	N	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	77	38	N	None	Recovered
			Mucosal inflammation	粘膜の炎症	2	Y	TE	91	15	N	Not applicable	Recovered
			Pneumonia	肺炎	2	N	TE	91	24	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dizziness	浮動性めまい	1	N	TE	95	1	N	Not applicable	Recovered
023002	Sweden	79/M/C	Bone pain	骨痛	2	N	TE	2	27	N	None	Recovered
			Fall	転倒・転落	1	N	TE	42	1	N	None	Recovered
			Amnesia	健忘	2	N	TE	42		N	None	Ongoing at time of death
			Balance disorder	平衡障害	3	N	TE	42		N	None	Ongoing at time of death
			Urinary incontinence	尿失禁	1	N	TE	42		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	56	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	85	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	113	2	Y	None	Recovered
			Fatigue	疲労	1	N	TE	131		N	None	Ongoing at time of death
			Post-traumatic pain	外傷後疼痛	2	N	TE	168		N	None	Ongoing at time of death
			Hydrocephalus	水頭症	2	Y	TE	168	62	N	Not applicable	Recovered with sequelae
			Dizziness	浮動性めまい	1	N	TE	169		N	None	Ongoing at time of death
			Urinary retention	尿閉	1	N	TE	169		N	None	Ongoing at time of death
			Insomnia	不眠症	2	N	TE	170		N	None	Ongoing at time of death
			Erythema	紅斑	1	N	TE	171	4	N	None	Recovered
			Constipation	便秘	1	N	TE	172		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	172		N	None	Ongoing at time of death
			Medical device pain	医療機器による疼痛	1	N	TE	173	2	N	None	Recovered
			Cystitis	膀胱炎	2	N	TE	177	4	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Medical device pain	医療機器による疼痛	1	N	TE	187	2	N	None	Recovered
			Haematuria	血尿	1	N	TE	187		N	None	Not recovered, but no changes expected
			Nausea	悪心	2	N	TE	188		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	1	N	TE	188		N	None	Not recovered, but no changes expected
			Apraxia	失行症	1	N	TE	190		N	None	Not recovered, but no changes expected
			Gastritis	胃炎	1	N	TE	202		N	None	Not recovered, but no changes expected
			Anxiety	不安	1	N	TE	202		N	None	Ongoing at time of death
024003	Sweden	71/M/C	Upper respiratory tract infection	上気道感染	2	N	TE	36	8	N	None	Recovered
			Anaemia	貧血	2	N	TE	56	30	N	None	Recovered
			Neutropenia	好中球減少症	2	N	TE	84	8	Y	Drug administration postponed	Recovered
			Neutropenia	好中球減少症	3	Y	TE	112		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	119	1	Y	Not applicable	Recovered
			Dry mouth	口内乾燥	2	N	TE	141	35	N	None	Recovered
			Infection	感染	2	N	TE	141		N	Not applicable	Ongoing at study termination / withdrawal
024005	Sweden	69/M/C	Anaemia	貧血	2	N	TE	57	3	Y	None	Recovered
			Infection	感染	2	N	TE	103	11	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	113	2	Y	None	Recovered
			General physical health deterioration	全身健康状態低下	3	N	TE	113		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	113	23	N	None	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	135	1	N	None	Death
024009	Sweden	73/M/C	Pathological fracture	病的骨折	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	11	50	N	None	Recovered
			Arrhythmia	不整脈	1	N	TE	29		N	None	Not recovered, but no changes expected
			Chills	悪寒	1	N	TE	29		Y	None	Recovered
			Oedema	浮腫	3	N	TE	29		N	Not applicable	Ongoing at time of death
			Magnesium deficiency	マグネシウム欠乏	1	N	TE	29	29	N	None	Recovered
			General physical health deterioration	全身健康状態低下	3	N	TE	57		N	None	Not recovered, but no changes expected
			Pathological fracture	病的骨折	2	N	TE	61		N	None	Not recovered, but no changes expected
			Dyspepsia	消化不良	2	N	TE	65		N	None	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	Y	TE	65	15	N	None	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	3	N	TE	66		N	None	Not recovered, but no changes expected
			Metastases to liver	肝転移	2	N	TE	86		N	None	Not recovered, but no changes expected
			Metastases to liver	肝転移	2	N	TE	86		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	91	5	Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary tract infection	尿路感染	2	N	TE	92		N	Not applicable	Ongoing at time of death
			Anxiety	不安	2	N	TE	93		N	Not applicable	Ongoing at time of death
			Myocardial infarction	心筋梗塞	3	Y	TE	95		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	97	1	N	Drug permanently withdrawn	Death
024014	Sweden	74/M/C	Dry eye	眼乾燥	1	N	TE	15		N	None	Ongoing at time of death
			Skin infection	皮膚感染	2	N	TE	53	9	N	None	Recovered
			Metastases to bone	骨転移	1	N	TE	53		N	None	Not recovered, but no changes expected
			Micturition urgency	尿意切迫	1	N	TE	53		N	None	Not recovered, but no changes expected
			Hypoaesthesia	感覚鈍麻	2	N	TE	61		N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	81		N	None	Not recovered, but no changes expected
			Dizziness	浮動性めまい	2	N	TE	81	27	N	None	Recovered
			Viral skin infection	皮膚ウイルス感染	2	N	TE	100		N	None	Ongoing at time of death
			Atrial fibrillation	心房細動	2	Y	TE	101	7	N	None	Recovered
			Oral fungal infection	口腔真菌感染	2	N	TE	103		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	126	1	N	Drug permanently withdrawn	Death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
024022	Sweden	84/M/C	Constipation	便秘	2	N	TE			N	Not applicable	Recovered
			Pneumonia	肺炎	4	Y	TE			N	Drug permanently withdrawn	Ongoing at time of death
			Hip fracture	股関節部骨折	3	Y	Pre			N	Drug administration postponed	Recovered
			Pulmonary oedema	肺水腫	4	Y	TE			N	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	Y	Pre	-33	14	N	Drug administration postponed	Recovered with sequelae
			Urinary retention	尿閉	2	Y	Pre	-33	14	N	Drug administration postponed	Recovered with sequelae
			Vomiting	嘔吐	3	N	Pre	-18	10	N	Not applicable	Recovered
			Pyrexia	発熱	3	N	Pre	-18	10	N	Not applicable	Recovered
			Dislocation of joint prosthesis	人工骨頭関節脱臼	3	Y	Pre	-18	10	N	Not applicable	Recovered
			Bone pain	骨痛	3	N	Pre	-18	10	N	Not applicable	Recovered
			Pathological fracture	病的骨折	3	Y	TE	6		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	6	43	N	Drug permanently withdrawn	Death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Sepsis	敗血症	3	Y	TE	15		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	48	1	N	Drug permanently withdrawn	Death
024024	Sweden	82/M/C	Fatigue	疲労	2	N	TE	59	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	112		N	None	Not recovered, but no changes expected
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	132	16	N	Drug permanently withdrawn	Not recovered, but no changes expected
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	148	14	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	161	1	N	Not applicable	Death
024026	Sweden	68/M/C	Nausea	悪心	2	N	TE			Y	None	Recovered
			Infection	感染	3	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE			N	Drug administration postponed	Death
			Restless legs syndrome	下肢静止不能症候群	1	N	TE	31	27	N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	57	30	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	57		N	None	Lost to follow-up
			Restless legs syndrome	下肢静止不能症候群	2	N	TE	57		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	79	8	N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	86		N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	86		N	None	Ongoing at time of death
			Fatigue	疲労	3	Y	TE	102	12	N	Drug administration postponed	Recovered
			Pyrexia	発熱	3	Y	TE	102	12	N	Drug administration postponed	Recovered
			Bone pain	骨痛	3	Y	TE	102	12	N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	126	1	N	Drug administration postponed	Death
025002	Sweden	64/M/C	Nausea	悪心	1	N	TE	60	149	Y	None	Recovered
			Tremor	振戦	1	N	TE	88		N	None	Ongoing at time of death
			Listeriosis	リステリア症	2	Y	TE	92	26	N	Drug administration postponed	Recovered
			Fatigue	疲労	2	N	TE	155		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Haematuria	血尿	1	N	TE	185		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	204	5	N	Not applicable	Death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	208	1	N	Not applicable	Death
026009	Sweden	71/M/C	Constipation	便秘	2	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE			Y	None	Not recovered, but no changes expected
			Nausea	悪心	2	N	TE			Y	None	Not recovered, but no changes expected
			Pathological fracture	病的骨折	2	N	TE			N	Not applicable	Ongoing at time of death
			Nausea	悪心	1	N	TE	1	1	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	3		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	29	1	Y	None	Recovered
			Fibroma	線維腫	1	N	TE	56		N	Not applicable	Ongoing at time of death
			Pyrexia	発熱	2	Y	TE	65	4	N	None	Recovered
			Myalgia	筋痛	2	Y	TE	65	5	N	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	68		N	Not applicable	Ongoing at time of death
			Pyrexia	発熱	2	Y	TE	85	27	N	Drug permanently withdrawn	Recovered with sequelae
			Anaemia	貧血	2	N	TE	103	1	N	Not applicable	Recovered
			Pyrexia	発熱	1	N	TE	111		N	Drug permanently withdrawn	Not recovered, but no changes expected
026017	Sweden	76/M/C	Fatigue	疲労	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			N	Not applicable	Not recovered, but no changes expected

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Diarrhoea	下痢	1	N	TE	2	2	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	28	2	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	56	2	N	None	Recovered
			Pyrexia	発熱	2	Y	TE	113	8	N	Drug administration postponed	Recovered
			Urinary tract infection	尿路感染	3	N	TE	113	8	N	None	Recovered
			Hypotension	低血圧	2	N	TE	114	7	N	None	Recovered
			Bone pain	骨痛	2	N	TE	132	57	N	None	Recovered
			Hypoaesthesia	感覚鈍麻	1	N	TE	160		N	None	Not recovered, but no changes expected
			Painful defaecation	排便痛	1	N	TE	188	70	N	None	Recovered
			Nausea	悪心	2	N	TE	207	220	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	207	220	N	Not applicable	Recovered
			Anorexia	食欲不振	1	N	TE	207	220	N	Not applicable	Recovered
			Deafness	難聴	3	N	TE	221		N	Not applicable	Not recovered, but no changes expected
028005	Belgium	70/M/C	Radiculitis	神経根炎	2	N	Pre	-8		N	None	Ongoing at time of death
			Pathological fracture	病的骨折	3	Y	TE	21	3	N	None	Recovered
			Anaemia	貧血	3	N	TE	22	1	N	None	Recovered
			General physical health deterioration	全身健康状態低下	3	Y	TE	26	14	Y	None	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	82	12	N	Drug permanently withdrawn	Death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	93	1	N	Drug permanently withdrawn	Death
029001	Belgium	56/M/C	Sciatica	坐骨神経痛	2	N	TE	4		N	None	Ongoing at study termination / withdrawal
			Constipation	便秘	1	N	TE	41		N	None	Ongoing at study termination / withdrawal
			Dysuria	排尿困難	1	N	TE	41	15	N	Drug administration postponed	Ongoing at study termination / withdrawal
			Dysuria	排尿困難	2	N	TE	55		N	Drug administration postponed	Ongoing at study termination / withdrawal
			Urinary retention	尿閉	2	N	TE	62	22	N	Not applicable	Recovered with sequelae
			Urinary retention	尿閉	3	Y	TE	83	4	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	3	N	TE	110		N	Not applicable	Ongoing at study termination / withdrawal
			General physical health deterioration	全身健康状態低下	3	Y	TE	110	44	N	Not applicable	Recovered
			Campylobacter infection	カンピロバクター感染	3	N	TE	110	44	N	Not applicable	Recovered
029002	Belgium	81/M/C	Fatigue	疲労	1	N	TE	41	32	N	None	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	1	N	TE	41	30	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Depression	うつ病	1	N	TE	59		N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	2	N	TE	72		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	105	2	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	106		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	Y	TE	106	12	N	None	Recovered
			Muscular weakness	筋力低下	1	N	TE	109		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	117		N	Not applicable	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	128	31	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	158	1	N	Not applicable	Death
033001	UK	84/M/C	Oedema peripheral	末梢性浮腫	1	N	Pre	1		N	None	Ongoing at time of death
			Lymphadenopathy	リンパ節症	1	N	TE	25		N	None	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	2	N	TE	25		N	None	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	25	14	N	None	Ongoing at time of death
			Muscular weakness	筋力低下	2	N	TE	29		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	2	N	TE	29		N	None	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	N	TE	38		N	None	Ongoing at time of death
			Pulmonary embolism	肺塞栓症	5	Y	TE	59	1	N	None	Death
033002	UK	72/M/B	Non-cardiac chest pain	非心臓性胸痛	2	N	TE			N	None	Recovered
			Weight decreased	体重減少	1	N	TE			N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE			N	None	Not recovered, but no changes expected
			Muscular weakness	筋力低下	2	N	TE			N	None	Ongoing at time of death
			Lethargy	嗜眠	2	N	TE			N	None	Not recovered, but no changes expected
			Mood altered	気分変化	1	N	TE			N	None	Not recovered, but no changes expected
			Cough	咳嗽	1	N	TE			N	None	Recovered
			Atrial fibrillation	心房細動	3	Y	Pre	-67	4	N	Not applicable	Recovered
			Urinary tract infection	尿路感染	2	Y	Pre	-67	4	N	Not applicable	Recovered
			Eyelid ptosis	眼瞼下垂	1	N	TE	3	7	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	46	8	N	None	Recovered
			Constipation	便秘	1	N	TE	56		Y	Drug administration postponed	Recovered
			Fatigue	疲労	1	N	TE	59		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	93	8	Y	None	Recovered
			Bone pain	骨痛	2	Y	TE	93	2	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	2	N	TE	113		N	None	Ongoing at time of death
033014	UK	73/M/C	Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Pitting oedema	圧痕浮腫	2	N	TE			N	None	Ongoing at time of death
			Weight increased	体重増加	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			Y	None	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	1	N	TE			N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	112		Y	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	112	2	N	None	Recovered
			Nausea	悪心	1	N	TE	177	3	Y	None	Recovered
			Dysphasia	不全失語症	3	N	TE	177	3	N	None	Recovered
			Pleuritic pain	胸膜痛	3	Y	TE	177	3	N	Not applicable	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	184	1	N	Not applicable	Death
033017	UK	80/M/C	Abdominal pain lower	下腹部痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			Y	None	Recovered
			Dysuria	排尿困難	1	N	TE			N	None	Recovered
			Pollakiuria	頻尿	2	N	TE			N	None	Recovered with sequelae
			Pollakiuria	頻尿	2	N	TE			N	None	Recovered
			Urine flow decreased	尿流量減少	2	N	TE			N	None	Not recovered, but no changes expected

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Skin lesion	皮膚病変	1	N	TE			N	None	Not recovered, but no changes expected
			Pulmonary embolism	肺塞栓症	5	Y	TE	124	1	N	None	Death
033025	UK	66/M/C	Fatigue	疲労	2	N	TE			N	None	Not recovered, but no changes expected
			Tooth fracture	歯牙破折	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			Y	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	Pre	-35		Y	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	4	14	Y	None	Recovered
			Anaemia	貧血	2	N	TE	29	64	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	85	2	Y	None	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE	88		N	None	Recovered
			Anaemia	貧血	3	N	TE	116	19	Y	None	Recovered
			Anaemia	貧血	2	N	TE	134	29	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	162	5	Y	None	Recovered
			Disseminated intravascular coagulation	播種性血管内凝固	4	Y	TE	165		N	Not applicable	Ongoing at time of death
			Respiratory failure	呼吸不全	4	Y	TE	168		N	Not applicable	Ongoing at time of death
			Haemorrhage intracranial	頭蓋内出血	5	Y	TE	169	1	N	Not applicable	Death
033026	UK	68/M/C	Constipation	便秘	1	N	TE			Y	None	Not recovered, but no changes expected

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	1	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE			Y	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			Y	None	Recovered
			Bone pain	骨痛	2	N	TE	106		N	None	Recovered
			Constipation	便秘	1	N	TE	128		Y	None	Not recovered, but no changes expected
			Gynaecomastia	女性化乳房	2	N	TE	128		N	None	Not recovered, but no changes expected
			Hot flush	ほてり	1	N	TE	128		N	None	Not recovered, but no changes expected
			Arrhythmia	不整脈	1	N	TE	171		N	None	Not recovered, but no changes expected
			Hypokalaemia	低カリウム血症	1	N	TE	178	15	N	Not applicable	Recovered
			Haemoptysis	喀血	1	N	TE	209	2	N	Not applicable	Recovered
			Lower respiratory tract infection	下気道感染	3	Y	TE	210	4	N	Not applicable	Recovered
			Pneumonia	肺炎	2	N	TE	213	19	N	None	Recovered
			Bone pain	骨痛	2	N	TE	215	3	N	Not applicable	Recovered with sequelae
			Musculoskeletal pain	筋骨格痛	3	Y	TE	217	10	N	Not applicable	Recovered
			Hyponatraemia	低ナトリウム血症	1	N	TE	220	14	N	Not applicable	Recovered
			Pyrexia	発熱	1	N	TE	221	6	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	221	6	N	Not applicable	Recovered
			Lymphopenia	リンパ球減少症	3	N	TE	223	11	Y	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	1	N	TE	223	1	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	223	1	N	Not applicable	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	223	2	N	Not applicable	Recovered
033031	UK	78/M/C	Constipation	便秘	1	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE			Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE			N	None	Not recovered, but no changes expected
			Lethargy	嗜眠	2	N	TE			N	Not applicable	Not recovered, but no changes expected
			Dyspnoea exertional	労作性呼吸困難	1	N	TE			N	None	Not recovered, but no changes expected
			Back pain	背部痛	1	N	Pre	-7	20	N	None	Recovered
			Anaemia	貧血	2	N	Pre	-1	29	N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	Pre	-1		N	None	Not recovered, but no changes expected
			Vomiting	嘔吐	1	N	TE	11	7	Y	None	Recovered
			Back pain	背部痛	3	N	TE	13	8	N	None	Recovered
			Urinary retention	尿閉	2	Y	TE	13	7	N	Drug administration postponed	Recovered
			Urinary retention	尿閉	2	N	TE	19	60	N	None	Recovered
			Anaemia	貧血	1	N	Pre	28	9	N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	Pre	36		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	60	32	Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	91	29	Y	None	Recovered
			Dysgeusia	味覚異常	1	N	TE	106		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	147	4	Y	Not applicable	Recovered
			Anaemia	貧血	2	Y	TE	150	2	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	224		Y	Not applicable	Not recovered, but no changes expected
034016	UK	66/M/C	Pain	疼痛	3	N	TE	8	4	N	None	Recovered
			Bone pain	骨痛	2	N	TE	8		N	None	Ongoing at time of death
			Pain	疼痛	2	N	TE	11	4	N	None	Recovered
			Lethargy	嗜眠	3	N	TE	11	4	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	14	2	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	22	10	N	None	Recovered
			Bone pain	骨痛	1	N	TE	22	10	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	33	12	N	None	Recovered
			Bone pain	骨痛	2	N	TE	33	10	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	51	3	N	None	Recovered
			Bone pain	骨痛	3	N	TE	54	17	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	61		N	None	Ongoing at time of death
			Pain	疼痛	3	N	TE	69		N	None	Ongoing at time of death
			Dysgeusia	味覚異常	2	N	TE	69	15	Y	None	Recovered
			Lethargy	嗜眠	2	N	TE	69		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	101		N	None	Ongoing at study termination / withdrawal
			Abdominal pain	腹痛	3	N	TE	140	8	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	2	N	TE	141	6	N	None	Recovered
			Pyonephrosis	膿腎症	3	Y	TE	141	18	N	Drug administration postponed	Recovered with sequelae
			Nausea	悪心	1	N	TE	144	14	N	None	Recovered
			Lobar pneumonia	大葉性肺炎	3	Y	TE	162	3	N	Drug permanently withdrawn	Recovered
			Stent occlusion	ステント閉塞	3	Y	TE	175	5	N	Not applicable	Recovered with sequelae
			Mobility decreased	運動性低下	3	N	TE	193		N	Not applicable	Ongoing at time of death
035011	UK	58/M/C	Bone pain	骨痛	1	N	TE	85	28	N	None	Recovered
			Large intestine perforation	大腸穿孔	3	Y	TE	167		N	Not applicable	Ongoing at study termination / withdrawal
035013	UK	71/M/C	Bone pain	骨痛	3	N	TE	6	24	N	None	Recovered
			Bone pain	骨痛	3	N	TE	28	2	N	None	Recovered
			Nausea	悪心	3	Y	TE	49	8	Y	None	Recovered
			Dehydration	脱水	3	N	TE	49	4	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	49	9	N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	50	1	N	None	Recovered
035015	UK	79/M/C	Vomiting	嘔吐	1	N	TE	58	11	N	None	Recovered
			Pain in extremity	四肢痛	1	N	TE	86	55	Y	None	Recovered
			Confusional state	錯乱状態	1	N	TE	122	4	Y	None	Recovered
			Transient ischaemic attack	一過性脳虚血発作	1	N	TE	160	1	N	None	Recovered
			Bone pain	骨痛	2	N	TE	212	9	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	220	8	N	Not applicable	Recovered
035017	UK	75/M/C	Diarrhoea	下痢	1	N	TE			Y	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE	106	8	N	None	Recovered
			Constipation	便秘	2	N	TE	127	10	N	None	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	135	7	N	None	Recovered
			Faecal incontinence	便失禁	2	N	TE	169	1	Y	Not applicable	Recovered
			Diarrhoea	下痢	2	N	TE	175		Y	None	Recovered
035022	UK	83/M/C	Bone pain	骨痛	2	N	TE	56	29	N	None	Recovered
			Asthenia	無力症	1	N	TE	66		N	None	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	TE	68	7	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	68	40	N	None	Recovered
			Constipation	便秘	2	N	TE	71		N	None	Ongoing at time of death
			Abdominal pain	腹痛	1	N	TE	77	4	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	77	16	N	None	Recovered
			Haemorrhoids	痔核	1	N	TE	77		N	None	Ongoing at time of death
			Hypoaesthesia facial	顔面感覚鈍麻	2	N	TE	86		N	None	Recovered
			Myalgia	筋痛	2	N	TE	97		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	101	4	N	None	Recovered
			Hypotension	低血圧	1	N	TE	107		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	Post	143	4	Y	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
035029	UK	64/M/C	Anaemia	貧血	2	N	TE			N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE			N	None	Not recovered, but no changes expected
			Fatigue	疲労	1	N	TE	1	28	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	1	28	Y	None	Recovered
			Constipation	便秘	1	N	TE	29		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	77	16	Y	None	Recovered
			Asthenia	無力症	1	N	TE	191		N	None	Not recovered, but no changes expected
035030	UK	63/M/C	Lower respiratory tract infection	下気道感染	2	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE			N	None	Not recovered, but no changes expected
			Toothache	歯痛	1	N	TE	23	41	N	None	Recovered
			Toothache	歯痛	2	N	TE	63	21	N	None	Recovered
			Spinal cord compression	脊髄圧迫	2	Y	TE	92	9	N	None	Recovered
			Tooth infection	歯感染	1	N	TE	107		N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	112		N	None	Recovered
036003	UK	67/M/C	Dysuria	排尿困難	1	N	Pre			N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Metastases to bone	骨転移	1	N	TE	29		N	None	Not recovered, but no changes expected
			Headache	頭痛	1	N	TE	29	30	N	None	Recovered
			Hypercalcaemia	高カルシウム血症	1	N	TE	58		Y	None	Ongoing at study termination / withdrawal
			Headache	頭痛	2	N	TE	58	123	N	None	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	212	13	N	Not applicable	Recovered
036004	UK	84/M/C	Pulmonary embolism	肺塞栓症	3	Y	TE	32		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
036011	UK	64/M/C	Nausea	悪心	1	N	Pre	-8		N	None	Ongoing at study termination / withdrawal
			Back pain	背部痛	1	N	Pre	-8		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	29		N	None	Ongoing at study termination / withdrawal
			Paraesthesia	錯感覚	1	N	TE	29		N	None	Ongoing at study termination / withdrawal
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	46		N	None	Ongoing at study termination / withdrawal
			Constipation	便秘	3	Y	TE	104	7	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
037018	UK	68/M/C	Somnolence	傾眠	1	N	TE			N	None	Recovered
			Tachycardia	頻脈	1	N	Pre	1	29	N	None	Recovered
			Muscle atrophy	筋萎縮	1	N	Pre	1		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	28	49	N	Drug administration postponed	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	63		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	76	4	N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	Y	TE	76		N	Drug administration postponed	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	76	30	N	None	Death
			Herpes zoster	帯状疱疹	2	Y	TE	78	8	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	79		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	79	9	N	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	79		N	None	Ongoing at time of death
			Fall	転倒・転落	1	N	TE	80	1	N	None	Recovered
			Bone pain	骨痛	2	N	TE	81		N	None	Ongoing at time of death
			Hypotension	低血圧	1	N	TE	85	2	N	None	Recovered
			Muscular weakness	筋力低下	1	N	TE	88	2	N	None	Recovered
			Cough	咳嗽	1	N	TE	90	4	N	None	Recovered
			Dyspnoea	呼吸困難	3	N	TE	92		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Lower respiratory tract infection	下気道感染	3	Y	TE	93	6	N	None	Recovered
			Somnolence	傾眠	1	N	TE	96		N	None	Ongoing at time of death
			Dry mouth	口内乾燥	1	N	TE	103		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	105	1	N	None	Death
039011	UK	65/M/C	Bone pain	骨痛	3	Y	Pre	-37	3	N	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	1	N	TE	3		N	None	Ongoing at time of death
			Nausea	悪心	3	Y	TE	4	4	Y	None	Recovered
			Dizziness	浮動性めまい	3	N	TE	5	17	Y	None	Ongoing at time of death
			Vomiting	嘔吐	3	N	TE	8		Y	None	Recovered
			Nausea	悪心	3	Y	TE	10		Y	Drug administration postponed	Ongoing at time of death
			Retching	レッチング	3	N	TE	10	12	Y	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	10	12	Y	None	Ongoing at time of death
			Paraesthesia	錯感覚	3	N	TE	10	12	N	None	Ongoing at time of death
			Somnolence	傾眠	1	N	TE	12		N	None	Ongoing at time of death
			Somnolence	傾眠	1	N	TE	12		N	None	Ongoing at time of death
			Tachycardia	頻脈	2	N	TE	13	9	N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Abdominal pain	腹痛	2	N	TE	13	9	N	None	Ongoing at time of death
			Pleural effusion	胸水	2	N	TE	13	9	N	None	Ongoing at time of death
			Pleural effusion	胸水	3	N	TE	14	5	N	Drug administration postponed	Death
			Sepsis	敗血症	2	N	TE	15	7	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	15	7	N	None	Ongoing at time of death
			Rash	発疹	2	N	TE	15	7	N	None	Ongoing at time of death
			Chest pain	胸痛	3	N	TE	17	5	N	None	Ongoing at time of death
			Depressed mood	抑うつ気分	2	N	TE	17	5	N	None	Ongoing at time of death
			Vomiting	嘔吐	3	N	TE	18		N	None	Ongoing at time of death
			Pleural effusion	胸水	4	Y	TE	18	4	N	Drug administration postponed	Death
			Constipation	便秘	3	N	TE	19	3	N	None	Ongoing at time of death
			Abdominal pain lower	下腹部痛	1	N	TE	20	2	N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	3	N	TE	20	2	N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	20	2	N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pleural effusion	胸水	5	Y	TE	21	1	N	Drug administration postponed	Death
039020	UK	80/M/C	Bone pain	骨痛	3	N	Pre			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at time of death
			Sleep disorder	睡眠障害	2	N	Pre			N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	N	TE	18		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	1	N	TE	28		N	None	Ongoing at time of death
			Pleural effusion	胸水	2	Y	TE	51	6	N	Drug permanently withdrawn	Recovered
039028	UK	84/M/C	Vomiting	嘔吐	2	N	Pre	-1	1	N	None	Recovered
			Syncope	失神	3	N	Pre	-1	1	N	None	Recovered
			Syncope	失神	3	Y	TE	27	2	N	Drug permanently withdrawn	Recovered
040006	UK	81/M/C	Bone pain	骨痛	1	N	Pre			N	None	Recovered
			Bone pain	骨痛	1	N	Pre			N	None	Ongoing at study termination / withdrawal
			Atrioventricular block complete	完全房室ブロック	4	Y	TE	39	2	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE	81		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	95	4	N	None	Recovered
			Atrial fibrillation	心房細動	3	Y	TE	129	18	N	Drug permanently withdrawn	Recovered with sequelae
			Cardiac failure	心不全	3	N	TE	146	21	N	Not applicable	Recovered with sequelae
			Cardiac failure	心不全	3	Y	TE	166	11	N	Not applicable	Recovered with sequelae
			Cardiac failure	心不全	3	N	TE	176	159	N	Not applicable	Ongoing at time of death
041007	UK	62/M/C	Lymphadenopathy	リンパ節症	1	N	Pre	1		N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	7		Y	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	7		N	None	Ongoing at time of death
			Eyelid function disorder	眼瞼機能障害	2	N	TE	12	19	N	None	Recovered
			Vision blurred	霧視	1	N	TE	12		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	29		Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	29		Y	None	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	29		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	60	6	N	None	Death
			Muscular weakness	筋力低下	2	N	TE	61		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	65	1	N	None	Death
042002	UK	64/M/C	Nausea	悪心	1	N	TE			Y	None	Recovered
			Vomiting	嘔吐	1	N	TE			Y	None	Recovered
			Peripheral coldness	末梢冷感	1	N	TE			N	None	Recovered
			Anorexia	食欲不振	1	N	TE			Y	None	Recovered
			Constipation	便秘	1	N	TE	3		Y	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	4	6	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	4	6	N	None	Recovered
			Bone pain	骨痛	2	N	TE	8	22	N	None	Recovered
			Tachycardia	頻脈	1	N	TE	28		N	None	Ongoing at time of death
			Hypotension	低血圧	1	N	TE	55	1	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	57	57	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	57	57	N	None	Recovered
			Spinal cord compression	脊髄圧迫	2	N	TE	58	56	N	None	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	164	12	N	Not applicable	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	192	1	N	Not applicable	Death
042003	UK	66/M/C	Anaemia	貧血	2	Y	TE	17	2	Y	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	17	7	N	None	Recovered
			Anaemia	貧血	3	N	TE	34	3	N	Not applicable	Recovered
			Cardiac failure congestive	うっ血性心不全	3	Y	TE	34	8	N	None	Death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	2	N	TE	34		N	Not applicable	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	34	4	N	Not applicable	Recovered
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	2	N	TE	34		N	Not applicable	Ongoing at time of death
			Hypokalaemia	低カリウム血症	3	N	TE	35	3	N	Not applicable	Recovered
			Rectal haemorrhage	直腸出血	1	N	TE	37	1	N	Not applicable	Recovered
			Neuropathy peripheral	末梢性ニューロパチー	2	N	TE	38		N	Not applicable	Ongoing at time of death
			Urinary tract obstruction	尿路閉塞	3	N	TE	38		N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	39		N	Not applicable	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	2	Y	TE	39		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	40	2	N	Not applicable	Recovered
			Pneumonia	肺炎	3	N	TE	40		N	Not applicable	Ongoing at time of death
			Confusional state	錯乱状態	1	N	TE	40		N	Not applicable	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	5	Y	TE	41	1	N	None	Death
042004	UK	74/M/C	Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Cough	咳嗽	1	N	TE			N	None	Ongoing at time of death
			Dysphonia	発声障害	1	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Small intestinal obstruction	小腸閉塞	2	Y	Pre	-35	9	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	3	27	N	None	Recovered
			Epistaxis	鼻出血	1	N	TE	5	1	N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	30	8	N	None	Recovered
			Lethargy	嗜眠	1	N	TE	30	140	Y	None	Ongoing at time of death
			Dysgeusia	味覚異常	2	N	TE	41	3	N	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	45	2	N	None	Recovered
			Pathological fracture	病的骨折	2	Y	TE	55	9	N	None	Recovered
			Nausea	悪心	1	N	TE	56		N	None	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	58	6	Y	None	Recovered
			Eye pain	眼痛	1	N	TE	80	3	N	None	Recovered
			Bone pain	骨痛	1	N	TE	106	1	N	None	Recovered
			Bone pain	骨痛	1	N	TE	112	1	N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	1	N	TE	113		N	None	Ongoing at time of death
			Oral pain	口腔内痛	1	N	TE	119	1	N	None	Recovered
			Palpitations	動悸	1	N	TE	121	1	N	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	141		N	None	Ongoing at time of death
			Contusion	挫傷	1	N	TE	141		N	None	Ongoing at time of death
			Lethargy	嗜眠	2	N	TE	169		Y	None	Ongoing at time of death
			Pleural effusion	胸水	1	N	TE	169		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	198	1	N	Not applicable	Death
042010	UK	61/M/C	Rectal haemorrhage	直腸出血	1	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Malaise	倦怠感	2	Y	Pre	-15	2	N	Not applicable	Recovered
			Venous thrombosis limb	四肢静脈血栓症	2	N	TE	19		N	None	Ongoing at time of death
			Arthritis infective	感染性関節炎	1	N	TE	64		Y	None	Recovered
			Gynaecomastia	女性化乳房	1	N	TE	64		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	152		N	None	Ongoing at time of death
			Neuralgia	神経痛	2	Y	TE	152	10	N	None	Recovered
			Muscle spasms	筋痙縮	1	N	TE	153		N	None	Ongoing at time of death
042024	UK	62/M/C	Fatigue	疲労	1	N	TE			N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE			N	None	Ongoing at time of death
			Confusional state	錯乱状態	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	1	29	Y	None	Recovered
			Anxiety	不安	1	N	TE	2	28	N	None	Recovered
			Hyperhidrosis	多汗症	2	N	TE	2		N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	8		N	None	Ongoing at time of death
			Pyrexia	発熱	1	N	TE	62	1	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	64		N	None	Ongoing at time of death
			Dysuria	排尿困難	2	N	TE	80	6	N	Not applicable	Recovered
			Vomiting	嘔吐	3	Y	TE	83	6	N	None	Recovered
			Pyrexia	発熱	3	Y	TE	83	6	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Confusional state	錯乱状態	3	Y	TE	83	1	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	99	23	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	121	1	N	Not applicable	Death
042025	UK	57/M/C	Nausea	悪心	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	1	85	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	29	85	N	None	Recovered
			Urinary retention	尿閉	3	Y	TE	51	2	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	52	4	N	None	Recovered
			Bone pain	骨痛	2	N	TE	58	8	Y	None	Recovered
			Fatigue	疲労	1	N	TE	85		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	134	92	N	None	Recovered
			Anaemia	貧血	2	N	TE	141		Y	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	142		N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	169	57	N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	169		N	None	Ongoing at time of death
			Weight decreased	体重減少	2	N	TE	225		N	None	Ongoing at time of death
042028	UK	70/M/C	Bone pain	骨痛	2	N	TE	15	155	Y	None	Recovered
			Nocturia	夜間頻尿	1	N	TE	23		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	35	3	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE	85	57	N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	88	18	Y	None	Recovered
			Viral infection	ウイルス感染	1	N	TE	88	18	N	None	Recovered
			Lethargy	嗜眠	1	N	TE	113		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	141		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	169	64	Y	None	Recovered
042031	UK	73/M/C	Depression	うつ病	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	-10	115	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	18	40	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	29	85	N	None	Recovered
			Decreased appetite	食欲減退	2	N	TE	29	85	N	None	Recovered
			Constipation	便秘	1	N	TE	53		N	None	Ongoing at time of death
			Cough	咳嗽	2	N	TE	53	8	N	None	Recovered
			Bone pain	骨痛	2	N	TE	105	22	N	None	Recovered
			Bone pain	骨痛	3	N	TE	126	16	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	142		N	Drug administration postponed	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	142	24	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	165	1	N	Drug permanently withdrawn	Death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
042038	UK	74/M/C	Vision blurred	霧視	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	2	N	TE	14	17	N	None	Recovered
			Acute myocardial infarction	急性心筋梗塞	3	Y	TE	31	12	N	None	Recovered
			Angina pectoris	狭心症	2	N	TE	31		N	None	Ongoing at study termination / withdrawal
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	3	Y	TE	46	18	N	Drug administration postponed	Recovered
			Pulmonary embolism	肺塞栓症	3	Y	TE	46	18	N	Drug administration postponed	Recovered
			Bone pain	骨痛	2	N	TE	70	16	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	85	148	N	None	Recovered
043015	UK	74/M/C	Ligament rupture	靭帯断裂	2	N	Pre			N	None	Recovered
			Arthralgia	関節痛	2	N	Pre	-4	64	N	None	
			Fatigue	疲労	2	N	Pre	1	35	N	None	Recovered
			Bone pain	骨痛	1	N	Pre	1		Y	None	Not recovered, but no changes expected
			Toothache	歯痛	1	N	TE	24	5	N	None	Recovered
			Fatigue	疲労	1	N	TE	29	148	Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	29		Y	None	Not recovered, but no changes expected
			Phlebitis	静脈炎	1	N	TE	41	15	N	None	Recovered
			Dysuria	排尿困難	2	N	TE	85	26	N	None	Recovered
			Haematuria	血尿	1	N	TE	86	90	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urethral obstruction	尿道閉塞	3	N	TE	86	50	N	Drug administration postponed	Recovered
			Urinary tract infection	尿路感染	2	N	TE	109		N	None	Recovered
			Genital pain	生殖器痛	3	N	TE	113		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	122	1	Y	None	Recovered
			Urinary retention	尿閉	3	Y	TE	122	4	N	None	Recovered
			Pelvic pain	骨盤痛	2	N	TE	126	2	N	None	Recovered
			Fatigue	疲労	1	N	TE	141		Y	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	151		Y	None	Not recovered, but no changes expected
			Myalgia	筋痛	1	N	TE	154		Y	None	Not recovered, but no changes expected
			Myalgia	筋痛	1	N	TE	154		Y	None	Not recovered, but no changes expected
			Dysuria	排尿困難	1	N	TE	155		N	None	Recovered
			Swollen tongue	舌腫脹	1	N	TE	164	1	N	None	Recovered
			Haemorrhoids	痔核	1	N	TE	171	7	N	None	Recovered
			Fatigue	疲労	2	N	TE	176		Y	None	Not recovered, but no changes expected
			Oedema peripheral	末梢性浮腫	1	N	TE	196		Y	None	Not recovered, but no changes expected
043016	UK	74/M/A	Fatigue	疲労	1	N	TE	2	8	Y	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	71		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	116	15	N	None	Recovered
			Bone pain	骨痛	2	N	TE	116	4	N	None	Recovered
			Bone pain	骨痛	1	N	TE	134		N	None	Not recovered, but no changes expected
			Paraesthesia	錯感覚	1	N	TE	134	15	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Stress urinary incontinence	腹圧性尿失禁	1	N	TE	148		N	None	Not recovered, but no changes expected
			Abdominal pain upper	上腹部痛	1	N	TE	180	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	180		N	Not applicable	Not recovered, but no changes expected
			Paraplegia	対麻痺	3	Y	TE	190	231	N	Not applicable	Not recovered, but no changes expected
			Spinal cord compression	脊髄圧迫	4	Y	TE	190	36	N	Not applicable	Recovered with sequelae
043017	UK	85/M/C	Deafness unilateral	片耳難聴	3	N	TE			N	None	Not recovered, but no changes expected
			Urinary tract infection	尿路感染	1	N	TE			N	None	Recovered
			Anorexia	食欲不振	2	N	TE			N	None	Recovered
			Urinary retention	尿閉	3	Y	Pre	-13	4	N	None	Recovered
			Bone pain	骨痛	1	N	Pre	1		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	Pre	1		N	None	Not recovered, but no changes expected
			Urinary tract infection	尿路感染	1	N	TE	29		N	None	Recovered
			Joint lock	関節ロック	1	N	TE	42		N	None	Not recovered, but no changes expected
			Post procedural infection	処置後感染	1	N	TE	43	16	N	Drug administration postponed	Recovered
			Nausea	悪心	1	N	TE	71		Y	None	Recovered
			Facial palsy	顔面神経麻痺	3	N	TE	71		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	99		N	None	Not recovered, but no changes expected

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
043018	UK	63/M/C	Neuropathy peripheral	末梢性ニューロパチー	3	N	Pre	-3		N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	4	4	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	23	9	N	None	Recovered
			Contusion	挫傷	2	N	TE	50		N	None	Ongoing at time of death
			Skin disorder	皮膚障害	2	N	TE	50	8	N	None	Recovered
			Hypoaesthesia	感覚鈍麻	2	N	TE	76		N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	90	25	Y	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	90	25	Y	None	Ongoing at time of death
			Metastases to central nervous system	中枢神経系転移	4	Y	TE	106	9	N	Drug permanently withdrawn	Death
			Metastases to central nervous system	中枢神経系転移	5	Y	TE	114	1	N	Drug permanently withdrawn	Death
045001	UK	74/M/C	Haematuria	血尿	3	Y	TE	6	5	N	None	Recovered
			Haematuria	血尿	3	N	TE	10	26	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	21	20	N	None	Recovered
			Haematuria	血尿	3	Y	TE	35	2	N	None	Recovered
			Hypoalbuminaemia	低アルブミン血症	2	N	TE	56		N	Not applicable	Ongoing at study termination / withdrawal
046008	UK	67/M/C	Urinary tract obstruction	尿路閉塞		N	TE			N	None	Ongoing at time of death
			Thrombophlebitis	血栓性静脈炎		N	TE			N	None	Recovered
			Brain oedema	脳浮腫	1	Y	TE	40	5	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pulmonary embolism	肺塞栓症	4	Y	TE	152		N	Not applicable	Not recovered, but no changes expected
047006	UK	73/M/C	Cardiac arrest	心停止	5	Y	TE	25	1	N	Drug permanently withdrawn	Death
048012	UK	68/M/C	Anorexia	食欲不振	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	8	76	N	None	Ongoing at time of death
			Asthenia	無力症	1	N	TE	41		Y	None	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE	51		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	57	2	N	None	Recovered
			Vision blurred	霧視	1	N	TE	69		N	None	Ongoing at time of death
			Headache	頭痛	2	N	TE	73	10	N	None	Recovered
			Bone pain	骨痛	1	N	TE	83		N	None	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	103	5	N	None	Recovered
			Anaemia	貧血	2	N	TE	112	3	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	189	1	N	Not applicable	Death
050001	UK	80/M/C	Anaemia	貧血	3	N	TE			N	Not applicable	Recovered with sequelae
			Fatigue	疲労	2	N	TE			Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Ear infection	耳感染	2	N	TE			N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	1	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at study termination / withdrawal
			Upper respiratory tract infection	上気道感染	2	N	Pre	-14	8	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	1	29	Y	-	
			Nausea	悪心	2	N	TE	2	2	Y	None	Recovered
			Fatigue	疲労	2	N	TE	8	14	Y	None	Recovered
			Muscular weakness	筋力低下	2	N	TE	8	14	N	None	Recovered
			Myalgia	筋痛	2	N	TE	8	22	N	None	Recovered
			Fatigue	疲労	3	N	TE	21	4	Y	None	Recovered
			Muscular weakness	筋力低下	3	N	TE	21	9	N	None	Recovered
			Fatigue	疲労	1	N	TE	24	37	Y	None	Recovered
			Anaemia	貧血	1	N	TE	29	29	Y	-	
			Nausea	悪心	2	N	TE	30	1	Y	None	Recovered
			Hot flush	ほてり	2	N	TE	30		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	34	1	Y	None	Recovered
			Anaemia	貧血	3	N	TE	57	5	Y	-	
			Anaemia	貧血	1	N	TE	61	12	Y	-	
			Urinary tract infection	尿路感染	2	N	TE	61	6	N	None	Recovered
			Urinary retention	尿閉	3	Y	TE	61	2	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	72	70	Y	-	
			Haemorrhage urinary tract	尿路出血	2	N	TE	80	2	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary retention	尿閉	1	N	TE	84		N	None	Ongoing at study termination / withdrawal
			Urinary retention	尿閉	1	N	TE	84	3	N	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	85	57	N	None	Ongoing at study termination / withdrawal
			Urinary retention	尿閉	2	N	TE	86		N	None	Ongoing at study termination / withdrawal
			Insomnia	不眠症	2	N	TE	101	5	N	None	Recovered
			Fatigue	疲労	3	N	TE	113		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Muscular weakness	筋力低下	2	N	TE	113		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	N	TE	141	9	Y	-	
			Constipation	便秘	1	N	TE	141		Y	Not applicable	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	2	N	TE	141		N	None	Ongoing at study termination / withdrawal
			Muscular weakness	筋力低下	3	N	TE	141		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	4	N	TE	149	3	Y	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	151		Y	None	Ongoing at study termination / withdrawal
			Cranial neuropathy	脳ニューロパチー	2	N	TE	155		N	None	Ongoing at time of death
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	2	N	TE	155		N	None	Ongoing at time of death
			Oral candidiasis	口腔カンジダ症	2	N	TE	190		N	None	Ongoing at time of death
			Anaemia	貧血	4	Y	TE	192	5	N	Not applicable	Recovered with sequelae
			Gastric cancer	胃癌	4	Y	TE	192	28	N	Not applicable	Death
			Gastric cancer	胃癌	5	Y	TE	219	1	N	Not applicable	Death
050003	UK	60/M/C	Nausea	悪心	1	N	TE			N	None	Recovered
			Fatigue	疲労	2	N	TE			N	-	
			Fatigue	疲労	3	N	TE			N	-	
			Weight decreased	体重減少	1	N	TE			N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE			N	None	Ongoing at time of death
			Muscular weakness	筋力低下	3	N	TE			N	None	Ongoing at time of death
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE			N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	N	TE	6	10	N	-	
			Oedema genital	性器浮腫		N	TE	10		N	None	Ongoing at time of death
			Pharyngolaryngeal pain	咽喉頭疼痛	1	N	TE	13		N	None	Recovered
			Contusion	挫傷	1	N	TE	14		Y	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	2	N	TE	15	9	N	-	
			Constipation	便秘	2	N	TE	16		Y	None	Ongoing at time of death
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE	16		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	18		N	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	19	3	N	-	
			Pollakiuria	頻尿	1	N	TE	19	4	N	None	Recovered
			Fatigue	疲労	3	N	TE	21		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	4	N	TE	23	8	N	-	
			Dysphagia	嚥下障害	2	N	TE	26		N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	1	N	TE	26	3	N	None	Recovered
			Oedema peripheral	末梢性浮腫	3	N	TE	29	2	N	Not applicable	Ongoing at time of death
			Abdominal pain	腹痛	3	N	TE	30	1	N	None	Recovered
			Oedema peripheral	末梢性浮腫	4	N	TE	30		N	Not applicable	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	4	N	TE	30		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	31	1	N	Drug permanently withdrawn	Death
			Agitation	激越	2	N	TE	31	1	N	Not applicable	Recovered
050016	UK	63/M/C	Constipation	便秘	1	N	TE			Y	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE			N	Not applicable	Ongoing at time of death
			Herpes zoster	帯状疱疹	2	N	TE			N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at time of death
			Memory impairment	記憶障害	1	N	TE			N	Not applicable	Ongoing at time of death
			Agitation	激越	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	Pre	-41	3	N	Not applicable	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	3	27	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	43	8	N	None	Recovered with sequelae
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	Y	TE	43	8	N	None	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	3	N	TE	43	16	N	None	Recovered
			Lung infection	肺感染	2	Y	TE	80	11	N	Drug administration postponed	Recovered with sequelae
			Fatigue	疲労	2	N	TE	99		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	99		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	100		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	134	4	Y	None	Recovered
			Nausea	悪心	2	N	TE	138		Y	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	148		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	165	4	Y	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			General physical health deterioration	全身健康状態低下	2	Y	TE	168	17	N	Not applicable	Death
			Oral candidiasis	口腔カンジダ症	2	N	TE	171	6	N	Not applicable	Recovered
			Epilepsy	てんかん	3	Y	TE	175	1	N	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	5	Y	TE	184	1	N	Not applicable	Death
050018	UK	70/M/C	Diarrhoea	下痢	3	N	TE			N	None	Recovered
			Diarrhoea	下痢	1	N	TE			N	Not applicable	Recovered
			Hypoaesthesia	感覚鈍麻	1	N	TE			N	Not applicable	Recovered
			Neuralgia	神経痛	2	N	TE			N	None	Recovered
			Lethargy	嗜眠	1	N	TE	2		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	5	53	N	None	Ongoing at study termination / withdrawal
			Dizziness	浮動性めまい	2	N	TE	5	32	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	5		N	None	Recovered
			Bone pain	骨痛	3	N	TE	10	1	Y	-	
			Bone pain	骨痛	2	N	TE	10	103	Y	-	
			Constipation	便秘	2	N	TE	32		Y	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	46	12	N	None	Recovered
			Nausea	悪心	1	N	TE	57		N	None	Ongoing at study termination / withdrawal
			Nasopharyngitis	鼻咽頭炎	2	N	TE	85	8	N	None	Recovered
			Bone pain	骨痛	3	N	TE	112	2	Y	-	

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	113	28	N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	120		N	None	Recovered
			Bone pain	骨痛	3	N	TE	140		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	150		N	Not applicable	Recovered
			Joint swelling	関節腫脹	1	N	TE	206		N	Not applicable	Ongoing at study termination / withdrawal
			Neuralgia	神経痛	2	Y	TE	217	1	N	Not applicable	Recovered
			Neuralgia	神経痛	2	Y	TE	217	1	N	Not applicable	Recovered
			Neuralgia	神経痛	2	N	TE	217		N	Not applicable	Ongoing at study termination / withdrawal
			Neuralgia	神経痛	2	N	TE	217		N	Not applicable	Ongoing at study termination / withdrawal
			Anxiety	不安	1	N	TE	227		N	Not applicable	Ongoing at study termination / withdrawal
055007	Netherlands	62/M/C	Confusional state	錯乱状態	2	Y	Pre	-13	2	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	8		N	Not applicable	Ongoing at time of death
			Nausea	悪心	2	N	TE	8		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Intertrigo	間擦疹	1	N	TE	8		Y	Not applicable	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	35	2	N	None	Recovered
			Anaemia	貧血	3	N	TE	36		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	85	1	N	Not applicable	Death
060008	Spain	63/M/C	Thrombocytopenia	血小板減少症	1	N	TE	29		Y	None	Ongoing at study termination / withdrawal
			Asthenia	無力症	2	N	TE	29	8	N	None	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	2	N	TE	29	8	N	None	Recovered
			Asthenia	無力症	1	N	TE	36		N	None	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	1	N	TE	36	64	N	None	Recovered
			Anaemia	貧血	2	N	TE	57	43	N	None	Recovered
			Hypocalcaemia	低カルシウム血症	1	N	TE	57	43	N	None	Recovered
			Bone pain	骨痛	2	N	TE	85	39	N	None	Recovered
			Anaemia	貧血	1	N	TE	99	22	N	None	Recovered
			Cushingoid	クッシング様	2	N	TE	99	22	N	None	Recovered
			Pupils unequal	瞳孔不同	1	N	TE	99	25	N	None	Recovered
			Aphasia	失語症	2	N	TE	119	2	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	120	2	N	None	Recovered
			Eyelid ptosis	眼瞼下垂	2	N	TE	120	4	N	None	Recovered
			Pyrexia	発熱	1	N	TE	120	1	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Aphasia	失語症	3	Y	TE	120	10	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	N	TE	121	2	N	None	Recovered
			Anaemia	貧血	1	N	TE	122	6	N	None	Recovered
			Hypertension	高血圧	1	N	TE	123	3	N	None	Ongoing at study termination / withdrawal
			Hypertension	高血圧	2	N	TE	125		N	None	Ongoing at study termination / withdrawal
			Arthralgia	関節痛	3	N	TE	134		N	None	Ongoing at study termination / withdrawal
060009	Spain	66/M/C	Asthenia	無力症	1	N	Pre	1	28	Y	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	Pre	1	116	N	None	Ongoing at time of death
			Hypophosphataemia	低リン酸血症	3	N	Pre	1	28	N	None	Recovered
			Nausea	悪心	1	N	TE	25	92	Y	None	Recovered
			Anaemia	貧血	2	N	TE	28	76	Y	-	
			Asthenia	無力症	2	N	TE	28	135	Y	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	28	61	N	None	Recovered
			Hypocalcaemia	低カルシウム血症	2	N	TE	28	5	N	-	
			Hypophosphataemia	低リン酸血症	2	N	Pre	28	61	N	None	Recovered
			Hypocalcaemia	低カルシウム血症	1	N	TE	32	120	N	-	
			Constipation	便秘	1	N	TE	57	32	N	None	Recovered
			Gastritis	胃炎	2	N	TE	88	29	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	88	149	N	None	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	101	3	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	N	TE	103	2	Y	-	
			Diarrhoea	下痢	1	Y	TE	103	2	N	None	Recovered
			Anaemia	貧血	1	N	TE	104	10	Y	-	
			Anaemia	貧血	2	N	TE	113	23	Y	-	
			Anorexia	食欲不振	1	N	Pre	116	54	N	None	Ongoing at time of death
			Asthenia	無力症	2	N	TE	131	11	N	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	131	11	N	None	Recovered
			Anaemia	貧血	1	N	TE	135	1	Y	-	
			Anaemia	貧血	2	N	TE	135	17	Y	-	
			Diarrhoea	下痢	3	N	TE	140		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	141	22	N	None	Recovered
			Acute myocardial infarction	急性心筋梗塞	4	Y	TE	143	5	N	Not applicable	Recovered
			Dysarthria	構語障害	2	N	TE	150	13	N	None	Recovered
			Facial paresis	顔面不全麻痺	2	N	TE	150	13	N	None	Recovered
			Anaemia	貧血	3	N	TE	151	11	Y	None	Ongoing at time of death
			Hypocalcaemia	低カルシウム血症	2	N	TE	151	19	N	-	
			Anaemia	貧血	2	N	TE	161		Y	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	162	36	N	None	Recovered
			Asthenia	無力症	3	N	TE	162		Y	None	Ongoing at time of death
			Facial paresis	顔面不全麻痺	1	N	TE	162	61	N	None	Recovered
			Anorexia	食欲不振	2	N	Pre	169		N	None	Ongoing at time of death
			Hypocalcaemia	低カルシウム血症	1	N	TE	169	64	N	None	Ongoing at time of death
			Hypocalcaemia	低カルシウム血症	2	N	TE	232		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
060012	Spain	73/M/C	Nausea	悪心	1	N	TE	29	75	Y	None	Recovered
			Anaemia	貧血	1	N	TE	57	22	Y	Not applicable	Recovered
			Asthenia	無力症	2	N	TE	57	18	N	Not applicable	Recovered
			Anorexia	食欲不振	2	N	TE	57	18	N	Not applicable	Recovered
			Asthenia	無力症	1	N	TE	74	30	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	78	7	Y	Not applicable	Recovered
			Leukopenia	白血球減少症	3	N	TE	83	2	N	Not applicable	Recovered
			Neutropenia	好中球減少症	2	N	TE	83	2	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	83	2	N	Not applicable	Recovered
			Pyrexia	発熱	1	N	TE	83	2	N	Not applicable	Recovered
			Cellulitis	蜂巣炎	3	Y	TE	83	10	N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	84	2	Y	Not applicable	Recovered
			Leukopenia	白血球減少症	2	N	TE	84	4	N	Not applicable	Recovered
			Neutropenia	好中球減少症	1	N	TE	84	4	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	84	9	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	86	1	N	Not applicable	Recovered
			Leukopenia	白血球減少症	1	N	TE	87	2	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	1	N	TE	92	11	N	Not applicable	Recovered
			Cellulitis	蜂巣炎	2	N	TE	92	12	N	Not applicable	Recovered
062004	Spain	81/M/C	Oedema peripheral	末梢性浮腫	2	N	Pre	1	57	N	None	Recovered
			Bone pain	骨痛	1	N	TE	28	29	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	56		N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	78	2	N	None	Recovered
			Vomiting	嘔吐	1	Y	TE	80	5	N	Not applicable	Recovered
			Fatigue	疲労	1	N	TE	81	84	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	81	84	N	None	Recovered
			Anorexia	食欲不振	3	N	TE	81	32	N	Not applicable	Recovered
			Hypocalcaemia	低カルシウム血症	2	N	TE	81		N	Not applicable	Ongoing at time of death
063003	Spain	66/M/C	Spinal cord compression	脊髄圧迫	2	Y	TE	30	20	N	Drug permanently withdrawn	Recovered
070002	Spain	55/M/C	Anaemia	貧血	1	N	TE			Y	Not applicable	Recovered
			Bone pain	骨痛	2	N	Pre	1	85	N	Drug permanently withdrawn	Ongoing at time of death
			Nausea	悪心	2	N	TE	8	8	Y	None	Recovered
			Anorexia	食欲不振	2	N	TE	8	8	Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	85	29	N	Drug permanently withdrawn	Ongoing at time of death
			Bone pain	骨痛	4	N	TE	113	112	N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	147	7	N	Not applicable	Recovered
071002	Spain	65/M/C	Bone pain	骨痛	3	N	Pre	-9	9	N	None	Recovered
			Bone pain	骨痛	2	N	Pre	-1	58	N	None	Recovered
			Dizziness	浮動性めまい	2	N	TE	28	2	N	None	Recovered
			Anxiety	不安	1	N	TE	28		N	None	Not recovered, but no changes expected
			Depression	うつ病	1	N	TE	28		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	57		N	None	Not recovered, but no changes expected
			Spinal cord compression	脊髄圧迫	3	Y	TE	221	15	N	Not applicable	Recovered
071008	Spain	70/M/C	Rectal tenesmus	直腸しぶり	2	N	TE			N	None	Recovered with sequelae
			Dysuria	排尿困難	2	N	TE			N	None	Recovered with sequelae
			Dysaesthesia	異常感覚	2	N	Pre	-20	21	N	None	Recovered
			Bone pain	骨痛	2	N	Pre	1	93	N	None	Not recovered, but no changes expected
			Urinary retention	尿閉	2	Y	TE	89	14	N	Drug permanently withdrawn	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pyrexia	発熱	2	N	TE	91	8	N	Drug permanently withdrawn	Recovered
			Bone pain	骨痛	3	N	TE	93	46	N	None	Not recovered, but no changes expected
			Spinal cord compression	脊髄圧迫	3	Y	TE	97	6	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	135	9	N	None	Recovered
			Bone pain	骨痛	2	N	TE	138		N	None	Not recovered, but no changes expected
072001	Spain	78/M/C	Fatigue	疲労	1	N	Pre			N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	10		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	21	7	N	None	Recovered
			Cardiac failure	心不全	4	Y	TE	31	5	N	None	Death
			Cardiac failure	心不全	5	Y	TE	35	1	N	None	Death
080001	Italy	73/M/C	Nausea	悪心	1	N	TE			Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE			Y	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	130	9	N	None	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	138	1	N	None	Death
084002	Israel	63/M/C	Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	TE	27		N	None	Not recovered, but no changes expected
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	2	N	TE	27		N	None	Not recovered, but no changes expected

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE	57		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	Y	TE	72	2	N	None	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	91		N	Drug permanently withdrawn	Not recovered, but no changes expected
			Nausea	悪心	2	N	TE	102	9	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	102	9	N	None	Recovered
			Anaemia	貧血	3	Y	TE	145	6	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	145	6	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	167	5	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	174	2	N	Not applicable	Recovered with sequelae
085001	Israel	58/M/C	Pyrexia	発熱	1	N	TE	31	1	N	None	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	58	7	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	58	7	N	None	Recovered with sequelae
			Pneumonia	肺炎	1	Y	TE	79		N	None	Ongoing at time of death
			Respiratory failure	呼吸不全	4	Y	TE	83	2	N	None	Death
			Respiratory failure	呼吸不全	5	Y	TE	84	1	N	None	Death
085003	Israel	74/M/C	Deep vein thrombosis	深部静脈血栓症	2	Y	Pre	-16	3	N	Not applicable	Recovered with sequelae
			Dermatitis contact	接触性皮膚炎	1	N	TE	37	8	N	None	Recovered
			Asthenia	無力症	1	N	TE	49	1	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	55		N	None	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	TE	62		N	None	Ongoing at time of death
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	3	N	TE	62		N	None	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	TE	63	11	N	None	Recovered
			Rectal haemorrhage	直腸出血	2	Y	TE	82	4	N	None	Recovered
			Haematuria	血尿	2	Y	TE	82	4	N	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	90		N	None	Ongoing at time of death
			Tremor	振戦	2	N	TE	90		N	None	Ongoing at time of death
			Hypochromic anaemia	低色素性貧血	2	N	TE	96		N	None	Ongoing at time of death
			Localised oedema	限局性浮腫	1	N	TE	104		N	None	Ongoing at time of death
			Lobar pneumonia	大葉性肺炎	3	Y	TE	104	8	N	Drug permanently withdrawn	Death
			General physical health deterioration	全身健康状態低下	3	Y	TE	107		N	Drug permanently withdrawn	Ongoing at time of death
			Urosepsis	尿路性敗血症	3	Y	TE	107		N	Drug permanently withdrawn	Ongoing at time of death
			Lobar pneumonia	大葉性肺炎	5	Y	TE	111	1	N	Drug permanently withdrawn	Death
085005	Israel	75/M/C	Anaemia	貧血	1	N	Pre	-9	2	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	TE	57		N	None	Not recovered, but no changes expected
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	1	N	TE	83		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	83		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	160	20	N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	Y	TE	166	4	N	Not applicable	Recovered
			Fatigue	疲労	2	Y	TE	166	4	N	Not applicable	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	167	1	N	None	Recovered
			Bone pain	骨痛	3	N	TE	179		N	None	Not recovered, but no changes expected
			Urinary tract infection	尿路感染	2	Y	TE	190	5	N	Not applicable	Recovered with sequelae
			Dermatitis	皮膚炎	1	N	TE	190	3	N	Not applicable	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	193	26	N	Not applicable	Ongoing at study termination / withdrawal
			Asthenia	無力症	2	Y	TE	196	19	N	Not applicable	Recovered with sequelae
			Haematuria	血尿	2	Y	TE	196	19	N	Not applicable	Recovered
086002	Israel	70/M/C	Bone pain	骨痛	2	N	Pre	1	30	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	30		N	None	Not recovered, but no changes expected

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	58	3	N	Drug administration postponed	Recovered with sequelae
			Dysuria	排尿困難	2	N	TE	58	9	N	Drug administration postponed	Recovered
093001	Slovakia	72/M/C	Anaemia	貧血	2	N	Pre	-13	14	N	None	Recovered
			Constipation	便秘	1	N	Pre	-13	57	N	None	Recovered with sequelae
			Hyperbilirubinaemia	高ビリルビン血症	2	Y	Pre	-13	5	N	Not applicable	Recovered with sequelae
			Weight decreased	体重減少	2	Y	Pre	-13	5	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	N	Pre	-13	5	N	Not applicable	Recovered with sequelae
			Hyperbilirubinaemia	高ビリルビン血症	2	N	Pre	-9	3	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	1	N	Pre	-9	10	N	None	Recovered with sequelae
			Hyperbilirubinaemia	高ビリルビン血症	2	Y	Pre	-7	7	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	Y	TE	1	40	N	None	Recovered with sequelae
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	TE	35		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	35		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	35		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	44		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	2	Y	TE	44	11	N	None	Recovered with sequelae
			Bone pain	骨痛	2	Y	TE	44	11	N	None	Recovered with sequelae
			Pneumonia	肺炎	4	Y	TE	75		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	90	1	N	None	Death
095001	Slovakia	75/M/C	Bone pain	骨痛	4	N	TE	3	8	Y	Drug administration postponed	Recovered
			Bone pain	骨痛	2	N	TE	10	26	Y	Drug administration postponed	Recovered
			Bone pain	骨痛	3	N	TE	14	61	Y	Drug administration postponed	Recovered
			Nausea	悪心	1	N	TE	20	64	N	None	Recovered
			Fatigue	疲労	2	N	TE	20	118	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	35	40	Y	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	83		Y	Not applicable	Ongoing at time of death
			Cardiopulmonary failure	心肺不全	4	Y	Post	235	13	Y	Not applicable	Death
			Cardiopulmonary failure	心肺不全	5	Y	Post	247	1	Y	Not applicable	Death
097001	Slovakia	70/M/C	Anaemia	貧血	2	N	Pre	1		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Sudden death	突然死	5	Y	TE	9	1	N	None	Death
097004	Slovakia	80/M/C	Fatigue	疲労	3	N	TE	3		N	None	Ongoing at time of death
			Cerebral ischaemia	脳虚血	4	Y	TE	3	36	N	Drug administration postponed	Recovered with sequelae
			Micturition disorder	排尿異常	2	N	TE	112		N	None	Ongoing at time of death
			Constipation	便秘	3	N	TE	114		N	None	Ongoing at time of death
			Diarrhoea	下痢	3	Y	TE	143	29	Y	Drug permanently withdrawn	Recovered
			Vomiting	嘔吐	3	Y	TE	143	29	Y	Drug permanently withdrawn	Recovered
			Pyrexia	発熱	3	Y	TE	143	29	N	Drug permanently withdrawn	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	143	29	N	Drug permanently withdrawn	Recovered
			Disorientation	失見当識	3	N	TE	143	29	N	Not applicable	Recovered
			Cardiopulmonary failure	心肺不全	5	Y	TE	176	1	N	Not applicable	Death
097007	Slovakia	70/M/C	Bone pain	骨痛	2	N	Pre	-9	38	N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	2	56	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	1	N	TE	29	84	N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	29	112	N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	57	56	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	112	9	Y	None	Recovered
			Anorexia	食欲不振	2	N	TE	112		N	None	Ongoing at time of death
			Sleep disorder	睡眠障害	1	N	TE	112	49	N	None	Recovered
			Mixed incontinence	混合性尿失禁	3	N	TE	112		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	120		Y	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	140		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	Pre	140		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	160	1	N	Not applicable	Death
097010	Slovakia	80/M/C	Nausea	悪心	1	N	TE	2	56	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	2		Y	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	29	58	N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	64	6	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	64	6	N	None	Recovered
			Nausea	悪心	1	N	TE	86	91	Y	None	Recovered
			Fatigue	疲労	3	Y	TE	86	5	Y	Drug administration postponed	Recovered with sequelae
			Weight decreased	体重減少	2	N	TE	86		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	90	68	Y	None	Recovered with sequelae
			Vomiting	嘔吐	2	N	TE	152	6	Y	None	Recovered
			Anaemia	貧血	2	N	TE	157	5	Y	None	Recovered
			Fatigue	疲労	3	Y	TE	157	5	Y	None	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	206	1	N	Not applicable	Death
097014	Slovakia	52/M/C	Anaemia	貧血	2	N	TE	28	29	N	None	Recovered with sequelae
			Anaemia	貧血	3	N	TE	56	3	N	None	Recovered with sequelae
			Anaemia	貧血	3	Y	TE	58	25	N	None	Recovered with sequelae
			Haemorrhage urinary tract	尿路出血	3	Y	TE	84	3	N	Not applicable	Recovered
105003	Hong Kong	75/M/A	Cough	咳嗽	1	N	TE	4	5	N	None	Recovered
			Pharyngolaryngeal pain	咽喉頭疼痛	1	N	TE	4	5	N	None	Recovered
			Rhinorrhoea	鼻漏	1	N	TE	4	5	N	None	Recovered
			Pruritus	そう痒症	1	N	TE	8	22	N	None	Recovered
			Chromaturia	着色尿	1	N	TE	22		N	None	Ongoing at time of death
			Cough	咳嗽	1	N	TE	32	9	N	None	Recovered
			Productive cough	湿性咳嗽	1	N	TE	32	15	N	None	Recovered
			Pharyngolaryngeal pain	咽喉頭疼痛	1	N	TE	33	14	N	None	Recovered
			Rhinorrhoea	鼻漏	1	N	TE	33	8	N	None	Recovered
			Oedema	浮腫	1	N	TE	66	8	N	None	Recovered
			Rash pruritic	そう痒性皮疹	1	N	TE	66	7	N	None	Recovered
			Gastrooesophageal reflux disease	胃食道逆流性疾患	1	N	TE	71		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE	71	8	N	None	Recovered
			Bone pain	骨痛	1	N	TE	85	47	N	None	Ongoing at time of death
			Chest discomfort	胸部不快感	1	N	TE	98	8	N	None	Recovered
			Pruritus	そう痒症	1	N	TE	98		N	None	Ongoing at time of death
			Pharyngolaryngeal pain	咽喉頭疼痛	1	N	TE	99	13	N	None	Recovered
			Cough	咳嗽	1	N	TE	105	7	N	None	Recovered
			Productive cough	湿性咳嗽	1	N	TE	107	5	N	None	Recovered
			Bone pain	骨痛	2	N	TE	131		N	None	Ongoing at time of death
			Bone pain	骨痛	2	Y	TE	131	50	N	Drug administration postponed	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	131		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	143		N	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	214	2	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	214		N	Not applicable	Ongoing at time of death
106001	Hong Kong	62/M/A	Bone pain	骨痛	2	N	TE	57	57	N	None	Recovered
			Urogenital disorder	尿生殖器障害	2	N	TE	57		N	None	Not recovered, but no changes expected
			Haematuria	血尿	1	N	TE	98	44	N	None	Recovered
			Hypersensitivity	過敏症	2	N	TE	101	5	N	None	Recovered
			Pharyngolaryngeal pain	咽喉頭疼痛	2	N	TE	101	5	N	None	Recovered
			Cough	咳嗽	2	N	TE	105	6	N	None	Recovered
			Nasal discomfort	鼻部不快感	2	N	TE	105	6	N	None	Recovered
			Rhinorrhoea	鼻漏	2	N	TE	105	6	N	None	Recovered
			Hyponatraemia	低ナトリウム血症	3	N	TE	113	9	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cystitis	膀胱炎	3	Y	TE	115	11	N	None	Recovered
			Urinary bladder haemorrhage	膀胱出血	3	Y	TE	115	11	N	None	Recovered
			Urinary retention	尿閉	3	Y	TE	115	11	N	None	Recovered
			Hyponatraemia	低ナトリウム血症	1	N	TE	121	21	N	None	Recovered
			Constipation	便秘	2	N	TE	141	28	N	None	Recovered
			Nausea	悪心	2	N	TE	141	28	N	None	Recovered
			Hyponatraemia	低ナトリウム血症	3	N	TE	141	28	N	None	Recovered
106012	Hong Kong	75/M/A	Cystitis	膀胱炎	2	N	TE	7	7	N	None	Recovered
			Anaemia	貧血	2	Y	TE	29	2	Y	None	Recovered
			Constipation	便秘	1	N	TE	29	29	Y	None	Recovered
			Faeces discoloured	変色便	1	N	TE	29	29	N	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	29	29	N	None	Recovered
			Anaemia	貧血	3	Y	TE	57	3	Y	Drug administration postponed	Recovered
			Hyperkalaemia	高カリウム血症	1	N	TE	57	23	N	None	Recovered
			Haematuria	血尿	1	N	TE	57	23	N	None	Recovered
			Gastroduodenal ulcer	胃十二指腸潰瘍	1	N	TE	73		N	None	Ongoing at time of death
			Haemorrhoids	痔核	1	N	TE	73	7	N	None	Recovered
			Muscular weakness	筋力低下	2	N	TE	77		N	None	Ongoing at time of death
			Sepsis	敗血症	2	N	TE	79	20	N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	79		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	79		N	Drug permanently withdrawn	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	2	N	TE	80		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Convulsion	痙攣	2	N	TE	85		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	4	Y	TE	90		N	Not applicable	Ongoing at time of death
			Pyrexia	発熱	2	N	TE	91	4	N	Not applicable	Recovered
			Diabetes mellitus	糖尿病	2	N	TE	91	16	N	Not applicable	Recovered
			Anxiety	不安	2	N	TE	94	13	N	Not applicable	Recovered
			Metastases to bone	骨転移	5	Y	TE	106	1	N	Not applicable	Death
128005	Canada	86/M/C	Bone pain	骨痛	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Musculoskeletal chest pain	筋骨格系胸痛	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Musculoskeletal pain	筋骨格痛	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Cough	咳嗽	1	N	Pre			N	None	Recovered
			Fatigue	疲労	1	N	TE	2	3	Y	None	Recovered
			Decreased appetite	食欲減退	2	N	TE	92	8	N	None	Recovered
			Atrial fibrillation	心房細動	3	Y	TE	121	3	N	Drug permanently withdrawn	Recovered
			Left ventricular failure	左室不全	3	Y	TE	121	3	N	Drug permanently withdrawn	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	121	11	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pleural effusion	胸水	2	N	TE	162	8	N	Not applicable	Recovered
129002	Canada	81/M/C	Nausea	悪心	1	N	TE			N	None	Recovered
			Rectal haemorrhage	直腸出血	1	N	Pre			N	None	Recovered
			Fatigue	疲労	2	N	Pre			Y	None	Recovered
			Depression	うつ病	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	Pre	-7	22	N	None	Recovered
			Nausea	悪心	1	N	Pre	-3	7	N	None	Recovered
			Fatigue	疲労	1	N	Pre	14	99	Y	None	Recovered
			Angina pectoris	狭心症	1	N	TE	39	1	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	57	27	N	None	Recovered
			Hand fracture	手骨折	1	N	TE	106	1	N	None	Recovered with sequelae
			Fatigue	疲労	2	N	TE	112		Y	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	113		N	None	Ongoing at study termination / withdrawal
			Dizziness	浮動性めまい	1	N	TE	113		N	None	Recovered
			Constipation	便秘	2	N	TE	141		N	None	Ongoing at study termination / withdrawal
			Gastroenteritis radiation	放射線胃腸炎	1	N	TE	174		N	None	Ongoing at study termination / withdrawal
			Muscular weakness	筋力低下	3	Y	TE	193	7	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
133010	Poland	74/M/C	General physical health deterioration	全身健康状態低下	4	Y	TE			N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	12		N	None	Ongoing at study termination / withdrawal
133013	Poland	69/M/C	Fatigue	疲労	3	Y	TE	29	11	N	Drug permanently withdrawn	Recovered
			Fatigue	疲労	2	N	TE	39	20	N	Not applicable	Recovered
133021	Poland	70/M/C	Bone pain	骨痛	2	N	TE	15	8	Y	None	Recovered
			Device dislocation	医療機器位置異常	1	Y	TE	77	3	N	None	Recovered
			Anaemia	貧血	3	Y	TE	171	2	N	Drug administration postponed	Recovered
			Fatigue	疲労	4	Y	TE	171		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Haematuria	血尿	2	N	TE	179		N	Not applicable	Not recovered, but no changes expected
133022	Poland	84/M/C	General physical health deterioration	全身健康状態低下	4	N	TE	77		N	None	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	3	Y	TE	77	8	N	Drug permanently withdrawn	Death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	5	Y	TE	84	1	N	Drug permanently withdrawn	Death
133025	Poland	66/M/C	Decubitus ulcer	褥瘡性潰瘍	3	N	TE			N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Arteriovenous graft site haemorrhage	動静脈グラフト部位出血	2	Y	Pre	-11	7	N	Not applicable	Recovered
			Paraplegia	対麻痺	3	Y	TE	48		N	Drug administration postponed	Not recovered, but no changes expected
			Insomnia	不眠症	1	N	TE	51		N	None	Ongoing at study termination / withdrawal
			Pyrexia	発熱	2	N	TE	118	10	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	118		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	Y	TE	157	6	N	Drug administration postponed	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	157		N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	2	N	TE	159	2	N	None	Recovered
133029	Poland	56/M/C	Nausea	悪心	1	N	TE	2	2	Y	None	Recovered
			Asthenia	無力症	2	N	TE	2	3	Y	None	Recovered
			Urinary retention	尿閉	2	N	TE	53	4	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Subileus	亜イレウス	3	Y	TE	63	5	Y	Drug administration postponed	Recovered
			Renal failure	腎不全	3	Y	TE	82	10	N	Drug permanently withdrawn	Death
			Renal failure	腎不全	5	Y	TE	91	1	N	Drug permanently withdrawn	Death
135005	Poland	65/M/C	Cerebral ischaemia	脳虚血	4	Y	TE	128	8	N	Drug administration postponed	Recovered with sequelae
137001	Poland	84/M/C	Peripheral motor neuropathy	末梢性運動ニューロパチー	3	Y	TE	16	10	N	Drug permanently withdrawn	Recovered with sequelae
			Muscular weakness	筋力低下	2	N	TE	25		N	Not applicable	Ongoing at time of death
137008	Poland	60/M/C	Bone pain	骨痛	2	Y	TE	101	13	N	None	Recovered
137010	Poland	65/M/C	Bone pain	骨痛	2	N	TE			Y	None	Recovered with sequelae
			Bone pain	骨痛	2	Y	TE	38	3	Y	None	Recovered with sequelae
			Anaemia	貧血	3	N	TE	85	2	N	Drug administration postponed	Recovered with sequelae
			Anaemia	貧血	3	Y	TE	86	6	N	Drug administration postponed	Recovered with sequelae

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	86	34	N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	127	2	N	Not applicable	Recovered
			Anaemia	貧血	3	Y	TE	128	4	N	Not applicable	Recovered
			Anaemia	貧血	2	Y	TE	176	3	N	Not applicable	Recovered
137012	Poland	71/M/C	Pathological fracture	病的骨折	3	Y	TE	62	10	N	Drug administration postponed	Recovered with sequelae
			Pathological fracture	病的骨折	3	N	TE	71		N	None	Not recovered, but no changes expected
			Depression	うつ病	3	N	TE	85		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
139002	Poland	71/M/C	Bone pain	骨痛	2	N	TE	117	47	N	None	Recovered
			Nausea	悪心	2	N	TE	217		N	Not applicable	Recovered
			Vomiting	嘔吐	2	N	TE	217		N	Not applicable	Recovered
			Dizziness	浮動性めまい	2	N	TE	217		N	Not applicable	Recovered
			Dysphasia	不全失語症	3	N	TE	217		N	Not applicable	Ongoing at time of death
			Ischaemic stroke	虚血性脳卒中	3	Y	TE	217	13	N	Not applicable	Recovered with sequelae
141002	Poland	60/M/C	Haematuria	血尿	2	Y	TE	10	27	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Haematuria	血尿	3	Y	TE	40	11	N	None	Recovered with sequelae
			Haematuria	血尿	2	N	TE	50		N	None	Not recovered, but no changes expected
			Hydronephrosis	水腎症	2	Y	TE	56	5	N	Drug administration postponed	Recovered with sequelae
			Anaemia	貧血	3	Y	TE	90	3	N	None	Recovered with sequelae
			Thrombocytopenia	血小板減少症	2	N	TE	92		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	2	N	TE	92		N	None	Ongoing at study termination / withdrawal
			Dyspnoea	呼吸困難	3	Y	TE	95	5	N	Not applicable	Death
			Dyspnoea	呼吸困難	5	Y	TE	99	1	N	Not applicable	Death
141003	Poland	57/M/C	Pathological fracture	病的骨折	3	Y	TE			N	Not applicable	Lost to follow-up
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE			Y	None	Ongoing at study termination / withdrawal
148005	Germany	63/M/C	Nausea	悪心	1	N	TE	27	1	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	57	38	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	57	29	Y	None	Recovered
			Nausea	悪心	1	N	TE	59	5	Y	None	Recovered
			Fatigue	疲労	2	N	TE	64		Y	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	1	N	TE	85	1	Y	None	Recovered
			Anaemia	貧血	1	Y	TE	94	2	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	112		N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	114	4	Y	None	Recovered
			Nausea	悪心	1	N	TE	114	4	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	114	4	Y	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	129	1	N	None	Death
148007	Germany	62/M/C	Anaemia	貧血	1	N	TE			N	Not applicable	Recovered
			Oesophageal pain	食道痛	1	N	Pre			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	Pre	-3	10	Y	-	
			Diarrhoea	下痢	1	N	TE	3	1	Y	None	Recovered
			Nausea	悪心	2	N	TE	3	2	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	3	6	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	3	5	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	3		Y	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	4	29	Y	None	Recovered
			Bone pain	骨痛	1	N	Pre	7	45	Y	-	
			Bone pain	骨痛	1	N	TE	7		Y	None	Recovered
			Lymphadenopathy	リンパ節症	2	N	TE	13	40	N	None	
			Bone pain	骨痛	2	N	Pre	51	7	Y	-	
			Lymphadenopathy	リンパ節症	3	N	TE	52	7	N	None	
			Bone pain	骨痛	1	N	Pre	57	2	Y	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	58		N	None	
			Bone pain	骨痛	2	N	Pre	58	2	Y	None	Recovered
			Bone pain	骨痛	1	N	Pre	59		Y	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Abdominal pain upper	上腹部痛	2	N	TE	67	37	N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	102	2	Y	None	Recovered
			Abdominal pain upper	上腹部痛	1	N	TE	103		N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	111	1	Y	None	Recovered
			Diarrhoea	下痢	3	Y	TE	162	12	N	Not applicable	Recovered
			Nausea	悪心	3	Y	TE	162	12	N	Not applicable	Recovered
			Vomiting	嘔吐	3	Y	TE	162	12	N	Not applicable	Recovered
			Weight decreased	体重減少	2	N	TE	162	91	N	Not applicable	Recovered
148015	Germany	68/M/C	Migraine with aura	前兆を伴う片頭痛	2	N	TE	3	3	Y	None	Recovered
			Metastases to lymph nodes	リンパ節転移	2	N	TE	15	115	N	None	Recovered with sequelae
			Anorexia	食欲不振	1	N	TE	113	56	Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	113	119	Y	None	Recovered
			Metastases to lymph nodes	リンパ節転移	3	Y	TE	129	2	N	None	Recovered with sequelae
			Metastases to lymph nodes	リンパ節転移	3	N	TE	130	101	N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	168		Y	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	169		N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Metastases to lymph nodes	リンパ節転移	1	N	TE	230		N	None	Not recovered, but no changes expected
148021	Germany	73/M/C	Dysphagia	嚥下障害	3	Y	TE	43	21	N	Drug permanently withdrawn	Recovered
			Fatigue	疲労	3	Y	TE	43	21	N	Drug permanently withdrawn	Recovered
			Prostatic specific antigen increased	前立腺特異性抗原増加	3	Y	TE	43		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	3	Y	TE	43	21	N	Drug permanently withdrawn	Recovered
			Gastritis	胃炎	1	N	TE	47		N	None	Ongoing at study termination / withdrawal
149004	Germany	65/M/C	Bone pain	骨痛	2	N	Pre	-7	37	N	None	Recovered
			Vomiting	嘔吐	2	N	Pre	-1	1	N	None	Recovered
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE	1	1	Y	None	Recovered
			Vertigo	回転性めまい	1	N	TE	15		N	None	Not recovered, but no changes expected
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE	31	1	Y	None	Recovered
			Anaemia	貧血	1	N	TE	51	16	Y	None	Recovered
			Depression	うつ病	1	N	TE	64		N	None	Not recovered, but no changes expected
			Hypertension	高血圧	2	N	TE	64		N	None	Not recovered, but no changes expected

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	2	N	TE	66	2	N	None	Recovered
			Bone pain	骨痛	1	N	TE	66	7	N	None	Recovered
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE	66	1	Y	None	Recovered
			Tooth infection	歯感染	1	N	TE	89	4	N	None	Recovered
			Constipation	便秘	1	N	TE	98		N	None	Ongoing at study termination / withdrawal
			Insomnia	不眠症	1	N	TE	99	10	N	None	Recovered
			Hyperhidrosis	多汗症	2	N	TE	129		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	149	3	N	None	Recovered
			Bone pain	骨痛	1	N	TE	220	19	N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	238	5	N	Not applicable	Recovered
			Anaemia	貧血	1	N	Post	505	2	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	Post	603	1	Y	Not applicable	Recovered
149005	Germany	73/M/C	Bone pain	骨痛	1	N	TE	13	31	Y	None	Recovered
			Abdominal pain	腹痛	1	N	TE	31	13	Y	None	Recovered
			Nausea	悪心	1	N	TE	64	3	N	None	Recovered
			Fatigue	疲労	1	N	TE	64	5	N	Drug permanently withdrawn	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	64		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	1	N	TE	64	28	N	-	
			Insomnia	不眠症	1	N	TE	64	4	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	68	13	N	Drug permanently withdrawn	Ongoing at time of death
			Fatigue	疲労	3	N	TE	80		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	91	24	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	114	2	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	115	1	N	Not applicable	Death
149006	Germany	60/M/C	Bone pain	骨痛	1	N	TE	63	29	Y	None	Recovered with sequelae
			Urine flow decreased	尿流量減少	1	N	TE	65	7	N	None	Recovered
			Insomnia	不眠症	1	N	TE	77		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	91	123	Y	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	113	3	Y	Drug administration postponed	Recovered
			Haematuria	血尿	1	N	TE	125	1	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	133	4	Y	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	133	39	N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	133		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Monoparesis	不全単麻痺	1	N	TE	133	18	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	134		N	Not applicable	Not recovered, but no changes expected
			Monoparesis	不全単麻痺	3	Y	TE	150		N	Not applicable	Ongoing at time of death
			Monoparesis	不全単麻痺	3	N	TE	150	29	N	Not applicable	Recovered
			Pleural effusion	胸水	1	N	TE	150		N	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	163	5	Y	Not applicable	Recovered
			Stomatitis radiation	放射線口内炎	2	N	TE	168	4	N	Not applicable	Recovered
			Stomatitis radiation	放射線口内炎	1	N	TE	171	8	N	Not applicable	Recovered
			Dysaesthesia	異常感覚	1	N	TE	171		N	Not applicable	Not recovered, but no changes expected
			Thrombocytopenia	血小板減少症	2	N	TE	178	29	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	TE	183	11	Y	Not applicable	Recovered
			Ureteric obstruction	尿管閉塞	1	N	TE	190		N	Not applicable	Not recovered, but no changes expected
			Gastritis	胃炎	3	Y	TE	191	11	N	Not applicable	Recovered
			General physical health deterioration	全身健康状態低下	3	Y	TE	191	11	N	Not applicable	Recovered
151002	Germany	69/M/C	Vomiting	嘔吐	1	N	TE	5	12	N	None	Recovered
			VIth nerve paralysis	第６脳神経麻痺	2	N	TE	7	30	N	None	Recovered
			Hypotension	低血圧	2	N	TE	16	7	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Metastases to soft tissue	軟部組織転移	3	N	TE	19		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	22		N	None	Ongoing at study termination / withdrawal
			Pain in jaw	顎痛	2	N	TE	22	91	N	None	Ongoing at study termination / withdrawal
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	TE	29	28	N	None	Ongoing at study termination / withdrawal
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	56	81	N	None	Ongoing at study termination / withdrawal
			Visual disturbance	視覚障害	3	N	TE	92	8	N	None	Ongoing at study termination / withdrawal
			Visual disturbance	視覚障害	4	N	TE	99		N	None	Ongoing at study termination / withdrawal
			Pain in jaw	顎痛	3	N	TE	112	43	N	None	Ongoing at study termination / withdrawal
			Urinary retention	尿閉	3	Y	TE	129	5	N	Not applicable	Recovered with sequelae
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	TE	136		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	Y	TE	137	4	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pain in jaw	顎痛	2	N	TE	154		N	None	Ongoing at study termination / withdrawal
			Abscess jaw	顎膿瘍	3	Y	TE	163	22	N	Not applicable	Recovered with sequelae
155006	Germany	70/M/C	Chills	悪寒	1	N	Pre			N	None	Recovered
			Nausea	悪心	1	N	TE	2		N	None	Not recovered, but no changes expected
			Device related infection	医療機器関連感染	3	Y	TE	92	25	N	Drug administration postponed	Recovered with sequelae
			Bone pain	骨痛	3	N	TE	175		N	Not applicable	Ongoing at study termination / withdrawal
155007	Germany	63/M/C	Metastases to bone	骨転移	3	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	Pre	-10		N	None	Not recovered, but no changes expected
			Benign urinary tract neoplasm	尿路の良性新生物	2	Y	TE	73	6	N	None	Recovered
			Metastases to liver	肝転移	2	N	TE	163		N	None	Not recovered, but no changes expected
155010	Germany	80/M/C	Gastritis	胃炎	1	N	TE			N	None	Recovered
			General physical health deterioration	全身健康状態低下	1	N	TE	1	86	N	None	Recovered
			Gastritis	胃炎	2	N	TE	54		N	None	Recovered
			Anaemia	貧血	2	N	TE	120		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			General physical health deterioration	全身健康状態低下	1	N	TE	120		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	135		N	Not applicable	Ongoing at time of death
			Atrial fibrillation	心房細動	4	N	TE	203		N	Not applicable	Ongoing at time of death
			Sinusitis	副鼻腔炎	1	N	TE	203		N	Not applicable	Ongoing at time of death
			Cerebral haemorrhage	脳出血	4	Y	TE	203		N	Not applicable	Ongoing at time of death
			Epilepsy	てんかん	2	N	TE	203	2	N	Not applicable	Ongoing at time of death
			Pneumonia aspiration	嚥下性肺炎	4	Y	TE	203	2	N	Not applicable	Death
			Pneumonia aspiration	嚥下性肺炎	5	Y	TE	204	1	N	Not applicable	Death
172001	Brazil	75/M/C	Fatigue	疲労	2	N	TE	31		N	None	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	1	N	TE	31	29	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	36	4	N	None	Recovered
			Nasal congestion	鼻閉	1	N	TE	38	22	N	None	Recovered
			Cachexia	悪液質	3	N	TE	59		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	86	2	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	86	28	N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	87		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	113		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	212	1	N	Not applicable	Death
174003	Brazil	71/M/A	Weight decreased	体重減少	1	N	Pre	1	76	N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	4	15	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	41	17	N	None	Recovered
			Bone pain	骨痛	3	N	TE	41	4	N	None	Recovered
			Bone pain	骨痛	3	N	TE	41	17	N	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	2	N	TE	44		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	44	14	N	None	Recovered
			Constipation	便秘	2	N	TE	48	10	N	None	Recovered
			Nausea	悪心	2	N	TE	51	7	N	None	Recovered
			Bone pain	骨痛	2	N	TE	57		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	57		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	57		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	63	28	N	None	Recovered
			Nausea	悪心	1	N	TE	63	156	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	76	116	N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	99	43	N	None	Recovered
			Bone pain	骨痛	1	N	TE	105	1	N	None	Recovered
			Anaemia	貧血	3	N	TE	106	29	Y	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	106	29	Y	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	1	N	TE	134		Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	162	30	Y	None	Recovered
			Weight decreased	体重減少	3	N	TE	191		N	None	Ongoing at time of death
			Pneumonia	肺炎		N	TE	225		N	Not applicable	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	4	Y	TE	240	8	N	Not applicable	Death
			General physical health deterioration	全身健康状態低下	5	Y	TE	247	1	N	Not applicable	Death
179005	Brazil	77/M/C	Monoparesis	不全単麻痺	1	N	Pre			N	Not applicable	Ongoing at study termination / withdrawal
			Urinary tract infection	尿路感染	3	Y	Pre	-67	9	N	Not applicable	Recovered
			Neutropenia	好中球減少症	3	N	TE	31	33	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	42		N	Not applicable	Recovered
			Asthenia	無力症	1	N	TE	42		N	Not applicable	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	1	N	TE	42	22	N	Not applicable	Recovered
			Diarrhoea	下痢	1	N	TE	44		N	Not applicable	Recovered
			Gait disturbance	歩行障害	1	N	TE	63		N	Not applicable	Lost to follow-up

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neutropenia	好中球減少症	3	N	TE	78	14	N	Not applicable	Recovered
181006	Brazil	75/M/B	Sepsis	敗血症	4	Y	TE	146	11	N	None	Death
			Hypernatraemia	高ナトリウム血症	4	N	TE	146		N	Drug administration postponed	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	146		N	None	Ongoing at time of death
			Renal failure acute	急性腎不全	4	N	TE	146		N	Drug permanently withdrawn	Ongoing at time of death
			Respiratory failure	呼吸不全	4	N	TE	146		N	Drug permanently withdrawn	Ongoing at time of death
			Sepsis	敗血症	5	Y	TE	156	1	N	None	Death
191006	Singapore	71/M/A	Hypoaesthesia	感覚鈍麻	1	N	Pre	-5		N	None	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	1	N	Pre	-4		N	None	Ongoing at time of death
			Myopathy	ミオパチー	1	N	Pre	-4		N	None	Ongoing at time of death
			Insomnia	不眠症	1	N	Pre	-4		N	None	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	Pre	1	7	N	None	Recovered
			Hyperkalaemia	高カリウム血症	2	N	Pre	1	28	N	None	Recovered
			Constipation	便秘	1	N	TE	16		Y	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	16		Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	24	46	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Headache	頭痛	1	N	TE	24		Y	None	Ongoing at time of death
			Urinary incontinence	尿失禁	2	N	TE	69		N	None	Ongoing at time of death
			Anal sphincter atony	肛門括約筋無緊張症	3	N	TE	118	59	N	Not applicable	Ongoing at time of death
			Somnolence	傾眠	3	N	TE	169		N	Not applicable	Ongoing at time of death
			Intestinal perforation	腸管穿孔	4	Y	TE	174		N	Not applicable	Ongoing at time of death
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	3	Y	TE	174		N	Not applicable	Ongoing at time of death
			Myocardial infarction	心筋梗塞	5	Y	TE	176	1	N	Not applicable	Death
200002	Australia	57/M/C	Arthralgia	関節痛	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			N	None	Recovered
			Osteoarthritis	骨関節炎	1	N	Pre			N	None	Recovered
			Synovial cyst	滑液嚢腫	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Non-cardiac chest pain	非心臓性胸痛	3	Y	Pre	-17	3	N	None	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	57	57	N	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	1	N	TE	92		N	None	Ongoing at study termination / withdrawal
			Constipation	便秘	1	N	TE	94	6	N	Not applicable	Recovered
			Insomnia	不眠症	1	N	TE	95		N	Not applicable	Recovered
			Dizziness	浮動性めまい	1	N	TE	99	1	N	Not applicable	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Upper respiratory tract infection	上気道感染	1	N	TE	110	8	N	Not applicable	Recovered
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE	110		N	Not applicable	Ongoing at study termination / withdrawal
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	TE	113	22	N	None	Recovered
			Cytokine release syndrome	サイトカイン放出症候群	2	N	TE	114	1	N	Not applicable	Recovered
			Pneumonia	肺炎	2	N	TE	172		N	Not applicable	Recovered
202003	Australia	64/M/C	Nausea	悪心	2	N	TE	11	18	N	None	Recovered
			Bone pain	骨痛	3	N	TE	11	2	Y	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	57	7	N	Not applicable	Recovered
			Diplopia	複視	1	N	TE	104	21	N	Not applicable	Recovered
203006	Australia	72/M/C	Anorexia	食欲不振	1	N	TE			N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	-1		N	None	
			Constipation	便秘	1	N	TE	10	50	N	None	Recovered
			Bone pain	骨痛	1	N	TE	20	24	N	None	Recovered
			Bone pain	骨痛	2	N	TE	26	18	N	None	Recovered
			Fatigue	疲労	1	N	TE	28	12	N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	39	194	N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	39	11	N	Drug permanently withdrawn	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	39	5	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	43		N	Not applicable	Ongoing at time of death
			Nausea	悪心	1	N	TE	44	1	N	Not applicable	Recovered
			Mobility decreased	運動性低下	1	Y	TE	51	13	N	Not applicable	Recovered
			Diarrhoea	下痢	1	N	TE	57	7	N	Not applicable	Recovered
			Asthenia	無力症	2	N	TE	62	15	N	Not applicable	Recovered
			Constipation	便秘	1	N	TE	63	175	N	Not applicable	Ongoing at time of death
			Gastrooesophageal reflux disease	胃食道逆流性疾患	1	N	TE	63		N	Not applicable	Ongoing at time of death
			Mucosal inflammation	粘膜の炎症	1	N	TE	63	153	N	Not applicable	Recovered
			Agitation	激越	1	N	TE	63	66	N	Not applicable	Recovered
			Fatigue	疲労	4	N	TE	232		N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	237		N	Not applicable	Ongoing at time of death
207002	Australia	81/M/C	Anorexia	食欲不振	2	N	TE			N	None	Lost to follow-up
			Urinary incontinence	尿失禁	2	N	TE			N	None	Lost to follow-up
			Oedema peripheral	末梢性浮腫	1	N	TE	58		N	None	Lost to follow-up
			Swelling face	顔面腫脹	1	N	TE	58		N	None	Lost to follow-up
			Faecal incontinence	便失禁	1	N	TE	104		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dementia	認知症	3	Y	TE	104	7	N	Drug permanently withdrawn	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	137	1	N	Not applicable	Death
212001	Australia	81/M/C	Thrombocytopenia	血小板減少症	1	N	TE	30	50	N	None	Recovered
			Atrial fibrillation	心房細動	2	Y	TE	38	11	N	None	Recovered
			Abdominal pain	腹痛	3	N	TE	59	8	N	Drug administration postponed	Recovered
			Nausea	悪心	3	N	TE	59		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	59	21	N	Drug administration postponed	Recovered
			Bone pain	骨痛	2	N	TE	59		N	Drug administration postponed	Ongoing at time of death
			Dyspnoea	呼吸困難	3	N	TE	59	21	N	Drug administration postponed	Recovered
			Tachycardia	頻脈	3	N	TE	198	68	N	Not applicable	Ongoing at time of death
			Nausea	悪心	2	N	TE	198	68	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	198	68	N	None	Ongoing at time of death
			Muscular weakness	筋力低下	3	N	TE	198	68	N	None	Ongoing at time of death
			Fatigue	疲労	3	Y	TE	205		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dehydration	脱水	3	Y	TE	205	3	N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	205	3	N	Not applicable	Recovered
			Weight decreased	体重減少	1	N	TE	247	19	N	None	Ongoing at time of death
213006	Australia	72/M/C	Constipation	便秘	1	N	TE			N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			N	None	Recovered
			Fatigue	疲労	1	N	TE	1	2	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	3	55	N	None	Recovered
			Ingrowing nail	嵌入爪	1	N	TE	18		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	29	3	Y	None	Recovered
			Fatigue	疲労	1	N	TE	57	3	Y	None	Recovered
			Constipation	便秘	1	N	TE	59	7	N	None	Recovered
			Fatigue	疲労	1	N	TE	85		Y	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	142		N	None	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	4	Y	TE	185	30	N	Not applicable	Recovered with sequelae
			Pneumonia	肺炎	3	Y	TE	188	5	N	Not applicable	Recovered
			Gastrointestinal haemorrhage	胃腸出血	3	Y	TE	196	2	N	Not applicable	Recovered
			Oral candidiasis	口腔カンジダ症	2	N	TE	200		N	Not applicable	Ongoing at time of death
			Postoperative wound infection	術後創感染	3	Y	TE	201	14	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Postoperative wound infection	術後創感染	2	N	TE	214		N	Not applicable	Ongoing at time of death
			Pulmonary embolism	肺塞栓症	4	Y	TE	220	5	N	Not applicable	Death
			Pulmonary embolism	肺塞栓症	5	Y	TE	224	1	N	Not applicable	Death
213009	Australia	76/M/C	Fatigue	疲労	1	N	TE	5	27	Y	None	Not recovered, but no changes expected
			Arthralgia	関節痛	1	N	TE	21	2	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	23	2	N	None	Recovered
			Fatigue	疲労	2	N	TE	31	26	Y	None	Not recovered, but no changes expected
			Lower respiratory tract infection	下気道感染	2	N	TE	32	26	N	None	Recovered
			Fatigue	疲労	1	N	TE	56		Y	None	Not recovered, but no changes expected
			Constipation	便秘	2	N	TE	105	4	N	Not applicable	Recovered
			Febrile neutropenia	発熱性好中球減少症	3	Y	TE	107	7	N	Not applicable	Recovered
			Abdominal pain	腹痛	2	N	TE	107		N	None	Not recovered, but no changes expected
			Diarrhoea	下痢	2	N	TE	108		N	Not applicable	Not recovered, but no changes expected
			Hypophosphataemia	低リン酸血症	3	N	TE	110	4	N	Not applicable	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	111	5	N	Not applicable	Recovered
			Thrombosis	血栓症	2	N	TE	138		N	Not applicable	Not recovered, but no changes expected

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
233003	UK	61/M/C	Anorexia	食欲不振	1	N	Pre	-13	22	N	None	Recovered with sequelae
			Fatigue	疲労	2	N	Pre	1	163	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre	1	29	N	None	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	29	36	Y	None	Recovered
			Bone pain	骨痛	2	N	Pre	29	36	N	None	Ongoing at time of death
			Ageusia	味覚消失	2	N	TE	29	36	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	58	4	N	None	Recovered
			Constipation	便秘	2	N	TE	60		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	64	25	N	None	Recovered
			Bone pain	骨痛	3	N	Pre	64		N	None	Ongoing at time of death
			Muscular weakness	筋力低下	3	N	TE	64		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	92	17	N	None	Recovered
			Tachycardia	頻脈	1	N	TE	92		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	92		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	104	60	N	None	Recovered
			Anaemia	貧血	3	Y	TE	135	3	N	Drug administration postponed	Recovered
			Asthenia	無力症	3	N	TE	135	3	Y	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	138		N	Drug administration postponed	Ongoing at study termination / withdrawal

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dysarthria	構語障害	1	N	TE	145		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	3	N	TE	152	12	N	None	Death
			Cardiac failure	心不全	4	Y	TE	152		N	Drug permanently withdrawn	Ongoing at time of death
			Pleural effusion	胸水	2	N	TE	152		N	Not applicable	Ongoing at time of death
			Nausea	悪心	2	N	TE	159	5	N	Not applicable	Ongoing at time of death
			Anaemia	貧血	5	Y	TE	163	1	N	None	Death
240010	USA	67/M/B	Nausea	悪心	1	N	TE	28	35	N	None	Recovered
			Arthralgia	関節痛	2	N	TE	28	35	N	None	Recovered
			Bone pain	骨痛	2	N	TE	28	35	N	None	Recovered
			Bone pain	骨痛	2	N	TE	28	35	N	None	Recovered
			Pain in extremity	四肢痛	2	N	TE	28	35	N	None	Recovered
			Urinary tract obstruction	尿路閉塞	2	N	TE	49		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	N	TE	56	3	Y	Drug administration postponed	Recovered
			Pericardial effusion	心嚢液貯留	1	N	TE	56		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	56	4	N	None	Recovered
			Gait disturbance	歩行障害	2	N	TE	56		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	56		N	None	Ongoing at study termination / withdrawal
			Urinary tract infection	尿路感染	1	N	TE	56	7	N	None	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	1	N	TE	56		N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	56	4	N	Drug permanently withdrawn	Recovered
			Muscular weakness	筋力低下	1	N	TE	56		N	None	Ongoing at time of death
			Atelectasis	無気肺	1	N	TE	56		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	58	64	Y	Drug administration postponed	Recovered
			Bone pain	骨痛	1	N	TE	59		N	Not applicable	Ongoing at time of death
			Bronchitis	気管支炎	1	N	TE	68	15	N	Not applicable	Recovered
			Productive cough	湿性咳嗽	1	N	TE	68	15	N	Not applicable	Recovered
			Pain in extremity	四肢痛	3	N	TE	82		N	Not applicable	Ongoing at time of death
			Decubitus ulcer	褥瘡性潰瘍	1	N	TE	82		N	Not applicable	Ongoing at time of death
251003	USA	83/M/O	Dyspnoea	呼吸困難	3	N	Pre	-7	2	N	None	Recovered
			Pleural effusion	胸水	2	Y	Pre	-6	1	N	None	Recovered
			Anaemia	貧血	2	N	Pre	-4	3	N	None	Recovered
			Oedema	浮腫	2	N	Pre	-4		N	None	Ongoing at study termination / withdrawal
			Pleural effusion	胸水	1	N	Pre	-4		N	None	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cardiac failure congestive	うっ血性心不全	3	Y	Pre	-3	4	N	Not applicable	Recovered
			Fatigue	疲労	1	N	Pre	-3	2	N	None	Recovered
			Fatigue	疲労	3	N	Pre	-3	4	N	None	Recovered
			Fluid retention	体液貯留	2	N	Pre	-3	4	N	None	Recovered
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	3	Y	Pre	-3	4	N	None	Recovered
			Tachypnoea	頻呼吸	2	N	Pre	-3	1	N	None	Recovered
			Hypotension	低血圧	1	N	Pre	-3		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	Pre	-2	3	N	None	Recovered
			Left ventricular hypertrophy	左室肥大	1	N	Pre	-1		N	None	Ongoing at time of death
			Mitral valve incompetence	僧帽弁閉鎖不全症	1	N	Pre	-1		N	None	Ongoing at time of death
			Lymphopenia	リンパ球減少症	4	Y	Pre	1	6	N	None	Recovered with sequelae
			Dizziness	浮動性めまい	2	N	TE	4		N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	23		N	Not applicable	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	23	2	N	Drug administration postponed	Recovered
			Abdominal pain	腹痛	2	N	TE	24		N	None	Recovered
			Gastritis	胃炎	2	N	TE	24		N	Drug administration postponed	Recovered
			Epigastric discomfort	心窩部不快感	2	N	TE	25	9	N	None	Recovered
			Chills	悪寒	1	N	TE	25	2	N	Drug administration postponed	Recovered

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pyrexia	発熱	1	N	TE	25	1	N	Drug administration postponed	Recovered
			Dyspnoea	呼吸困難	3	N	TE	25	1	N	None	Recovered
			Acute myocardial infarction	急性心筋梗塞	4	Y	TE	26	9	N	Drug administration postponed	Recovered
			Cardiac failure congestive	うっ血性心不全	2	N	TE	26	24	N	Drug administration postponed	Recovered
			Tachycardia	頻脈	3	N	TE	26	1	N	Drug administration postponed	Recovered
			Vomiting	嘔吐	1	N	TE	26		N	Drug administration postponed	Recovered
			Pyrexia	発熱	1	N	TE	26	2	Y	Drug administration postponed	Recovered
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	3	Y	TE	26	9	N	Drug administration postponed	Recovered
			Hypoxia	低酸素症	3	N	TE	26		N	Drug administration postponed	Ongoing at study termination / withdrawal
			Tachypnoea	頻呼吸	3	N	TE	26		N	Drug administration postponed	Ongoing at time of death
			Diabetes mellitus	糖尿病	2	N	TE	27		N	Drug administration postponed	Ongoing at time of death

表 2.7.4.7- 4 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anxiety	不安	2	N	TE	30		N	None	Ongoing at study termination / withdrawal
			Asthenia	無力症	3	N	TE	43		N	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	43		N	Not applicable	Ongoing at study termination / withdrawal
			Haematuria	血尿	2	N	TE	43	2	N	Not applicable	Recovered
			Epistaxis	鼻出血	2	Y	TE	43	4	N	None	Recovered
			Anaemia	貧血	3	N	TE	44	2	N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	49		N	Not applicable	Ongoing at study termination / withdrawal
			Cardiac failure congestive	うっ血性心不全	3	Y	TE	49		N	Not applicable	Ongoing at study termination / withdrawal
			Pneumonia	肺炎	3	N	TE	49		N	Not applicable	Ongoing at study termination / withdrawal
			Dizziness	浮動性めまい	3	N	TE	49		N	Not applicable	Ongoing at study termination / withdrawal
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	3	Y	TE	49		N	Not applicable	Ongoing at study termination / withdrawal
			Chronic respiratory failure	慢性呼吸不全	3	Y	TE	49		N	Not applicable	Ongoing at study termination / withdrawal

表 2.7.4.7- 4　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Orthostatic hypotension	起立性低血圧	3	Y	TE	49		N	Not applicable	Ongoing at study termination / withdrawal

Sex is identified as: M = Male.

Race is identified as: A = Asian, B = Black, C = Caucasian, O = Other.

The unit for "Age" is years.

Phase is identified as: Pre = Pre-Treatment, TE = Treatment-Emergent, Post = Post-Treatment

Source: 5.3.5.1.4 BC1-06_J-table 2/Table 1.4/1

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
001003	Norway	67/M/C	Nausea	悪心	1	N	TE	23	1	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	23	1	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	28	29	Y	None	Not recovered, but no changes expected
			Nausea	悪心	2	N	TE	31	12	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	31	12	Y	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	35	11	Y	None	Recovered
			Nausea	悪心	2	N	TE	56	8	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	56	8	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	56		Y	None	Not recovered, but no changes expected
			Weight decreased	体重減少	2	N	TE	84		Y	None	Not recovered, but no changes expected
			Nausea	悪心	2	N	TE	87	8	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	87	8	Y	None	Recovered
			Nausea	悪心	2	N	TE	114	40	Y	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	2	N	TE	114	40	Y	Not applicable	Recovered with sequelae
			Pathological fracture	病的骨折	2	N	TE	115		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	Y	TE	127	15	N	None	Recovered
			Nausea	悪心	3	Y	TE	153	6	Y	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	3	Y	TE	153	6	Y	Not applicable	Recovered with sequelae
			Nausea	悪心	2	N	TE	158	17	Y	None	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	174	5	Y	Not applicable	Recovered with sequelae

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	3	Y	TE	174	5	Y	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	3	Y	TE	174	5	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	3	N	TE	174	5	Y	Not applicable	Ongoing at study termination / withdrawal
			Infection	感染	1	Y	TE	174	5	Y	Not applicable	Recovered
			Bone pain	骨痛	2	Y	TE	174	5	Y	Not applicable	Recovered
			Nausea	悪心	2	N	TE	178		Y	None	Ongoing at study termination / withdrawal
			General physical health deterioration	全身健康状態低下	2	N	TE	178		Y	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	Y	TE	192	2	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	197	14	Y	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	2	Y	TE	197	14	N	Not applicable	Recovered with sequelae
			Infection	感染	2	Y	TE	197	14	N	Not applicable	Recovered
001012	Norway	52/M/C	Bone pain	骨痛	2	Y	TE	105	2	N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	106		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	Y	TE	141	4	N	Not applicable	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	2	N	TE	166	57	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	Y	TE	184	3	N	Not applicable	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	TE	222		N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	2	N	TE	222		N	Not applicable	Not recovered, but no changes expected
001019	Norway	70/M/C	Ankle fracture	足関節部骨折	2	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE	118	56	Y	None	Recovered
			Chest pain	胸痛	2	Y	TE	133	2	Y	None	Recovered
			Anaemia	貧血	2	N	TE	145	63	Y	Not applicable	Recovered with sequelae
			Dysgeusia	味覚異常	2	N	TE	145	29	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	207	4	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	TE	210		Y	Not applicable	Ongoing at study termination / withdrawal
001021	Norway	66/M/C	Lung infection	肺感染	2	Y	Pre	-13	5	N	Not applicable	Recovered
			Anaemia	貧血	2	N	Pre	1		Y	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	57	1	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dizziness	浮動性めまい	1	N	TE	57		Y	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	112	6	Y	None	Recovered
			Nausea	悪心	2	N	TE	148		Y	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	148		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	156		Y	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	2	N	TE	183		Y	None	Ongoing at study termination / withdrawal
001023	Norway	62/M/C	Bone pain	骨痛	2	N	Pre	1		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	29		Y	None	Ongoing at study termination / withdrawal
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	57		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	TE	57		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	57		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	57	19	N	Drug permanently withdrawn	Death
			Metastases to liver	肝転移	3	Y	TE	57		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	75	1	N	Drug permanently withdrawn	Death
001025	Norway	77/M/C	Bone pain	骨痛	2	Y	Pre	-14	2	N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	57	16	N	None	Recovered
			Nausea	悪心	2	N	TE	69		Y	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	2	N	TE	85		Y	None	Ongoing at study termination / withdrawal
001029	Norway	66/M/C	Diarrhoea	下痢	1	N	TE	3	8	Y	None	Recovered
			Nausea	悪心	2	N	TE	3	4	Y	None	Recovered
			Fatigue	疲労	1	N	TE	57		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	57		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	87	7	Y	Drug administration postponed	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	90	4	Y	Drug administration postponed	Recovered
			Nausea	悪心	2	N	TE	90	4	Y	Drug administration postponed	Recovered
			Dehydration	脱水	2	Y	TE	90	4	Y	Drug administration postponed	Recovered
			Weight decreased	体重減少	2	N	TE	106	29	Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	Y	TE	134	2	Y	Drug permanently withdrawn	Recovered with sequelae
			Leukopenia	白血球減少症	2	Y	TE	134		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	3	Y	TE	134		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	3	N	TE	134		Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	135		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
001035	Norway	75/M/C	Anaemia	貧血	2	N	TE	3	8	Y	None	Recovered
			Nausea	悪心	2	N	TE	3	8	Y	None	Recovered
			Infection	感染	2	Y	TE	3	8	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pathological fracture	病的骨折	3	Y	TE	66	12	N	None	Recovered with sequelae
			Mobility decreased	運動性低下	2	N	TE	77		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	85		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	Y	TE	141	10	Y	Drug administration postponed	Recovered with sequelae
			Medical device complication	医療機器合併症	3	Y	TE	141	10	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	Y	TE	156	10	Y	Drug administration postponed	Recovered with sequelae
			Urinary tract infection	尿路感染	3	Y	TE	156	10	Y	Drug administration postponed	Recovered
			Urinary retention	尿閉	3	Y	TE	189		N	Drug permanently withdrawn	Ongoing at time of death
001041	Norway	63/M/C	Bone pain	骨痛	1	N	TE	29	71	Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	85	29	Y	Drug permanently withdrawn	Recovered with sequelae
			Pyrexia	発熱	2	N	TE	85	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	99		Y	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Diarrhoea	下痢	1	N	TE	107	5	Y	None	Recovered
			Pneumonia	肺炎	2	N	TE	111	17	N	None	Recovered
			Anaemia	貧血	1	N	TE	113	32	Y	Drug permanently withdrawn	Recovered with sequelae
			Weight decreased	体重減少	2	N	TE	113		Y	None	Ongoing at study termination / withdrawal
			Dehydration	脱水	3	Y	TE	115	8	Y	None	Recovered
			Tumour associated fever	腫瘍熱	1	N	TE	115		N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	141	4	Y	Drug permanently withdrawn	Recovered with sequelae
			Metastases to lung	肺転移	3	N	TE	141		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Cough	咳嗽	1	N	TE	141		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	Y	TE	144	6	Y	Drug permanently withdrawn	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	2	Y	TE	144	6	Y	Drug permanently withdrawn	Recovered with sequelae
			Dehydration	脱水	2	Y	TE	144	6	Y	Drug permanently withdrawn	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	149		Y	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
002006	Norway	66/M/C	Bone pain	骨痛	2	N	Pre			N	None	Ongoing at study termination / withdrawal
			Urinary tract infection	尿路感染	3	N	TE	10	10	N	None	Recovered
			Anaemia	貧血	2	N	TE	29	34	N	None	Recovered
			Bone pain	骨痛	1	N	Pre	29	29	N	None	Ongoing at study termination / withdrawal
			Ascites	腹水	1	N	TE	57	6	N	None	Recovered
			Bone pain	骨痛	2	N	Pre	57		N	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	Y	TE	62	18	N	Drug permanently withdrawn	Recovered with sequelae
			Fungal infection	真菌感染	2	N	TE	76	5	N	None	Recovered
			Anxiety	不安	2	N	TE	77		N	None	Not recovered, but no changes expected
			Sepsis	敗血症	4	Y	TE	79	5	N	Not applicable	Death
			Anaemia	貧血	2	N	TE	81	2	N	None	Recovered
			Sepsis	敗血症	5	Y	TE	83	1	N	Not applicable	Death
002008	Norway	69/M/C	Nausea	悪心	1	N	TE	29	3	N	None	Recovered
			Nausea	悪心	1	N	TE	34		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	105	21	N	None	Recovered
			Constipation	便秘	1	N	TE	120		Y	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	125	5	N	None	Recovered
			Hyperglycaemia	高血糖	4	Y	TE	159	4	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	161	3	N	Not applicable	Recovered
			Ascites	腹水	1	N	TE	176		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	183	2	N	Not applicable	Recovered
			Infection	感染	2	N	TE	183	3	N	Not applicable	Recovered
			Infection	感染	3	Y	TE	185	5	N	Not applicable	Recovered
			Anaemia	貧血	4	Y	TE	216	2	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	4	Y	TE	216		Y	Not applicable	Ongoing at time of death
002009	Norway	73/M/C	Diarrhoea	下痢	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	2	N	TE	2	3	Y	None	Recovered
			Osteoporosis	骨粗鬆症	3	Y	TE	39	6	N	None	Recovered with sequelae
			Atrial fibrillation	心房細動	2	N	TE	71	2	N	None	Recovered
			Pneumonia	肺炎	2	N	TE	71	14	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	71	14	N	None	Recovered with sequelae
			Urinary retention	尿閉	2	N	TE	71	14	N	None	Recovered

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oral infection	口腔感染	2	N	TE	79	5	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	79	2	N	None	Recovered
			Bone pain	骨痛	3	N	TE	113		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	132	47	N	None	Recovered with sequelae
			Constipation	便秘	2	N	TE	225		N	None	Not recovered, but no changes expected
002013	Norway	69/M/C	Vision blurred	霧視	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	2	5	Y	None	Recovered
			Metastases to skin	皮膚転移	1	N	TE	57		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	85		N	None	Ongoing at study termination / withdrawal
			Metastases to soft tissue	軟部組織転移	1	N	TE	86		N	None	Ongoing at time of death
			Cerebral haemorrhage	脳出血	3	Y	TE	100	38	Y	Drug permanently withdrawn	Death
			Anaemia	貧血	2	N	TE	110		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	111		Y	Not applicable	Ongoing at time of death
			Cerebral haemorrhage	脳出血	5	Y	TE	137	1	Y	Drug permanently withdrawn	Death
002017	Norway	79/M/C	Nausea	悪心	1	N	TE	4	2	Y	None	Recovered

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	2	N	TE	28	4	Y	None	Recovered
			Dizziness	浮動性めまい	2	N	TE	28	4	Y	None	Recovered
			Localised infection	限局性感染	2	N	TE	54	116	N	None	Recovered
			Nausea	悪心	2	N	TE	57	4	Y	None	Recovered
			Dizziness	浮動性めまい	2	N	TE	57	4	Y	None	Recovered
			Wound	創傷	2	N	TE	68	122	N	None	Recovered
			Supraventricular tachycardia	上室性頻脈	3	Y	TE	176	7	N	Not applicable	Recovered
			Urinary tract infection	尿路感染	2	N	TE	177	7	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	N	TE	178	4	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	205	10	N	None	Recovered
			Atrial flutter	心房粗動	2	Y	TE	230	4	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	N	TE	230	3	N	Not applicable	Recovered
003001	Norway	64/M/C	Dizziness	浮動性めまい	1	N	TE			Y	None	Ongoing at study termination / withdrawal
			Constipation	便秘	1	N	TE	1	21	Y	None	Recovered
			Nausea	悪心	1	N	TE	2	82	Y	None	Recovered
			Insomnia	不眠症	2	N	TE	2		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	8	18	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	28	98	N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	Y	TE	84		Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Leukopenia	白血球減少症	1	N	TE	84		Y	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	1	N	TE	84		Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	N	TE	112	2	Y	Drug administration postponed	Recovered
			Neutropenia	好中球減少症	3	Y	TE	112	3	Y	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	112		Y	Drug administration postponed	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	125	52	Y	Drug permanently withdrawn	Recovered with sequelae
			Leukopenia	白血球減少症	1	N	TE	125		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	1	N	TE	125		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	3	N	TE	125		N	None	Ongoing at study termination / withdrawal
			Pyrexia	発熱	2	N	TE	131	5	Y	Not applicable	Recovered
003005	Norway	58/M/C	Spinal cord compression	脊髄圧迫	2	N	TE			N	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nasopharyngitis	鼻咽頭炎	2	N	Pre	-1	9	N	None	Recovered
			Bone pain	骨痛	1	N	Pre	-1	9	N	None	Recovered
			Nausea	悪心	1	N	TE	29	30	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	64	84	Y	None	Recovered
			Nausea	悪心	1	N	TE	87	33	Y	None	Recovered
			Anaemia	貧血	2	N	TE	119	123	Y	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	1	N	TE	119		Y	None	Ongoing at study termination / withdrawal
			Muscular weakness	筋力低下	2	N	TE	147		N	None	Ongoing at study termination / withdrawal
			Pneumonia	肺炎	3	Y	TE	187	3	N	Not applicable	Recovered
			Pneumonia	肺炎	1	N	TE	189	25	N	Not applicable	Recovered with sequelae
			Pleural effusion	胸水	3	N	TE	209	5	N	Not applicable	Recovered with sequelae
			Hypovitaminosis	ビタミン欠乏症	1	N	TE	211		N	Not applicable	Ongoing at time of death
			Pleural effusion	胸水	3	Y	TE	213	6	N	Not applicable	Recovered with sequelae
			Insomnia	不眠症	1	N	TE	221		N	Not applicable	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	221		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	1	N	TE	241		Y	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
003007	Norway	51/M/C	Anxiety	不安	1	N	Pre			N	None	Ongoing at study termination / withdrawal
			Radiation associated pain	放射線関連痛	2	N	TE	17	4	N	None	Recovered
			Hypoaesthesia	感覚鈍麻	2	N	TE	20	123	N	None	Recovered with sequelae
			Radiation associated pain	放射線関連痛	3	N	TE	32	55	N	None	Ongoing at study termination / withdrawal
			Radiation associated pain	放射線関連痛	2	N	TE	86		N	None	Ongoing at study termination / withdrawal
			Hypoaesthesia	感覚鈍麻	1	N	TE	86	60	N	None	Recovered
			Neuralgia	神経痛	1	N	TE	86	29	N	None	Recovered
			Micturition urgency	尿意切迫	2	N	TE	144	2	N	Not applicable	Recovered
			Micturition urgency	尿意切迫	1	Y	TE	145	5	N	Not applicable	Recovered
			Hydronephrosis	水腎症	3	N	TE	195	39	N	Not applicable	Recovered
003014	Norway	55/M/C	Diarrhoea	下痢	1	N	TE	1		Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	27	86	Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	2	N	TE	126	49	N	Not applicable	Recovered with sequelae
			Nausea	悪心	2	N	TE	140	5	N	None	Recovered
			Nausea	悪心	3	N	TE	144	5	N	None	Recovered
			Nausea	悪心	1	N	TE	148	25	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	174	1	N	Not applicable	Recovered
			Musculoskeletal pain	筋骨格痛	3	Y	TE	174	21	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Insomnia	不眠症	2	N	TE	174		N	Not applicable	Ongoing at time of death
			Tooth extraction	抜歯	2	N	TE	176	1	N	Not applicable	Recovered
			Thrombosis	血栓症	3	N	TE	187		N	Not applicable	Not recovered, but no changes expected
			Musculoskeletal pain	筋骨格痛	3	Y	TE	201	17	N	Not applicable	Recovered with sequelae
			Depression	うつ病	2	N	TE	209		N	Not applicable	Ongoing at study termination / withdrawal
003015	Norway	72/M/C	Constipation	便秘	2	N				N	None	Recovered
			Oral candidiasis	口腔カンジダ症	1	N	TE	15	43	N	None	Recovered
			Sinus tachycardia	洞性頻脈	3	N	TE	57	29	N	None	Not recovered, but no changes expected
			Rib fracture	肋骨骨折	2	Y	TE	82	4	N	None	Recovered with sequelae
			Sinus tachycardia	洞性頻脈	1	N	TE	85		N	None	Not recovered, but no changes expected
			Herpes zoster	帯状疱疹	3	N	TE	98	9	N	None	Recovered
			Herpes zoster	帯状疱疹	1	N	TE	106	36	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	141		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	1	N	TE	160	9	N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	168	9	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	168	9	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cough	咳嗽	1	N	TE	176		N	Not applicable	Ongoing at study termination / withdrawal
003016	Norway	77/M/C	Spinal compression fracture	脊椎圧迫骨折	1	N	TE	95	5	N	None	Recovered
			Constipation	便秘	3	Y	TE	99	2	Y	None	Recovered
			Nausea	悪心	2	N	TE	99	49	N	None	Recovered
			Spinal compression fracture	脊椎圧迫骨折	3	Y	TE	99	7	N	None	Recovered
			Insomnia	不眠症	1	N	TE	99		N	None	Not recovered, but no changes expected
			Constipation	便秘	1	N	TE	100	1	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	105	38	N	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	142	6	N	None	Recovered with sequelae
			Osteoporosis	骨粗鬆症	2	N	TE	143		N	Not applicable	Not recovered, but no changes expected
			Musculoskeletal pain	筋骨格痛	1	N	TE	147		N	None	
			Constipation	便秘	2	N	TE	197		N	Not applicable	Ongoing at study termination / withdrawal
003017	Norway	63/M/C	Nausea	悪心	1	N	TE	4	54	Y	None	Recovered
			Constipation	便秘	2	N	TE	10	48	Y	None	Recovered
			Hyperchlorhydria	胃酸過多	1	N	TE	29		Y	None	Ongoing at study termination / withdrawal
			Constipation	便秘	3	N	TE	57	110	Y	None	Recovered
			Nausea	悪心	2	N	TE	57	110	Y	None	Recovered
			Fatigue	疲労	2	N	TE	84	83	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

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			Musculoskeletal pain	筋骨格痛	2	N	TE	84	23	N	None	Recovered with sequelae
			Cystitis	膀胱炎	2	N	TE	106	11	N	None	Recovered
			Musculoskeletal pain	筋骨格痛	2	Y	TE	106	4	N	None	Recovered with sequelae
			Musculoskeletal pain	筋骨格痛	2	N	TE	109	4	N	None	Recovered
			Musculoskeletal pain	筋骨格痛	3	Y	TE	112	8	N	None	Recovered
			Depression	うつ病	2	N	TE	112	50	N	None	Recovered
			Nausea	悪心	1	N	TE	116	4	Y	None	Recovered
			Anaemia	貧血	2	N	TE	137	1	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	166		N	None	Ongoing at study termination / withdrawal
			Femoral neck fracture	大腿骨頚部骨折	3	Y	TE	191	7	N	Not applicable	Recovered
003018	Norway	71/M/C	Constipation	便秘	2	N	TE			N	Not applicable	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	2	N	TE	2	134	N	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	1	N	TE	57	102	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	116	57	N	Not applicable	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	3	N	TE	135	24	N	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	2	N	TE	147	72	N	Not applicable	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	3	Y	TE	158	5	N	Not applicable	Recovered with sequelae
			Pelvic pain	骨盤痛	3	N	TE	162		Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

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			Nausea	悪心	2	N	TE	172		N	Not applicable	Ongoing at time of death
			Weight decreased	体重減少	3	N	TE	172		N	Not applicable	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	3	Y	TE	172	38	N	Not applicable	Recovered with sequelae
			Gastric ulcer	胃潰瘍	3	N	TE	181		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	187	1	Y	Not applicable	Recovered
			Depression	うつ病	3	N	TE	208		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	218	1	N	Not applicable	Death
004001	Norway	60/M/C	Dysgeusia	味覚異常	1	N	TE	2	28	Y	None	Recovered
			Anaemia	貧血	1	N	TE	92	24	Y	None	Recovered
			Anaemia	貧血	1	N	TE	92	24	Y	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	92	113	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	120		Y	None	Ongoing at time of death
			Respiratory tract infection viral	ウイルス性気道感染	2	N	TE	134	11	N	None	Recovered
			Anaemia	貧血	2	N	TE	144		Y	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	2	N	TE	148	37	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	148	12	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	148	12	Y	None	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

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			Pancytopenia	汎血球減少症	3	N	TE	155	5	Y	Not applicable	Recovered with sequelae
			Pancytopenia	汎血球減少症	3	Y	TE	159	11	Y	Not applicable	Recovered with sequelae
			Oedema	浮腫	2	Y	TE	159	11	Y	Not applicable	Recovered with sequelae
			Dyspnoea	呼吸困難	3	Y	TE	159	11	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	Y	TE	159	11	Y	Not applicable	Recovered with sequelae
			Pancytopenia	汎血球減少症	2	N	TE	169	16	Y	Not applicable	Recovered with sequelae
			Dyspnoea	呼吸困難	2	N	TE	169	16	Y	Not applicable	Recovered
			Pleural effusion	胸水	1	N	TE	170	15	Y	Not applicable	Recovered
			Pancytopenia	汎血球減少症	3	Y	TE	184	15	Y	Not applicable	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	3	Y	TE	184	15	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	Y	TE	184	15	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	Y	TE	184	15	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	198	7	Y	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	198	7	Y	Not applicable	Recovered with sequelae
			Pancytopenia	汎血球減少症	4	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	204		Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	3	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	3	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Pleural effusion	胸水	2	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Renal failure	腎不全	5	Y	TE	208	1	N	Not applicable	Death
005002	Norway	75/M/C	Bone pain	骨痛	1	N	TE			N	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	85		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	162	36	N	Not applicable	Recovered
			Pneumonia	肺炎	3	Y	TE	169	15	N	Not applicable	Recovered
			Atrial fibrillation	心房細動	2	Y	TE	180	1	N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	197	7	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	198	6	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	1	N	TE	203		Y	Not applicable	Ongoing at time of death
			Pulmonary embolism	肺塞栓症	4	Y	TE	222	5	Y	Not applicable	Death
			Pulmonary embolism	肺塞栓症	5	Y	TE	226	1	Y	Not applicable	Death
006001	Norway	76/M/C	Bone pain	骨痛	2	N	TE	75	20	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	82	13	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary tract infection	尿路感染	3	Y	TE	82	13	N	Drug administration postponed	Recovered
			Bone pain	骨痛	3	N	TE	113	27	N	None	Recovered
			Renal failure	腎不全	3	Y	TE	113	8	N	None	Recovered
			Reflux gastritis	逆流性胃炎	1	N	TE	114		N	None	Recovered
			Anaemia	貧血	2	N	TE	167	2	N	Not applicable	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	167	86	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	167	3	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	1	N	TE	168		N	Not applicable	Ongoing at time of death
			Hypomagnesaemia	低マグネシウム血症	2	N	TE	191	62	N	None	Not recovered, but no changes expected
			Hypomagnesaemia	低マグネシウム血症	1	N	TE	252		N	None	Not recovered, but no changes expected
006004	Norway	53/M/C	Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE			Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	2	15	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	2	4	Y	None	Recovered
			Nausea	悪心	2	N	TE	15	68	Y	None	Recovered
			Anorexia	食欲不振	2	N	TE	56		N	None	Not recovered, but no changes expected
			Insomnia	不眠症	2	N	TE	166		N	None	Not recovered, but no changes expected
			Upper respiratory tract infection	上気道感染	2	Y	TE	180	10	N	Not applicable	Recovered
			Oesophagitis	食道炎	2	N	TE	217		N	Not applicable	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
006005	Norway	72/M/C	Diarrhoea	下痢	1	N	TE	3	1	Y	None	Recovered
			Pyrexia	発熱	2	Y	TE	22	7	N	None	Recovered
			Dehydration	脱水	2	Y	TE	22	7	N	None	Recovered
			Vomiting	嘔吐	1	Y	TE	38	1	N	None	Recovered
			Pyrexia	発熱	2	Y	TE	38	1	Y	None	Recovered
			Dehydration	脱水	2	Y	TE	38	6	Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	2	Y	TE	38	6	N	None	Recovered
			Vomiting	嘔吐	2	Y	TE	62	11	Y	None	Recovered
			Dehydration	脱水	2	Y	TE	62	11	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	62	11	N	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	85	15	N	None	Recovered with sequelae
			Dyspepsia	消化不良	2	N	TE	86		N	None	Ongoing at time of death
			Depression	うつ病	2	N	TE	99		N	None	Ongoing at time of death
			Pneumonia	肺炎	3	Y	TE	176	2	N	Not applicable	Death
			Bone pain	骨痛	3	Y	TE	176		N	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	5	Y	TE	177	1	N	Not applicable	Death
006008	Norway	70/M/C	Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	Pre	-1	29	N	None	Ongoing at time of death
			Hydronephrosis	水腎症	3	Y	Pre	-1	3	N	None	Recovered
			Constipation	便秘	2	N	TE	2	25	Y	None	Recovered
			Nausea	悪心	1	N	TE	2	6	Y	None	Recovered
			Fatigue	疲労	2	N	TE	2	6	N	None	Recovered
			Hyperhidrosis	多汗症	2	N	TE	2	6	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	17	11	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	Pre	28		N	None	Ongoing at time of death
			Small intestinal obstruction	小腸閉塞	3	Y	TE	55	3	N	Drug administration postponed	Recovered
			Death	死亡	5	Y	TE	60	1	N	Drug permanently withdrawn	Death
006009	Norway	75/M/C	Dizziness	浮動性めまい	1	N	TE			N	None	Recovered
			Diarrhoea	下痢	1	N	TE	2	1	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	2	2	Y	None	Recovered
			Fatigue	疲労	3	Y	TE	16	9	Y	None	Recovered
			Dehydration	脱水	2	N	TE	19	6	Y	None	Recovered
			Influenza	インフルエンザ	1	N	TE	43	8	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	73	12	Y	None	Recovered
			Nausea	悪心	1	N	TE	84	37	N	None	Recovered
			Fatigue	疲労	2	N	TE	84		Y	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	84	29	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	84	29	Y	None	Ongoing at study termination / withdrawal
			Mood altered	気分変化	1	N	TE	84		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	107		N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	112	5	Y	None	Recovered

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	2	N	TE	112		Y	None	Ongoing at study termination / withdrawal
			Cachexia	悪液質	2	N	TE	112		N	Not applicable	Ongoing at study termination / withdrawal
006011	Norway	68/M/C	Weight decreased	体重減少	2	N	TE	2		Y	None	Not recovered, but no changes expected
			Diarrhoea	下痢	1	N	TE	8	10	N	None	Recovered
			Nausea	悪心	1	N	TE	8	10	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	8	10	N	None	Recovered
			Bone pain	骨痛	2	N	TE	28	29	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	36	10	N	None	Recovered
			Nausea	悪心	1	N	TE	36	10	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	36	10	N	None	Recovered
			Bone pain	骨痛	2	N	TE	103	6	N	None	Recovered
			Nausea	悪心	1	N	TE	114	27	Y	None	Recovered
			Fatigue	疲労	1	N	TE	114		Y	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	114	27	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	140	16	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	Y	TE	155	13	N	Not applicable	Recovered with sequelae
			Nausea	悪心	2	N	TE	157	11	N	None	Recovered
			Anaemia	貧血	2	N	TE	225		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	225	64	N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	225	4	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	4	N	TE	288		N	Not applicable	Ongoing at time of death
006016	Norway	59/M/C	Thrombocytopenia	血小板減少症	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	92	8	N	None	Recovered
			Venous thrombosis	静脈血栓症	2	N	TE	105		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	132		N	None	Ongoing at time of death
			Prostatic haemorrhage	前立腺出血	3	Y	TE	132	29	N	Drug administration postponed	Recovered
			Bone pain	骨痛	2	N	TE	141		N	None	Ongoing at time of death
			Catheter related infection	カテーテル関連感染	3	Y	TE	166		N	Drug permanently withdrawn	Recovered
006017	Norway	59/M/C	Nausea	悪心	1	N	TE	10	3	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	10	1	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	10	75	N	None	Recovered
			Bone pain	骨痛	2	N	TE	10	75	N	None	Recovered
			Anaemia	貧血	3	Y	TE	84	6	Y	-	
			Thrombocytopenia	血小板減少症	4	Y	TE	84	58	Y	Drug permanently withdrawn	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	84		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	Y	TE	89	3	Y	-	
			Anaemia	貧血	2	Y	TE	91	8	Y	-	

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	98	13	Y	-	
			Anaemia	貧血	2	Y	TE	110	2	Y	-	
			Anaemia	貧血	3	Y	TE	111	2	Y	-	
			Anaemia	貧血	2	Y	TE	112	2	Y	-	
			Anaemia	貧血	1	Y	TE	113	2	Y	-	
			Cerebral haemorrhage	脳出血	2	Y	TE	113		Y	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	114	19	Y	-	
			Anaemia	貧血	1	Y	TE	132	3	Y	-	
			Anaemia	貧血	2	Y	TE	134	2	Y	-	
			Anaemia	貧血	1	Y	TE	135	2	Y	-	
			Anaemia	貧血	2	Y	TE	136	3	Y	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	1	Y	TE	138	3	Y	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	140		Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	Y	TE	141	2	Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	Y	TE	142		Y	Drug permanently withdrawn	Ongoing at time of death
006018	Norway	62/M/C	Pyrexia	発熱	2	N	TE	25	2	Y	None	Recovered
			Pyrexia	発熱	1	N	TE	26	2	Y	None	Recovered
			Weight decreased	体重減少	1	N	TE	33	29	N	None	Not recovered, but no changes expected
			Nausea	悪心	2	N	TE	37	2	N	None	Recovered

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	2	N	TE	37	2	N	None	Recovered
			Pyrexia	発熱	2	Y	TE	37	8	Y	None	Recovered
			Anaemia	貧血	2	N	TE	40	3	Y	None	Recovered
			Nausea	悪心	2	N	TE	48	29	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	48	2	N	None	Recovered
			Pyrexia	発熱	2	Y	TE	49	21	Y	None	Recovered
			Anaemia	貧血	2	N	TE	59	2	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	61		N	None	Not recovered, but no changes expected
			Pyrexia	発熱	2	Y	TE	76	2	Y	None	Recovered with sequelae
			Dyspnoea	呼吸困難	1	N	TE	76	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	89	2	N	None	Recovered
			Bone pain	骨痛	2	N	TE	89	26	N	None	Recovered
			Anaemia	貧血	2	N	TE	114	20	N	-	
			Pyrexia	発熱	2	N	TE	114	4	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	114	7	N	None	Recovered
			Pyrexia	発熱	2	N	TE	120		Y	None	Recovered
			Spinal cord compression	脊髄圧迫	2	Y	TE	132	7	N	None	Recovered
			Anaemia	貧血	1	N	TE	133	1	N	-	
			Anaemia	貧血	2	N	TE	133	9	N	-	
			Anaemia	貧血	1	N	TE	141	28	N	-	
			Anaemia	貧血	2	N	TE	168	9	N	-	
			Leukopenia	白血球減少症	2	N	TE	168	15	N	None	Recovered
			Neutropenia	好中球減少症	1	N	TE	168	14	N	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	168	31	N	None	Recovered
			Anaemia	貧血	1	N	TE	176	7	N	-	
			Anorexia	食欲不振	1	N	TE	176	14	N	None	Recovered
			Bone pain	骨痛	2	N	TE	176	14	N	None	Recovered
			Bone pain	骨痛	2	N	TE	176	54	N	None	Recovered
			Diplopia	複視	2	N	TE	177	53	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	181	10	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	TE	182	8	N	-	
			Leukopenia	白血球減少症	1	N	TE	182	8	N	None	Recovered
			Pyrexia	発熱	2	N	TE	182	1	Y	None	Recovered
			Pyrexia	発熱	1	N	TE	182	5	Y	None	Recovered
			Anaemia	貧血	1	N	TE	189	10	N	-	
			Leukopenia	白血球減少症	3	N	TE	189	41	N	None	Recovered
			Neutropenia	好中球減少症	2	N	TE	189	10	N	None	Recovered
			Bone pain	骨痛	1	N	TE	190	40	N	None	Recovered
			Anaemia	貧血	2	N	TE	198	35	N	None	Not recovered, but no changes expected
			Neutropenia	好中球減少症	3	N	TE	198	32	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	198	32	N	None	Recovered
			Diplopia	複視	1	N	TE	229		N	None	Recovered
			Anaemia	貧血	1	N	TE	232		N	None	Not recovered, but no changes expected
006020	Norway	77/M/C	Nausea	悪心	1	N	TE			N	None	Recovered
			Anorexia	食欲不振	1	N	TE	28	134	N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	64	36	N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	2	N	TE	99		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	161		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	198	22	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	TE	205	6	N	Not applicable	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	210		N	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	219		N	None	Not recovered, but no changes expected
			Constipation	便秘	2	N	TE	232	3	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	232	4	N	Not applicable	Recovered with sequelae
006024	Norway	67/M/C	Gastrointestinal pain	消化器痛	3	Y	Pre	-9	2	N	None	Recovered
			Constipation	便秘	2	N	Pre	-1	29	N	None	Recovered
			Fatigue	疲労	2	N	TE	28	92	N	None	Recovered
			Arthralgia	関節痛	1	N	TE	91	29	N	None	Not recovered, but no changes expected
			Paraesthesia	錯感覚	1	N	TE	91	29	N	None	Recovered
			Arthralgia	関節痛	2	N	TE	119	36	N	None	Not recovered, but no changes expected
			Arthralgia	関節痛	1	N	TE	154		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	182	64	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	245		N	None	Not recovered, but no changes expected
006026	Norway	71/M/C	Nausea	悪心	1	N	TE			Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	2	8	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	55	10	N	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	64	11	N	None	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	70	3	Y	-	Ongoing at study termination / withdrawal
			Insomnia	不眠症	2	N	TE	71		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	72		Y	-	Ongoing at study termination / withdrawal
			Accidental overdose	偶発的過量投与	2	Y	TE	75	2	N	None	Recovered
			Infection	感染	3	N	TE	87		N	Not applicable	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	Y	TE	87		N	None	Ongoing at study termination / withdrawal
			Confusional state	錯乱状態	2	N	TE	87		N	None	Ongoing at study termination / withdrawal
006030	Norway	64/M/C	Insomnia	不眠症	1	N	TE			N	None	Lost to follow-up
			Spinal cord compression	脊髄圧迫	3	Y	TE	12	7	N	Drug administration postponed	Recovered
			Weight decreased	体重減少	2	N	TE	47	57	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	62	14	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	103	29	N	None	Recovered
			Bone pain	骨痛	1	N	TE	103		Y	None	Ongoing at study termination / withdrawal
			Leukopenia	白血球減少症	2	N	TE	131	29	Y	None	Recovered
			Neutropenia	好中球減少症	2	N	TE	131	29	Y	None	Recovered
			Leukopenia	白血球減少症	1	N	TE	159	92	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neutropenia	好中球減少症	1	N	TE	159	31	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	159		Y	None	Ongoing at study termination / withdrawal
			Metastases to central nervous system	中枢神経系転移	3	Y	TE	184	27	N	Not applicable	Recovered with sequelae
			Nausea	悪心	2	N	TE	195		N	Not applicable	Recovered
			Vomiting	嘔吐	2	N	TE	195		N	Not applicable	Recovered
			Dysarthria	構語障害	2	N	TE	195	16	N	Not applicable	Recovered
006032	Norway	77/M/C	Musculoskeletal pain	筋骨格痛	1	Y	Pre	-5	2	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	N	Pre	-1	29	N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	28		N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	1	N	TE	30	62	N	None	Recovered
			Nausea	悪心	1	N	TE	31	4	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	31	4	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	91		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	91	65	N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	92	64	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	119	37	N	None	Recovered
			Urinary retention	尿閉	2	N	TE	119		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	155		N	None	Ongoing at time of death
006036	Norway	76/M/C	Patella fracture	膝蓋骨骨折	2	Y	TE	12	2	N	None	Recovered with sequelae
			Patella fracture	膝蓋骨骨折	2	N	TE	13	16	N	None	Recovered
			Anaemia	貧血	1	N	TE	28	85	N	-	
			Neutropenia	好中球減少症	1	N	TE	28	113	N	None	Recovered
			Nausea	悪心	2	N	TE	28	29	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	28	57	N	None	Recovered
			Anorexia	食欲不振	2	N	TE	28	85	N	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	56		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	56	85	N	None	Recovered with sequelae
			Oedema genital	性器浮腫	2	N	TE	80	5	N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	84	57	N	None	Recovered
			Oedema genital	性器浮腫	1	N	TE	84	57	N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	112	72	N	-	
			Nausea	悪心	1	N	TE	140		N	None	Ongoing at time of death
			Localised oedema	限局性浮腫	1	N	TE	140	18	N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	140	18	N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	140		N	None	Ongoing at time of death
			Oedema genital	性器浮腫	2	N	TE	140		N	None	Ongoing at time of death

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Lymphadenopathy mediastinal	縦隔リンパ節腫脹	2	N	TE	154		N	None	Ongoing at time of death
			Metastases to lung	肺転移	2	N	TE	154		N	None	Ongoing at time of death
			Localised oedema	限局性浮腫	2	N	TE	157		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	157		N	None	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	TE	170	8	N	None	Recovered
			Anaemia	貧血	1	N	TE	183	15	N	-	
			Pleural effusion	胸水	2	N	TE	196	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	197	5	N	-	
			Haematuria	血尿	3	Y	TE	197	21	N	Not applicable	Recovered
			Pneumonia	肺炎	2	N	TE	200	19	N	None	Recovered
			Anaemia	貧血	1	N	TE	201	2	N	-	
			Anaemia	貧血	2	N	TE	202	2	N	-	
			Anaemia	貧血	1	N	TE	203	4	N	-	
			Anaemia	貧血	2	N	TE	206	3	N	-	
			Anaemia	貧血	1	N	TE	208	5	N	-	
			Anaemia	貧血	2	N	TE	212	2	N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	213		N	None	Ongoing at time of death
006038	Norway	60/M/C	Bone pain	骨痛	3	Y	Pre	-46	3	N	Not applicable	Recovered
			Pyelonephritis	腎盂腎炎	3	Y	TE	61	10	N	None	Recovered
			Constipation	便秘	2	N	TE	63		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	64	2	N	-	

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	65	13	N	-	
			Anaemia	貧血	2	N	TE	77	28	N	-	
			Vomiting	嘔吐	2	N	TE	77	3	Y	None	Recovered
			General physical health deterioration	全身健康状態低下	3	Y	TE	77	16	N	Drug administration postponed	Recovered with sequelae
			Infection	感染	3	Y	TE	77	16	N	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	78	18	N	Not applicable	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	78	18	N	None	Recovered with sequelae
			Pyrexia	発熱	1	N	TE	79	8	Y	None	Recovered
			Pyrexia	発熱	2	N	TE	86	2	Y	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	90		N	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	2	N	TE	95	7	N	Not applicable	Ongoing at study termination / withdrawal
			Pyrexia	発熱	1	N	TE	95	3	Y	None	Recovered
			Bone pain	骨痛	3	Y	TE	95	11	N	None	Recovered with sequelae
			Pyrexia	発熱	2	N	TE	97	4	Y	None	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	101		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	N	TE	104		N	Not applicable	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	105		N	None	Ongoing at study termination / withdrawal
006039	Norway	72/M/C	Nausea	悪心	1	N	TE	2	8	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	72	36	N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	82	26	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	99	34	N	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	2	N	TE	99		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	111	11	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	111	11	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	111	11	N	None	Recovered
			Constipation	便秘	2	N	TE	131	7	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	N	TE	131		N	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	Y	TE	131		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Urinary retention	尿閉	2	N	TE	131		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	N	TE	132	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	133	9	N	None	Recovered
006040	Norway	72/M/C	Pain	疼痛	1	N	Pre	-1	29	N	None	Recovered
			Bone pain	骨痛	2	N	TE	84	14	N	None	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	97	4	N	None	Recovered with sequelae
			Insomnia	不眠症	2	N	TE	97		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	98	5	N	None	Recovered
			Bone pain	骨痛	2	N	TE	99	9	Y	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	102	5	N	None	Recovered
			Vomiting	嘔吐	2	Y	TE	102	10	N	None	Recovered
			Infection	感染	3	N	TE	102	6	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	105	7	N	None	Recovered
			Nausea	悪心	1	N	TE	106	6	N	None	Recovered
			Infection	感染	2	N	TE	107	3	N	None	Recovered
			Bone pain	骨痛	1	N	TE	107		Y	None	Ongoing at study termination / withdrawal
			Infection	感染	1	N	TE	109	3	N	None	Recovered
			Nausea	悪心	2	N	TE	117	5	Y	None	Recovered
			Vomiting	嘔吐	2	Y	TE	117	8	N	None	Recovered
			Infection	感染	3	N	TE	117	5	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	119		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	121	9	Y	None	Recovered
			Infection	感染	2	N	TE	121	11	Y	None	Recovered
			Duodenitis	十二指腸炎	1	N	TE	124		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	129	3	Y	None	Recovered
			Vomiting	嘔吐	2	Y	TE	129	3	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	2	N	TE	136		Y	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	3	Y	TE	136		N	None	Ongoing at study termination / withdrawal
			Infection	感染	2	N	TE	136		N	None	Ongoing at study termination / withdrawal
			Hypomagnesaemia	低マグネシウム血症	1	N	TE	138		N	None	Ongoing at study termination / withdrawal
			Constipation	便秘	2	N	TE	140		Y	None	Ongoing at study termination / withdrawal
			Pulmonary oedema	肺水腫	2	N	TE	141	3	N	None	Recovered
006041	Norway	56/M/C	Nausea	悪心	1	N	TE	1	8	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	8	161	Y	None	Recovered
			Nausea	悪心	1	N	TE	29	19	Y	None	Recovered
			Nausea	悪心	1	N	TE	65	14	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	65	14	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	98	71	Y	None	Recovered
			Nausea	悪心	1	N	TE	99	4	Y	None	Recovered
			Pneumonia	肺炎	2	Y	TE	104	6	N	None	Recovered
			Nausea	悪心	1	N	TE	135	59	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	135	35	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	169	25	Y	None	Recovered
			Pyrexia	発熱	1	N	TE	173	4	Y	Not applicable	Recovered
			Infection	感染	2	Y	TE	173	8	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	173	4	N	Not applicable	Recovered
			Leukopenia	白血球減少症	2	N	TE	176	21	Y	Not applicable	Recovered
			Neutropenia	好中球減少症	1	N	TE	177	2	Y	Not applicable	Recovered
			Neutropenia	好中球減少症	2	N	TE	178	19	Y	Not applicable	Recovered
			Leukopenia	白血球減少症	1	N	TE	196	48	Y	Not applicable	Recovered
			Neutropenia	好中球減少症	1	N	TE	196	48	Y	Not applicable	Recovered
			Pyrexia	発熱	1	N	TE	243	4	N	Not applicable	Recovered
			Infection	感染	3	Y	TE	243	38	N	Not applicable	Recovered
			Cough	咳嗽	1	N	TE	243	4	N	Not applicable	Recovered
			Hypotension	低血圧	2	N	TE	243	1	N	Not applicable	Recovered
006046	Norway	76/M/C	Dizziness	浮動性めまい	1	N	TE			N	Not applicable	Recovered
			Anaemia	貧血	1	N	Pre	-1	59	N	None	
			Bone pain	骨痛	1	N	TE	28	57	N	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	56	3	Y	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	58	5	N	None	
			Leukopenia	白血球減少症	2	N	TE	58	3	Y	None	Recovered
			Nausea	悪心	2	N	TE	58	3	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	58	2	Y	None	Recovered
			Pyrexia	発熱	3	Y	TE	58	3	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pyrexia	発熱	1	N	TE	58	2	N	None	Recovered
			Dyspnoea	呼吸困難	2	Y	TE	58	3	Y	None	Recovered with sequelae
			Cardiomegaly	心拡大	2	N	TE	59	39	N	None	Recovered
			Leukopenia	白血球減少症	3	N	TE	60	3	Y	None	Recovered
			Neutropenia	好中球減少症	3	Y	TE	60	3	Y	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	60	25	N	None	Recovered
			Anaemia	貧血	1	N	TE	62	126	N	None	
			Leukopenia	白血球減少症	1	N	TE	62	23	Y	None	Recovered
			Hypertension	高血圧	2	N	TE	97	77	N	None	Recovered
			Anaemia	貧血	2	N	TE	187	2	N	-	
			Abdominal pain	腹痛	3	Y	TE	187	4	N	Not applicable	Recovered
			Diarrhoea	下痢	2	N	TE	187	3	N	Not applicable	Recovered
			Rectal haemorrhage	直腸出血	2	N	TE	187	4	N	Not applicable	Recovered
			Vomiting	嘔吐	2	N	TE	187	3	N	Not applicable	Recovered
			Chills	悪寒	2	N	TE	187	3	N	Not applicable	Recovered
			Anaemia	貧血	1	N	TE	188	1	N	-	
			Anaemia	貧血	2	N	TE	188	2	N	-	
			Infection	感染	2	N	TE	188	3	N	Not applicable	Recovered
			Anaemia	貧血	1	N	TE	189		N	Not applicable	Not recovered, but no changes expected
			Diarrhoea	下痢	1	N	TE	189	2	N	Not applicable	Recovered
			Pyrexia	発熱	2	N	TE	193	4	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Infection	感染	3	Y	TE	193	19	N	Not applicable	Recovered
			Pyrexia	発熱	1	N	TE	196	3	N	Not applicable	Recovered
			Pyrexia	発熱	2	N	TE	202		N	Not applicable	Recovered
006047	Norway	73/M/C	Nausea	悪心	1	N	TE	2	23	N	None	Recovered
			Nausea	悪心	1	N	TE	28	21	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	55	22	Y	-	
			Nausea	悪心	1	N	TE	57	27	Y	None	Recovered
			Nerve root compression	神経根圧迫	3	Y	TE	76	6	N	None	Recovered
			Bone pain	骨痛	1	N	TE	81		N	None	Not recovered, but no changes expected
			Oedema peripheral	末梢性浮腫	1	N	TE	111		N	None	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	1	N	TE	111	57	N	None	Recovered
			Epigastric discomfort	心窩部不快感	1	N	TE	167	43	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	167	43	Y	Not applicable	Recovered
006052	Norway	73/M/C	Constipation	便秘	2	N	TE	14	2	N	None	Recovered
			Hydronephrosis	水腎症	3	Y	TE	14	5	N	None	Recovered
			Urinary retention	尿閉	2	N	TE	27	1	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	70	6	N	None	Recovered
			Nausea	悪心	2	N	TE	70	4	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	70	4	N	None	Recovered
			Pyrexia	発熱	1	N	TE	70	4	N	None	Recovered
			Sepsis	敗血症	3	Y	TE	70	6	N	None	Recovered
			Anaemia	貧血	2	N	TE	71	2	Y	None	
			Thrombocytopenia	血小板減少症	1	N	TE	71	3	Y	None	Recovered

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hypokalaemia	低カリウム血症	1	N	TE	71	4	N	None	Recovered
			Anaemia	貧血	1	N	TE	72	40	Y	None	
			Weight decreased	体重減少	2	N	TE	83	29	N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	111	29	Y	None	
			Thrombocytopenia	血小板減少症	1	N	TE	111	85	N	None	Not recovered, but no changes expected
			Oedema peripheral	末梢性浮腫	1	N	TE	111	83	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	111	29	N	None	Not recovered, but no changes expected
			Urinary retention	尿閉	3	Y	TE	131	4	N	None	Recovered
			Anaemia	貧血	1	N	TE	139	28	Y	None	
			Weight decreased	体重減少	2	N	TE	139		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	166	28	Y	None	
			Bone pain	骨痛	1	N	TE	167	21	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	187	18	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	3	N	TE	193	3	Y	None	
			Leukopenia	白血球減少症	3	N	TE	193	3	Y	Not applicable	Recovered
			Neutropenia	好中球減少症	2	N	TE	193	3	Y	Not applicable	Recovered
			Chills	悪寒	2	N	TE	193	1	N	Not applicable	Recovered
			Fatigue	疲労	3	N	TE	193	2	N	Not applicable	Not recovered, but no changes expected
			Pyrexia	発熱	3	N	TE	193	1	N	Not applicable	Recovered
			Pyrexia	発熱	2	N	TE	193	5	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urosepsis	尿路性敗血症	3	Y	TE	193	12	N	Not applicable	Recovered
			Fatigue	疲労	2	N	TE	194		N	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	195	3	N	Not applicable	Not recovered, but no changes expected
			Leukopenia	白血球減少症	1	N	TE	195	3	Y	Not applicable	Recovered
			Neutropenia	好中球減少症	1	N	TE	195	3	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	195	11	N	None	Not recovered, but no changes expected
			Anaemia	貧血	1	N	TE	197		N	Not applicable	Not recovered, but no changes expected
			Pyrexia	発熱	1	N	TE	197		N	Not applicable	Recovered
			Bone pain	骨痛	2	Y	TE	204	5	N	Not applicable	Recovered with sequelae
			Thrombocytopenia	血小板減少症	1	N	TE	205		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	208		N	Not applicable	Not recovered, but no changes expected
006055	Norway	63/M/C	Petechiae	点状出血	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Nerve root compression	神経根圧迫	3	Y	Pre	-33	4	N	None	Recovered
			Groin pain	鼠径部痛	2	N	Pre	-2	3	N	None	Recovered
			Nerve root compression	神経根圧迫	3	Y	TE	1	4	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	1	4	N	None	Recovered
			Pyrexia	発熱	1	N	TE	23	3	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	3	Y	TE	24	4	N	None	Recovered with sequelae
			Hypoalbuminaemia	低アルブミン血症	2	N	TE	24	4	N	None	Ongoing at study termination / withdrawal
			Hypoaesthesia	感覚鈍麻	1	N	TE	24		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	27	8	N	None	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	2	N	TE	27	8	N	None	Ongoing at study termination / withdrawal
			Hypoalbuminaemia	低アルブミン血症	1	N	TE	27		N	None	Ongoing at study termination / withdrawal
			Cardiac failure	心不全	2	N	TE	28		N	None	Ongoing at study termination / withdrawal
			Pyrexia	発熱	1	N	TE	28	2	N	None	Recovered
			Pneumonia	肺炎	3	Y	TE	28	6	N	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	28	7	N	None	Recovered
			Pleural effusion	胸水	2	N	TE	28	7	N	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	30	3	N	None	Recovered
			Pulmonary hypertension	肺高血圧症	2	N	TE	32		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	34	5	N	None	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	1	N	TE	34		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	38	31	N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	52	18	N	None	Ongoing at study termination / withdrawal
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	Y	TE	52	3	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	53	11	N	None	Recovered
			Thrombocytopenia	血小板減少症	4	Y	TE	66	2	Y	Drug administration postponed	Recovered with sequelae
			Hypokalaemia	低カリウム血症	1	N	TE	66		N	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	Y	TE	66		N	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	3	N	TE	67	4	N	None	Ongoing at study termination / withdrawal
			Urinary tract infection	尿路感染	1	N	TE	67		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	N	TE	68		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	69		N	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	3	N	TE	70		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	4	N	TE	70	1	N	None	Ongoing at study termination / withdrawal
			General physical health deterioration	全身健康状態低下	3	N	TE	71		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	84	1	N	Not applicable	Death
008001	Norway	66/M/C	Haemorrhoids	痔核	1	N	TE			N	None	Recovered
			Decreased appetite	食欲減退	2	N	TE			N	None	Ongoing at time of death
			Depressed mood	抑うつ気分	2	N	TE			N	None	Ongoing at time of death
			Pathological fracture	病的骨折	3	Y	Pre	-48	14	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	Pre	-26	15	Y	-	
			Post procedural infection	処置後感染	3	Y	Pre	-26	29	N	Drug administration postponed	Recovered
			Nausea	悪心	1	N	Pre	-20	77	N	None	Recovered
			Vomiting	嘔吐	1	N	Pre	-20	77	N	None	Recovered
			Anaemia	貧血	1	N	Pre	-12	4	Y	-	
			Anaemia	貧血	2	N	Pre	-9	86	Y	-	
			Soft tissue infection	軟部組織感染	2	N	TE	3		N	None	Recovered
			Nausea	悪心	2	N	TE	57	14	N	None	Recovered
			Fatigue	疲労	2	N	TE	57		N	None	Ongoing at time of death
			Nausea	悪心	2	Y	TE	70	11	N	None	Recovered
			Anaemia	貧血	1	N	Pre	77	51	Y	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	86	7	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	92		N	Not applicable	Ongoing at time of death
			Pyrexia	発熱	2	N	TE	112	1	N	None	Recovered
			Anaemia	貧血	2	N	Pre	127		Y	None	Ongoing at time of death
008003	Norway	79/M/C	Nausea	悪心	2	N	Pre	1	25	N	None	Recovered
			Nausea	悪心	2	Y	TE	25	4	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	25		N	None	Ongoing at time of death
			Hypercalcaemia	高カルシウム血症	1	N	TE	25	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	27	2	Y	None	Recovered
			Nausea	悪心	2	N	TE	28		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	35	25	N	Drug permanently withdrawn	Recovered
			Dehydration	脱水	2	N	TE	51		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	59	1	N	Not applicable	Death
008007	Norway	62/M/C	Fatigue	疲労	1	N	TE			N	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE			N	Not applicable	Recovered
			Anaemia	貧血	1	N	Pre	1	85	Y	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	21	78	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	85	16	Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	98		N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	98	13	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	99	1	N	Not applicable	Recovered
			Anaemia	貧血	1	N	TE	100		Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	106		N	Not applicable	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	106	1	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	110		N	Not applicable	Ongoing at time of death
			Infection	感染	3	Y	TE	112	6	N	Not applicable	Recovered
008008	Norway	74/M/C	Anorexia	食欲不振	1	N	TE			Y	None	Not recovered, but no changes expected
			Fatigue	疲労	2	N	Pre	-1		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	1		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	29	40	Y	None	Recovered
			Anorexia	食欲不振	2	N	TE	29		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	3	Y	TE	68	1	Y	None	Recovered
			Anaemia	貧血	2	N	TE	68	78	Y	-	
			Atrial fibrillation	心房細動	3	N	TE	68	1	Y	None	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	131	38	Y	-	

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Leukopenia	白血球減少症	2	N	TE	141	14	Y	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	145	1	Y	-	
			Anaemia	貧血	2	N	TE	145	16	Y	-	
			Leukopenia	白血球減少症	1	N	TE	154	7	Y	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	160	7	Y	-	
			Leukopenia	白血球減少症	2	N	TE	160	35	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	166	18	Y	-	
			Thrombocytopenia	血小板減少症	4	N	TE	168	7	Y	-	
			General physical health deterioration	全身健康状態低下	2	Y	TE	168	2	Y	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	169		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	174	28	Y	-	
			Anaemia	貧血	3	N	TE	183	7	Y	-	
			Anaemia	貧血	2	N	TE	189	13	Y	-	
			Anaemia	貧血	1	N	TE	201	8	Y	-	
			Thrombocytopenia	血小板減少症	4	N	TE	201	39	Y	-	
			Anaemia	貧血	2	N	TE	208	31	Y	-	
			Leukopenia	白血球減少症	3	N	Post	236	2	Y	-	
			Leukopenia	白血球減少症	2	N	Post	237	17	Y	-	
			Anaemia	貧血	1	N	TE	238	2	Y	-	
			Anaemia	貧血	2	N	TE	239	15	Y	-	
			Thrombocytopenia	血小板減少症	3	N	TE	239	7	Y	-	
			Thrombocytopenia	血小板減少症	4	N	TE	245	16	Y	-	
			Anaemia	貧血	1	N	TE	253	5	Y	-	
			Leukopenia	白血球減少症	3	N	Post	253	11	Y	-	
			Anaemia	貧血	2	N	TE	257	2	Y	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	258	13	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	260	3	Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	262		Y	Drug permanently withdrawn	Ongoing at time of death
			Leukopenia	白血球減少症	4	N	Post	263	5	Y	Not applicable	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	Post	267	4	Y	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	270		Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	Post	270		Y	Not applicable	Ongoing at time of death
008011	Norway	69/M/C	Nausea	悪心	1	N	TE			N	None	Recovered
			Vomiting	嘔吐	1	N	TE			N	None	Recovered
			Fatigue	疲労	1	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE	2	2	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	2	2	N	None	Recovered
			Tendonitis	腱炎	2	N	TE	35		N	None	Recovered
			Constipation	便秘	1	N	TE	37		N	None	Recovered
			Nausea	悪心	1	N	TE	37	5	N	None	Recovered
			Musculoskeletal stiffness	筋骨格硬直	2	N	TE	99	15	N	None	Recovered
			Pharyngitis	咽頭炎	1	N	TE	138	3	N	None	Recovered
			Pathological fracture	病的骨折	2	N	TE	149		N	Not applicable	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	149	9	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Spinal cord compression	脊髄圧迫	2	N	TE	157	10	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	166	6	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	167	22	N	None	Recovered
			Spinal cord compression	脊髄圧迫	3	N	TE	171	42	N	Not applicable	Ongoing at time of death
			Subileus	亜イレウス	2	Y	TE	181	4	N	Not applicable	Recovered
			Oesophageal pain	食道痛	1	N	TE	198	1	N	Not applicable	Recovered
			Cystitis	膀胱炎	1	N	TE	201	11	N	Not applicable	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	212	1	N	Not applicable	Death
008013	Norway	77/M/C	Weight decreased	体重減少	2	N	TE	15		Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	1	N	TE	29		N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	29	50	N	None	Recovered
			Nausea	悪心	1	N	TE	57	22	N	None	Recovered
			Pathological fracture	病的骨折	2	N	TE	73		N	None	Not recovered, but no changes expected
			Atrial fibrillation	心房細動	3	Y	TE	221	5	N	Not applicable	Recovered
008015	Norway	63/M/C	Vomiting	嘔吐	1	N	TE			N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	2	N	TE			N	None	Not recovered, but no changes expected
			Diarrhoea	下痢	1	N	TE	1	9	Y	None	Recovered
			Nausea	悪心	1	N	TE	1	9	Y	None	Recovered
			Skin laceration	皮膚裂傷	2	N	TE	28	1	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	29		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	74	45	N	None	Not recovered, but no changes expected
			Constipation	便秘	2	N	TE	114		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	116	3	N	None	Recovered
			Nausea	悪心	2	N	TE	117	29	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	118	8	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	125		N	None	Not recovered, but no changes expected
			Nausea	悪心	3	Y	TE	145	10	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	154		N	Not applicable	Not recovered, but no changes expected
			Urinary retention	尿閉	1	N	TE	180	1	N	Not applicable	Recovered
010008	Czech Republic	75/M/C	Viral infection	ウイルス感染	1	N	TE	84	8	N	None	Recovered
			Anaemia	貧血	3	N	TE	91	13	N	Drug permanently withdrawn	Recovered with sequelae
			Leukopenia	白血球減少症	2	N	TE	91	127	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	98	52	N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	2	N	TE	98	21	N	Not applicable	Recovered
			Anaemia	貧血	3	Y	TE	103	12	N	Drug permanently withdrawn	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	114	266	N	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	149	69	N	None	Recovered
			Anaemia	貧血	3	N	TE	379		N	Not applicable	Ongoing at time of death
011006	Czech Republic	68/M/C	Diarrhoea	下痢	1	N	TE	2	11	Y	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	150	256	Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	Y	TE	405		Y	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	4	Y	Post	405	2	Y	Not applicable	Death
			Pneumonia	肺炎	5	Y	Post	406	1	Y	Not applicable	Death
012001	Czech Republic	60/M/C	Blood testosterone abnormal	血中テストステロン異常	1	Y	Pre	-35	4	N	None	Recovered
			Anaemia	貧血	3	Y	TE	169	2	Y	Not applicable	Recovered
017003	Czech Republic	80/M/C	Cachexia	悪液質	4	Y	TE	115	10	N	None	Death
			Pneumonitis	肺臓炎	3	N	TE	115		N	None	Ongoing at time of death
			Cachexia	悪液質	5	Y	TE	124	1	N	None	Death
017004	Czech Republic	83/M/C	Angina pectoris	狭心症	3	Y	TE	105	15	N	None	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Depression	うつ病	2	N	TE	105	8	N	Drug administration postponed	Recovered
			Angina pectoris	狭心症	2	N	TE	119	184	N	None	Death
			Hypokalaemia	低カリウム血症	1	N	TE	119		N	None	Not recovered, but no changes expected
			Angina pectoris	狭心症	5	Y	TE	302	1	N	None	Death
017005	Czech Republic	80/M/C	Anaemia	貧血	4	Y	TE	168	7	N	Not applicable	Recovered
			Anorexia	食欲不振	1	N	TE	174		N	None	Not recovered, but no changes expected
017007	Czech Republic	80/M/C	Malignant neoplasm progression	悪性新生物進行	4	Y	TE	178	3	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	180	1	N	Not applicable	Death
017017	Czech Republic	77/M/C	General physical health deterioration	全身健康状態低下	4	Y	TE	151	2	N	Not applicable	Death
			General physical health deterioration	全身健康状態低下	5	Y	TE	152	1	N	Not applicable	Death
017018	Czech Republic	76/M/C	Bone pain	骨痛	1	Y	Pre	-61	10	N	None	Recovered
			Myocardial ischaemia	心筋虚血	4	Y	TE	146		N	Not applicable	Ongoing at time of death
			Myocardial infarction	心筋梗塞	5	Y	TE	154	1	N	Not applicable	Death
017027	Czech Republic	60/M/C	Anaemia	貧血	2	N	TE	79	43	N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	116	6	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	121	1	N	Drug permanently withdrawn	Death
017030	Czech Republic	86/M/C	Leukopenia	白血球減少症			TE			N	None	Recovered
			Anaemia	貧血	2	N	Pre	1		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	28		N	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	Y	TE	50	8	N	None	Recovered
			Thrombocytopenia	血小板減少症	3	Y	TE	50	8	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	Y	TE	57		N	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	5	Y	TE	59	1	N	None	Death
017031	Czech Republic	71/M/C	Duodenal ulcer	十二指腸潰瘍	2	Y	TE	155	6	N	Not applicable	Recovered
			Intervertebral disc disorder	椎間板障害	2	N	TE	202	16	N	Not applicable	Not recovered, but no changes expected
			Intervertebral disc disorder	椎間板障害	3	N	TE	217		N	Not applicable	Not recovered, but no changes expected
017032	Czech Republic	57/M/C	Malignant neoplasm progression	悪性新生物進行	5	Y	TE	97	1	N	None	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
018004	Czech Republic	62/M/C	Bone pain	骨痛	2	N	TE	19	18	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	1	N	TE	19		N	None	Ongoing at time of death
			Gastritis	胃炎	1	Y	TE	127	4	N	None	Recovered
			Pancytopenia	汎血球減少症	4	Y	TE	169	44	Y	Not applicable	Recovered
			Gastritis	胃炎	1	N	TE	169		N	None	Ongoing at time of death
			Metastases to central nervous system	中枢神経系転移	3	N	TE	178		N	None	Ongoing at time of death
020005	Sweden	71/M/C	Anorexia	食欲不振	2	N	TE			N	None	Ongoing at time of death
			Micturition urgency	尿意切迫	2	N	Pre			N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	1	4	Y	None	Recovered
			Fatigue	疲労	2	N	TE	1		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	1		Y	None	Not recovered, but no changes expected
			Musculoskeletal pain	筋骨格痛	1	N	TE	1	4	Y	None	Recovered
			Haematuria	血尿	2	N	TE	11		N	None	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	17	3	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	33	5	Y	None	Recovered
			Constipation	便秘	3	N	TE	39		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Chills	悪寒	1	N	TE	54		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	Y	TE	75	14	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	91	22	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	112	1	N	Drug permanently withdrawn	Death
020015	Sweden	74/M/C	Nausea	悪心	1	N	Pre			N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE			N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	N	TE			Y	None	Ongoing at time of death
			Myalgia	筋痛	1	N	Pre			N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE			Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	19		Y	None	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	3	Y	TE	28	15	Y	Drug administration postponed	Recovered with sequelae
			Constipation	便秘	2	N	TE	28		Y	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	28	15	Y	None	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	1	N	TE	42		Y	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	1	N	TE	42		Y	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	106	5	N	Drug permanently withdrawn	Death
021002	Sweden	63/M/C	Vomiting	嘔吐	1	N	TE	2	49	N	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	26	10	N	None	Recovered
			Cough	咳嗽	1	N	TE	26		N	None	Recovered
			Nausea	悪心	2	N	TE	30	21	N	None	Recovered
			Erosive duodenitis	びらん性十二指腸炎	3	Y	TE	32	6	Y	None	Recovered
			Erosive duodenitis	びらん性十二指腸炎	2	N	TE	38	16	Y	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	44		N	None	Ongoing at time of death
			Nausea	悪心	3	Y	TE	50	4	N	None	Recovered
			Vomiting	嘔吐	3	Y	TE	50	4	N	None	Recovered
			Anorexia	食欲不振	3	Y	TE	50	4	N	None	Recovered
			Dehydration	脱水	3	Y	TE	50	4	N	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	50	4	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	57	29	N	None	Recovered
			Anxiety	不安	1	N	TE	57		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	63	79	N	None	Recovered
			Bone pain	骨痛	2	N	TE	96	5	N	None	Recovered
			Bone pain	骨痛	2	N	TE	100	42	N	None	Recovered
			Abdominal pain	腹痛	2	N	TE	130	32	N	None	Recovered
			Nausea	悪心	2	N	TE	130	32	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	147	15	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	204	6	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	2	N	TE	209	4	N	Not applicable	Recovered
			Oedema peripheral	末梢性浮腫	3	N	TE	210		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	210	3	N	Not applicable	Recovered with sequelae
			Hypoaesthesia	感覚鈍麻	2	N	TE	210		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	212		N	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	213	42	N	None	Recovered
021003	Sweden	63/M/C	Bone pain	骨痛	2	N	Pre	-10	40	N	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	Pre	-7	5	N	None	Recovered
			Weight decreased	体重減少	3	N	Pre	-2		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	Pre	-2	149	N	None	Recovered
			Nausea	悪心	1	N	TE	1		N	None	Recovered
			Paraesthesia	錯感覚	1	N	Pre	1		N	None	Recovered
			Fatigue	疲労	2	N	TE	15	42	N	None	Recovered
			Diarrhoea	下痢	2	Y	TE	29	5	N	None	Recovered
			Myasthenia gravis	重症筋無力症	2	N	TE	29	442	N	None	Recovered
			Myasthenia gravis	重症筋無力症	1	N	TE	29	29	N	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	29		N	None	Recovered
			Pyrexia	発熱	2	Y	TE	44	13	Y	None	Recovered
			Headache	頭痛	1	N	TE	44	11	N	None	Recovered
			Dysphagia	嚥下障害	1	N	TE	57	57	N	None	Recovered
			Pyrexia	発熱	1	N	TE	59	3	N	None	Recovered
			Myalgia	筋痛	1	N	TE	66	4	N	None	Recovered
			Bone pain	骨痛	2	N	TE	72		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	138	12	N	None	Recovered
			Respiratory tract infection	気道感染	1	N	TE	142	12	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	216	82	N	Not applicable	Recovered
022004	Sweden	84/M/C	Weight decreased	体重減少	1	N	TE	25	151	N	None	Recovered
			Increased upper airway secretion	上気道分泌増加	1	N	TE	98	15	N	None	Recovered
			Nausea	悪心	1	N	TE	101	75	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	116	60	N	None	Recovered with sequelae
			Cystitis	膀胱炎	2	N	TE	141	35	N	None	Recovered
			Sternal fracture	胸骨骨折	2	Y	TE	190	7	N	Not applicable	Recovered
			Anaemia	貧血	1	N	TE	226		N	None	Not recovered, but no changes expected
022009	Sweden	75/M/C	Fatigue	疲労	1	N	TE	116		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	116		N	None	Not recovered, but no changes expected
			Spinal cord compression	脊髄圧迫	3	N	TE	176	67	N	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	178	7	N	Not applicable	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	2	N	TE	242	137	N	Not applicable	Not recovered, but no changes expected
			Spinal cord compression	脊髄圧迫	3	N	TE	378		N	Not applicable	Not recovered, but no changes expected
023003	Sweden	57/M/C	Anorexia	食欲不振	2	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Haematuria	血尿	2	N	Pre	-7		N	None	Ongoing at time of death
			Cushing's syndrome	クッシング症候群	1	N	TE	29		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	149	82	N	None	Recovered
			Bacterial sepsis	細菌性敗血症	4	Y	TE	149	21	Y	Not applicable	Recovered with sequelae
			Renal failure	腎不全	1	N	TE	150	3	N	None	Recovered
			Oral candidiasis	口腔カンジダ症	2	N	TE	151	18	N	None	Recovered
			Fatigue	疲労	2	N	TE	155		N	None	Ongoing at time of death
024007	Sweden	63/M/C	Insomnia	不眠症	1	N	Pre	-2		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	Pre	-1		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	1	2	Y	None	Recovered
			Cystitis	膀胱炎	2	N	TE	30	41	N	None	Recovered
			Oedema	浮腫	2	N	TE	63	106	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	75		N	None	Not recovered, but no changes expected
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	114		N	None	Not recovered, but no changes expected
			Erysipelas	丹毒	2	N	TE	128		N	None	Recovered
			Thrombophlebitis	血栓性静脈炎	1	N	TE	128		N	None	Recovered
			Bone pain	骨痛	3	Y	TE	138		N	None	Ongoing at time of death
			Metastases to liver	肝転移	3	N	TE	141	28	N	Not applicable	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	158	4	Y	Not applicable	Recovered
			Metastases to liver	肝転移	5	Y	TE	168	1	N	Not applicable	Death
024010	Sweden	75/M/C	Anaemia	貧血	2	N	TE			N	Not applicable	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	Y	Pre	1	12	N	None	Recovered with sequelae
			Pathological fracture	病的骨折	2	N	TE	5	145	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	31		Y	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	59		N	None	Not recovered, but no changes expected
			Rash	発疹	1	N	TE	66	84	N	None	Recovered
			Abdominal pain upper	上腹部痛	2	N	TE	78	38	N	None	Recovered
			Anaemia	貧血	1	N	TE	114	37	Y	None	Recovered
			Nausea	悪心	2	N	TE	131		N	None	Recovered
			Oedema genital	性器浮腫	1	N	TE	150		N	None	Not recovered, but no changes expected
			Metastases to central nervous system	中枢神経系転移	3	N	TE	198		N	None	Not recovered, but no changes expected
			Pathological fracture	病的骨折	3	N	TE	213		N	None	Not recovered, but no changes expected
024011	Sweden	87/M/C	Diarrhoea	下痢	1	N	Pre	-5	2	N	None	Recovered
			Anaemia	貧血	2	N	Pre	-1	30	N	None	Recovered
			Bone pain	骨痛	3	N	Pre	-1	30	N	None	Recovered
			Dysgeusia	味覚異常	1	N	Pre	1		N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	49		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	2	N	TE	60		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	63	18	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	82	11	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	91		N	None	Ongoing at study termination / withdrawal
			Dry mouth	口内乾燥	1	N	TE	91		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	135		N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	2	N	TE	135		N	None	Ongoing at study termination / withdrawal
024016	Sweden	73/M/C	Injury	損傷	3	Y	TE			N	-	Recovered with sequelae
			Post-traumatic pain	外傷後疼痛	3	Y	TE			N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	3	N	TE			N	None	Not recovered, but no changes expected
			Fatigue	疲労	1	N	TE	29		N	None	Not recovered, but no changes expected
			Cushingoid	クッシング様	2	N	TE	57		N	None	Not recovered, but no changes expected
			Oedema peripheral	末梢性浮腫	2	N	TE	57		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	113	29	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
024017	Sweden	73/M/C	Bone pain	骨痛	2	N	TE	34		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	64	27	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	64		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	117	30	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	204	1	N	Not applicable	Death
024023	Sweden	81/M/C	Bone pain	骨痛	2	Y	TE	16	2	N	None	Recovered
			Bone pain	骨痛	3	N	TE	28		N	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	2	N	TE	29		N	None	Ongoing at study termination / withdrawal
			Rash	発疹	2	N	TE	29		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	57		N	None	Ongoing at study termination / withdrawal
025001	Sweden	66/M/C	Pyrexia	発熱	2	N	TE			N	Not applicable	Recovered
			Cough	咳嗽	1	N	TE			N	Not applicable	Recovered
			Arrhythmia	不整脈	1	N	Pre	-1		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	4	6	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	57	4	Y	Drug permanently withdrawn	Recovered
			Thrombocytopenia	血小板減少症	2	Y	TE	57	4	Y	None	Recovered with sequelae
			Dyspnoea	呼吸困難	2	N	TE	57	4	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	59	39	N	Not applicable	Recovered
			Polyneuropathy	多発ニューロパチー	2	N	TE	94		N	Not applicable	Not recovered, but no changes expected
025004	Sweden	63/M/C	Fatigue	疲労	1	N	TE	31	-1	Y	None	Recovered
			Upper respiratory tract infection bacterial	細菌性上気道感染	1	N	TE	48	12	N	None	Recovered
			Haematuria	血尿	3	Y	TE	82		N	Drug administration postponed	Ongoing at time of death
			Cardiac failure	心不全	4	Y	TE	90	2	N	Drug permanently withdrawn	Death
			Cardiac failure	心不全	5	Y	TE	91	1	N	Drug permanently withdrawn	Death
025012	Sweden	74/M/C	Vomiting	嘔吐	2	N	TE	53	1	N	None	Recovered
			Hydronephrosis	水腎症	2	Y	TE	172	7	N	Not applicable	Recovered
			Hypercreatininaemia	高クレアチニン血症	2	N	TE	175		N	None	Ongoing at time of death
			Ureteric obstruction	尿管閉塞	3	N	TE	175		N	Not applicable	Not recovered, but no changes expected

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
025013	Sweden	71/M/C	Dry mouth	口内乾燥	1	N	TE			N	None	Recovered
			Increased bronchial secretion	気管支分泌増加	1	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	Pre	1		N	None	Ongoing at study termination / withdrawal
			Pyrexia	発熱	1	N	TE	79	12	N	None	Recovered
			Leukopenia	白血球減少症	2	N	TE	102	104	N	None	Recovered
			Anaemia	貧血	2	N	TE	121		N	None	Ongoing at time of death
			Infection	感染	2	N	TE	137	2	N	Drug administration postponed	Recovered
			Infection	感染	3	Y	TE	138	4	N	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	148	29	N	Drug administration postponed	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	176	57	N	Drug administration postponed	Ongoing at time of death
			Pyrexia	発熱	2	Y	TE	185	6	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	4	N	TE	232		N	Drug administration postponed	Ongoing at time of death
025014	Sweden	82/M/C	Haematuria	血尿	2	N	Pre			N	None	Recovered
			Fatigue	疲労	3	N	TE	29		N	Drug permanently withdrawn	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hepatic failure	肝不全	3	Y	TE	29	9	N	Drug permanently withdrawn	Death
			Bone pain	骨痛	2	Y	TE	29		N	Drug permanently withdrawn	Ongoing at time of death
			Hepatic failure	肝不全	5	Y	TE	37	1	N	Drug permanently withdrawn	Death
025015	Sweden	72/M/C	Fatigue	疲労	2	N	TE	57		N	None	Ongoing at study termination / withdrawal
			Lymphadenopathy	リンパ節症	2	N	TE	62		N	None	Ongoing at time of death
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	TE	62		N	None	Ongoing at study termination / withdrawal
			Metastases to liver	肝転移	5	Y	TE	88	1	N	Not applicable	Death
025020	Sweden	61/M/C	Bone pain	骨痛	2	Y	TE	42	3	N	None	Recovered
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE	70	71	N	None	Recovered
			Bone pain	骨痛	1	N	TE	127		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	132	8	N	None	Recovered
			Sepsis	敗血症	4	Y	TE	160	11	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	4	Y	TE	160	14	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	2	N	TE	166		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	220	1	N	Not applicable	Death
025022	Sweden	61/M/C	Anorexia	食欲不振	1	N	TE			N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	25	2	Y	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	30	9	Y	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	3	N	TE	30	9	Y	None	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	TE	30	9	Y	None	Recovered
			Chills	悪寒	1	N	TE	32		N	None	Ongoing at study termination / withdrawal
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	2	N	TE	38	20	Y	None	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	2	N	TE	38	20	Y	None	Recovered
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	2	N	TE	38	20	N	None	Recovered
			Bone pain	骨痛	2	N	TE	42	44	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	85	7	N	Drug administration postponed	Recovered
			Bone pain	骨痛	1	N	TE	86	64	N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	2	N	TE	91	30	N	Drug administration postponed	Recovered
			Fatigue	疲労	2	N	TE	149		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	150		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	177		Y	Not applicable	Ongoing at time of death
			Nausea	悪心	2	N	TE	177	3	N	Not applicable	Recovered
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	177	3	N	Not applicable	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	179		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	233	8	Y	Not applicable	
026001	Sweden	78/M/C	Bone pain	骨痛	3	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	3		N	None	Not recovered, but no changes expected
			Haematuria	血尿	1	N	TE	106	4	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	114		N	None	Ongoing at time of death
			Dehydration	脱水	2	Y	TE	117	12	N	None	Recovered
			Confusional state	錯乱状態	2	Y	TE	117	12	N	None	Recovered with sequelae
			Urinary retention	尿閉	2	N	TE	118		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	137	2	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	138	1	N	Drug permanently withdrawn	Death
026002	Sweden	66/M/C	Oesophageal spasm	食道痙攣	1	N	TE			N	None	Recovered
			Bone pain	骨痛	3	Y	Pre	-2	8	N	Not applicable	Recovered with sequelae
			Polyneuropathy	多発ニューロパチー	1	Y	TE	91	4	N	None	Recovered with sequelae
			Faecal incontinence	便失禁	3	Y	TE	108	8	N	None	Recovered with sequelae
			Hyperglycaemia	高血糖	3	Y	TE	108	8	N	None	Recovered with sequelae
			Urinary incontinence	尿失禁	3	Y	TE	108	8	N	None	Recovered with sequelae
			Pancytopenia	汎血球減少症	2	N	TE	124	6	N	Drug permanently withdrawn	Ongoing at time of death
			Fall	転倒・転落	3	Y	TE	124		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	124	13	N	None	Death
			Urinary retention	尿閉	2	N	TE	124		N	Not applicable	Ongoing at time of death
			Mouth ulceration	口腔内潰瘍形成	2	N	TE	125		N	Not applicable	Ongoing at time of death
			Pancytopenia	汎血球減少症	3	Y	TE	129		N	Drug permanently withdrawn	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	136	1	N	None	Death
026003	Sweden	55/M/C	Nausea	悪心	1	N	TE			Y	None	Not recovered, but no changes expected
			Fatigue	疲労	1	N	TE			N	None	Not recovered, but no changes expected
			Pneumonia	肺炎	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			Y	None	Not recovered, but no changes expected
			Sciatica	坐骨神経痛	2	N	TE			N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	2	2	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	2	2	Y	None	Recovered
			Nausea	悪心	1	N	TE	31	2	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	31	2	Y	None	Recovered
			Anorexia	食欲不振	2	N	TE	116	119	N	None	Recovered
			Anaemia	貧血	2	N	TE	197		Y	None	
			General physical health deterioration	全身健康状態低下	2	Y	TE	219	5	N	Not applicable	Recovered
			Pneumonia	肺炎	3	Y	TE	219	15	N	Not applicable	Recovered
			Compression fracture	圧迫骨折	1	N	TE	220		N	Not applicable	Not recovered, but no changes expected
026005	Sweden	66/M/C	Lymphadenopathy	リンパ節症	1	N	Pre			N	Not applicable	Ongoing at time of death
			Toothache	歯痛	1	N	TE			N	None	Recovered
			Dizziness	浮動性めまい	1	N	TE			N	Not applicable	Recovered
			Insomnia	不眠症	2	N	Pre	1		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary tract infection	尿路感染	2	N	TE	109		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	127		N	None	Ongoing at time of death
			Hydronephrosis	水腎症	3	Y	TE	136	5	N	None	Recovered with sequelae
			Weight decreased	体重減少	1	N	TE	147		N	Not applicable	Ongoing at time of death
			Anxiety	不安	2	N	TE	147		N	None	Ongoing at time of death
			Hyponatraemia	低ナトリウム血症	1	N	TE	161	26	N	None	Recovered
			Depression	うつ病	2	N	TE	161		N	None	Recovered with sequelae
			Rectal haemorrhage	直腸出血	3	Y	TE	167	4	N	Not applicable	Recovered
			General physical health deterioration	全身健康状態低下	1	Y	TE	167	4	N	Not applicable	Recovered
			Lymphadenopathy	リンパ節症	2	N	TE	171		N	Not applicable	Ongoing at time of death
			Oral fungal infection	口腔真菌感染	1	N	TE	186		N	Not applicable	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	186	6	N	Not applicable	Recovered
			Dehydration	脱水	2	Y	TE	199	3	N	Not applicable	Recovered
			Bone pain	骨痛	2	Y	TE	199	3	N	Not applicable	Recovered
026007	Sweden	66/M/C	Nausea	悪心	1	N	TE			Y	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE			Y	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Upper respiratory tract infection	上気道感染	1	N	TE			N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			N	None	Recovered
			Stent occlusion	ステント閉塞	2	Y	Pre	-10	5	N	None	Recovered
			Herpes zoster	帯状疱疹	2	N	TE	6	10	N	None	Recovered
			Lymphadenopathy	リンパ節症	2	N	TE	119	43	N	None	Recovered with sequelae
026010	Sweden	66/M/C	Bone pain	骨痛	2	N	TE	3	4	Y	None	Recovered
			Anaemia	貧血	2	N	TE	170		Y	None	Not recovered, but no changes expected
			Convulsion	痙攣	4	Y	TE	193	3	N	Not applicable	Recovered with sequelae
			Metastases to nervous system	神経系転移	2	N	TE	195		N	Not applicable	Ongoing at time of death
026016	Sweden	72/M/C	Fatigue	疲労	1	N	TE			N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Nocturia	夜間頻尿	1	N	TE			N	None	Ongoing at time of death
			Hyperhidrosis	多汗症	2	N	TE			N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	2	11	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	2	11	Y	None	Recovered
			Anaemia	貧血	2	N	TE	29		Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	68		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	3	Y	TE	83	24	Y	Drug permanently withdrawn	Recovered with sequelae
			Thrombocytopenia	血小板減少症	3	N	TE	83	25	Y	Not applicable	Ongoing at time of death
			Mucosal inflammation	粘膜の炎症	2	N	TE	83	18	N	None	Recovered
			Pneumonia	肺炎	3	Y	TE	83	24	N	Drug administration postponed	Recovered
			Petechiae	点状出血	2	N	TE	83		N	None	Ongoing at time of death
			Epistaxis	鼻出血	1	N	TE	84	1	N	None	Recovered
			Thrombocytopenia	血小板減少症	4	N	TE	107		Y	Not applicable	Ongoing at time of death
027001	Sweden	72/M/C	Dry mouth	口内乾燥	1	N	TE	29	204	Y	None	Recovered
			Fatigue	疲労	1	N	TE	29	204	Y	None	Recovered with sequelae
			Anorexia	食欲不振	2	N	TE	29	141	Y	None	Recovered
			Arthralgia	関節痛	2	N	TE	29	56	N	None	Not recovered, but no changes expected
			Arthralgia	関節痛	1	N	TE	84		N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	113	120	Y	None	Recovered
			Circulatory collapse	循環虚脱	4	Y	TE	176	9	N	Not applicable	Recovered
027002	Sweden	67/M/C	Hypertension	高血圧	2	N	TE	29		N	None	Not recovered, but no changes expected
			Onycholysis	爪甲離床症	2	N	TE	78	64	N	None	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	4	Y	Post	684	9	Y	Not applicable	Death
			Constipation	便秘	5	Y	Post	692	1	Y	Not applicable	Death
			Multi-organ failure	多臓器不全	5	Y	Post	692	1	Y	Not applicable	Death
028001	Belgium	63/M/C	Bone pain	骨痛	2	N	Pre	-102	103	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	Pre	1		N	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	2	N	TE	18	103	Y	None	Recovered with sequelae
			Sinus tachycardia	洞性頻脈	1	N	TE	26	73	N	None	Recovered
			Hepatic function abnormal	肝機能異常	2	N	TE	28		N	None	Ongoing at time of death
			Jaundice	黄疸	3	N	TE	28	10	N	None	Recovered
			Jaundice	黄疸	1	N	TE	37	48	N	None	Recovered
			Hypotension	低血圧	2	N	TE	37	62	N	None	Recovered
			Anaemia	貧血	2	N	TE	56	29	Y	Drug permanently withdrawn	Recovered with sequelae
			Leukopenia	白血球減少症	1	N	TE	56	29	Y	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	56	29	Y	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	56	29	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	56	65	N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	56	29	N	None	Recovered with sequelae
			Dyspnoea	呼吸困難	2	N	TE	72	13	N	None	Recovered with sequelae

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	2	N	TE	77	8	N	None	Recovered
			Anaemia	貧血	4	Y	TE	84	15	Y	Drug permanently withdrawn	Recovered with sequelae
			Leukopenia	白血球減少症	2	N	TE	84	49	Y	None	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	84	15	Y	None	Ongoing at time of death
			Vomiting	嘔吐	1	Y	TE	84	2	N	None	Recovered
			Anorexia	食欲不振	1	Y	TE	84	2	N	None	Recovered with sequelae
			Dyspnoea	呼吸困難	2	Y	TE	84	2	N	None	Recovered with sequelae
			Anorexia	食欲不振	1	N	TE	85		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	98	23	Y	Not applicable	Recovered with sequelae
			Thrombocytopenia	血小板減少症	4	N	TE	98		Y	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	120	2	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	3	Y	TE	120	2	Y	Not applicable	Recovered with sequelae
			Weight decreased	体重減少	2	N	TE	120		N	None	Ongoing at time of death
			Cough	咳嗽	1	N	TE	120		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	121	12	Y	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	2	N	TE	121	12	Y	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	132		Y	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			General physical health deterioration	全身健康状態低下	3	Y	TE	132	4	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	2	N	TE	135	8	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	3	Y	TE	142	2	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	2	N	TE	143	10	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	3	Y	TE	152	4	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	2	N	Post	155		Y	Not applicable	Ongoing at time of death
028002	Belgium	72/M/C	General physical health deterioration	全身健康状態低下	2	Y	Pre	-9	19	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	Y	Pre	-9	19	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	3	N	Pre	-1	2	N	None	Recovered
			Anal ulcer	肛門潰瘍	2	N	Pre	-1	88	N	None	Recovered
			General physical health deterioration	全身健康状態低下	1	N	Pre	10		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	Pre	10		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	3	Y	TE	29	7	Y	Drug administration postponed	Recovered
			Weight decreased	体重減少	2	N	TE	29	28	N	None	Recovered
			Anorexia	食欲不振	3	N	TE	56	28	N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	56		N	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	Y	TE	83		Y	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	3	Y	TE	83	24	N	Drug permanently withdrawn	Death
			Anorexia	食欲不振	1	N	TE	83		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	87	20	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	91		N	Drug permanently withdrawn	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	105		N	Not applicable	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	5	Y	TE	106	1	N	Drug permanently withdrawn	Death
028003	Belgium	83/M/C	Nausea	悪心	1	N	TE	2	1	Y	None	Recovered
			Fatigue	疲労	1	N	TE	29		N	None	Ongoing at time of death
			Skin irritation	皮膚刺激	2	N	TE	50	15	N	None	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	55		Y	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	4	Y	TE	55		N	None	Ongoing at time of death
			Renal failure	腎不全	4	Y	TE	55		N	Drug permanently withdrawn	Ongoing at time of death
			Pulmonary oedema	肺水腫	4	Y	TE	55		N	None	Ongoing at time of death
			Multi-organ failure	多臓器不全	4	Y	TE	59	6	N	None	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Multi-organ failure	多臓器不全	5	Y	TE	64	1	N	None	Death
028004	Belgium	84/M/C	Transient ischaemic attack	一過性脳虚血発作	2	Y	Pre	-13	55	N	Not applicable	Recovered
			Urinary retention	尿閉	2	N	Pre	-7	6	N	None	Recovered
			Pruritus	そう痒症	1	N	TE	8	7	N	None	Recovered with sequelae
			Pruritus	そう痒症	1	N	TE	8	27	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	14	48	N	None	Recovered
			Urinary tract infection	尿路感染	1	N	TE	28	29	N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	30		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	51		N	None	Ongoing at time of death
			Hypercholesterolaemia	高コレステロール血症	2	N	TE	51		N	None	Ongoing at time of death
			Inguinal hernia	鼠径ヘルニア	1	N	TE	55	14	N	None	Recovered
			Bone pain	骨痛	3	N	TE	57		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	93	1	N	Not applicable	Death
028007	Belgium	65/M/C	Fatigue	疲労	1	N	TE	28		Y	None	Ongoing at study termination / withdrawal
			Feeling cold	冷感	1	N	TE	28	36	Y	None	Recovered
			Pallor	蒼白	1	N	TE	28		Y	None	Ongoing at study termination / withdrawal
			Pyrexia	発熱	2	N	TE	50	6	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary retention	尿閉	3	Y	TE	50	2	N	None	Recovered with sequelae
			Anaemia	貧血	3	N	TE	55	9	Y	None	Recovered with sequelae
			Pleurisy	胸膜炎	2	N	TE	56	23	N	None	Recovered
			Anaemia	貧血	2	N	TE	63		Y	None	Ongoing at study termination / withdrawal
			Tachycardia	頻脈	2	N	TE	91	15	N	None	Recovered
			Pleural effusion	胸水	2	N	TE	167	15	N	Not applicable	Recovered
			Paraesthesia	錯感覚	2	N	TE	168		N	None	Ongoing at study termination / withdrawal
			Lymphangiosis carcinomatosa	癌性リンパ管症	4	Y	TE	181	19	N	Not applicable	Recovered with sequelae
			Pleural effusion	胸水	4	Y	TE	181	2	N	Not applicable	Recovered
			Lymphangiosis carcinomatosa	癌性リンパ管症	4	N	TE	199	5	N	Not applicable	Recovered with sequelae
			Lymphangiosis carcinomatosa	癌性リンパ管症	5	Y	TE	203	1	N	Not applicable	Death
033005	UK	83/M/C	Bone pain	骨痛	1	N	TE	1	3	Y	None	Recovered
			Myocardial infarction	心筋梗塞	4	Y	TE	82	3	N	None	Death
			Myocardial infarction	心筋梗塞	5	Y	TE	84	1	N	None	Death
033006	UK	76/M/C	Bone pain	骨痛	2	N	TE			N	None	Not recovered, but no changes expected
			Constipation	便秘	3	Y	TE	77	10	N	Drug administration postponed	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cellulitis	蜂巣炎	3	Y	TE	77	10	N	Drug administration postponed	Recovered
			Pneumonia	肺炎	3	Y	TE	89		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Pathological fracture	病的骨折	3	Y	TE	89		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
033011	UK	84/M/C	Abdominal distension	腹部膨満	2	N	TE			N	None	Recovered
			Fatigue	疲労	1	N	TE			Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE			N	None	Recovered with sequelae
			Contusion	挫傷	1	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Balance disorder	平衡障害	1	N	TE			N	None	Not recovered, but no changes expected
			Hallucination	幻覚	1	N	TE			N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	2	N	TE			N	None	Not recovered, but no changes expected
			Orthostatic hypotension	起立性低血圧	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	71	43	N	None	Recovered with sequelae
			Haematemesis	吐血	3	Y	TE	195	5	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hyperaesthesia	知覚過敏	2	N	TE	214		N	None	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	214		N	None	Ongoing at time of death
033012	UK	72/M/C	Constipation	便秘	2	N	TE			N	None	Recovered
			Mouth ulceration	口腔内潰瘍形成	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Mobility decreased	運動性低下	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Dizziness	浮動性めまい	2	N	TE	11	1	N	None	Recovered
			Dizziness	浮動性めまい	2	N	TE	47	1	N	None	Recovered
			Bone pain	骨痛	3	N	TE	55		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	106	16	N	Drug administration postponed	Recovered
			Hypokalaemia	低カリウム血症	3	N	TE	111	3	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	142		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	144	15	N	None	Recovered with sequelae
			Nausea	悪心	1	N	TE	158		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	158	8	N	None	Recovered with sequelae
033019	UK	71/M/C	Oedema peripheral	末梢性浮腫	1	N	TE			N	None	Not recovered, but no changes expected

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

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Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Spinal compression fracture	脊椎圧迫骨折	2	N	TE			Y	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Not recovered, but no changes expected
			Paraesthesia	錯感覚	1	N	TE			N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	2	N	Pre			N	None	Not recovered, but no changes expected
			Pleuritic pain	胸膜痛	1	N	TE			N	None	Recovered
			Spinal cord compression	脊髄圧迫	3	N	Pre	-6	13	N	None	Recovered
			Anaemia	貧血	1	N	TE	2	181	Y	None	Not recovered, but no changes expected
			Deep vein thrombosis	深部静脈血栓症	2	Y	TE	26	4	N	Drug administration postponed	Recovered with sequelae
			Deep vein thrombosis	深部静脈血栓症	1	N	TE	29		N	Drug administration postponed	Recovered with sequelae
			Deep vein thrombosis	深部静脈血栓症	1	N	TE	29		N	None	Not recovered, but no changes expected
			Pulmonary embolism	肺塞栓症	3	Y	TE	59	79	N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	3	N	TE	169		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	182	65	Y	None	Recovered
033022	UK	82/M/C	Constipation	便秘	2	N	TE			N	None	Recovered
			Nausea	悪心	2	N	TE			N	None	Recovered
			Vomiting	嘔吐	2	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			N	Drug permanently withdrawn	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	77	15	N	Drug permanently withdrawn	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	77	15	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	91		N	Not applicable	Ongoing at time of death
033023	UK	69/M/C	Post-traumatic pain	外傷後疼痛	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at time of death
			Muscular weakness	筋力低下	3	N	TE			N	None	Ongoing at time of death
			Pathological fracture	病的骨折	2	N	TE			N	None	Not recovered, but no changes expected
			Constipation	便秘	1	N	Pre	-673	882	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	28		N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	85	65	N	None	Recovered with sequelae
			Pathological fracture	病的骨折	3	Y	TE	149	20	Y	Drug administration postponed	Recovered
			Mobility decreased	運動性低下	2	N	TE	168	42	N	None	Ongoing at time of death
			Pathological fracture	病的骨折	2	N	TE	168		Y	None	Not recovered, but no changes expected
			Paraesthesia	錯感覚	1	Y	TE	175	5	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hypokalaemia	低カリウム血症	1	N	TE	178	7	N	None	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	178	32	N	None	Ongoing at time of death
			Upper limb fracture	上肢骨折	3	Y	TE	202		Y	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	5	Y	TE	209	1	N	Not applicable	Death
033027	UK	58/M/C	Diarrhoea	下痢	1	N	TE			Y	None	Recovered
			Nausea	悪心	1	N	TE			Y	None	Recovered
			Gingival infection	歯肉感染	1	N	TE			N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			N	None	Not recovered, but no changes expected
			Pain in jaw	顎痛	1	N	TE			Y	None	Recovered
			Hypoaesthesia	感覚鈍麻	1	N	TE			N	None	Not recovered, but no changes expected
			Depression	うつ病	1	N	TE			N	None	Not recovered, but no changes expected
			Palpitations	動悸	2	N	TE	40	1	N	None	Recovered
			Dyspepsia	消化不良	2	N	TE	40		N	None	Ongoing at time of death
			Hyperhidrosis	多汗症	2	N	TE	40	1	N	None	Recovered
			Vomiting	嘔吐	3	Y	TE	44	3	N	None	Recovered
			Nausea	悪心	1	N	TE	57		N	None	Recovered
			Diarrhoea	下痢	1	N	TE	60	10	Y	None	Recovered
			Osteonecrosis	骨壊死	2	N	TE	100		Y	None	Not recovered, but no changes expected
			Defaecation urgency	便意切迫	3	N	TE	120	1	Y	None	Recovered
			Defaecation urgency	便意切迫	3	N	TE	120	2	Y	None	Recovered
			Faecal incontinence	便失禁	3	N	TE	120	2	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	193		N	None	Recovered
			Diarrhoea	下痢	3	Y	TE	196	8	N	Not applicable	Recovered
			Vomiting	嘔吐	3	Y	TE	196	8	N	Not applicable	Recovered
			Intervertebral disc degeneration	椎間板変性症	3	Y	TE	196	8	N	Not applicable	Recovered
			Paraesthesia	錯感覚	2	N	TE	196	8	N	None	Recovered
034004	UK	63/M/C	Nausea	悪心	1	N	TE	8		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	8		Y	None	Ongoing at time of death
			Oral candidiasis	口腔カンジダ症	1	N	TE	8		N	None	Ongoing at time of death
			Dizziness	浮動性めまい	1	N	TE	8		N	None	Ongoing at time of death
			Cerebral ischaemia	脳虚血	4	Y	TE	43	5	N	None	Recovered with sequelae
			Anorexia	食欲不振	3	N	TE	53		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	92	9	N	Not applicable	Recovered
			Diarrhoea	下痢	3	N	TE	95	6	Y	Not applicable	Recovered
			Vomiting	嘔吐	3	N	TE	95	6	N	Not applicable	Recovered
			Anaemia	貧血	4	N	TE	98	2	N	Not applicable	Recovered
			Bone marrow failure	骨髄機能不全	4	Y	TE	98	9	N	Not applicable	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Sinus tachycardia	洞性頻脈	1	N	TE	98		N	Not applicable	Ongoing at time of death
			Confusional state	錯乱状態	3	N	TE	98	2	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	98	2	N	Not applicable	Recovered
			Rash	発疹	2	N	TE	98		N	None	Ongoing at time of death
			Haematemesis	吐血	3	N	TE	99	2	N	Not applicable	Recovered with sequelae
			Oesophagitis	食道炎	2	N	TE	99		N	Not applicable	Ongoing at time of death
			Bone marrow failure	骨髄機能不全	5	Y	TE	106	1	N	Not applicable	Death
034017	UK	83/M/C	Rash	発疹	1	N	TE			N	None	Recovered
			Vision blurred	霧視	3	N	TE	25	2	N	None	Ongoing at time of death
			Vision blurred	霧視	2	N	TE	26		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	42	57	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	42	57	N	None	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	2	N	TE	42		N	None	Ongoing at time of death
			Oral candidiasis	口腔カンジダ症	2	N	TE	70	29	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	95	1	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	98		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	114		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
035006	UK	62/M/C	Fatigue	疲労	1	N	Pre	-22	23	N	None	Recovered
			Conjunctivitis	結膜炎	1	N	TE	13	15	N	None	Recovered
			Polyneuropathy	多発ニューロパチー	1	N	TE	27	28	N	None	Recovered
			Paresis cranial nerve	脳神経不全麻痺	3	Y	TE	30		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	84	35	N	None	Recovered
			Constipation	便秘	1	N	TE	85		N	None	Ongoing at study termination / withdrawal
			Oral candidiasis	口腔カンジダ症	2	N	TE	86		N	None	Recovered
			Respiratory tract infection	気道感染	1	N	TE	86		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	87		N	None	Ongoing at time of death
			Urinary tract obstruction	尿路閉塞	2	N	TE	101		N	None	Recovered with sequelae
			Decreased appetite	食欲減退	1	N	TE	111	2	N	None	Recovered
035016	UK	62/M/C	Diarrhoea	下痢	2	N	TE	3	11	N	None	Recovered
			Nausea	悪心	2	N	TE	3	11	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	109	9	N	None	Recovered
			Constipation	便秘	1	N	TE	111	8	N	None	Recovered
			Oral candidiasis	口腔カンジダ症	2	N	TE	112	42	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	112	7	N	Drug administration postponed	Recovered
			Dyspepsia	消化不良	1	N	TE	113	3	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	1	N	TE	113	3	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	113		N	None	Recovered
			Bone pain	骨痛	3	N	TE	118	36	N	None	Not recovered, but no changes expected
			Diarrhoea	下痢	3	Y	TE	150	4	Y	Not applicable	Recovered
			Vomiting	嘔吐	3	Y	TE	150	4	Y	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	153		N	None	Not recovered, but no changes expected
			Diarrhoea	下痢	3	Y	Post	337	10	Y	Not applicable	Recovered
035019	UK	67/M/C	Nausea	悪心	2	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	Pre	1	4	Y	None	Recovered
			Bone pain	骨痛	2	Y	TE	106	5	N	None	Recovered with sequelae
			Urinary tract infection	尿路感染	1	N	TE	128	11	N	None	Recovered
			Constipation	便秘	1	N	TE	132	5	N	None	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	152	6	Y	Not applicable	Recovered
			Nausea	悪心	1	N	TE	158	46	N	Not applicable	Recovered
			Fatigue	疲労	1	N	TE	163		N	Not applicable	Not recovered, but no changes expected
035023	UK	70/M/C	Fatigue	疲労	1	N	TE	66		Y	None	Not recovered, but no changes expected
			Fatigue	疲労	2	N	TE	66		Y	None	Not recovered, but no changes expected
			Dyspepsia	消化不良	2	N	TE	70		N	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Decreased appetite	食欲減退	2	N	TE	70		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	84		Y	None	Not recovered, but no changes expected
			Gastrointestinal haemorrhage	胃腸出血	3	Y	TE	94	8	N	None	Recovered
			Electrocardiogram QT prolonged	心電図ＱＴ延長	1	N	TE	105		N	Not applicable	Not recovered, but no changes expected
			Clostridium difficile colitis	クロストリジウム・ディフィシレ大腸炎	2	Y	TE	110	9	N	Not applicable	Recovered
			Clostridium difficile colitis	クロストリジウム・ディフィシレ大腸炎	1	N	TE	150	9	N	None	Recovered
035027	UK	68/M/C	Decreased appetite	食欲減退	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	1	3	Y	None	Recovered
			Constipation	便秘	2	N	TE	44		Y	None	Ongoing at time of death
			Intestinal obstruction	腸閉塞	4	Y	TE	54	2	Y	None	Death
			Intestinal obstruction	腸閉塞	5	Y	TE	55	1	Y	None	Death
035028	UK	70/M/C	Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Recovered
			Urine flow decreased	尿流量減少	1	N	TE	11	19	N	None	Recovered
			Bone pain	骨痛	2	N	TE	29		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	44	18	N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	44		N	None	Recovered
			Constipation	便秘	2	Y	TE	66	6	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	71	79	N	Not applicable	Death
			Constipation	便秘	1	N	TE	72	42	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	141		Y	None	Ongoing at time of death
			Confusional state	錯乱状態	3	Y	TE	150	11	N	Not applicable	Death
			Confusional state	錯乱状態	5	Y	TE	160	1	N	Not applicable	Death
035031	UK	63/M/C	Pollakiuria	頻尿	1	N	TE	2	2	Y	None	Recovered
			Sepsis	敗血症	4	Y	TE	50	19	N	Drug permanently withdrawn	Recovered
			Bone pain	骨痛	4	Y	TE	50	24	N	Drug permanently withdrawn	Recovered
			Haematuria	血尿	3	N	TE	50		N	Not applicable	Not recovered, but no changes expected
			Herpes zoster	帯状疱疹	2	N	TE	86	6	N	Not applicable	Recovered
			Renal impairment	腎機能障害	2	N	TE	86	5	N	Not applicable	Recovered
035033	UK	63/M/C	Angina pectoris	狭心症	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			N	None	Ongoing at time of death
			Blood urea increased	血中尿素増加	1	N	TE	41	57	N	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	87	1	N	None	Recovered
			Constipation	便秘	2	N	TE	159	3	N	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	202	1	N	None	Recovered
			Myocardial ischaemia	心筋虚血	4	Y	TE	203	3	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
036001	UK	82/M/C	Bone pain	骨痛	1	N	TE	43		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	56	8	N	None	Recovered
			Bone pain	骨痛	4	Y	TE	63	11	N	None	Recovered
			Arrhythmia	不整脈	3	Y	TE	111	16	N	None	Recovered
			Anaemia	貧血	2	N	TE	149		Y	Not applicable	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	149		N	None	Ongoing at study termination / withdrawal
036005	UK	63/M/C	Dysphagia	嚥下障害	1	N	Pre			N	None	Ongoing at study termination / withdrawal
			Dizziness	浮動性めまい	1	N	TE			N	None	Recovered
			Diarrhoea	下痢	2	N	TE	24	6	N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE	24		N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	3	N	TE	36	28	Y	None	Recovered
			Disturbance in attention	注意力障害	1	N	TE	63		N	None	Ongoing at study termination / withdrawal
			Tremor	振戦	2	N	TE	63		N	None	Not recovered, but no changes expected
			Hyperhidrosis	多汗症	1	N	TE	63		N	None	Ongoing at study termination / withdrawal
			Wheezing	喘鳴	2	N	TE	91		N	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Lower respiratory tract infection	下気道感染	2	N	TE	182		N	None	Ongoing at study termination / withdrawal
			Pneumonia	肺炎	3	Y	TE	182		N	Not applicable	Recovered with sequelae
			Pneumonia	肺炎	3	Y	TE	205	14	N	Not applicable	Recovered
037007	UK	72/M/C	Constipation	便秘	1	N	TE			Y	None	Recovered
			Vomiting	嘔吐	1	N	TE			N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE			N	None	Recovered
			Muscle spasms	筋痙縮	2	N	TE			N	None	Not recovered, but no changes expected
			Hypertension	高血圧	1	N	TE			Y	None	Not recovered, but no changes expected
			Diarrhoea	下痢	3	N	TE	2	3	Y	None	Recovered
			Nausea	悪心	1	N	TE	2	8	Y	None	Recovered
			Fatigue	疲労	1	N	TE	2	7	Y	None	Recovered
			Influenza	インフルエンザ	2	N	TE	11	8	Y	None	Recovered
			Cough	咳嗽	1	N	TE	18	12	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	54	4	Y	None	Recovered
			Chills	悪寒	1	N	TE	54	1	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	54	10	N	None	Recovered
			Cough	咳嗽	1	N	TE	64	9	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	68	3	Y	None	Recovered
			Urge incontinence	切迫性尿失禁	1	N	TE	68	1	N	None	Recovered
			Nausea	悪心	1	Y	TE	72	1	Y	None	Recovered
			Vomiting	嘔吐	1	Y	TE	72	1	Y	None	Recovered
			Hydronephrosis	水腎症	3	Y	TE	72	12	N	None	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Renal failure	腎不全	3	Y	TE	72	4	N	Drug administration postponed	Recovered with sequelae
			Renal failure	腎不全	2	N	TE	75		N	None	Not recovered, but no changes expected
			Catheter related infection	カテーテル関連感染	2	N	TE	152	40	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	160	3	N	None	Recovered
			Gynaecomastia	女性化乳房	1	N	TE	162	30	N	None	Recovered
037008	UK	81/M/C	Mobility decreased	運動性低下	2	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	2	1	N	None	Recovered
			Musculoskeletal pain	筋骨格痛	1	N	TE	2	1	N	None	Recovered
			Constipation	便秘	1	N	TE	63		N	None	Not recovered, but no changes expected
			Eye infection	眼感染	2	N	TE	99	19	N	None	Recovered
			Gastritis	胃炎	2	N	TE	221	3	N	Not applicable	Recovered
			Gastritis	胃炎	3	Y	TE	223	2	N	Not applicable	Recovered
037012	UK	67/M/C	Abdominal pain	腹痛	1	N	TE			N	None	Not recovered, but no changes expected
			Hiatus hernia	裂孔ヘルニア	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			N	None	Recovered
			Pain in jaw	顎痛	1	N	TE			N	None	Ongoing at time of death
			Deep vein thrombosis	深部静脈血栓症	3	N	TE			Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	28	2	N	Drug administration postponed	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	113		N	None	Ongoing at time of death
			Osteoarthritis	骨関節炎	1	N	TE	163		N	None	Not recovered, but no changes expected
			Dyspnoea exertional	労作性呼吸困難	1	N	TE	171		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	198		N	None	Ongoing at time of death
			Head injury	頭部損傷	3	N	TE	212	1	N	None	Recovered with sequelae
			Disseminated intravascular coagulation	播種性血管内凝固	3	N	TE	214		N	None	Not recovered, but no changes expected
			Thrombocytopenia	血小板減少症	3	Y	TE	214		N	Not applicable	Ongoing at time of death
			Extradural haematoma	硬膜外血腫	5	Y	TE	214	1	N	Not applicable	Death
037013	UK	70/M/C	Anorexia	食欲不振	1	N	TE			Y	None	Recovered
			Dysarthria	構語障害	1	N	TE			N	None	Not recovered, but no changes expected
			Non-cardiac chest pain	非心臓性胸痛	1	N	TE	3	8	N	None	Recovered
			Non-cardiac chest pain	非心臓性胸痛	2	N	TE	10	24	N	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	19	6	N	None	Recovered
			Bursitis infective	感染性滑液包炎	1	N	TE	30	8	N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	30		N	None	Not recovered, but no changes expected
			Bursitis infective	感染性滑液包炎	2	Y	TE	37	3	N	None	Recovered
			Nausea	悪心	1	N	TE	46	4	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	48	2	Y	None	Recovered
			Lethargy	嗜眠	1	N	TE	59		Y	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	1	N	TE	61	4	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	118	9	Y	None	Recovered
			Rectal haemorrhage	直腸出血	1	N	TE	118	1	Y	None	Recovered
			Nausea	悪心	1	N	TE	141		Y	None	Not recovered, but no changes expected
			Diarrhoea	下痢	1	N	TE	143	3	Y	None	Recovered
			Anaemia	貧血	3	N	TE	190	44	Y	None	Recovered
038003	UK	80/M/C	Vomiting	嘔吐	3	N	TE	1	2	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	2	7	Y	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	4	4	N	None	Recovered
			Haematuria	血尿	2	N	TE	4	6	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	8	2	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	16	6	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	28	2	Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	2	N	TE	28		Y	None	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	29	2	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	35	2	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	56		N	None	Ongoing at time of death
			Muscular weakness	筋力低下	4	Y	TE	56		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	57	2	Y	None	Recovered
039005	UK	72/M/C	Constipation	便秘	3	N	TE	4	38	N	None	Recovered
			Nausea	悪心	3	N	TE	13	29	N	None	Recovered
			Nausea	悪心	3	N	TE	35	7	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	35		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Spinal cord compression	脊髄圧迫	3	N	TE	35	8	N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	42	1	N	None	Death
039007	UK	68/M/C	Bone pain	骨痛	1	N	Pre			N	None	Ongoing at time of death
			Anaemia	貧血	1	Y	Pre	-23	2	N	Drug administration postponed	Recovered
			Decreased appetite	食欲減退	1	N	Pre	-11		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	-11		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	-11	5	N	None	Recovered
			Nausea	悪心	1	N	Pre	-4		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	Pre	-4		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	4	23	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	27		Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	29	36	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	60		Y	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	70	1	N	None	Recovered
			Anaemia	貧血	2	N	TE	92		Y	Drug administration postponed	Ongoing at time of death
			Joint injury	関節損傷	2	N	TE	94		N	None	Ongoing at time of death

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	1	N	TE	95		Y	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	118	2	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	180	2	Y	Not applicable	Recovered
			Skin lesion	皮膚病変	3	N	TE	183		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	214	1	N	Not applicable	Death
039012	UK	82/M/C	Anaemia	貧血	3	N	TE			N	None	Recovered
			Hyperchlorhydria	胃酸過多	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	2	N	Pre	-2	26	N	None	Recovered
			Hypoaesthesia	感覚鈍麻	2	N	Pre	-2		N	None	Ongoing at study termination / withdrawal
			Hypoaesthesia	感覚鈍麻	2	N	TE	8		N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	2	N	TE	8		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	24		N	None	Ongoing at time of death
			Pathological fracture	病的骨折	3	Y	TE	35	33	N	Drug administration postponed	Recovered
			Nausea	悪心	2	N	TE	71	86	Y	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dry mouth	口内乾燥	3	N	TE	87	70	N	None	Ongoing at time of death
			Back injury	背部損傷	3	N	TE	91	66	N	None	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	125		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	156	1	N	None	Death
039015	UK	79/M/C	Abdominal distension	腹部膨満	2	N	TE			N	None	Recovered
			Nausea	悪心	2	N	TE			Y	None	Recovered
			Fatigue	疲労	3	N	TE			N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	Pre	1	85	N	None	Recovered
			Bone pain	骨痛	2	N	Pre	1	85	N	None	Recovered
			Bone pain	骨痛	2	N	Pre	1	111	N	None	Recovered
			Incontinence	失禁	2	N	Pre	1	85	N	None	Recovered
			Decreased appetite	食欲減退	2	N	TE	29		N	None	Ongoing at study termination / withdrawal
			Haematuria	血尿	3	Y	TE	85	7	N	Drug administration postponed	Recovered
			Cystitis radiation	放射線性膀胱炎	3	Y	TE	93	5	N	Drug administration postponed	Recovered
			Cystitis radiation	放射線性膀胱炎	2	N	TE	97		N	None	Recovered
			Urinary tract infection	尿路感染	3	N	TE	146	18	N	None	Recovered
			Urinary tract infection	尿路感染	3	N	TE	167		N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oesophageal obstruction	食道閉塞症	3	N	TE	176		N	None	Ongoing at study termination / withdrawal
			Hyperchlorhydria	胃酸過多	2	N	TE	179		N	None	Ongoing at time of death
039016	UK	69/M/C	Fatigue	疲労	2	N	TE			Y	None	Recovered
			Cellulitis	蜂巣炎	3	N	Pre			N	None	Recovered
			Rhinitis	鼻炎	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	Pre			N	None	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	7	9	N	None	Recovered
			Oedema peripheral	末梢性浮腫	3	N	TE	25	296	N	None	Recovered
			Dyspnoea	呼吸困難	2	N	TE	146		N	None	Not recovered, but no changes expected
039025	UK	78/M/C	Asthenia	無力症	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	Pre	1	57	N	None	Recovered
			Bone pain	骨痛	2	N	Pre	1	29	N	None	Recovered
			Bone pain	骨痛	2	N	TE	83		N	None	Ongoing at time of death
			Metastases to central nervous system	中枢神経系転移	3	Y	TE	109		N	Drug permanently withdrawn	Ongoing at time of death
			Dysphasia	不全失語症	2	N	TE	109		N	None	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	113		N	Not applicable	Ongoing at time of death
039027	UK	74/M/C	Nausea	悪心	2	N	TE	1		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	1		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	2	N	Pre	1		N	None	Ongoing at time of death
			Dizziness	浮動性めまい	2	N	TE	1		N	None	Ongoing at time of death
			Headache	頭痛	1	N	TE	1		N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	1	N	TE	1		N	None	Ongoing at time of death
			Dehydration	脱水	3	Y	TE	8	7	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	18	20	N	Drug administration postponed	Death
			Renal failure	腎不全	3	Y	TE	18	1	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	N	TE	19	4	N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	37	1	N	Drug administration postponed	Death
040004	UK	67/M/C	Nausea	悪心	1	N	Pre			N	None	Recovered
			Vomiting	嘔吐	1	N	Pre			N	None	Recovered
			Upper respiratory tract infection	上気道感染	2	N	TE	29	8	N	None	Recovered
			Nausea	悪心	2	Y	TE	70	2	Y	None	Recovered
			Vomiting	嘔吐	2	Y	TE	70	2	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	105		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	142		Y	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	1	N	TE	142		Y	None	Ongoing at study termination / withdrawal
040005	UK	67/M/C	Bone pain	骨痛	3	N	TE			N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	2	3	Y	None	Recovered
			Malaise	倦怠感	2	N	TE	2	3	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	2		N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	29	4	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	29	4	N	None	Recovered
			Lower respiratory tract infection	下気道感染	3	N	TE	49	13	N	None	Recovered
			Anaemia	貧血	2	N	TE	57	56	Y	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	68	60	N	Drug permanently withdrawn	Death
			Anaemia	貧血	3	Y	TE	112	3	Y	None	Recovered
			Fatigue	疲労	3	Y	TE	112	3	Y	Not applicable	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	114		Y	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	2	N	TE	114		Y	Not applicable	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	127	1	N	Drug permanently withdrawn	Death
040007	UK	68/M/C	Breast tenderness	乳房圧痛	1	N	Pre			N	None	Recovered
			Breast tenderness	乳房圧痛	1	N	TE			Y	None	Recovered
			Nausea	悪心	1	N	TE	4	16	Y	None	Recovered
			Fatigue	疲労	1	N	TE	4	16	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	67	29	Y	None	Recovered
			Bone pain	骨痛	3	Y	TE	84	2	N	None	Recovered
			Fatigue	疲労	2	N	TE	132		N	None	Ongoing at study termination / withdrawal
			Dyspnoea	呼吸困難	1	N	TE	132		N	None	Ongoing at study termination / withdrawal
			Joint swelling	関節腫脹	1	N	TE	139		N	None	Ongoing at study termination / withdrawal
040008	UK	75/M/C	Bone pain	骨痛	2	N	Pre	-10	8	N	None	Recovered
			Headache	頭痛	1	N	Pre	-10	8	N	None	Recovered
			Nausea	悪心	2	N	Pre	-8	40	N	None	Recovered
			Anorexia	食欲不振	2	N	Pre	-8	5	N	None	Recovered
			Vomiting	嘔吐	1	N	Pre	-5	1	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	1	N	Pre	-5		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	Pre	1	79	N	None	Recovered
			Bone pain	骨痛	1	N	Pre	1	79	N	None	Recovered
			Bone pain	骨痛	1	N	Pre	1	79	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	33	30	Y	None	Recovered
			Dyspepsia	消化不良	2	N	TE	67		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	72	1	N	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	85	30	Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	3	N	TE	114		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Mouth haemorrhage	口腔内出血	3	Y	TE	135		Y	Not applicable	Ongoing at study termination / withdrawal
041001	UK	56/M/C	Pulmonary embolism	肺塞栓症	4	Y	Pre	-39	8	N	Not applicable	Recovered with sequelae
			Intertrigo	間擦疹	2	N	Pre	-33	30	N	None	Recovered
			Nausea	悪心	1	N	Pre	1	57	N	None	Recovered
			Decreased appetite	食欲減退	1	N	Pre	1	113	N	None	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	2	4	Y	None	Recovered
			Fatigue	疲労	1	N	TE	2	15	N	None	Recovered
			Bone pain	骨痛	2	N	TE	2	112	Y	None	Recovered
			Weight decreased	体重減少	1	N	TE	29	85	N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	46	96	N	None	Recovered
			Pain in extremity	四肢痛	2	N	TE	46		N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	57	203	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	57		N	None	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	3	Y	TE	81	5	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	113		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	3	N	TE	113	57	N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	141	8	N	None	Recovered
			Bone pain	骨痛	3	N	TE	148	21	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	168		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	169		N	None	Ongoing at time of death
			Night sweats	寝汗	2	N	TE	192		N	None	Ongoing at time of death
			Oral candidiasis	口腔カンジダ症	2	N	TE	202		N	None	Ongoing at time of death
			Abdominal pain upper	上腹部痛	1	N	TE	223		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	223		N	None	Ongoing at time of death
041003	UK	59/M/C	Dry mouth	口内乾燥	1	N	TE			N	None	Ongoing at time of death
			Abdominal distension	腹部膨満	1	N	Pre	-13	52	N	None	Recovered
			Bone pain	骨痛	3	N	Pre	-13	4	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Joint swelling	関節腫脹	1	N	Pre	-13		N	None	Ongoing at time of death
			Hot flush	ほてり	1	N	Pre	-13		N	None	Ongoing at time of death
			Pitting oedema	圧痕浮腫	1	N	Pre	1	39	N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	1	N	Pre	1		N	None	Ongoing at time of death
			Lethargy	嗜眠	2	N	TE	2	52	Y	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	4	50	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	30	140	N	None	Recovered
			Insomnia	不眠症	1	N	TE	30	124	N	None	Ongoing at time of death
			Depressed mood	抑うつ気分	1	N	TE	42		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	43	15	Y	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	43	69	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	44	126	N	None	Recovered
			Pain in jaw	顎痛	1	N	TE	44	4	N	None	Recovered
			Bone pain	骨痛	2	N	TE	50	8	N	None	Recovered
			Lethargy	嗜眠	3	N	TE	53		Y	None	Ongoing at time of death
			Musculoskeletal stiffness	筋骨格硬直	1	N	TE	55	57	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	57	55	N	None	Ongoing at time of death
			Ligament injury	靭帯損傷	2	N	TE	74	38	N	None	Recovered
			Lower limb fracture	下肢骨折	2	N	TE	74		N	None	Ongoing at time of death
			Dysgeusia	味覚異常	1	N	TE	83		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	103	3	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	105	2	Y	None	Recovered
			Oral herpes	口腔ヘルペス	2	N	TE	107		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	111	16	Y	-	
			Weight decreased	体重減少	2	N	TE	111		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	2	N	TE	111	59	N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	124	1	Y	None	Recovered
			Anaemia	貧血	2	N	TE	126	12	Y	-	
			Vomiting	嘔吐	1	N	TE	126	1	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	129	1	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	136	1	Y	None	Recovered
			Anaemia	貧血	3	N	TE	137	5	Y	-	
			Anaemia	貧血	2	N	TE	141		Y	None	Ongoing at time of death
			Insomnia	不眠症	2	N	TE	153		N	None	Ongoing at time of death
			Restless legs syndrome	下肢静止不能症候群	2	N	TE	165		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	169		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	169	50	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	218		N	None	Ongoing at time of death
			Epistaxis	鼻出血	1	N	TE	218		N	None	Ongoing at time of death
041005	UK	76/M/C	Bone pain	骨痛	2	N	TE	7	191	N	None	Not recovered, but no changes expected
			Defaecation urgency	便意切迫	1	N	TE	8	21	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Frequent bowel movements	排便回数増加	1	N	TE	8	21	Y	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	78	5	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	80	1	Y	None	Recovered
			Pathological fracture	病的骨折	2	Y	TE	118	51	N	None	Recovered
			Bone pain	骨痛	3	N	TE	197		N	None	Not recovered, but no changes expected
			Musculoskeletal stiffness	筋骨格硬直	1	N	TE	197		N	None	Not recovered, but no changes expected
			Pain in extremity	四肢痛	1	N	TE	197		N	None	Not recovered, but no changes expected
			Soft tissue infection	軟部組織感染	2	N	TE	222		N	None	Not recovered, but no changes expected
041006	UK	64/M/C	Lower respiratory tract infection	下気道感染	2	Y	Pre	-65	8	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	2	2	Y	None	Recovered
			Contusion	挫傷	1	N	TE	39	110	N	None	Recovered
			Joint sprain	関節捻挫	1	N	TE	39	110	N	None	Recovered
			Skin laceration	皮膚裂傷	1	N	TE	39	110	N	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	60	7	N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	Y	TE	66	20	N	None	Recovered
			Therapeutic agent toxicity	治療薬毒性	4	Y	TE	73	1	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	92	6	Y	None	Recovered
			Bone pain	骨痛	3	Y	TE	100	17	N	None	Recovered
			Bone pain	骨痛	3	N	TE	116	2	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	117	25	N	None	Recovered
			Bone pain	骨痛	2	N	TE	141		N	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
041008	UK	74/M/C	Anaemia	貧血	2	N	Pre	1	29	N	Drug administration postponed	Recovered
			Nausea	悪心	2	N	TE	1	3	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	1	3	N	None	Recovered
			Anaemia	貧血	2	Y	TE	29	4	N	Drug administration postponed	Recovered
			Acute myocardial infarction	急性心筋梗塞	4	Y	TE	29	4	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	32	19	N	Drug administration postponed	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE	35	13	N	None	Recovered
			Anaemia	貧血	3	Y	TE	50	4	N	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	50	3	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	52		N	None	Ongoing at time of death
			Anaemia	貧血		Y	TE	76		N	Drug administration postponed	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	5	Y	TE	79	1	N	None	Death
041011	UK	58/M/C	Oral candidiasis	口腔カンジダ症	2	N	Pre	1		N	None	Recovered
			Metastases to bone	骨転移	2	N	TE	27	6	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	29	84	Y	None	Ongoing at time of death
			Metastases to bone	骨転移	2	Y	TE	32	18	N	None	Recovered
			Metastases to bone	骨転移	2	N	TE	49		N	None	Not recovered, but no changes expected
			Oedema peripheral	末梢性浮腫	2	N	TE	57	57	N	None	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	3	Y	TE	63	6	N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	63	6	N	Drug administration postponed	Recovered
			Diabetes mellitus	糖尿病	2	N	TE	71	56	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	84	58	Y	Drug administration postponed	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	85	79	N	Drug permanently withdrawn	Death
			Anaemia	貧血	1	N	TE	112	30	Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	113	38	N	None	Ongoing at time of death
			Memory impairment	記憶障害	1	N	TE	113		N	None	Ongoing at time of death
			Rales	ラ音	1	N	TE	113		N	None	Ongoing at time of death
			Dizziness postural	体位性めまい	2	N	TE	116		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Diabetes mellitus	糖尿病	1	N	TE	126		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	141		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	141	5	Y	Drug administration postponed	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	145		Y	Drug administration postponed	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	Y	TE	150		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	163	1	N	Drug permanently withdrawn	Death
041012	UK	62/M/C	Nausea	悪心	1	N	TE			N	None	Recovered
			Ingrowing nail	嵌入爪	2	N	Pre			N	Not applicable	Recovered
			Lower respiratory tract infection	下気道感染	2	N	Pre	-2		N	None	Recovered
			Bone pain	骨痛	2	N	TE	1	5	Y	None	Recovered
			Nightmare	悪夢	2	N	TE	1	20	N	None	Recovered
			Skin odour abnormal	皮膚異常臭	2	N	TE	1	57	Y	None	Recovered
			Nail infection	爪感染	2	N	TE	5	1	N	None	Recovered
			Anaemia	貧血	2	N	TE	29	29	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	29	3	Y	None	Recovered
			Fatigue	疲労	2	N	TE	40		Y	None	Not recovered, but no changes expected
			Insomnia	不眠症	2	N	TE	40	176	N	None	Recovered
			Anaemia	貧血	1	N	TE	57	29	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea exertional	労作性呼吸困難	1	N	TE	57	57	Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	61	4	Y	None	Recovered
			Dry skin	皮膚乾燥	2	N	TE	80	154	N	None	Recovered
			Skin exfoliation	皮膚剥脱	2	N	TE	80	153	N	None	Recovered
			Anaemia	貧血	2	N	TE	85	85	Y	None	Recovered
			Nasopharyngitis	鼻咽頭炎	2	N	TE	110	32	N	None	Recovered
			Odynophagia	嚥下痛	1	N	TE	113	6	N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	2	N	TE	113		Y	None	Not recovered, but no changes expected
			Pharyngolaryngeal pain	咽喉頭疼痛	2	N	TE	113	6	N	None	Recovered
			Oral candidiasis	口腔カンジダ症	2	Y	TE	118	2	N	None	Recovered
			Oral candidiasis	口腔カンジダ症	1	N	TE	119	7	N	None	Recovered
			Pain of skin	皮膚疼痛	1	N	TE	120	113	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	133	2	N	None	Recovered
			Stomach discomfort	胃不快感	2	N	TE	148	22	N	Not applicable	Recovered
			Decreased appetite	食欲減退	2	N	TE	148	17	N	Not applicable	Recovered
			Oral candidiasis	口腔カンジダ症	2	N	TE	154		N	Not applicable	Recovered
			Decreased appetite	食欲減退	1	N	TE	164	53	N	Not applicable	Recovered
			Anaemia	貧血	3	Y	TE	169	2	Y	Not applicable	Recovered
			Leukopenia	白血球減少症	3	N	TE	169		N	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	1	N	TE	169	21	Y	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	1	N	TE	169		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	N	TE	170	11	Y	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	180	16	Y	Not applicable	Not recovered, but no changes expected
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	189	13	N	Not applicable	Recovered
			Anaemia	貧血	1	N	TE	195		Y	Not applicable	Not recovered, but no changes expected
042015	UK	72/M/C	Increased appetite	食欲亢進	1	N	TE			N	None	Recovered
			Somnolence	傾眠	2	N	TE			N	None	Recovered
			Diplopia	複視	3	N	TE	14	10	Y	None	Recovered
			Balance disorder	平衡障害	1	N	TE	14	10	N	None	Recovered
			Confusional state	錯乱状態	3	N	TE	14	10	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	15	15	Y	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	53	6	N	None	Recovered
			Agitation	激越	2	N	TE	114	2	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	115	1	N	None	Death
			Increased bronchial secretion	気管支分泌増加	2	N	TE	115	1	N	None	Recovered
042020	UK	73/M/C	Aphthous stomatitis	アフタ性口内炎	1	N	TE			N	None	Recovered
			Diarrhoea	下痢	1	N	TE	4	6	Y	None	Recovered
			Decreased appetite	食欲減退	2	N	TE	4	150	N	None	Ongoing at time of death
			Lethargy	嗜眠	2	N	TE	4	146	N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

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Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	1	N	TE	23		N	None	Ongoing at time of death
			Radius fracture	橈骨骨折	3	N	TE	48	33	N	None	Recovered
			Bone pain	骨痛	2	N	TE	63		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	67	122	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	89	71	N	None	Recovered
			Melaena	メレナ	1	N	TE	99		N	None	Ongoing at time of death
			Haematuria	血尿	1	Y	TE	125	2	N	None	Recovered
			Haematuria	血尿	2	N	TE	140	4	N	Drug administration postponed	Recovered
			Haematuria	血尿	2	Y	TE	143	2	N	Drug administration postponed	Recovered
			Lethargy	嗜眠	1	N	TE	149		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	153		N	None	Ongoing at time of death
			Renal tubular necrosis	腎尿細管壊死	3	Y	TE	210	89	N	Not applicable	Recovered
042030	UK	61/M/C	Proctalgia	肛門周囲痛	2	N	TE			N	None	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	TE			N	None	Ongoing at time of death
			Depressed mood	抑うつ気分	1	N	TE			N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	1		N	None	
			Vomiting	嘔吐	1	N	TE	1		N	None	Recovered
			Bone pain	骨痛	1	N	TE	2	28	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

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Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Haematuria	血尿	3	Y	TE	12	5	N	None	Recovered
			Constipation	便秘	1	N	TE	29	39	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	52		N	None	Recovered
			Renal failure acute	急性腎不全	3	Y	TE	52	8	N	Drug administration postponed	Recovered
			Hypotension	低血圧	2	N	TE	52		N	None	Recovered
			Constipation	便秘	3	Y	TE	67	6	N	Drug administration postponed	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	132	3	N	None	Recovered
			Deep vein thrombosis	深部静脈血栓症	2	N	TE	177		N	Drug permanently withdrawn	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	207		N	None	Ongoing at time of death
042034	UK	75/M/C	Oedema peripheral	末梢性浮腫	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	141		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	141		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	172	1	N	Not applicable	Death
042041	UK	80/M/C	Fatigue	疲労	2	N	TE			N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cauda equina syndrome	馬尾症候群	3	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	5		Y	None	Recovered
			Urinary incontinence	尿失禁	1	N	TE	29	115	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	41	22	N	Drug administration postponed	Recovered with sequelae
			Bone pain	骨痛	3	N	TE	42	93	N	None	Recovered
			Pathological fracture	病的骨折	2	N	TE	62	73	N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	84	6	N	None	Recovered
			Cellulitis	蜂巣炎	2	N	TE	85	7	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	85	59	N	None	Recovered
			Bone pain	骨痛	2	N	TE	87		N	None	Ongoing at time of death
			Urine flow decreased	尿流量減少	1	N	TE	127	17	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	134	57	N	None	Recovered
			Haematuria	血尿	1	N	TE	142		N	Not applicable	Ongoing at time of death
			Dysarthria	構語障害	2	Y	TE	143	9	N	None	Recovered
			Aggression	攻撃性	2	Y	TE	143	5	N	None	Recovered
			Confusional state	錯乱状態	2	Y	TE	143	9	N	None	Recovered
			Urinary retention	尿閉	2	Y	TE	143	5	N	None	Recovered with sequelae
			Confusional state	錯乱状態	1	N	TE	151	40	N	None	Recovered
			Urinary retention	尿閉	3	N	TE	151		N	Not applicable	Ongoing at time of death
043003	UK	64/M/C	Anaemia	貧血	1	N	Pre	-5	99	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	1	29	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	1	6	Y	None	Recovered
			Mouth ulceration	口腔内潰瘍形成	2	N	TE	73	29	N	None	Recovered
			Bone pain	骨痛	2	N	TE	75	6	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Lower respiratory tract infection	下気道感染	1	N	TE	96	6	N	None	Recovered
			Bone pain	骨痛	2	N	TE	96		Y	None	Not recovered, but no changes expected
			Lower respiratory tract infection	下気道感染	3	Y	TE	101	3	N	None	Recovered
			Metastases to central nervous system	中枢神経系転移	4	Y	TE	121	9	N	Drug permanently withdrawn	Recovered
			Fatigue	疲労	1	N	TE	175	6	Y	None	Recovered
043005	UK	66/M/C	Bone pain	骨痛	2	N	Pre	-5	29	N	Not applicable	Recovered
			Myalgia	筋痛	1	N	TE	52	29	N	None	Recovered
			Myalgia	筋痛	1	N	TE	52	29	N	None	Recovered
			Fatigue	疲労	1	N	TE	108	42	N	None	Recovered
			Myalgia	筋痛	1	N	TE	148		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	216	3	N	Not applicable	Recovered
043007	UK	60/M/A	Urinary retention	尿閉	2	N	TE			N	Not applicable	Recovered
			Diarrhoea	下痢	2	N	TE	1		Y	None	Recovered
			Fatigue	疲労	1	N	TE	1		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	Pre	1	9	N	None	Recovered
			Bone pain	骨痛	2	N	TE	29	1	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	47	3	Y	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	85	29	N	None	Recovered
			Skin nodule	皮膚小結節	1	N	TE	85	29	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	94	4	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cough	咳嗽	1	N	TE	94	7	Y	None	Recovered
			Skin discolouration	皮膚変色	1	N	TE	107		Y	None	Recovered
			Bone pain	骨痛	1	N	TE	113		N	None	Not recovered, but no changes expected
			Dysuria	排尿困難	3	N	TE	122		N	None	Recovered with sequelae
			Urinary retention	尿閉	3	Y	TE	152	4	N	Not applicable	Recovered
			Micturition disorder	排尿異常	2	N	TE	156		N	Not applicable	Not recovered, but no changes expected
			Vertigo	回転性めまい	2	N	TE	198	41	N	None	Recovered
			Bone pain	骨痛	2	N	TE	198		N	None	Not recovered, but no changes expected
043011	UK	77/M/A	Vision blurred	霧視	1	N	TE			N	None	Recovered
			Diarrhoea	下痢	1	N	TE			Y	None	Recovered
			Paraesthesia	錯感覚	1	N	TE			N	None	Not recovered, but no changes expected
			Fatigue	疲労	2	N	TE	1		Y	None	Not recovered, but no changes expected
			Hypocalcaemia	低カルシウム血症	2	N	TE	10		N	None	Not recovered, but no changes expected
			Dizziness	浮動性めまい	2	Y	TE	36	2	N	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	56	29	N	None	Recovered
			Dizziness	浮動性めまい	2	N	TE	84	6	N	None	Recovered
			Skin discolouration	皮膚変色	1	N	TE	86		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	2	Y	TE	88	2	Y	None	Recovered
			Vertigo	回転性めまい	1	N	TE	106	3	N	None	Recovered
			Fatigue	疲労	3	N	TE	120		Y	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
043012	UK	55/M/C	Diarrhoea	下痢	1	N	TE			Y	None	Recovered
			Nocturia	夜間頻尿	1	N	TE			N	None	Not recovered, but no changes expected
			Myalgia	筋痛	1	N	Pre	-6	64	N	None	Recovered
			Paraesthesia	錯感覚	1	N	TE	30	29	Y	None	Recovered
			Abdominal pain	腹痛	1	N	TE	86		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	135	14	N	None	Recovered
			Hydronephrosis	水腎症	3	Y	TE	135	14	N	None	Recovered
			Renal failure acute	急性腎不全	3	Y	TE	135	14	N	Drug permanently withdrawn	Recovered
			Nausea	悪心	2	N	TE	137		N	None	Recovered
			Pulmonary embolism	肺塞栓症	4	Y	TE	142	7	N	Drug permanently withdrawn	Recovered
			Constipation	便秘	2	N	TE	173		N	Not applicable	Recovered
044004	UK	76/M/C	Vomiting	嘔吐	1	N	TE			Y	None	
			Haematuria	血尿	1	N	TE			N	None	Recovered
			Ataxia	運動失調	2	N	TE	23		N	None	
			Speech disorder	会話障害	3	N	TE	23	29	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	23		N	None	
			Deafness	難聴	2	N	TE	51		N	None	
			Tinnitus	耳鳴	2	N	TE	51		N	None	
			Fatigue	疲労	1	N	TE	71		Y	None	
			Radiation skin injury	放射線皮膚損傷	1	N	TE	71		N	None	
			Arthralgia	関節痛	2	N	TE	71		Y	None	
			Alopecia	脱毛症	1	N	TE	71		N	None	
			Faecal incontinence	便失禁	1	N	TE	75	1	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	76	1	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary tract infection	尿路感染	1	N	TE	76		N	None	Recovered
			Aphasia	失語症	3	Y	TE	76	4	N	None	Recovered
			Bone pain	骨痛	1	N	TE	78	2	N	None	Recovered
			Bone pain	骨痛	1	N	TE	99		Y	None	
			Bone pain	骨痛	2	N	TE	121		N	None	Not recovered, but no changes expected
			Confusional state	錯乱状態	2	N	TE	121	15	N	None	Recovered
			Mobility decreased	運動性低下	2	N	TE	135		N	None	Ongoing at time of death
			Haematuria	血尿	2	N	TE	154	88	N	Not applicable	Recovered
			Mania	躁病	2	N	TE	159		N	None	Ongoing at study termination / withdrawal
			Haematuria	血尿	2	Y	TE	227	14	N	Not applicable	Recovered
			Urinary retention	尿閉	3	Y	TE	227	15	N	Not applicable	Recovered with sequelae
044005	UK	76/M/C	Cardiac failure congestive	うっ血性心不全	4	N	TE			N	Drug administration postponed	Death
			Fatigue	疲労	2	N	TE			Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	7	1	Y	None	Recovered
			Left ventricular dysfunction	左室機能不全	3	N	TE	54	73	N	Drug administration postponed	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	54	73	N	Drug administration postponed	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	3	N	TE	54	17	N	Drug administration postponed	Ongoing at time of death
			Troponin T increased	トロポニンＴ増加	4	N	TE	57	70	N	Drug administration postponed	Ongoing at time of death
			Pleural effusion	胸水	2	N	TE	57	70	N	Drug administration postponed	Ongoing at time of death
			Pulmonary embolism	肺塞栓症	3	Y	TE	57	3	N	Drug permanently withdrawn	Recovered with sequelae
			Pulmonary oedema	肺水腫	1	N	TE	58	69	N	Drug administration postponed	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	70	57	N	Drug administration postponed	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	5	Y	TE	126	1	N	Drug administration postponed	Death
044009	UK	67/M/C	Diarrhoea	下痢	1	N	TE			Y	None	Recovered
			Bone pain	骨痛	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Haematuria	血尿	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	2		Y	None	Recovered
			Pelvic pain	骨盤痛	2	N	TE	56		N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Deep vein thrombosis	深部静脈血栓症	3	Y	TE	107	8	N	Drug administration postponed	Recovered
			Intestinal perforation	腸管穿孔	4	Y	TE	167	10	N	Drug administration postponed	Recovered
			Anorexia	食欲不振	2	Y	TE	167	10	N	Drug administration postponed	Recovered
			Dehydration	脱水	3	Y	TE	167	10	N	Drug administration postponed	Recovered
			Deep vein thrombosis	深部静脈血栓症	3	Y	TE	167	11	N	Drug permanently withdrawn	Recovered with sequelae
			Pathological fracture	病的骨折	2	Y	TE	173	5	N	Drug administration postponed	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	173		N	Drug permanently withdrawn	Not recovered, but no changes expected
			Cellulitis	蜂巣炎	3	Y	TE	200	7	N	Not applicable	Recovered
045009	UK	57/M/C	Neutropenia	好中球減少症	4	N	TE	154	15	Y	Drug administration postponed	Recovered
			Bone pain	骨痛	2	N	TE	169	37	Y	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	176	31	N	Not applicable	Recovered
046002	UK	78/M/C	Urinary tract infection	尿路感染	2	N	TE			N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary incontinence	尿失禁	1	N	TE			N	None	Recovered
			Anaemia	貧血	2	N	Post	250	138	Y	Not applicable	Recovered
			Anaemia	貧血	3	Y	Post	387	2	Y	Not applicable	Recovered
046004	UK	64/M/C	Nausea	悪心		N	TE			Y	None	Recovered
			Vomiting	嘔吐		N	TE			Y	None	Recovered
			Bone pain	骨痛	3	N	TE			Y	None	Ongoing at study termination / withdrawal
			Night sweats	寝汗		N	TE			N	None	Recovered
			Nausea	悪心	2	N	TE	2	1	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	3	2	Y	None	Recovered
			Diarrhoea	下痢	2	N	TE	28	19	Y	None	Recovered
			Diarrhoea	下痢	2	N	TE	28	16	N	None	Recovered
			Bone pain	骨痛	2	N	TE	33	25	N	None	Recovered
			Anaemia	貧血	2	N	TE	56	108	Y	Not applicable	Recovered
			Diarrhoea	下痢	2	N	TE	57	2	N	None	Recovered
			Cough	咳嗽	1	N	TE	83	64	N	None	Recovered
			Anaemia	貧血	2	N	TE	107	57	Y	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	163	39	Y	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	163	39	Y	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	201	22	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	201	103	Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	N	TE	222	11	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	232	3	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	234	18	Y	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	251	14	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	264	31	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	294	10	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	303	21	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	303	76	Y	Not applicable	Ongoing at time of death
			Anaemia	貧血	3	N	TE	323	8	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	330	30	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	359	20	Y	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	378	9	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	378	77	Y	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	386		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	Post	454	23	Y	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	1	N	Post	476		Y	None	Ongoing at time of death
047002	UK	81/M/C	Anaemia	貧血	3	N	TE	2	1	Y	None	Recovered
			Anaemia	貧血	3	N	TE	39	1	Y	None	Recovered
			Anaemia	貧血	3	N	TE	73	1	Y	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	3	N	TE	85		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	2	N	TE	136		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	154	1	N	Not applicable	Death
047003	UK	75/M/C	Urinary tract infection	尿路感染	2	N	TE	14	8	N	None	Recovered with sequelae
			Urinary tract infection	尿路感染	2	N	TE	64	10	N	None	Recovered with sequelae
			Urinary retention	尿閉	3	Y	TE	98	3	N	None	Recovered with sequelae
			Infection	感染	2	N	TE	142	14	N	None	Recovered with sequelae
			Anaemia	貧血	3	N	TE	155	1	Y	None	Recovered
048001	UK	59/M/C	Decreased appetite	食欲減退	1	N	TE			N	None	Recovered
			Anaemia	貧血	1	N	Pre	-35	71	N	None	Recovered
			Constipation	便秘	2	N	Pre	-12	11	N	None	Recovered
			Musculoskeletal pain	筋骨格痛	3	Y	Pre	-4	12	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	3	1	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	6	1	N	None	Recovered

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	8	97	N	None	Ongoing at time of death
			Hypocalcaemia	低カルシウム血症	2	N	TE	29	6	N	None	Recovered
			Vomiting	嘔吐	3	N	TE	33	1	N	None	Recovered
			Hypocalcaemia	低カルシウム血症	3	Y	TE	34	4	N	None	Recovered
			Anaemia	貧血	2	N	TE	36	34	N	None	Recovered
			Hypocalcaemia	低カルシウム血症	2	N	TE	37	21	N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE	58	6	N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE	58	13	N	None	Recovered
			Constipation	便秘	2	N	TE	62	24	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	62	1	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	62	1	N	None	Recovered
			Decreased appetite	食欲減退	2	N	TE	62	17	N	None	Recovered
			Lower respiratory tract infection	下気道感染	3	Y	TE	63	3	N	None	Recovered
			Depression	うつ病	2	N	TE	70		N	None	Ongoing at time of death
			Lymphadenopathy	リンパ節症	1	N	TE	85		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	104	37	N	None	Ongoing at time of death
			Decreased appetite	食欲減退	2	N	TE	113		N	None	Recovered
			Neutropenia	好中球減少症	2	N	TE	129	13	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	134	1	N	None	Recovered
			Bone pain	骨痛	2	N	TE	140		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neutropenia	好中球減少症	3	N	TE	141	15	N	Drug administration postponed	Recovered
			Amnesia	健忘	1	N	TE	141		N	None	Ongoing at time of death
			Headache	頭痛	2	N	TE	141		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	145		N	None	Ongoing at time of death
			Anxiety	不安	2	N	TE	147		N	None	Ongoing at time of death
			Oral candidiasis	口腔カンジダ症	1	N	TE	155		N	None	Ongoing at study termination / withdrawal
048003	UK	60/M/C	Anaemia	貧血	3	N	TE			N	Not applicable	Recovered
			Abdominal distension	腹部膨満	2	N	TE			N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE			N	Not applicable	Recovered
			Oral candidiasis	口腔カンジダ症	1	N	TE			N	Not applicable	Recovered
			Fatigue	疲労	1	N	TE	2	8	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	6	6	N	None	Recovered
			Asthenopia	眼精疲労	1	N	TE	29		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	60		N	None	Ongoing at time of death
			Myalgia	筋痛	2	N	TE	115		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Lethargy	嗜眠	1	N	TE	148		N	None	Ongoing at time of death
			Metastases to central nervous system	中枢神経系転移	4	Y	TE	164	19	N	Not applicable	Recovered with sequelae
048004	UK	71/M/C	Diarrhoea	下痢	2	N	TE			N	None	Recovered
			Nausea	悪心	2	N	TE			N	None	Recovered
			Vomiting	嘔吐	2	N	TE			N	None	Recovered
			Constipation	便秘	2	N	Pre	-2	4	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	4	2	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	8	3	N	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	37	107	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	109	3	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	109	3	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	168	16	N	Not applicable	Recovered
			Dyspepsia	消化不良	1	N	TE	169	4	N	Not applicable	Recovered
			Faecal incontinence	便失禁	2	N	TE	194	1	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	195	5	N	Not applicable	Recovered with sequelae
048007	UK	79/M/C	Bone pain	骨痛	2	N	Pre	1	31	N	Drug administration postponed	Recovered
			Constipation	便秘	2	N	TE	29		N	None	Recovered
			Bone pain	骨痛	2	N	TE	29		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	31	29	N	Drug administration postponed	Recovered
048010	UK	77/M/C	Decreased appetite	食欲減退	1	N	TE	4	2	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	6	3	N	None	Recovered
			Hot flush	ほてり	1	N	TE	6		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	8	62	N	-	
			Nausea	悪心	1	N	TE	25	4	N	None	Recovered
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2	N	TE	29	29	Y	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	TE	29	29	Y	None	Recovered
			Nail avulsion	爪裂離	2	N	TE	52		N	None	Recovered with sequelae
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	3	N	TE	57	29	Y	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	57	29	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	69	144	N	Not applicable	Recovered
			Constipation	便秘	1	N	TE	70		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	72		N	None	Ongoing at time of death
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2	N	TE	85	29	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	TE	85	29	Y	None	Recovered
			Paraesthesia	錯感覚	1	N	TE	127		N	None	Ongoing at time of death
			Bone pain	骨痛	2	Y	TE	212	8	N	Not applicable	Recovered
			Urinary incontinence	尿失禁	2	N	TE	212	8	N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	219		N	Not applicable	Ongoing at time of death
049002	UK	73/M/C	Lower respiratory tract infection	下気道感染	3	Y	TE	9	11	N	None	Recovered
			Oral candidiasis	口腔カンジダ症	2	N	TE	57	53	Y	None	Recovered
			Paraesthesia	錯感覚	1	N	TE	100	30	N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	Y	TE	109	3	N	Drug administration postponed	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	4	Y	TE	129		N	None	Ongoing at time of death
			Pneumonia	肺炎	4	Y	TE	135	7	N	Drug permanently withdrawn	Death
			Pneumonia	肺炎	5	Y	TE	141	1	N	Drug permanently withdrawn	Death
049007	UK	80/M/C	Nausea	悪心	2	N	TE	3		Y	None	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	3		Y	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Mucosal inflammation	粘膜の炎症	2	N	TE	29		Y	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	29		Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	120		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	128		N	None	Ongoing at time of death
			Headache	頭痛	2	N	TE	148	51	N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	176	3	N	Not applicable	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	198		N	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	3	Y	TE	198		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	198	12	N	Not applicable	Death
			Headache	頭痛	4	N	TE	198		N	None	Ongoing at time of death
			Urinary retention	尿閉	2	N	TE	204		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	209	1	N	Not applicable	Death
049008	UK	72/M/C	Decreased appetite	食欲減退	2	N	TE			N	None	Ongoing at time of death
			Lymphoedema	リンパ浮腫	1	N	Pre			N	None	Recovered
			Ear pain	耳痛	1	N	Pre	-7		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre	-3	5	N	None	Recovered

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	29		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	29	50	Y	None	Recovered
			Constipation	便秘	2	N	TE	40		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	40	2	N	None	Recovered with sequelae
			Palpitations	動悸	1	N	TE	54	4	N	Not applicable	Recovered
			Depressed mood	抑うつ気分	1	N	TE	54		N	None	Ongoing at time of death
			Vomiting	嘔吐	2	Y	TE	57	6	N	Drug administration postponed	Recovered
			Pyrexia	発熱	1	Y	TE	61	2	N	Drug administration postponed	Recovered
			Nausea	悪心	2	Y	TE	65	6	N	Drug administration postponed	Recovered with sequelae
			Vomiting	嘔吐	2	Y	TE	65	6	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	N	TE	67	1	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	89	1	N	Not applicable	Recovered
			Abdominal pain	腹痛	3	Y	TE	111		N	Not applicable	Ongoing at time of death
			Nausea	悪心	3	Y	TE	111		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	3	Y	TE	111		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	111	11	N	Not applicable	Death
			Anaemia	貧血	2	N	TE	113		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	121	1	N	Not applicable	Death
050005	UK	77/M/C	Diarrhoea	下痢	1	N	TE	3	2	N	None	Recovered
			Bone pain	骨痛	3	N	TE	18		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	18	29	N	None	Recovered
			Muscular weakness	筋力低下	1	N	TE	29	26	N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	46		N	None	Recovered
			Muscular weakness	筋力低下	2	N	TE	54	5	N	None	Ongoing at study termination / withdrawal
			Muscular weakness	筋力低下	3	N	TE	58		N	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	2	Y	TE	60	13	N	None	Recovered with sequelae
			Cerebrovascular accident	脳血管発作	4	Y	TE	64	9	N	Drug administration postponed	Recovered with sequelae
			Eye infection	眼感染	2	N	TE	70		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Spinal cord compression	脊髄圧迫	2	N	TE	72	12	N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	82	2	N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	Y	TE	83		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	2	Y	TE	83	2	N	None	Recovered
			Spinal cord compression	脊髄圧迫	2	Y	TE	83		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
050019	UK	70/M/C	Urine output increased	尿量増加	1	N	TE			N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Night sweats	寝汗	1	N	TE			N	Not applicable	Recovered
			Dehydration	脱水	2	Y	Pre	-6	2	N	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	1	N	TE	55	3	N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	55	3	N	None	Recovered
			Infection	感染	3	Y	TE	60	3	N	None	Recovered with sequelae
			Gout	痛風	2	N	TE	74	14	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE	99		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	113		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE	141		N	None	Ongoing at time of death
			Transient ischaemic attack	一過性脳虚血発作	2	Y	TE	189	4	N	Not applicable	Recovered
			Confusional state	錯乱状態	3	Y	TE	195	9	N	Not applicable	Recovered
			Urinary retention	尿閉	2	N	TE	195	6	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	196	4	N	Not applicable	Recovered
			Rash	発疹	1	N	TE	200	89	N	Not applicable	Recovered
051003	UK	65/M/C	Bone pain	骨痛	2	N	TE	3		Y	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	5		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	2	N	TE	5		N	None	Ongoing at time of death
			Dysgeusia	味覚異常	1	N	TE	5		Y	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	12		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	42		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Spinal cord compression	脊髄圧迫	4	Y	TE	42		N	Drug permanently withdrawn	Ongoing at time of death
051007	UK	75/M/C	Bone pain	骨痛	2	N	Pre	-8	59	N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	2	1	Y	None	Recovered
			Bone pain	骨痛	1	N	Pre	51		N	None	Ongoing at time of death
			Dyspepsia	消化不良	1	N	TE	63	25	Y	None	Ongoing at time of death
			Dyspepsia	消化不良	3	N	TE	87	2	Y	None	Ongoing at time of death
			Dyspepsia	消化不良	1	N	TE	88		Y	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	90	80	Y	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	106	26	N	None	Recovered
			Nerve root compression	神経根圧迫	4	Y	TE	119	2	N	Drug administration postponed	Recovered with sequelae
			Night sweats	寝汗	1	N	TE	119	35	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	147		N	Drug administration postponed	Ongoing at time of death
			Night sweats	寝汗	2	N	TE	153		N	None	Ongoing at time of death
			Oedema	浮腫	1	N	TE	159		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	169		Y	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Metastases to central nervous system	中枢神経系転移	2	Y	TE	174		N	Not applicable	Not recovered, but no changes expected
051010	UK	68/M/C	Bone pain	骨痛	2	N	TE	21		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	47		N	None	Not recovered, but no changes expected
			Urinary bladder haemorrhage	膀胱出血	1	N	TE	47	49	N	Drug administration postponed	Not recovered, but no changes expected
			Fatigue	疲労	2	N	TE	58		N	None	Ongoing at time of death
			Pilonidal cyst	毛巣嚢胞	2	N	TE	64	65	N	None	Recovered
			Bone pain	骨痛	2	N	TE	83	23	N	None	Recovered
			Urinary bladder haemorrhage	膀胱出血	3	N	TE	95		N	Drug administration postponed	Not recovered, but no changes expected
			Renal failure acute	急性腎不全	3	Y	TE	204	10	N	Not applicable	Recovered with sequelae
051011	UK	77/M/C	Bone pain	骨痛	2	N	TE	2	5	Y	None	Recovered
			Fatigue	疲労	2	N	TE	30	4	N	None	Recovered
			Bone pain	骨痛	2	N	TE	30	2	Y	None	Recovered
			Nausea	悪心	1	N	TE	44		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	44	32	N	None	Recovered
			Bone pain	骨痛	2	N	TE	75	39	N	None	Recovered
			Bile duct obstruction	胆管閉塞	2	Y	TE	166	12	N	Not applicable	Recovered with sequelae
			Bile duct obstruction	胆管閉塞	2	Y	TE	177		N	Not applicable	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Insomnia	不眠症	1	N	TE	219		N	None	Ongoing at time of death
051012	UK	73/M/C	Decreased appetite	食欲減退	1	N	TE	30		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	108	1	N	None	Death
051021	UK	74/M/C	Gastric ulcer	胃潰瘍	1	N	TE			N	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE			N	None	Recovered
			Pulmonary embolism	肺塞栓症	4	N	TE			N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	8	41	Y	None	Recovered
			Intervertebral disc protrusion	椎間板突出	1	N	TE	8		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	42	7	N	None	Recovered with sequelae
			Anorexia	食欲不振	2	N	TE	94		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	120	211	N	None	Recovered
			Constipation	便秘	2	N	TE	125		N	None	Ongoing at time of death
			Dehydration	脱水	2	Y	TE	125	8	N	None	Recovered
			Helicobacter infection	ヘリコバクター感染	2	N	TE	131	7	N	None	Recovered
053002	Netherlands	79/M/C	Balance disorder	平衡障害	1	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	Pre	-9	19	N	None	Recovered
			Fatigue	疲労	2	N	TE	1	224	Y	None	Recovered with sequelae
			Nausea	悪心	2	N	TE	2	6	Y	None	Recovered
			Nausea	悪心	1	N	TE	7	232	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	1	N	TE	7	1	Y	None	Recovered
			Increased tendency to bruise	挫傷発生の増加傾向	1	N	TE	29		Y	None	Not recovered, but no changes expected
			Gastrointestinal pain	消化器痛	1	N	TE	113	1	N	None	Recovered
			Bone pain	骨痛	2	N	TE	116	54	N	None	Recovered with sequelae
			Eructation	おくび	1	N	TE	149		N	None	Not recovered, but no changes expected
			Vomiting	嘔吐	2	N	TE	149	6	Y	Not applicable	Recovered
			Dizziness postural	体位性めまい	1	N	TE	162		N	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	169		N	None	Not recovered, but no changes expected
			Thrombocytopenia	血小板減少症	2	N	TE	176		N	Not applicable	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	176		N	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	3	Y	TE	177	2	Y	Not applicable	Recovered with sequelae
			Fatigue	疲労	3	N	TE	224		Y	None	Not recovered, but no changes expected
053004	Netherlands	72/M/C	Bone pain	骨痛	1	N	Pre	-1	4	N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	3	22	Y	None	Recovered with sequelae
			Headache	頭痛	1	N	TE	3	22	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	24		N	None	Not recovered, but no changes expected
			Chills	悪寒	1	N	TE	31	4	Y	None	Recovered
			Pruritus	そう痒症	1	N	TE	31	4	Y	None	Recovered

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	2	N	TE	32	3	Y	None	Recovered
			Myalgia	筋痛	1	N	TE	32	3	Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	1	N	TE	38	70	N	None	Recovered
			Bone pain	骨痛	1	N	TE	79	15	N	None	Recovered with sequelae
			Faecal incontinence	便失禁	1	N	TE	81	31	N	None	Not recovered, but no changes expected
			Back pain	背部痛	2	N	TE	93	12	N	None	Recovered
			Back pain	背部痛	3	N	TE	104	38	N	None	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	104		N	None	Not recovered, but no changes expected
			Faecal incontinence	便失禁	2	N	TE	111		N	None	Not recovered, but no changes expected
			Faecal incontinence	便失禁	2	N	TE	111	60	N	None	Recovered
			Gastritis	胃炎	1	N	TE	113	24	N	None	Recovered
			Rash pruritic	そう痒性皮疹	1	N	TE	130	7	Y	None	Recovered
			Nausea	悪心	2	N	TE	141	7	Y	Not applicable	Recovered
			Fatigue	疲労	3	N	TE	141	7	Y	Not applicable	Recovered
			Constipation	便秘	1	N	TE	150	8	N	Not applicable	Recovered
			Radicular syndrome	根症候群	3	Y	TE	150	8	N	Not applicable	Recovered with sequelae
			Haematuria	血尿	1	N	TE	153	5	N	Not applicable	Recovered
			Radicular syndrome	根症候群	2	N	TE	157		N	Not applicable	Not recovered, but no changes expected
054001	Netherlands	75/M/C	Upper respiratory tract infection	上気道感染	1	N	Pre	-15	8	N	Drug administration postponed	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Diarrhoea	下痢	1	N	TE	3		Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	57	7	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	63	2	Y	None	Recovered
			Colitis	大腸炎	2	N	TE	86		Y	None	Ongoing at study termination / withdrawal
055002	Netherlands	66/M/C	Lung infection	肺感染	2	N	TE	18	27	N	None	Recovered
			Anorexia	食欲不振	2	N	TE	54		Y	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	54		Y	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	59		Y	None	Ongoing at time of death
			Drug intolerance	薬物不耐性	4	Y	TE	71	3	N	None	Recovered with sequelae
			Pulmonary embolism	肺塞栓症	4	Y	TE	71		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	74	1	N	None	Death
060002	Spain	84/M/C	Anorexia	食欲不振	2	N	TE	29		N	None	Ongoing at time of death
			Cardiac failure	心不全	3	N	TE	100		N	None	Ongoing at study termination / withdrawal
			Dyspnoea	呼吸困難	2	N	TE	100		N	None	Ongoing at time of death

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	1	N	TE	101	31	N	Not applicable	Ongoing at time of death
			Bronchitis	気管支炎	2	N	TE	107	2	N	None	Recovered
			Renal failure	腎不全	2	N	TE	107	3	N	None	Recovered
			Bronchitis	気管支炎	3	Y	TE	108		N	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	N	TE	109	5	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	113	11	Y	None	Ongoing at time of death
			Hyperuricaemia	高尿酸血症	1	N	TE	113		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	123		Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	129	1	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	131		N	Not applicable	Ongoing at time of death
			Death	死亡	5	Y	TE	137	1	N	Not applicable	Death
060003	Spain	85/M/C	Bone pain	骨痛	3	N	TE	31	26	N	None	Ongoing at time of death
			Weight decreased	体重減少	2	N	TE	56	6	N	None	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	2	N	TE	56	11	N	None	Recovered
			Bone pain	骨痛	2	N	TE	56		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	57		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	1	N	TE	61		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	111	1	N	Not applicable	Death
060007	Spain	79/M/C	Nausea	悪心	1	N	Pre	-20	28	N	None	Recovered
			Anorexia	食欲不振	2	N	Pre	-20		N	None	Ongoing at time of death
			Haematuria	血尿	2	N	TE	5		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	6	4	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	6	12	N	Drug permanently withdrawn	Death
			Pyrexia	発熱	1	N	TE	7	2	N	None	Recovered
			Respiratory tract infection	気道感染	2	N	TE	7		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	3	N	TE	8		N	None	Ongoing at time of death
			Asthenia	無力症	1	N	TE	12	2	N	None	Ongoing at time of death
			Asthenia	無力症	3	N	TE	13		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	17	1	N	Drug permanently withdrawn	Death
060010	Spain	75/M/C	Pruritus	そう痒症	1	N	TE	1	37	N	None	Recovered
			Anaemia	貧血	1	N	TE	29	2	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cholestasis	胆汁うっ滞	3	Y	TE	29	9	N	Drug permanently withdrawn	Recovered
			Hyperbilirubinaemia	高ビリルビン血症	3	N	TE	29	3	N	None	Recovered
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	3	N	TE	29	3	N	-	
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	29	3	N	-	
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	TE	29	60	N	None	Not recovered, but no changes expected
			Pollakiuria	頻尿	1	N	TE	29	29	N	None	Recovered
			Anaemia	貧血	1	N	TE	31	80	Y	None	Recovered
			Hyperbilirubinaemia	高ビリルビン血症	2	N	TE	31	6	N	None	Recovered
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2	N	TE	31	6	N	-	
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	TE	31	3	N	-	
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1	N	TE	33	22	N	-	
			Hyperbilirubinaemia	高ビリルビン血症	1	N	TE	36	19	N	None	Recovered
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	1	N	TE	36	19	N	-	
			Cholestasis	胆汁うっ滞	1	N	TE	37	35	N	None	Recovered
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2	N	TE	54	18	N	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	TE	54	18	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	57	57	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cholestasis	胆汁うっ滞	3	Y	TE	71	3	N	Not applicable	Recovered
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	1	N	TE	71	34	N	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1	N	TE	71	40	N	None	Recovered
			Cholestasis	胆汁うっ滞	1	N	TE	73	30	N	None	Recovered
			Hyperbilirubinaemia	高ビリルビン血症	2	N	TE	88	17	N	None	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	4	N	TE	88	23	N	None	Not recovered, but no changes expected
			Chromaturia	着色尿	1	N	TE	88	26	N	None	Recovered
			Cholestasis	胆汁うっ滞	3	Y	TE	102	3	N	Not applicable	Recovered
			Hyperbilirubinaemia	高ビリルビン血症	3	N	TE	104	7	N	None	Recovered
			Hyperbilirubinaemia	高ビリルビン血症	1	N	TE	110	13	N	None	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	TE	110		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	122	41	Y	None	Recovered
			Anaemia	貧血	1	N	TE	162	64	Y	None	Recovered
063002	Spain	64/M/C	Dizziness	浮動性めまい	1	N	Pre			N	None	Recovered
			Respiratory tract infection	気道感染	2	N	TE	16	9	N	None	Recovered
			Muscle spasms	筋痙縮	1	N	TE	29	29	N	None	Recovered
			Discomfort	不快感	1	N	TE	57	3	Y	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	143	29	N	None	Recovered
			Gastroenteritis	胃腸炎	2	Y	TE	183	4	N	Not applicable	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	226	34	N	Not applicable	Recovered
063004	Spain	74/M/C	Abdominal pain upper	上腹部痛	1	N	TE	32	55	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Somnolence	傾眠	2	N	TE	32	55	N	None	Recovered
			Anaemia	貧血	3	N	TE	58	29	N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	86		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	86	29	N	Not applicable	Ongoing at time of death
			Asthenia	無力症	1	N	TE	86		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	86		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	114		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	128	8	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	135	1	N	Drug permanently withdrawn	Death
066004	Spain	78/M/C	Asthenia	無力症	1	N	TE	30	58	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	30	28	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	87	27	N	None	Recovered
			Toothache	歯痛	1	N	TE	113	32	N	None	Recovered
			Pancytopenia	汎血球減少症	4	Y	TE	144		Y	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	144	44	Y	None	Ongoing at time of death
			Asthenia	無力症	1	N	TE	177	78	N	Not applicable	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	177	51	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
070003	Spain	74/M/C	Constipation	便秘	2	N	TE	57	29	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	85	50	N	None	Recovered
			Dyspepsia	消化不良	1	N	TE	85	50	N	None	Recovered
			Nausea	悪心	2	N	TE	85	50	Y	None	Recovered
			Anorexia	食欲不振	2	N	TE	85	50	N	None	Recovered
			Cardiac failure	心不全	3	Y	TE	105	15	N	Drug administration postponed	Recovered
			Renal failure	腎不全	3	Y	TE	105	3	N	Drug administration postponed	Recovered
			Constipation	便秘	1	N	TE	218	29	N	None	Recovered
071006	Spain	76/M/C	Oedema peripheral	末梢性浮腫	1	N	Pre	1	29	N	None	Recovered
			Constipation	便秘	2	Y	TE	35	19	N	None	Recovered
			Asthenia	無力症	2	Y	TE	35	19	N	None	Recovered
			Anorexia	食欲不振	2	Y	TE	35	19	N	None	Recovered
			Renal failure	腎不全	2	Y	TE	52	2	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	80	37	N	None	Recovered
			Bone pain	骨痛	2	N	TE	199	155	N	Not applicable	Recovered
			Headache	頭痛	2	N	TE	199	59	N	None	Recovered
074002	Italy	79/M/C	Muscle spasms	筋痙縮	1	N	Pre	-10	11	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	28	8	N	None	Recovered
			Asthenia	無力症	2	N	TE	33	3	N	None	Recovered
			Pyrexia	発熱	1	N	TE	33	15	N	Drug administration postponed	Recovered
			Urinary tract infection	尿路感染	2	N	TE	46	39	N	None	Recovered
			Dry skin	皮膚乾燥	1	N	TE	75	10	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Asthenia	無力症	1	N	TE	84	83	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	131	29	Y	None	Recovered
			Neutropenia	好中球減少症	2	N	TE	131	29	Y	Drug permanently withdrawn	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	131	29	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	159	18	Y	None	Recovered
			Leukopenia	白血球減少症	4	N	TE	159	4	Y	None	Recovered
			Neutropenia	好中球減少症	4	N	TE	159	4	Y	Drug permanently withdrawn	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	159	15	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	162	5	Y	None	Recovered
			Neutropenia	好中球減少症	1	N	TE	162	5	Y	Drug permanently withdrawn	Recovered
			Blood urea increased	血中尿素増加	1	N	TE	162	43	N	None	Recovered
			Asthenia	無力症	2	N	TE	166		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	173	8	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	180	8	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	183	5	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	187	32	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	187	8	Y	None	Ongoing at time of death

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	2	N	TE	194	11	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	204	15	Y	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	218	5	Y	None	Recovered
			Thrombocytopenia	血小板減少症	4	N	TE	218	5	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	222	2	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	222	2	Y	None	Ongoing at time of death
			Bone marrow tumour cell infiltration	腫瘍細胞の骨髄浸潤	3	Y	TE	222	37	N	Not applicable	Death
			Anaemia	貧血	3	N	TE	223	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	223	2	Y	None	
			Neutropenia	好中球減少症	1	N	TE	223	5	Y	Not applicable	
			Thrombocytopenia	血小板減少症	4	N	TE	223	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	1	N	TE	224	2	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	225	8	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	225	1	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	1	N	TE	225	3	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	225	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	227	3	Y	None	Ongoing at time of death

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neutropenia	好中球減少症	2	N	TE	227	3	Y	Not applicable	
			Thrombocytopenia	血小板減少症	4	N	TE	227	4	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	229	2	Y	None	
			Neutropenia	好中球減少症	3	N	TE	229	2	Y	Not applicable	
			Leukopenia	白血球減少症	2	N	TE	230	4	Y	None	
			Neutropenia	好中球減少症	2	N	TE	230	2	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	230	3	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	1	N	TE	231	3	Y	Not applicable	Recovered
			Anaemia	貧血	1	N	TE	232	4	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	232	4	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	233	2	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	2	N	TE	233	2	Y	Not applicable	Recovered
			Leukopenia	白血球減少症	2	N	TE	234	4	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	235	7	Y	None	Recovered
			Neutropenia	好中球減少症	1	N	Post	235	3	Y	-	
			Thrombocytopenia	血小板減少症	3	N	TE	235	2	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	236	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	237	7	Y	None	
			Neutropenia	好中球減少症	2	N	Post	237	2	Y	-	

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neutropenia	好中球減少症	3	N	Post	238	5	Y	-	
			Thrombocytopenia	血小板減少症	3	N	TE	238	4	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	241	2	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	241	3	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	242	8	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	2	N	Post	242	4	Y	Not applicable	Recovered
			Leukopenia	白血球減少症	2	N	TE	243	3	Y	None	
			Thrombocytopenia	血小板減少症	3	N	TE	243	2	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	244		Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	1	N	TE	245	9	Y	None	
			Anaemia	貧血	1	N	TE	249		Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	253	2	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	1	N	Post	253	4	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	1	N	TE	254	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	256		Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	2	N	Post	256		Y	None	Ongoing at time of death
			Bone marrow tumour cell infiltration	腫瘍細胞の骨髄浸潤	5	Y	TE	258	1	N	Not applicable	Death

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
075001	Italy	59/M/C	Strangury	有痛性排尿困難		N	TE	2	2	N	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	14	28	N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	33	10	Y	Drug administration postponed	Recovered
			Vomiting	嘔吐	1	N	TE	33	10	Y	Drug administration postponed	Recovered
			Anorexia	食欲不振	1	N	TE	33	10	Y	Drug administration postponed	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	41		N	None	Ongoing at time of death
			Strangury	有痛性排尿困難	2	N	TE	78	1	N	None	Recovered
			Death	死亡	5	Y	TE	93	1	N	None	Death
078001	Italy	76/M/C	Constipation	便秘	1	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE			N	None	Recovered
			Pyrexia	発熱	1	N	TE			N	None	Recovered
			Confusional state	錯乱状態	1	N	TE			N	None	Recovered
			Hyperhidrosis	多汗症	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE	2	11	Y	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	38	21	N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	58	21	N	None	Ongoing at time of death
			Asthenia	無力症	2	N	TE	78	37	Y	None	Recovered
			Pyrexia	発熱	1	N	TE	78	29	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	78		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	2	N	TE	78	37	N	None	Recovered
			Fatigue	疲労	2	N	TE	127	14	N	None	Ongoing at time of death
			Depression	うつ病	2	N	TE	127		N	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	141		N	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	147	2	Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	Y	TE	147	2	Y	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	149	14	Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	Y	TE	149	11	Y	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	1	Y	TE	163		Y	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	163	15	N	Not applicable	Death
078003	Italy	74/M/C	Somnolence	傾眠	2	N	Pre	1		N	None	Ongoing at time of death
			Confusional state	錯乱状態	2	N	Pre	1		N	None	Ongoing at time of death
			Upper limb fracture	上肢骨折	2	N	TE	20	25	N	None	Recovered
			Asthenia	無力症	2	N	TE	49		Y	None	Ongoing at time of death

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	N	TE	187		N	Not applicable	Ongoing at time of death
			Amnesia	健忘	2	N	TE	198		N	Not applicable	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	3	Y	TE	213	8	N	Not applicable	Death
			General physical health deterioration	全身健康状態低下	5	Y	TE	220	1	N	Not applicable	Death
078006	Italy	77/M/C	Pyrexia	発熱	1	N	TE	39	34	N	None	Recovered
			Pyrexia	発熱	1	N	TE	91	14	N	None	Recovered
			Anaemia	貧血	2	N	TE	104		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	104		Y	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	104	28	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	131	1	N	Drug permanently withdrawn	Death
080004	Italy	72/M/C	Weight decreased	体重減少	1	N	Pre	-13	13	N	None	Ongoing at time of death
			Weight decreased	体重減少	2	N	Pre	-1		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	Pre	-1	50	N	None	Recovered
			Bone pain	骨痛	3	N	TE	49	85	N	None	Recovered
			Fatigue	疲労	3	N	TE	133		N	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	133		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	161	1	N	Not applicable	Death
085004	Israel	61/M/C	Asthenia	無力症	1	N	Pre	-4	1	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	Pre	1	30	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	10	3	N	None	Recovered
			Pyrexia	発熱	1	N	TE	36	8	N	None	Recovered
			Arthralgia	関節痛	1	N	TE	100	16	N	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	2	N	TE	115		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	148		N	None	Not recovered, but no changes expected
			Anaemia	貧血	3	N	TE	167	3	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	2	Y	TE	167	4	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	TE	220	7	N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	Y	TE	220	7	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	220	7	N	Not applicable	Recovered with sequelae
			Oral fungal infection	口腔真菌感染	1	N	TE	222	6	N	Not applicable	Recovered
087002	Israel	69/M/C	Dysgeusia	味覚異常	1	N	TE	29	28	Y	None	Recovered
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	2	N	TE	29	13	N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	33		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	3	N	TE	41		N	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	3	Y	TE	44	2	N	None	Recovered with sequelae
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	44	68	N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Haematoma	血腫	1	N	TE	44		N	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	3	N	TE	45		N	None	Ongoing at study termination / withdrawal
			Oral candidiasis	口腔カンジダ症	1	N	TE	56	36	N	None	Recovered
			Blood urea increased	血中尿素増加	1	N	TE	56		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	56	36	N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	3	N	TE	91		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	91		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	91		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Decubitus ulcer	褥瘡性潰瘍	3	N	TE	111		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
093002	Slovakia	81/M/C	Anaemia	貧血	2	N	TE	29	48	N	-	
			Nausea	悪心	2	N	TE	29	85	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	29	6	Y	None	Recovered
			Constipation	便秘	1	N	TE	56	58	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	56	4	Y	None	Recovered
			Anaemia	貧血	3	N	TE	76	10	N	-	
			Bone pain	骨痛	3	Y	TE	76	8	N	None	Recovered with sequelae
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	76		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	85	29	N	-	
			Diarrhoea	下痢	2	N	TE	85	5	Y	None	Recovered
			Anaemia	貧血	2	N	TE	113	31	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	Y	TE	143	5	N	Drug administration postponed	Recovered
			Bronchopneumonia	気管支肺炎	3	N	TE	150		N	None	Ongoing at time of death
			Cardiopulmonary failure	心肺不全	5	Y	TE	160	1	N	Not applicable	Death
096002	Slovakia	84/M/C	Anaemia	貧血	1	N	TE	58	29	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	86	112	Y	Not applicable	Recovered
			Haematuria	血尿	1	N	TE	90	9	N	None	Recovered

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	197	4	Y	Not applicable	Recovered
097002	Slovakia	73/M/C	Pyrexia	発熱	1	N	TE	50	3	N	None	Recovered
			Pyrexia	発熱	1	N	TE	59	8	N	None	Recovered
			Pyrexia	発熱	1	N	TE	59	8	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	85	57	N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	107	15	N	None	Recovered
			Fatigue	疲労	3	Y	TE	107	15	Y	None	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	2	N	TE	107		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	107	15	N	None	Recovered with sequelae
			Vomiting	嘔吐	1	N	TE	113	5	Y	None	Recovered
			Anaemia	貧血	1	N	TE	141	22	N	Not applicable	Recovered
			Weight decreased	体重減少	2	N	TE	141		N	None	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	162	7	N	Not applicable	Recovered
			Fatigue	疲労	3	Y	TE	162	7	Y	Not applicable	Recovered with sequelae
			Anorexia	食欲不振	3	Y	TE	162	7	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	1	N	TE	168		N	Not applicable	Ongoing at time of death
			Fatigue	疲労	2	N	TE	168		Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	2	N	TE	168		N	Not applicable	Ongoing at time of death
097006	Slovakia	73/M/C	Fatigue	疲労	2	N	Pre	1	10	N	None	Recovered
			Mixed incontinence	混合性尿失禁	3	N	Pre	1		N	None	Ongoing at study termination / withdrawal
			Spinal column stenosis	脊柱管狭窄症	4	Y	TE	2	17	N	None	Recovered with sequelae
			Fatigue	疲労	3	N	TE	10	161	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	15	14	N	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	28		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	86	85	Y	None	Recovered
			Weight decreased	体重減少	1	N	TE	113	29	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	113	58	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	113	62	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	141	30	N	None	Recovered
			Fatigue	疲労	1	N	TE	170	57	N	None	Recovered
097015	Slovakia	75/M/C	Calculus ureteric	尿管結石	3	Y	TE	203	9	N	Not applicable	Recovered
099002	Slovakia	69/M/C	Nausea	悪心	1	N	Pre	-3	32	N	None	Recovered
			Bone pain	骨痛	1	N	Pre	-3	32	N	None	Recovered
			Nausea	悪心	1	N	Pre	29	35	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	57	58	N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	57	2	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	1	N	TE	79		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	85		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	102	68	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	105	7	N	None	Recovered
			Urinary tract infection	尿路感染	1	N	TE	106	8	N	None	Recovered
			Anaemia	貧血	1	N	TE	107	63	N	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	2	N	TE	114		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	169		N	None	Ongoing at study termination / withdrawal
			Hypocalcaemia	低カルシウム血症	1	N	TE	169		N	None	Ongoing at study termination / withdrawal
			Hypophosphataemia	低リン酸血症	2	N	TE	169	64	N	None	Recovered
			Bone pain	骨痛	2	N	TE	207	2	N	Not applicable	Recovered
			Bone pain	骨痛	2	Y	TE	208	14	N	Not applicable	Recovered
103001	Hong Kong	74/M/A	Hypoaesthesia	感覚鈍麻	1	N	Pre	-6	22	N	None	Recovered
			Fatigue	疲労	1	N	TE	5		Y	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neutropenia	好中球減少症	2	N	TE	12	37	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	12	2	N	None	Recovered
			Abdominal distension	腹部膨満	1	N	TE	13	61	Y	None	Recovered
			Abdominal pain	腹痛	1	N	TE	13	17	Y	None	Recovered
			Headache	頭痛	1	N	TE	14	27	N	None	Recovered
			Constipation	便秘	1	N	TE	25		Y	None	Ongoing at study termination / withdrawal
			Abdominal pain	腹痛	2	N	TE	29	28	Y	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	40	5	N	None	Recovered
			Intentional overdose	企図的過量投与	4	Y	TE	48	7	N	Not applicable	Recovered
			Hypoalbuminaemia	低アルブミン血症	1	N	TE	48	64	N	None	Recovered
			Depression	うつ病	4	Y	TE	48	26	N	Not applicable	Recovered with sequelae
			Intentional self-injury	故意の自傷行為	4	Y	TE	48	7	N	Not applicable	Recovered
			Intentional self-injury	故意の自傷行為	2	Y	TE	48	7	N	Not applicable	Recovered
			Depression	うつ病	2	N	TE	54		N	Not applicable	Ongoing at study termination / withdrawal
			Rash	発疹	1	N	TE	59	24	N	None	Recovered
103002	Hong Kong	75/M/A	Constipation	便秘	1	N	TE	28	30	N	None	Ongoing at study termination / withdrawal
			Constipation	便秘	2	N	TE	57		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Tinea pedis	足部白癬	1	N	TE	105		N	None	Ongoing at study termination / withdrawal
			Dysuria	排尿困難	1	N	TE	147	36	N	None	Recovered
			Cough	咳嗽	1	N	TE	167	10	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	194	3	N	None	Recovered
			Lower respiratory tract infection	下気道感染	3	Y	TE	196	4	N	Not applicable	Recovered
104005	Hong Kong	73/M/A	Constipation	便秘	1	N	TE	1	29	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	64	2	Y	None	Recovered
			Pneumonia	肺炎	2	N	TE	87		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	87	18	N	Drug permanently withdrawn	Death
			Spinal cord compression	脊髄圧迫	5	Y	TE	104	1	N	Drug permanently withdrawn	Death
105004	Hong Kong	70/M/A	Urinary retention	尿閉	2	N	Pre	-14	15	N	Drug administration postponed	Recovered
			Malaise	倦怠感	1	N	TE	2		Y	None	Not recovered, but no changes expected
			Abdominal pain	腹痛	1	N	TE	80	23	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	80	23	N	None	Recovered
			Muscle spasms	筋痙縮	2	N	TE	85		N	None	Not recovered, but no changes expected
			Muscle spasms	筋痙縮	2	N	TE	85		N	None	Not recovered, but no changes expected
			Pyrexia	発熱	1	N	TE	89	11	N	None	Recovered

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Musculoskeletal chest pain	筋骨格系胸痛	2	Y	TE	99	4	N	None	Recovered
			Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	2	N	TE	100	19	N	None	Recovered
			Anaemia	貧血	3	Y	TE	118	2	N	None	Recovered
			Musculoskeletal chest pain	筋骨格系胸痛	2	Y	TE	118	2	N	Drug administration postponed	Recovered with sequelae
			Abdominal pain upper	上腹部痛	2	Y	TE	120	5	N	Drug administration postponed	Recovered
			Faecal incontinence	便失禁	2	Y	TE	120	5	N	Drug administration postponed	Recovered with sequelae
			Musculoskeletal chest pain	筋骨格系胸痛	2	Y	TE	120	5	N	None	Recovered
			Haematuria	血尿	2	Y	TE	120	5	N	Drug administration postponed	Recovered
			Urinary incontinence	尿失禁	2	Y	TE	120	5	N	Drug administration postponed	Recovered with sequelae
			Faecal incontinence	便失禁	2	N	TE	125		N	Drug administration postponed	Not recovered, but no changes expected
			Hearing impaired	聴覚障害	2	N	TE	129		N	None	Ongoing at study termination / withdrawal
			Dizziness	浮動性めまい	1	N	TE	134		N	None	Not recovered, but no changes expected
			Haematuria	血尿	2	N	TE	134	8	N	None	Recovered
			Anaemia	貧血	3	N	TE	141	8	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	1	N	TE	141		N	Not applicable	Ongoing at study termination / withdrawal
			Cellulitis	蜂巣炎	3	Y	TE	148	10	N	Not applicable	Recovered
			Urinary tract infection	尿路感染	3	N	TE	148	4	N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	2	N	TE	148	3	N	None	Recovered
			Anaemia	貧血	3	Y	TE	170	4	N	Not applicable	Recovered
			Haematuria	血尿	2	Y	TE	170	4	N	Not applicable	Recovered
106002	Hong Kong	76/M/A	Hypoaesthesia	感覚鈍麻	1	N	TE	29	57	N	None	Recovered
			Pathological fracture	病的骨折	2	N	TE	85		N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	1	N	TE	113	3	N	None	Recovered
			Sleep disorder	睡眠障害	1	N	TE	113	29	N	None	Recovered
			Constipation	便秘	1	N	TE	141	29	Y	None	Recovered
			Cough	咳嗽	1	N	TE	169		N	None	Ongoing at time of death
			Haemophilus infection	ヘモフィルス感染	2	N	TE	178	14	N	None	Recovered
			Cardiac failure congestive	うっ血性心不全	3	Y	TE	221	26	N	Not applicable	Recovered
			Musculoskeletal pain	筋骨格痛	3	Y	TE	221	26	N	Not applicable	Recovered
			Insomnia	不眠症	2	N	TE	221	3	N	None	Recovered
106005	Hong Kong	79/M/A	Decreased appetite	食欲減退	1	N	TE	29	85	Y	None	Recovered
			Dysuria	排尿困難	1	N	TE	29		N	None	Ongoing at time of death
			Nocturia	夜間頻尿	2	N	TE	29	57	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	113	3	Y	Drug administration postponed	Recovered with sequelae
			Constipation	便秘	2	N	TE	113	29	N	None	Recovered
			Sleep disorder	睡眠障害	1	N	TE	113	3	N	None	Recovered
			Spinal compression fracture	脊椎圧迫骨折	3	N	TE	115		N	None	Ongoing at time of death
			Sepsis	敗血症	3	Y	TE	155		N	Not applicable	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	3	N	TE	156		N	Not applicable	Ongoing at time of death
			Haematuria	血尿	3	Y	TE	159		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	165	1	N	Not applicable	Death
106007	Hong Kong	61/M/A	Nerve root compression	神経根圧迫	3	Y	Pre	-17	18	N	Not applicable	Recovered
			Constipation	便秘	1	N	TE	57	29	Y	None	Recovered
			Hypoaesthesia	感覚鈍麻	1	N	TE	113		N	None	Not recovered, but no changes expected
			Lymphadenopathy	リンパ節症	3	N	TE	225	64	N	None	Recovered
106011	Hong Kong	79/M/A	Decreased appetite	食欲減退	1	N	TE	29	29	N	None	Recovered
			Abdominal pain upper	上腹部痛	1	N	TE	57	29	N	None	Recovered
			Liver function test abnormal	肝機能検査異常	3	Y	TE	57	13	N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	218	1	N	Not applicable	Death
106016	Hong Kong	75/M/A	Constipation	便秘	2	N	TE	29	126	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspepsia	消化不良	2	N	TE	29	84	N	None	Recovered
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	3	Y	TE	41	3	N	None	Recovered
			Cough	咳嗽	1	N	TE	41	150	N	None	Recovered
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	1	N	TE	57	29	N	None	Recovered
			Headache	頭痛	1	N	TE	127	36	N	None	Recovered
			Dry skin	皮膚乾燥	2	N	TE	127	28	N	None	Recovered
110002	France	79/M/C	Hypertension	高血圧	2	N	TE			N	None	Recovered
			Somnolence	傾眠	2	N	Pre	-11	4	N	None	Recovered
			Neuralgia	神経痛	3	N	Pre	-5	34	N	None	Recovered
			Depression	うつ病	1	N	Pre	1	141	N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	Y	TE	3	5	Y	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	50	8	N	None	Recovered
			Bone pain	骨痛	3	N	TE	141		N	None	Ongoing at study termination / withdrawal
			Depression	うつ病	2	N	TE	141		N	None	Ongoing at study termination / withdrawal
111001	France	70/M/C	Nausea	悪心	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	2	N	TE			N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Headache	頭痛	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	Pre	1	55	N	Drug administration postponed	Recovered
			Pyrexia	発熱	2	N	TE	9		N	None	Not recovered, but no changes expected
			Anaemia	貧血	3	N	TE	55	4	N	Drug administration postponed	Recovered
			Malnutrition	栄養障害	2	N	TE	56		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	4	N	TE	87	1	N	Drug administration postponed	Recovered
			Lymphopenia	リンパ球減少症	3	N	TE	87	2	N	None	Recovered
			Anaemia	貧血	3	Y	TE	113	1	N	Drug administration postponed	Recovered
			Confusional state	錯乱状態	3	Y	TE	113		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Cerebral haemorrhage	脳出血	3	Y	TE	114		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
111002	France	72/M/C	Abdominal pain upper	上腹部痛	2	N	TE			N	None	Recovered
			Anorexia	食欲不振	2	N	TE	51	195	N	None	Recovered
			Pleural effusion	胸水	2	Y	TE	51	2	N	None	Recovered
			Pleural effusion	胸水	2	Y	TE	65	5	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pulmonary embolism	肺塞栓症	4	Y	TE	120	6	N	None	Recovered
			Deep vein thrombosis	深部静脈血栓症	3	Y	TE	120	6	N	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	146	29	N	None	Recovered
			Dyspnoea	呼吸困難	2	Y	TE	146	4	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	150	96	N	Not applicable	Recovered
			Pleural effusion	胸水	2	N	TE	174	1	N	None	Recovered
			Pleural effusion	胸水	2	Y	TE	218	2	N	Not applicable	Recovered
			Pleural effusion	胸水	1	N	TE	220	26	N	None	Recovered
117008	France	82/M/C	Weight decreased	体重減少	1	N	TE			N	Not applicable	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	Pre	1	29	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	29		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	29		N	None	Ongoing at study termination / withdrawal
			Dementia Alzheimer's type	アルツハイマー型認知症	2	Y	TE	45	11	N	None	Recovered
			Lung infection	肺感染	2	N	TE	60	58	N	Not applicable	Recovered
			Leukocytosis	白血球増加症	1	N	TE	88	5	N	None	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	88		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Asthenia	無力症	1	N	TE	111		N	Not applicable	Ongoing at study termination / withdrawal
129006	Canada	88/M/C	Vomiting	嘔吐	2	N	Pre			N	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	Pre			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre			N	None	Recovered
			Bone pain	骨痛	1	N	Pre			N	Drug administration postponed	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			N	None	Ongoing at time of death
			Headache	頭痛	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE			N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Somnolence	傾眠	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Confusional state	錯乱状態	1	N	TE			N	None	Recovered
			Depression	うつ病	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Dysphonia	発声障害	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	Pre	-8		N	Not applicable	Ongoing at study termination / withdrawal

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	Pre	-8	25	N	None	Recovered with sequelae
			Bone pain	骨痛	4	N	TE	29		N	Drug administration postponed	Ongoing at time of death
			Bone pain	骨痛	4	N	TE	29		N	Drug administration postponed	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	4	Y	TE	29		N	Drug permanently withdrawn	Ongoing at time of death
			Confusional state	錯乱状態	2	N	TE	29		N	Drug permanently withdrawn	Ongoing at time of death
			Cough	咳嗽	1	N	TE	29		N	None	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	TE	30		N	None	Ongoing at study termination / withdrawal
			Excoriation	擦過傷	1	N	TE	30		N	Not applicable	Ongoing at time of death
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	31		N	None	Ongoing at time of death
			Herpes simplex	単純ヘルペス	2	N	TE	33		N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	36		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	36		N	Not applicable	Ongoing at time of death
			Dysphagia	嚥下障害	2	N	TE	37		N	Not applicable	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oral candidiasis	口腔カンジダ症	2	N	TE	37		N	Not applicable	Ongoing at study termination / withdrawal
			Oral candidiasis	口腔カンジダ症	2	N	TE	38		N	None	Ongoing at time of death
129007	Canada	81/M/0	Anaemia	貧血			TE			N	Not applicable	Recovered with sequelae
			Abdominal distension	腹部膨満	1	N	TE			N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE			Y	None	Not recovered, but no changes expected
			Weight decreased	体重減少	2	N	Pre	1		N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	2		Y	None	Not recovered, but no changes expected
			Stomatitis	口内炎	1	N	TE	9		N	None	Recovered
			Anaemia	貧血	3	Y	TE	119	3	N	Drug administration postponed	Recovered with sequelae
			Anaemia	貧血	2	N	TE	121	27	N	None	Recovered
			Anaemia	貧血	3	Y	TE	147	4	Y	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	150	26	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	3	Y	TE	175	10	N	Not applicable	Recovered with sequelae
			Thrombocytopenia	血小板減少症	1	N	TE	175	9	N	None	Recovered
			Fall	転倒・転落	1	N	TE	181	1	N	None	Recovered
			Anxiety	不安	1	N	TE	181		N	None	Not recovered, but no changes expected
			Thrombocytopenia	血小板減少症	3	N	TE	183	51	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	4	N	TE	233	12	N	None	Recovered
			Asthenia	無力症	1	N	TE	234		N	None	Ongoing at time of death
130004	Canada	82/M/C	Hip fracture	股関節部骨折	3	Y	TE	32		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
130009	Canada	72/M/C	Diarrhoea	下痢	1	N	TE			Y	None	Recovered
			Fatigue	疲労	2	N	TE			Y	None	Ongoing at study termination / withdrawal
			Decreased appetite	食欲減退	1	N	TE			Y	None	Recovered
			Bone pain	骨痛	1	N	TE			Y	None	Recovered
			Bone pain	骨痛	1	N	TE			Y	None	Recovered
			Anaemia	貧血	2	N	Pre	1	86	Y	-	
			Lymphopenia	リンパ球減少症	3	N	Pre	1	29	N	None	Ongoing at study termination / withdrawal
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	Pre	1	57	N	None	Recovered
			Lymphopenia	リンパ球減少症	2	N	Pre	29	29	N	None	Ongoing at study termination / withdrawal
			Injection site reaction	注射部位反応	1	N	TE	31	3	Y	None	Recovered
			Lymphopenia	リンパ球減少症	3	N	Pre	57		N	None	Ongoing at study termination / withdrawal
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	Pre	57	86	N	None	Recovered
			Gynaecomastia	女性化乳房	2	N	TE	57	114	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	62	1	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cough	咳嗽	1	N	TE	65		Y	None	Recovered
			Anaemia	貧血	1	N	Pre	86	29	Y	-	
			Anaemia	貧血	2	N	Pre	114	29	Y	-	
			Anaemia	貧血	1	N	Pre	142	29	Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	Pre	170		Y	None	Ongoing at study termination / withdrawal
			Blood urea increased	血中尿素増加	1	N	TE	170		Y	None	Ongoing at study termination / withdrawal
			Hypercreatininaemia	高クレアチニン血症	1	N	TE	170	23	Y	None	Recovered
			Bone pain	骨痛	3	Y	TE	191	7	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	1	N	Post	228	82	Y	None	Recovered
133002	Poland	78/M/C	Pyrexia	発熱	1	N	TE	3	14	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	3	6	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	8	44	Y	None	Recovered
			Pathological fracture	病的骨折	2	Y	TE	43		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	51	53	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	72	34	N	None	Recovered
			Fatigue	疲労	3	N	TE	88	26	N	Drug permanently withdrawn	Ongoing at time of death
			Fatigue	疲労	4	N	TE	113		N	Drug permanently withdrawn	Ongoing at time of death
			Weight decreased	体重減少	2	N	TE	113		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	162	1	N	Not applicable	Death
133003	Poland	77/M/C	Arthralgia	関節痛	2	N	TE	3	3	Y	None	Recovered
			Neutropenia	好中球減少症	3	N	TE	56	9	Y	Drug administration postponed	Recovered
			Anaemia	貧血	3	Y	TE	65	2	Y	None	Recovered
			Anaemia	貧血	2	N	TE	85	5	Y	Drug permanently withdrawn	Recovered
			Anaemia	貧血	3	Y	TE	89	5	Y	Drug permanently withdrawn	Recovered
			Neutropenia	好中球減少症	3	N	TE	89	5	Y	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	89	2	Y	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	3	N	TE	90		Y	None	Ongoing at study termination / withdrawal
			Fibrin D dimer increased	フィブリンDダイマー増加	2	N	TE	99		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	4	Y	TE	130	2	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	TE	131		N	None	Ongoing at study termination / withdrawal
133005	Poland	62/M/C	Nausea	悪心	1	N	TE			Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Paraparesis	不全対麻痺	3	Y	TE	14		N	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	141		N	None	Ongoing at study termination / withdrawal
133006	Poland	53/M/C	Bone pain	骨痛	2	N	TE	2	10	Y	None	Recovered
			Hypertension	高血圧	2	N	TE	29	29	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	50		N	None	Recovered
			Abdominal pain	腹痛	2	N	TE	71		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	140	29	N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	168		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	168		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	184	2	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	185	1	N	Not applicable	Death
133009	Poland	75/M/C	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2	N	TE	85	29	N	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1	N	TE	85	29	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	141	29	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	198	1	N	Not applicable	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
133011	Poland	66/M/C	Anaemia	貧血	2	N	Pre	1		N	None	Ongoing at time of death
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	Pre	1		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre	1		N	None	Not recovered, but no changes expected
			Tremor	振戦	4	Y	TE	25	1	Y	None	Recovered
			Confusional state	錯乱状態	4	Y	TE	25		Y	None	Ongoing at time of death
			Death	死亡	5	Y	TE	29	1	Y	None	Death
133012	Poland	67/M/C	Spinal cord compression	脊髄圧迫	3	Y	Pre	-35		N	Drug administration postponed	Ongoing at time of death
			Dyspnoea	呼吸困難	4	Y	TE	2	1	N	None	Death
			Dyspnoea	呼吸困難	5	Y	TE	2	1	N	None	Death
133017	Poland	61/M/C	Hyperthyroidism	甲状腺機能亢進症	1	N	TE	3		N	None	Not recovered, but no changes expected
			Upper gastrointestinal haemorrhage	上部消化管出血	2	Y	TE	3		N	None	Ongoing at study termination / withdrawal
133018	Poland	72/M/C	Diarrhoea	下痢	1	N	TE	39	5	Y	None	Recovered
			Dehydration	脱水	1	N	TE	57	3	N	None	Recovered
			Leukopenia	白血球減少症	3	N	TE	106		Y	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	3	N	TE	106		Y	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	4	Y	TE	106		N	Drug permanently withdrawn	Not recovered, but no changes expected
133020	Poland	76/M/C	Nausea	悪心	3	N	TE	1		Y	None	Not recovered, but no changes expected
			Vomiting	嘔吐	3	N	TE	1		Y	None	Not recovered, but no changes expected
			Dehydration	脱水	3	Y	TE	8	4	Y	Drug permanently withdrawn	Recovered
			Anaemia	貧血	2	N	TE	9	1	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	25		N	None	Ongoing at study termination / withdrawal
			Dehydration	脱水	2	N	TE	36		N	Not applicable	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	2	N	TE	36	1	N	None	Recovered
133026	Poland	50/M/C	Neutropenia	好中球減少症	2	N	TE	57	15	Y	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	57	15	Y	Drug administration postponed	Recovered
			Pollakiuria	頻尿	1	N	TE	99	53	N	None	
			Urinary retention	尿閉	2	N	TE	151	1	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	155		N	None	Recovered
			Haematuria	血尿	2	Y	TE	200	6	N	Not applicable	Recovered
134001	Poland	57/M/C	Paralysis	麻痺	4	Y	Pre	-10		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	20	1	N	None	Death
135003	Poland	62/M/C	Bone pain	骨痛	3	N	TE			N	None	Recovered
			Anaemia	貧血	3	Y	TE	114	3	Y	None	Recovered
			Anaemia	貧血	2	N	TE	115	2	Y	None	Recovered
137006	Poland	71/M/C	Anaemia	貧血	3	Y	TE	139	8	N	Not applicable	Recovered with sequelae
			Urinary tract infection	尿路感染	2	N	TE	157	8	N	Not applicable	Recovered
			Haematuria	血尿	3	Y	TE	197	7	N	Not applicable	Recovered
			Anaemia	貧血	4	Y	TE	203		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	213	1	N	Not applicable	Death
139001	Poland	76/M/C	Anaemia	貧血	1	N	TE	29		N	None	Ongoing at time of death
			Malaise	倦怠感	3	N	TE	29		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	46	1	N	None	Death
139005	Poland	71/M/C	Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre			N	None	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	57	5	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	120	1	N	None	Death
139006	Poland	76/M/C	Oedema peripheral	末梢性浮腫	3	N	TE			N	None	Not recovered, but no changes expected
			Vomiting	嘔吐	2	N	TE	31	3	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	88	5	Y	None	Recovered with sequelae
			Renal failure	腎不全	2	N	TE	119	26	N	None	Ongoing at study termination / withdrawal
			General physical health deterioration	全身健康状態低下	3	N	TE	144		Y	Drug permanently withdrawn	Not recovered, but no changes expected
			Renal failure	腎不全	1	N	TE	144		N	None	Ongoing at study termination / withdrawal
139009	Poland	57/M/C	Pancytopenia	汎血球減少症	3	Y	TE	117	8	Y	Drug administration postponed	Recovered with sequelae
			Leukopenia	白血球減少症	3	Y	TE	172	10	Y	Drug administration postponed	Recovered with sequelae
			Leukopenia	白血球減少症	2	N	TE	181		Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	181	1	Y	None	Ongoing at time of death
139012	Poland	67/M/C	Thrombophlebitis	血栓性静脈炎	2	Y	Pre	-26	12	N	Drug administration postponed	Recovered with sequelae

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombophlebitis	血栓性静脈炎	1	N	Pre	-15		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	29	8	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	29	8	Y	None	Recovered
			Nausea	悪心	1	N	TE	57	8	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	57	8	Y	None	Recovered
			Nausea	悪心	1	N	TE	85	7	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	85	7	Y	None	Recovered
144002	Germany	77/M/C	Hyperthyroidism	甲状腺機能亢進症	1	N	TE			Y	None	Recovered
			Dysgeusia	味覚異常	1	N	TE			Y	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	2	4	Y	None	Recovered
			Fatigue	疲労	2	N	TE	3	3	Y	None	Recovered with sequelae
			Urinary retention	尿閉	1	N	TE	47	37	N	None	Recovered with sequelae
			Benign neoplasm of bladder	膀胱の良性新生物	3	Y	TE	77	7	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	101	4	N	None	Recovered
			Haematuria	血尿	1	N	TE	158	6	N	None	Recovered
			Haematuria	血尿	1	N	TE	216	3	N	None	Recovered
144004	Germany	68/M/C	Pneumonia	肺炎	3	Y	TE	59	6	N	None	Recovered
146001	Germany	70/M/C	Paraesthesia	錯感覚	2	N	TE	73		N	None	Recovered with sequelae
			Herpes zoster	帯状疱疹	2	Y	TE	169	12	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary incontinence	尿失禁	1	N	TE	174		N	Not applicable	Ongoing at study termination / withdrawal
146004	Germany	77/M/C	Anaemia	貧血	2	N	TE	17	5	N	Drug administration postponed	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	17		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Multi-organ failure	多臓器不全	4	Y	TE	17	12	N	None	Death
			Anaemia	貧血	4	N	TE	21		N	Drug administration postponed	Ongoing at time of death
			Multi-organ failure	多臓器不全	5	Y	TE	28	1	N	None	Death
148009	Germany	71/M/C	Nasopharyngitis	鼻咽頭炎	1	N	Pre	-14	15	N	None	Recovered
			Anaemia	貧血	2	N	Pre	1	57	Y	Drug administration postponed	Recovered
			Fatigue	疲労	2	N	TE	8		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	29	4	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	57	4	Y	Drug administration postponed	Recovered
			Anaemia	貧血	1	N	TE	60	31	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	60	1	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	60	2	Y	None	Recovered
			Herpes zoster	帯状疱疹	3	Y	TE	96	12	Y	Drug administration postponed	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	Y	TE	98	1	Y	None	Recovered
			Anaemia	貧血	4	Y	TE	125	3	Y	Drug administration postponed	Recovered
			Syncope	失神	3	Y	TE	125	1	Y	Drug administration postponed	Recovered
			Pancytopenia	汎血球減少症		N	TE	140		Y	None	Ongoing at time of death
			Metastases to liver	肝転移	3	Y	TE	140	10	N	Drug permanently withdrawn	Death
			Epistaxis	鼻出血	2	N	TE	140	1	N	Not applicable	Recovered
			Metastases to liver	肝転移	5	Y	TE	149	1	N	Drug permanently withdrawn	Death
148012	Germany	72/M/C	Acute coronary syndrome	急性冠動脈症候群	3	Y	TE	6	3	N	None	Recovered
			Angina pectoris	狭心症	2	N	TE	76	15	N	None	Recovered
			Angina pectoris	狭心症	3	Y	TE	90	3	N	None	Recovered
			Anaemia	貧血	3	N	TE	141	15	Y	Drug administration postponed	Ongoing at time of death
			Anaemia	貧血	2	N	TE	155		Y	Drug administration postponed	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	155	29	Y	None	Recovered
			Arthralgia	関節痛	2	N	TE	169		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pigmentation disorder	色素沈着障害	1	N	TE	183		N	None	Recovered
148014	Germany	62/M/C	Nausea	悪心	1	N	TE	29	1	Y	None	Recovered
			Ageusia	味覚消失	1	N	TE	29	1	Y	None	Recovered
			Cataract	白内障	3	Y	TE	154	3	N	Not applicable	Recovered
148019	Germany	65/M/C	Conjunctivitis	結膜炎	2	N	TE	2	8	N	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	29	1	Y	None	Recovered
			Nausea	悪心	1	N	TE	31	4	Y	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	32	1	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	32	1	Y	None	Recovered
			Pleural effusion	胸水	1	N	TE	93		N	None	Ongoing at time of death
			Blood urea increased	血中尿素増加	2	N	TE	109	11	N	None	Recovered
			Blood creatinine increased	血中クレアチニン増加	2	N	TE	113	7	N	None	Recovered
			Hydronephrosis	水腎症	3	Y	TE	113	2	N	None	Recovered
			Dyspnoea	呼吸困難	2	N	TE	113		N	None	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	119	4	N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	119		N	None	Ongoing at time of death
			Blood creatinine increased	血中クレアチニン増加	3	N	TE	119	4	N	None	Recovered
			Blood urea increased	血中尿素増加	3	N	TE	119	4	N	None	Recovered
			Hydronephrosis	水腎症	3	Y	TE	119	4	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	143	1	N	Drug permanently withdrawn	Death
149009	Germany	72/M/C	Bone pain	骨痛	1	N	TE	1	3	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	29	3	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	36	21	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Insomnia	不眠症	1	N	TE	56		N	None	Not recovered, but no changes expected
			Diarrhoea	下痢	1	N	TE	58	18	Y	None	Recovered
			Anaemia	貧血	1	N	TE	82	2	Y	Drug administration postponed	Recovered
			Bone pain	骨痛	1	N	TE	83	87	Y	None	Recovered with sequelae
			Pancytopenia	汎血球減少症	2	N	TE	140		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	169	27	Y	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	176		Y	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	208	2	Y	Not applicable	Recovered
			Anaemia	貧血	3	N	Post	251	3	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	Post	265	2	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	Post	279	9	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	Post	307	4	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	Post	356	2	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	Post	371	14	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	Post	412	17	Y	Not applicable	Recovered
			Anaemia	貧血	3	N	Post	470	7	Y	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Aplastic anaemia	再生不良性貧血	3	Y	Post	526		Y	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	Post	540	2	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	Post	575	2	Y	Not applicable	Recovered
150002	Germany	72/M/C	Nausea	悪心	2	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE			N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	23	4	N	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	26	8	N	None	Recovered with sequelae
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	4	N	TE	29	26	N	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	4	N	TE	29	2	N	None	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	TE	29	2	N	None	Recovered
			Neuralgia	神経痛	2	N	TE	29	5	N	None	Recovered with sequelae
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	30	25	N	None	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	2	N	TE	30	25	N	None	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1	N	TE	54	13	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nerve root compression	神経根圧迫	2	Y	TE	66	3	N	None	Recovered with sequelae
			Nausea	悪心	2	N	TE	69	11	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	69	11	N	None	Recovered
			Fatigue	疲労	1	N	TE	69	11	N	None	Recovered
			Urinary retention	尿閉	2	Y	TE	69	11	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	177	11	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	178	1	N	None	Recovered
			Headache	頭痛	2	N	TE	180	1	N	None	Recovered
150003	Germany	70/M/C	Nausea	悪心	1	N	TE	72		N	None	Ongoing at time of death
			Hydronephrosis	水腎症	2	Y	TE	100	2	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	141	5	N	None	Recovered
			Hypercreatininaemia	高クレアチニン血症	2	N	TE	141	16	N	None	Recovered
			Hydronephrosis	水腎症	2	Y	TE	141	6	N	None	Recovered with sequelae
			Anaemia	貧血	3	N	TE	143		N	None	Ongoing at time of death
			Hypercreatininaemia	高クレアチニン血症	1	N	TE	156	32	N	None	Recovered
151005	Germany	83/M/C	Diarrhoea	下痢	1	N	TE			N	None	Recovered
			Cystitis	膀胱炎	3	N	TE	44	5	Y	None	Recovered
			Urinary retention	尿閉	3	Y	TE	130	7	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	131		Y	None	Ongoing at time of death
			Hypoglycaemia	低血糖症	3	Y	TE	214	4	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary tract infection	尿路感染	1	N	TE	215	8	N	None	Recovered
152003	Germany	49/M/C	Nausea	悪心	1	N	TE			N	Not applicable	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE			N	Not applicable	Recovered with sequelae
			Escherichia urinary tract infection	大腸菌性尿路感染	1	N	TE			N	Not applicable	Recovered
			Depression	うつ病	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	1	85	N	Drug administration postponed	Recovered with sequelae
			Productive cough	湿性咳嗽	1	N	TE	22	11	N	None	Recovered
			Injection site swelling	注射部位腫脹	1	N	TE	34		Y	None	Recovered
			Injection site swelling	注射部位腫脹	1	N	TE	58		Y	None	Recovered
			Bone pain	骨痛	3	Y	TE	85	10	N	Drug administration postponed	Recovered with sequelae
			Anaemia	貧血	2	N	TE	115	18	N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	115		N	Not applicable	Recovered with sequelae
			Dehydration	脱水	2	N	TE	115		N	None	Recovered
			Bone pain	骨痛	3	Y	TE	115	18	N	Not applicable	Recovered with sequelae
152004	Germany	75/M/C	Bone pain	骨痛	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	1	N	TE	1		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	1	N	TE	79		N	None	Recovered
			Bone pain	骨痛	3	Y	TE	79	14	N	Drug administration postponed	Recovered with sequelae
			Disturbance in attention	注意力障害	1	N	TE	79		N	None	Ongoing at study termination / withdrawal
			Insomnia	不眠症	1	N	TE	79		N	None	Recovered
			Pleural effusion	胸水	1	N	TE	79		N	None	Recovered
			Bone pain	骨痛	2	N	TE	92	37	N	None	Recovered with sequelae
			Pancytopenia	汎血球減少症	2	N	TE	128		N	None	Recovered with sequelae
			Nausea	悪心	1	N	TE	128	8	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	128	8	N	None	Recovered
			Infection	感染	2	N	TE	128	8	N	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	128	8	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	128	8	N	None	Recovered with sequelae
			Pneumonia primary atypical	原発性異型肺炎	3	Y	TE	147	22	N	Drug administration postponed	Recovered with sequelae
			Asthenia	無力症	2	N	TE	161		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			General physical health deterioration	全身健康状態低下	5	Y	TE	195	1	N	None	Death
154001	Germany	65/M/C	Coronary artery disease	冠動脈疾患	3	Y	Pre	-12	3	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hypercholesterolaemia	高コレステロール血症	1	N	Pre	-12		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	50	32	N	None	Recovered
			Anaemia	貧血	2	N	TE	59		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	80	75	N	None	Recovered
			Coronary artery disease	冠動脈疾患	2	Y	TE	122	8	N	Not applicable	Recovered
154002	Germany	71/M/C	Nausea	悪心	1	N	Pre			N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Pain	疼痛	3	N	TE			N	None	Ongoing at study termination / withdrawal
			Angina pectoris	狭心症	1	N	TE	1	15	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	42		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	42		N	None	Ongoing at time of death
			Joint injury	関節損傷	1	N	TE	61	1	N	None	Recovered
			Anaemia	貧血	2	N	TE	85		N	None	Ongoing at study termination / withdrawal
			Gait disturbance	歩行障害	3	N	TE	94		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	123	13	N	Drug administration postponed	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Facial palsy	顔面神経麻痺	3	N	TE	155	15	N	Drug administration postponed	Ongoing at time of death
			Facial palsy	顔面神経麻痺	3	Y	TE	169	7	N	Drug administration postponed	Ongoing at time of death
			Facial palsy	顔面神経麻痺	2	N	TE	175		N	Drug administration postponed	Ongoing at study termination / withdrawal
154004	Germany	62/M/C	Atrial fibrillation	心房細動	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Renal failure	腎不全	2	N	TE			N	None	Recovered with sequelae
			Cystitis	膀胱炎	1	N	Pre	-3	7	N	None	Recovered
			Nausea	悪心	1	N	TE	2		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	2		Y	None	Not recovered, but no changes expected
			Abdominal pain upper	上腹部痛	1	N	TE	7	23	Y	None	Recovered
			Abdominal pain	腹痛	1	N	TE	29	56	N	Not applicable	Ongoing at study termination / withdrawal
			Nocturia	夜間頻尿	2	N	TE	57		N	None	Ongoing at time of death
			Acute prerenal failure	急性腎前性腎不全	2	Y	TE	81	4	N	Not applicable	Recovered
			Abdominal pain	腹痛	2	N	TE	84		N	Not applicable	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	85		N	None	Ongoing at time of death
			Peritonitis bacterial	細菌性腹膜炎	3	Y	TE	86	22	N	Drug permanently withdrawn	Recovered
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	107	6	N	Drug permanently withdrawn	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	112		N	Drug permanently withdrawn	Not recovered, but no changes expected
155004	Germany	63/M/C	Vomiting	嘔吐	2	N	TE			Y	None	Recovered
			Vomiting	嘔吐	1	N	TE			Y	None	Recovered
			Depression	うつ病	1	N	Pre	1	217	N	None	Not recovered, but no changes expected
			Constipation	便秘	1	Y	TE	26	3	N	None	Recovered
			Reflux oesophagitis	逆流性食道炎	1	N	TE	32	46	N	None	Recovered
			Fatigue	疲労	2	N	TE	32		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	32		N	None	Not recovered, but no changes expected
			Night sweats	寝汗	1	N	TE	32	31	N	None	Recovered
			Reflux oesophagitis	逆流性食道炎	2	N	TE	77	95	N	None	Recovered
			Depression	うつ病	2	N	TE	217		N	None	Not recovered, but no changes expected
157002	Germany	76/M/C	General physical health deterioration	全身健康状態低下	2	N	TE			N	None	Not recovered, but no changes expected
			General physical health deterioration	全身健康状態低下	1	N	TE			N	None	Not recovered, but no changes expected

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	3	Y	Pre	-10	2	N	Not applicable	Recovered
			Anaemia	貧血	2	N	Pre	1	37	Y	None	Recovered with sequelae
			Fatigue	疲労	2	N	TE	5		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	5		Y	None	Ongoing at time of death
			Night sweats	寝汗	1	N	TE	5		Y	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	37	2	Y	None	Recovered with sequelae
			Anaemia	貧血	3	N	TE	38	6	Y	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	43		Y	None	Not recovered, but no changes expected
170004	Brazil	78/M/C	Pathological fracture	病的骨折	3	N	TE	127		N	Drug administration postponed	Ongoing at time of death
			Urinary retention	尿閉	3	N	TE	156	1	N	None	Recovered
			Anaemia	貧血	2	N	TE	211		N	None	Ongoing at time of death
			Bone pain	骨痛	4	Y	TE	230		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	230	3	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	232	1	N	Drug permanently withdrawn	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
173008	Brazil	67/M/C	Anaemia	貧血	2	N	Pre	1	33	N	Drug administration postponed	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	Pre	1	63	N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	33	2	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	34	30	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	N	TE	63	3	N	Drug administration postponed	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	Pre	63		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	65	83	N	Drug administration postponed	Recovered
			Anorexia	食欲不振	2	N	TE	87	70	N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	147	5	N	Drug administration postponed	Recovered
			Anorexia	食欲不振	3	N	TE	156		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	156		N	None	Ongoing at time of death
			Weight decreased	体重減少	3	N	TE	183		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	3	N	TE	184	11	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	1	N	TE	184	11	N	None	Ongoing at time of death
			Anaemia	貧血	4	N	TE	194	5	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	194	5	N	None	Ongoing at time of death
			Neutropenia	好中球減少症	4	N	TE	198		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	198		N	None	Ongoing at time of death
			Cerebrovascular accident	脳血管発作	4	Y	TE	198	4	Y	Not applicable	Death
			Cerebrovascular accident	脳血管発作	5	Y	TE	201	1	Y	Not applicable	Death
173009	Brazil	66/M/O	Bone pain	骨痛	2	N	Pre	-9		N	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	4	Y	TE	29	20	N	Drug permanently withdrawn	Death
			General physical health deterioration	全身健康状態低下	5	Y	TE	48	1	N	Drug permanently withdrawn	Death
173011	Brazil	62/M/B	Constipation	便秘	2	N	Pre	-7	13	N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	Pre	-7	8	N	None	Ongoing at time of death
			Arthralgia	関節痛	2	N	Pre	-7		N	None	Ongoing at time of death
			Anorexia	食欲不振	3	N	TE	1		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	1	N	Pre	6		N	None	Ongoing at time of death
			Anaemia	貧血	4	N	TE	29		N	Drug permanently withdrawn	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	4	Y	TE	30		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
178007	Brazil	71/M/0	Hypercalcaemia	高カルシウム血症	3	N	Pre	1	88	Y	None	Recovered
			Neutropenia	好中球減少症	2	N	TE	29	29	Y	Drug administration postponed	Recovered
			Bone pain	骨痛	2	N	TE	48	77	N	None	Ongoing at time of death
			Neutropenia	好中球減少症	3	N	TE	57	4	Y	Drug administration postponed	Recovered
			Neutropenia	好中球減少症	2	N	TE	60	65	Y	Drug administration postponed	Recovered
			Insomnia	不眠症	2	N	TE	78		N	None	Ongoing at time of death
			Pathological fracture	病的骨折	3	Y	TE	121	28	N	Drug administration postponed	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	124		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	124	15	N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	138	25	N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	2	N	TE	139	7	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	141	1	N	Not applicable	Recovered
			Anaemia	貧血	3	Y	TE	147	2	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	148		N	Not applicable	Lost to follow-up
			Device dislocation	医療機器位置異常	3	Y	TE	162	3	N	Not applicable	Recovered
			Procedural pain	処置による疼痛	3	Y	TE	162	3	N	Not applicable	Recovered
			Pneumonia	肺炎	3	Y	TE	165	3	N	Not applicable	Recovered
			Pulmonary embolism	肺塞栓症	3	Y	TE	165	3	N	Not applicable	Death
			Pneumonia	肺炎	4	Y	TE	167	28	N	Not applicable	Recovered
			Pulmonary embolism	肺塞栓症	4	Y	TE	167	63	N	Not applicable	Death
			Pulmonary embolism	肺塞栓症	5	Y	TE	229	1	N	Not applicable	Death
179001	Brazil	77/M/C	Hypercreatininaemia	高クレアチニン血症	2	N	Pre	1	59	N	None	Ongoing at study termination / withdrawal
			Hypercreatininaemia	高クレアチニン血症	1	N	Pre	59	29	N	None	Ongoing at study termination / withdrawal
			Asthenia	無力症	1	N	TE	69	1	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hypercreatininaemia	高クレアチニン血症	2	N	Pre	87		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	Y	TE	93	4	N	None	Recovered
			Anaemia	貧血	2	Y	TE	114	3	N	None	Recovered
			Asthenia	無力症	2	Y	TE	126	5	N	Drug administration postponed	Recovered with sequelae
			Fatigue	疲労	3	Y	TE	146	9	N	Drug permanently withdrawn	Recovered
179006	Brazil	79/M/C	Nausea	悪心	1	N	Pre	-17	3	N	Not applicable	Recovered
			Cough	咳嗽	1	N	Pre	-6	5	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	34	99	N	None	Recovered
			Arthralgia	関節痛	1	N	TE	132		N	None	Recovered
			Bone pain	骨痛	1	N	TE	159	2	N	None	Recovered
			Myocardial infarction	心筋梗塞	5	Y	TE	244	1	N	Not applicable	Death
181005	Brazil	74/M/C	Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	Pre	1		N	None	Ongoing at time of death
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	Pre	1		N	None	Ongoing at time of death
			Hypoglycaemia	低血糖症	3	Y	TE	29	2	N	None	Recovered
			Pneumonia	肺炎	2	Y	TE	30	16	N	Not applicable	Death
			Acute pulmonary oedema	急性肺水腫	2	Y	TE	30		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pneumonia	肺炎	5	Y	TE	45	1	N	Not applicable	Death
181048	Brazil	70/M/C	Thrombosis	血栓症	2	N	Pre	-1		N	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	29		N	None	Ongoing at study termination / withdrawal
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	1	N	TE	141		N	None	Ongoing at study termination / withdrawal
			Constipation	便秘	2	N	TE	158		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	Y	TE	176	5	N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	176	5	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	209		N	Not applicable	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	4	Y	TE	209	23	N	Not applicable	Recovered with sequelae
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1	N	TE	209		N	Not applicable	Ongoing at study termination / withdrawal
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1	N	TE	209		N	Not applicable	Ongoing at study termination / withdrawal

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
201002	Australia	72/M/C	Dysphagia	嚥下障害	2	N	Pre	-7	70	N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	48	46	N	None	Recovered
			Muscle strain	筋挫傷	2	N	TE	49	15	N	None	Recovered
			Dysphagia	嚥下障害	1	N	Pre	63	71	N	None	Ongoing at time of death
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	2	N	TE	93	4	N	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	99	8	N	None	Recovered
			Anaemia	貧血	3	Y	TE	132	9	N	Not applicable	Recovered
			Supraventricular tachycardia	上室性頻脈	2	Y	TE	132	1	N	Not applicable	Recovered
			Abdominal distension	腹部膨満	3	Y	TE	132	9	N	Not applicable	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	3	N	TE	132		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	132	39	N	Not applicable	Death
			Anxiety	不安	2	N	TE	132		N	Not applicable	Ongoing at time of death
			Dysphagia	嚥下障害	2	N	Pre	133		N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	1	N	TE	137	3	N	Not applicable	Recovered
			Abdominal distension	腹部膨満	2	N	TE	140		N	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	147		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	161		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	170	1	N	Not applicable	Death
203004	Australia	70/M/C	Constipation	便秘	1	N	Pre	-7		N	None	Recovered
			Hypophosphataemia	低リン酸血症	4	N	Pre	-2	29	N	-	
			Lethargy	嗜眠	1	N	TE	4	1	Y	None	Recovered
			Hypophosphataemia	低リン酸血症	3	N	Pre	27	64	N	-	
			Hypomagnesaemia	低マグネシウム血症	1	N	TE	55	36	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	56	1	N	None	Recovered
			Lethargy	嗜眠	1	N	TE	79	69	Y	None	Ongoing at study termination / withdrawal
			Cough	咳嗽	1	N	TE	79	15	N	None	Recovered
			Dyspepsia	消化不良	1	N	TE	84	15	N	None	Recovered
			Hypophosphataemia	低リン酸血症	4	N	Pre	90	29	N	-	
			Paraesthesia	錯感覚	1	N	TE	91		N	None	Ongoing at time of death
			Hypophosphataemia	低リン酸血症	3	N	Pre	118	15	N	-	
			Dyspepsia	消化不良	1	N	TE	120		N	None	Recovered
			Hypophosphataemia	低リン酸血症	4	N	Pre	132	6	N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	132	115	N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	132	115	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	133	114	N	Not applicable	Recovered
			Hypophosphataemia	低リン酸血症	4	Y	TE	137	4	N	Not applicable	Recovered
			Hyperparathyroidism	副甲状腺機能亢進症	1	N	TE	139		N	Not applicable	Recovered

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cachexia	悪液質	2	N	TE	139		N	Not applicable	
			Osteomalacia	骨軟化症	2	N	TE	139		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	146	20	N	Not applicable	Recovered
			Lethargy	嗜眠	2	N	TE	147		Y	None	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	1	N	TE	166		N	Not applicable	Ongoing at time of death
203007	Australia	70/M/C	Bone pain	骨痛	2	N	Pre	-7	63	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	Pre	-7	63	N	None	Recovered
			Constipation	便秘	2	Y	Pre	-1	3	N	None	Recovered
			Anorexia	食欲不振	2	N	TE	3		N	None	Ongoing at time of death
			Dysgeusia	味覚異常	1	N	TE	3		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	4	2	Y	None	Recovered
			Anaemia	貧血	2	N	TE	28	49	Y	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	28	29	N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	28	83	N	Not applicable	Death
			Fatigue	疲労	2	N	TE	35		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	53	5	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	56	3	N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	56	3	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	56	3	N	None	Recovered
			Bone pain	骨痛	1	N	TE	58		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	58		N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	66	8	N	Not applicable	Recovered
			Constipation	便秘	3	Y	TE	73	6	N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	76	3	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	78		Y	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	110	1	N	Not applicable	Death
204001	Australia	76/M/C	Dyspnoea	呼吸困難	1	N	Pre	-392	366	N	None	Recovered
			Nausea	悪心	1	N	TE	1		Y	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	2		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	2		Y	None	Ongoing at study termination / withdrawal
			Chills	悪寒	1	N	TE	6	1	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	8	1	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	1	N	TE	9		Y	None	Ongoing at study termination / withdrawal
			Contusion	挫傷	1	N	TE	10		N	None	Ongoing at study termination / withdrawal
			Gastroenteritis	胃腸炎	4	Y	TE	18	6	Y	None	Recovered with sequelae
			Renal failure acute	急性腎不全	2	Y	TE	18	6	Y	None	Recovered
			Gastroenteritis	胃腸炎	3	N	TE	21	3	Y	None	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	22	2	Y	None	Recovered
			Gastroenteritis	胃腸炎	2	N	TE	23	1	Y	None	Recovered with sequelae
			Bone pain	骨痛	1	N	TE	34		Y	None	Ongoing at time of death
			Mobility decreased	運動性低下	1	N	TE	34		Y	None	Ongoing at time of death
			Tremor	振戦	1	N	TE	34		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	43	26	N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	63	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	68	9	N	Not applicable	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	76		N	Not applicable	Ongoing at study termination / withdrawal
			Anxiety	不安	1	N	TE	79	1	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anxiety	不安	1	N	TE	83	3	Y	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	116	1	N	Drug permanently withdrawn	Death
205004	Australia	82/M/C	Bone pain	骨痛	2	N	TE			Y	None	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	Pre	1		N	None	Ongoing at time of death
			Urinary incontinence	尿失禁	2	N	TE	6		Y	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	33		Y	None	Ongoing at time of death
			Hydrocephalus	水頭症	4	Y	TE	107	20	N	Drug permanently withdrawn	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	127	14	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	140	1	N	Drug permanently withdrawn	Death
206001	Australia	83/M/C	Meniere's disease	メニエール病	2	N	TE	78	18	Y	Drug administration postponed	Recovered with sequelae
			Deep vein thrombosis	深部静脈血栓症	3	Y	TE	90	6	Y	None	Recovered with sequelae
			Constipation	便秘	1	N	TE	91	4	N	Drug administration postponed	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pollakiuria	頻尿	3	N	TE	189		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	201		N	Not applicable	Ongoing at time of death
			Nausea	悪心	3	N	TE	201		N	Not applicable	Ongoing at time of death
			Pain	疼痛	3	N	TE	201		N	Not applicable	Ongoing at time of death
			Urinary tract infection	尿路感染	3	N	TE	201		N	Not applicable	Ongoing at time of death
			Hydronephrosis	水腎症	3	Y	TE	201		N	Not applicable	Ongoing at time of death
			Fluid overload	水分過負荷	3	N	TE	202		N	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	4	N	TE	202		N	Not applicable	Ongoing at time of death
			Lung consolidation	肺硬化	3	N	TE	202		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	212	1	N	Not applicable	Death
209001	Australia	78/M/C	Stomatitis	口内炎	1	N	Pre	-2	17	N	None	Recovered
			Lethargy	嗜眠	1	N	TE	2	105	N	None	Recovered
			Bone pain	骨痛	1	N	TE	29	84	N	None	Recovered
			Fatigue	疲労	3	Y	TE	107	6	N	Drug administration postponed	Recovered
			Bone pain	骨痛	1	N	TE	107	3	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	107	6	N	Drug administration postponed	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	1	N	TE	108	3	N	Not applicable	Recovered
			Headache	頭痛	1	N	TE	112	1	N	Not applicable	Recovered
			Lethargy	嗜眠	3	N	TE	113		N	Not applicable	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	126	8	N	Not applicable	Recovered
209002	Australia	78/M/C	Bone pain	骨痛	1	N	Pre	1	71	N	None	Recovered
			Rash	発疹	1	N	Pre	1	57	N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	2		N	None	Ongoing at time of death
			Neutropenia	好中球減少症	3	N	TE	29	42	N	Drug administration postponed	Recovered
			Diarrhoea	下痢	1	N	TE	29	99	N	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	29	29	N	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	57		N	None	Ongoing at time of death
			Lymphadenopathy	リンパ節症	1	N	TE	57		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	84	59	N	None	Recovered
			Hypoalbuminaemia	低アルブミン血症	1	N	TE	98		N	None	Ongoing at time of death
			Pallor	蒼白	2	N	TE	98	33	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	99		N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	99	29	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neutropenia	好中球減少症	4	N	TE	126	5	N	Drug permanently withdrawn	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	126		N	Not applicable	Ongoing at time of death
			Rectal tenesmus	直腸しぶり	1	N	TE	127		N	Not applicable	Ongoing at study termination / withdrawal
			Crepitations	捻髪音	1	N	TE	127		N	Not applicable	Ongoing at time of death
			Breath sounds abnormal	呼吸音異常	1	N	TE	127		N	Not applicable	Ongoing at time of death
			Wheezing	喘鳴	1	N	TE	127		N	Not applicable	Ongoing at time of death
			Neutropenia	好中球減少症	3	N	TE	130	15	N	Drug permanently withdrawn	Recovered
			Anaemia	貧血	2	N	TE	133	13	N	Not applicable	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	137	6	N	Not applicable	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	TE	142	22	N	Not applicable	Ongoing at time of death
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1	N	TE	142	12	N	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	3	Y	TE	143	12	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	153	61	N	Not applicable	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	2	N	TE	153	11	N	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	1	N	TE	155		N	Not applicable	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	TE	163		N	Not applicable	Ongoing at time of death
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	TE	163		N	Not applicable	Ongoing at time of death
209003	Australia	56/M/C	Bone pain	骨痛	1	N	Pre	-22		N	None	Ongoing at time of death
			Oesophagitis	食道炎	1	N	TE	29		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	29		N	None	Ongoing at time of death
			Muscle spasms	筋痙縮	1	N	TE	57		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	78		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	78		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	78		N	None	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	85		N	None	Ongoing at time of death
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	1	N	TE	85		N	None	Ongoing at time of death
			Breath sounds abnormal	呼吸音異常	1	N	TE	85		N	None	Ongoing at time of death
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1	N	TE	85		N	None	Ongoing at time of death
			Neuropathy peripheral	末梢性ニューロパチー	1	N	TE	88		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	4	Y	TE	94	16	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Burning sensation	灼熱感	1	N	TE	102	1	N	None	Recovered
			Rash	発疹	1	N	TE	103		N	None	Ongoing at time of death
			Pyrexia	発熱	1	N	TE	108	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	109		N	Not applicable	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	109		N	Not applicable	Ongoing at time of death
			Radiation skin injury	放射線皮膚損傷	1	N	TE	109		N	Not applicable	Ongoing at time of death
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	Y	TE	109	7	N	Drug permanently withdrawn	Recovered
			Anxiety	不安	1	N	TE	109		N	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	138		N	Not applicable	Ongoing at time of death
			Ascites	腹水	1	Y	TE	149		N	Not applicable	Ongoing at time of death
			Epistaxis	鼻出血	1	N	TE	149	18	N	Not applicable	Recovered
			Dry skin	皮膚乾燥	1	N	TE	149		N	Not applicable	Ongoing at time of death
			Pruritus	そう痒症	1	N	TE	149		N	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE	153		N	None	Ongoing at time of death
			Rectal haemorrhage	直腸出血	1	N	TE	158		N	Not applicable	Ongoing at time of death
			Pitting oedema	圧痕浮腫	1	N	TE	158		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	158	9	N	Not applicable	Death
			Confusional state	錯乱状態	1	N	TE	158		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	166	1	N	Not applicable	Death
213002	Australia	49/M/O	Cough	咳嗽	1	N	Pre	-10	31	N	None	Recovered
			Musculoskeletal pain	筋骨格痛	3	N	TE	17	2	Y	None	Recovered
			Dyspnoea	呼吸困難	3	N	TE	82		Y	None	Not recovered, but no changes expected
			Abdominal pain	腹痛	2	N	TE	85	3	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	85	1	N	None	Recovered
			Pulmonary haemorrhage	肺出血	1	N	TE	85	1	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	140	29	N	None	Not recovered, but no changes expected
			Rectal haemorrhage	直腸出血	1	N	TE	159		N	None	Not recovered, but no changes expected
			Fatigue	疲労	2	N	TE	161		N	None	Not recovered, but no changes expected
			Headache	頭痛	1	N	TE	161		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	163	9	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	163	9	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	168	28	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	168	3	N	Not applicable	Recovered
			Insomnia	不眠症	1	N	TE	168		N	None	Not recovered, but no changes expected

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	1	N	TE	195		N	None	Not recovered, but no changes expected
213008	Australia	74/M/C	Bone pain	骨痛	1	N	TE			N	None	Recovered
			Hypotension	低血圧	1	N	TE			N	Not applicable	Recovered
			Hypotension	低血圧	2	N	TE			N	Not applicable	Not recovered, but no changes expected
			Hypotension	低血圧	3	N	TE			N	Not applicable	Not recovered, but no changes expected
			Nausea	悪心	2	N	TE	2	6	Y	None	Recovered
			Fatigue	疲労	1	N	TE	2	6	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	2	10	Y	None	Recovered
			Headache	頭痛	1	N	TE	2	6	Y	None	Recovered
			Constipation	便秘	1	N	TE	4	8	N	None	Recovered
			Nausea	悪心	1	N	TE	7	5	Y	None	Recovered
			Skin laceration	皮膚裂傷	3	Y	TE	25	2	N	None	Recovered
			Hypotension	低血圧	1	N	TE	45	15	N	None	Recovered
			Nausea	悪心	1	N	TE	64	29	Y	None	Recovered
			Fatigue	疲労	1	N	TE	65	8	Y	None	Recovered
			Fatigue	疲労	1	N	TE	92		Y	None	Not recovered, but no changes expected
			Paraesthesia	錯感覚	1	N	TE	92	24	N	None	Recovered
			Fatigue	疲労	1	N	TE	120		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	120		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	146	4	N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE	149	28	N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	149		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	176		N	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	176		N	None	Ongoing at study termination / withdrawal
214003	Australia	68/M/C	Rash	発疹	2	N	TE	3	20	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	8	10	N	None	Recovered
			Bone pain	骨痛	3	N	TE	42	16	N	Drug administration postponed	Recovered
			Constipation	便秘	1	N	TE	54	4	N	None	Recovered
			Fatigue	疲労	3	N	TE	58	28	Y	None	Recovered
			Constipation	便秘	1	N	TE	60	3	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	61		Y	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	85	29	N	None	Recovered
			Hydronephrosis	水腎症	3	N	TE	85	36	N	None	Recovered
			Myositis	筋炎	2	N	TE	101	15	N	None	Recovered
			Anaemia	貧血	2	N	TE	122	3	N	None	Ongoing at time of death
			Procedural pain	処置による疼痛	3	Y	TE	122	4	N	None	Recovered
			Dysuria	排尿困難	2	N	TE	122	3	N	None	Recovered
			Haematuria	血尿	1	N	TE	122	15	N	None	Recovered
			Anaemia	貧血	1	N	TE	124		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	3	N	TE	124	18	Y	Drug permanently withdrawn	Ongoing at time of death
			Nausea	悪心	2	N	TE	124	18	Y	None	Recovered
			Diarrhoea	下痢	2	N	TE	130	8	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	141	61	Y	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	173	5	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	201		Y	Drug permanently withdrawn	Ongoing at time of death
230002	UK	66/M/C	Muscle spasms	筋痙縮	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE	28		N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	38	8	Y	None	Recovered
			Anaemia	貧血	2	N	TE	56	29	Y	None	Recovered with sequelae
			Arthralgia	関節痛	2	N	TE	84	86	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	94	6	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	98	44	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	159		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	169	33	Y	None	Recovered
			Hypocalcaemia	低カルシウム血症	1	N	TE	169	79	N	None	Recovered
			Hypophosphataemia	低リン酸血症	4	N	TE	169		Y	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Arthralgia	関節痛	3	N	TE	169		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	169	28	N	Not applicable	Recovered
			Pathological fracture	病的骨折	3	Y	TE	197	9	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	203	15	Y	None	Recovered
			Anaemia	貧血	3	N	TE	245	2	Y	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	245	11	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	1	N	TE	247	6	Y	Not applicable	Recovered
230003	UK	73/M/C	Diarrhoea	下痢	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	1	N	Pre			N	None	Ongoing at study termination / withdrawal
			Scrotal swelling	陰嚢腫脹	1	N	TE			N	Not applicable	Ongoing at time of death
			Urosepsis	尿路性敗血症	3	Y	Pre	-15	4	N	Drug administration postponed	Recovered
			Hypoglycaemia	低血糖症	4	Y	Pre	-15	1	N	Drug administration postponed	Recovered
			Dizziness	浮動性めまい	1	N	TE	68		N	Not applicable	Recovered
			Rectal discharge	直腸分泌物	1	N	TE	69	10	N	Not applicable	Recovered

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dysuria	排尿困難	1	N	TE	73		N	Not applicable	Recovered
			Groin pain	鼠径部痛	3	N	TE	75		Y	Not applicable	Recovered
			Nausea	悪心	1	N	TE	83		N	Not applicable	Ongoing at study termination / withdrawal
230005	UK	64/M/C	Bone pain	骨痛	3	N	TE	62		N	None	Not recovered, but no changes expected
			Hypoaesthesia	感覚鈍麻	2	N	TE	62		N	None	Not recovered, but no changes expected
			Pyrexia	発熱	3	N	TE	69	3	N	None	Recovered
			Infection	感染	3	Y	TE	69	3	N	None	Recovered
			Hyperglycaemia	高血糖	4	Y	TE	77	8	N	None	Recovered with sequelae
			Hyperglycaemia	高血糖	2	N	TE	84		Y	None	Ongoing at study termination / withdrawal
233001	UK	75/M/C	Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE			Y	None	Recovered
			Bone pain	骨痛	2	N	Pre	-2	33	N	None	Recovered
			Bone pain	骨痛	3	N	TE	85		N	Drug administration postponed	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	85		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	4	Y	TE	103	7	N	Drug administration postponed	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Atrial fibrillation	心房細動	3	Y	TE	116	2	Y	None	Recovered
			Cardiac failure congestive	うっ血性心不全	3	Y	TE	131		Y	Not applicable	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	N	TE	131	22	N	Not applicable	Recovered
			Hypokalaemia	低カリウム血症	3	N	TE	132	3	N	Not applicable	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	135	3	N	Not applicable	Recovered
233002	UK	70/M/C	Bone pain	骨痛	2	N	Pre	1		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	4	4	Y	None	Recovered
			Productive cough	湿性咳嗽	2	N	TE	4	4	Y	None	Recovered
			Sepsis	敗血症	4	Y	TE	5	11	Y	Drug permanently withdrawn	Recovered
233005	UK	78/M/C	Nausea	悪心	1	N	TE	1	209	N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	29	181	Y	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	29	29	N	None	Recovered
			Anorexia	食欲不振	3	N	TE	29	113	Y	None	Ongoing at time of death
			Dehydration	脱水	3	N	TE	29	4	Y	Drug administration postponed	Recovered
			Malaise	倦怠感	2	Y	TE	32	6	Y	Drug administration postponed	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dehydration	脱水	3	Y	TE	32	6	Y	Drug administration postponed	Recovered
			Dehydration	脱水	2	Y	TE	45	5	Y	Drug administration postponed	Recovered
			Anaemia	貧血	3	Y	TE	53	3	Y	None	Recovered
			Hypertension	高血圧	3	N	TE	85	125	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	134	3	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	136	3	Y	None	Recovered
			Dehydration	脱水	2	N	TE	136	3	Y	None	Recovered
			Dyspnoea	呼吸困難	3	N	TE	136	2	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	141		Y	None	Ongoing at time of death
			Abdominal pain upper	上腹部痛	1	N	TE	167	3	Y	None	Recovered
			Anaemia	貧血	1	Y	TE	168	2	Y	None	Recovered
			Fatigue	疲労	2	N	TE	168		N	None	Ongoing at time of death
			Dehydration	脱水	2	Y	TE	168	2	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	176	3	Y	Not applicable	Recovered
			Cough	咳嗽	2	N	TE	176	3	N	None	Recovered
			Cough	咳嗽	1	N	TE	176	3	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	N	TE	176	3	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	190		Y	Not applicable	Ongoing at time of death
			Neutropenia	好中球減少症	2	Y	TE	190		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	Y	TE	190		Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Abdominal pain	腹痛	1	N	TE	190	1	Y	Not applicable	Recovered
			Decreased appetite	食欲減退	3	N	TE	190		N	None	Ongoing at time of death
			Dehydration	脱水	3	Y	TE	190	4	Y	Not applicable	Recovered
			Hyperkalaemia	高カリウム血症	2	N	TE	190	20	Y	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	190		Y	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	190	4	Y	Not applicable	Recovered
			Dizziness	浮動性めまい	2	N	TE	190		N	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	3	Y	TE	209		N	Not applicable	Ongoing at time of death
			Bronchopneumonia	気管支肺炎	5	Y	TE	209	1	N	Not applicable	Death
			Dehydration	脱水	3	Y	TE	209		Y	Not applicable	Ongoing at time of death
			Agitation	激越	2	N	TE	209	1	N	None	Ongoing at time of death
234005	UK	58/M/C	Nausea	悪心	2	N	Pre			N	None	Recovered
			Vomiting	嘔吐	2	N	Pre			Y	None	Recovered
			Anaemia	貧血	2	N	Pre	-1	85	N	None	Recovered with sequelae
			Anaemia	貧血	3	Y	TE	84	4	Y	Drug permanently withdrawn	Recovered
			Pancytopenia	汎血球減少症	3	N	TE	87		Y	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cerebrovascular accident	脳血管発作	4	Y	TE	94		Y	None	Ongoing at study termination / withdrawal
240002	USA	68/M/C	Anaemia	貧血	3	N	TE	33	6	Y	Drug administration postponed	Recovered with sequelae
			Pneumonia	肺炎	3	Y	TE	33	6	N	Drug administration postponed	Recovered
			Sepsis	敗血症	4	Y	TE	33	6	N	Drug administration postponed	Recovered
			Pleural effusion	胸水	2	N	TE	33	4	N	None	Recovered
			Hypotension	低血圧	3	N	TE	33	1	N	None	Recovered
			Anaemia	貧血	1	N	TE	38	48	Y	None	Recovered with sequelae
			Diarrhoea	下痢	1	N	TE	62		Y	None	Ongoing at time of death
			Muscle spasms	筋痙縮	1	N	TE	72	43	N	None	Recovered
			Anaemia	貧血	2	N	TE	85	97	Y	None	Recovered with sequelae
			Nausea	悪心	1	N	TE	114	3	N	None	Recovered
			Fatigue	疲労	2	N	TE	114		Y	None	Ongoing at time of death
			Haematuria	血尿	1	N	TE	133	7	N	None	Recovered
			Leukopenia	白血球減少症	2	N	TE	139		Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	1	N	TE	139		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	139		Y	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	1	N	TE	140		N	None	Ongoing at time of death
			Contusion	挫傷	1	N	TE	140		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	140		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	170		N	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	180	3	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	3	Y	TE	180	6	Y	Not applicable	Recovered
			Urinary tract infection	尿路感染	1	N	TE	180	11	N	Not applicable	Recovered
			Bone pain	骨痛	3	N	TE	180	6	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	180	62	N	Not applicable	Death
			Haematuria	血尿	2	Y	TE	180	6	Y	Not applicable	Recovered
			Urinary retention	尿閉	2	Y	TE	180	6	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	N	TE	180	24	N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	181	2	Y	None	Recovered with sequelae
			Dyspnoea	呼吸困難	1	N	TE	181	5	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	182	50	Y	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	194		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	4	N	TE	199	5	Y	Not applicable	Ongoing at time of death
			Abdominal pain	腹痛	2	N	TE	199	11	N	Not applicable	Recovered
			Diarrhoea	下痢	1	N	TE	199	11	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	199	11	N	Not applicable	Recovered
			Vomiting	嘔吐	2	N	TE	199	11	N	Not applicable	Recovered
			Asthenia	無力症	2	N	TE	199		N	Not applicable	Ongoing at time of death
			Arthralgia	関節痛	1	N	TE	199	11	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	199	11	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	N	TE	199	5	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	203		Y	Not applicable	Ongoing at time of death
			Skin laceration	皮膚裂傷	2	N	TE	205		N	Not applicable	Ongoing at time of death
			Haemorrhoids	痔核	1	N	TE	210	6	N	Not applicable	Recovered
			Convulsion	痙攣	2	N	TE	223	1	N	Not applicable	Recovered
			Subcutaneous abscess	皮下組織膿瘍	2	N	TE	227		N	Not applicable	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	229		N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	231		Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary retention	尿閉	2	N	TE	240	1	Y	Not applicable	Recovered
			Salivary hypersecretion	流涎過多	1	N	TE	241		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	241	1	N	Not applicable	Death
			Confusional state	錯乱状態	3	N	TE	241		N	Not applicable	Ongoing at time of death
240006	USA	75/M/C	Constipation	便秘	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	Pre	-7	100	N	None	Recovered
			Cardiac murmur	心雑音	1	N	Pre	-2	35	N	None	Recovered
			Bone pain	骨痛	1	N	TE	31	63	N	None	Recovered
			Contusion	挫傷	1	N	TE	33		N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	3	N	TE	47	11	Y	None	Recovered
			Abdominal pain upper	上腹部痛	1	N	TE	64	25	N	None	Recovered
			Fatigue	疲労	1	N	TE	64		Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	64	60	N	None	Recovered
			Weight increased	体重増加	1	N	TE	64		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	64	25	N	Drug administration postponed	Recovered
			Muscular weakness	筋力低下	1	N	TE	64		N	None	Ongoing at time of death
			Bone pain	骨痛	4	Y	TE	88	6	N	Drug administration postponed	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Spinal cord compression	脊髄圧迫	3	Y	TE	88	115	N	Drug permanently withdrawn	Recovered
			Anaemia	貧血	2	N	TE	109	33	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	110	87	Y	Not applicable	Recovered
			Asthenia	無力症	2	N	TE	110		N	Not applicable	Ongoing at time of death
			Depression	うつ病	2	N	TE	110		N	Not applicable	Ongoing at time of death
			Fluid intake reduced	水分摂取量減少	2	N	TE	116	8	N	Not applicable	Recovered
			Cough	咳嗽	1	N	TE	118	17	N	None	Recovered
			Hypotension	低血圧	2	N	TE	120	55	N	Not applicable	Recovered
			Anorexia	食欲不振	2	N	TE	124		Y	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	145	203	N	Drug permanently withdrawn	Death
			Spinal cord compression	脊髄圧迫	3	N		202		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	347	1	N	Drug permanently withdrawn	Death
242001	USA	80/M/C	Vomiting	嘔吐	1	N	TE	83	1	N	None	Recovered
			Fatigue	疲労	2	N	TE	83	5	N	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	83	31	N	Drug administration postponed	Recovered
			Muscular weakness	筋力低下	2	N	TE	83	5	N	Drug administration postponed	Recovered
			Pyrexia	発熱	1	N	TE	85	3	N	Drug administration postponed	Recovered
			Viral infection	ウイルス感染	2	N	TE	85	3	N	Drug administration postponed	Recovered
			Confusional state	錯乱状態	1	N	TE	85	15	N	Drug administration postponed	Recovered
			Fatigue	疲労	1	N	TE	87	13	N	None	Not recovered, but no changes expected
			Pyrexia	発熱	1	N	TE	88	6	N	None	Recovered
			Dyspepsia	消化不良	1	N	TE	89	116	N	None	Recovered
			Eructation	おくび	1	N	TE	89	116	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	99	40	N	Not applicable	Recovered
			Fatigue	疲労	2	N	TE	99		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	109	31	N	None	Not recovered, but no changes expected
			Diarrhoea	下痢	1	N	TE	135	7	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	135	4	N	Not applicable	Recovered
			Asthenia	無力症	2	N	TE	137	16	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Chills	悪寒	1	N	TE	137	2	N	Not applicable	Recovered
			Dehydration	脱水	3	Y	TE	137	5	N	Not applicable	Recovered
			Dizziness	浮動性めまい	1	N	TE	137	2	N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	139	14	N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	147	4	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	150	5	N	Not applicable	Recovered
			Vomiting	嘔吐	2	N	TE	150	5	N	Not applicable	Recovered
			Angina pectoris	狭心症	1	N	TE	152	4	N	Not applicable	Recovered
			Abdominal pain upper	上腹部痛	1	N	TE	152	2	N	Not applicable	Recovered
			Dysphagia	嚥下障害	2	N	TE	152	4	N	Not applicable	Recovered
			Asthenia	無力症	3	N	TE	152	4	N	Not applicable	Recovered
			Skin laceration	皮膚裂傷	1	N	TE	152	11	N	Not applicable	Recovered
			Dehydration	脱水	3	Y	TE	152	4	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	152		N	None	Not recovered, but no changes expected
			Cough	咳嗽	1	N	TE	152		N	Not applicable	Not recovered, but no changes expected
			Hypoxia	低酸素症	3	N	TE	152	11	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hypophosphataemia	低リン酸血症	3	N	TE	154		N	Not applicable	Not recovered, but no changes expected
			Pleural effusion	胸水	2	N	TE	154		N	Not applicable	Not recovered, but no changes expected
			Hypokalaemia	低カリウム血症	1	N	TE	155	50	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	155		N	Not applicable	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	162		N	Not applicable	Not recovered, but no changes expected
253001	USA	72/M/C	Constipation	便秘	1	N	Pre	1	29	N	None	Recovered
			Asthenia	無力症	1	N	Pre	1	13	N	None	Ongoing at time of death
			Micturition frequency decreased	排尿回数減少	1	N	Pre	1	13	N	None	Recovered
			Bone pain	骨痛	2	N	TE	3	11	N	None	Recovered
			Nausea	悪心	1	N	TE	13	29	N	None	Recovered
			Asthenia	無力症	2	N	TE	13	157	N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	13	17	Y	-	
			Anorexia	食欲不振	2	N	TE	13	218	N	None	Recovered
			Hypocalcaemia	低カルシウム血症	1	N	TE	13	31	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	29	141	Y	-	
			Dehydration	脱水	2	N	TE	29	1	N	None	Recovered
			Neck pain	頚部痛	2	N	TE	29	13	N	None	Recovered
			Dizziness	浮動性めまい	2	N	TE	34		Y	None	Ongoing at time of death
			Ventricular extrasystoles	心室性期外収縮	2	N	TE	41	3	N	None	Recovered
			Skin laceration	皮膚裂傷	2	N	TE	41	17	N	None	Recovered
			Bone pain	骨痛	1	N	TE	41	3	N	None	Recovered
			Memory impairment	記憶障害	1	N	TE	41	3	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Syncope	失神	3	Y	TE	41	3	N	None	Recovered
			Hypertension	高血圧	3	N	TE	41		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	42	44	Y	None	Recovered
			Hypocalcaemia	低カルシウム血症	2	N	TE	43	15	N	None	Recovered
			Constipation	便秘	1	N	TE	57	56	N	None	Recovered
			Hypocalcaemia	低カルシウム血症	1	N	TE	57	13	N	None	Recovered
			Ocular hyperaemia	眼充血	1	N	TE	140	7	N	None	Recovered
			Micturition frequency decreased	排尿回数減少	1	N	TE	140	30	N	None	Recovered
			Asthenia	無力症	3	N	TE	169		N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	169	61	Y	-	
			Depression	うつ病	2	N	TE	169		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
001014	Norway	67/M/C	Bone pain	骨痛	3	N	TE			N	None	Recovered
			Insomnia	不眠症	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	2	N	TE	39	4	Y	None	Recovered
			Nausea	悪心	2	N	TE	48	2	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	48	2	Y	None	Recovered
			Somnolence	傾眠	3	Y	TE	49	5	N	None	Recovered
			Depression	うつ病	2	N	TE	52		N	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	57	85	Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	85	29	Y	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	136		Y	None	Ongoing at study termination / withdrawal
			Confusional state	錯乱状態	1	N	TE	136		Y	None	Ongoing at study termination / withdrawal
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	2	N	TE	141	36	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	141	36	Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	141	6	Y	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	Y	TE	146	6	Y	Not applicable	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	1	N	TE	176		Y	None	Ongoing at study termination / withdrawal
001015	Norway	65/M/C	Anaemia	貧血	2	N	Pre	1	85	Y	None	Not recovered, but no changes expected
			Bronchitis	気管支炎	2	Y	TE	38	9	N	None	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1	N	TE	57	46	Y	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	57	36	Y	None	Not recovered, but no changes expected
			Hyperhidrosis	多汗症	2	N	TE	57		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	3	N	TE	85	8	Y	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	92		Y	None	Not recovered, but no changes expected
			Weight decreased	体重減少	2	N	TE	92		Y	None	Not recovered, but no changes expected
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	2	N	TE	102		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	102	18	N	Drug permanently withdrawn	Recovered with sequelae
			Nausea	悪心	2	N	TE	113	7	N	None	Recovered
			Anxiety	不安	1	N	TE	113		N	None	Not recovered, but no changes expected
			Depression	うつ病	1	N	TE	113		N	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
001020	Norway	69/M/C	Atrial flutter	心房粗動	2	Y	TE	2	6	Y	Drug permanently withdrawn	Recovered
			Anxiety	不安	1	N	TE	2		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	Y	TE	54	16	N	Drug permanently withdrawn	Recovered with sequelae
001022	Norway	72/M/C	Paresis anal sphincter	肛門括約筋不全麻痺	1	N	TE	43	12	N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Paresis anal sphincter	肛門括約筋不全麻痺	2	N	TE	54	8	N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Paresis anal sphincter	肛門括約筋不全麻痺	3	N	TE	61		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Gait disturbance	歩行障害	3	Y	TE	61		N	Not applicable	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	Y	TE	61	3	N	Drug permanently withdrawn	Recovered with sequelae
			Urinary incontinence	尿失禁	4	N	TE	61		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	N	TE	63		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
001027	Norway	83/M/C	Paresis anal sphincter	肛門括約筋不全麻痺	1	N	TE	52		Y	None	Ongoing at study termination / withdrawal
			Polyneuropathy	多発ニューロパチー	4	Y	TE	52	2	Y	None	Recovered with sequelae
			Urinary incontinence	尿失禁	2	N	TE	52		Y	None	Ongoing at study termination / withdrawal
			Polyneuropathy	多発ニューロパチー	4	N	TE	53		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	63		N	None	Ongoing at study termination / withdrawal
001028	Norway	85/M/C	Fatigue	疲労	2	N	TE	62	29	Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	90		Y	Not applicable	Ongoing at study termination / withdrawal
			Fatigue	疲労	3	N	TE	90		Y	None	Ongoing at study termination / withdrawal
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	90		Y	None	Ongoing at study termination / withdrawal
			Dehydration	脱水	2	Y	TE	90		Y	Not applicable	Ongoing at study termination / withdrawal
001030	Norway	66/M/C	Nausea	悪心	1	N	TE	5	2	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	1	N	TE	6	1	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	28	20	Y	None	Recovered
			Nausea	悪心	2	N	TE	33	2	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	34	1	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	53		N	None	Ongoing at study termination / withdrawal
			Metastases to bone	骨転移	2	N	TE	85		N	Drug administration postponed	Ongoing at study termination / withdrawal
			Confusional state	錯乱状態	4	Y	TE	90	17	N	Drug permanently withdrawn	Recovered with sequelae
			Peroneal nerve palsy	腓骨神経麻痺	1	N	TE	99		N	None	Ongoing at study termination / withdrawal
001038	Norway	61/M/C	Diarrhoea	下痢	1	N	TE	4	4	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	4		Y	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	29		Y	Drug administration postponed	Ongoing at study termination / withdrawal
			Urinary tract infection	尿路感染	2	N	TE	31		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	Y	TE	34		Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	Y	TE	34		Y	Drug permanently withdrawn	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Haematuria	血尿	3	Y	TE	34		Y	Drug permanently withdrawn	Ongoing at time of death
002004	Norway	81/M/C	Anorexia	食欲不振	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	1	54	N	None	Ongoing at time of death
			Dizziness	浮動性めまい	2	N	Pre	1		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	54	9	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	57		Y	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	57		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	62		N	None	Ongoing at time of death
			Left ventricular dysfunction	左室機能不全	5	Y	TE	68	1	N	None	Death
002011	Norway	69/M/C	Oral fungal infection	口腔真菌感染	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Dysuria	排尿困難	2	N	TE	49	10	N	None	Recovered
			Dysuria	排尿困難	2	N	TE	83	10	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	93	16	Y	None	Recovered
			Sepsis	敗血症	3	Y	TE	99	10	N	None	Recovered
			Sepsis	敗血症	2	N	TE	108	8	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
002014	Norway	76/M/C	Abdominal pain	腹痛	1	N	TE	1	4	Y	None	Recovered
			Arthralgia	関節痛	1	N	TE	1	4	Y	None	Recovered
			Abdominal pain	腹痛	1	N	TE	2	4	N	None	Recovered
			Arthralgia	関節痛	1	N	TE	2	4	N	None	Recovered
			Anaemia	貧血	2	N	TE	29	3	Y	None	Recovered
			Arthralgia	関節痛	1	N	TE	57	3	Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	1	N	TE	57	3	Y	None	Recovered
			Arthralgia	関節痛	1	N	TE	58	3	N	None	Recovered
			Musculoskeletal pain	筋骨格痛	1	N	TE	58	3	N	None	Recovered
			Chills	悪寒	2	N	TE	81	1	N	None	Recovered
			Anaemia	貧血	3	N	TE	85	3	Y	Drug administration postponed	Recovered
			Bone pain	骨痛	3	Y	TE	100	5	N	None	Recovered
			Bone pain	骨痛	2	N	TE	104		N	Drug administration postponed	Not recovered, but no changes expected
			Spinal cord compression	脊髄圧迫	3	Y	TE	118	12	N	None	Recovered
			Infection	感染	3	Y	TE	133	14	N	Drug administration postponed	Recovered
			Fungal skin infection	皮膚真菌感染	2	N	TE	141	15	N	None	Recovered
002015	Norway	83/M/C	Oral candidiasis	口腔カンジダ症	2	N	TE			N	Not applicable	Ongoing at time of death
			Cough	咳嗽	2	N	TE			N	Not applicable	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	37	14	N	None	Recovered
			Conjunctivitis	結膜炎	2	N	TE	50	7	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	100	30	N	Drug permanently withdrawn	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cerebral haemorrhage	脳出血	2	Y	TE	100		Y	Drug permanently withdrawn	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	100	19	N	Not applicable	Recovered with sequelae
			Confusional state	錯乱状態	2	N	TE	127		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	129	1	N	Drug permanently withdrawn	Death
002018	Norway	70/M/C	Bone pain	骨痛	2	N	TE	2	21	Y	None	Recovered
			Stomatitis	口内炎	2	N	TE	22	9	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	22	14	Y	None	Recovered
			Insomnia	不眠症	1	N	TE	22		N	None	Ongoing at study termination / withdrawal
			Constipation	便秘	2	N	TE	29	5	N	None	Recovered
			Bone pain	骨痛	2	N	TE	35		Y	None	Not recovered, but no changes expected
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	44	63	N	None	Ongoing at time of death
			Pneumonia	肺炎	2	N	TE	75		N	Not applicable	Ongoing at study termination / withdrawal
			Metastases to central nervous system	中枢神経系転移	4	Y	TE	79		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	106	1	N	None	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
003003	Norway	77/M/C	Fatigue	疲労	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	15		Y	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	23	3	N	None	Recovered
			Nausea	悪心	3	Y	TE	25	12	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	25	12	N	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	56	11	Y	None	Recovered
			Spinal cord compression	脊髄圧迫	2	N	TE	56	3	N	None	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	3	Y	TE	58	21	N	None	Recovered with sequelae
			Urinary tract infection	尿路感染	3	N	TE	73		N	Not applicable	Ongoing at study termination / withdrawal
003010	Norway	69/M/C	Nausea	悪心	1	N	TE	1	6	Y	None	Recovered
			Joint range of motion decreased	関節運動範囲減少	2	N	TE	1	6	Y	None	Recovered
			Bone pain	骨痛	3	Y	TE	161	21	N	Not applicable	Recovered
003011	Norway	72/M/C	Insomnia	不眠症	1	N	TE	97		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	107	3	N	None	Recovered
			Vomiting	嘔吐	3	Y	TE	109	12	N	None	Recovered
			Pneumonia	肺炎	2	N	TE	109	16	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	112		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	112	16	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	2	N	TE	120	32	Y	None	Recovered
			Pneumonia	肺炎	2	Y	TE	124	4	N	None	Recovered
			Urticaria	蕁麻疹	1	N	TE	127	57	N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	146		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	151	3	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	173	11	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	3	N	TE	175	9	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	TE	181	29	Y	Not applicable	Not recovered, but no changes expected
			Stomatitis	口内炎	2	N	TE	190	3	N	Not applicable	Recovered
			Stomatitis	口内炎	1	N	TE	192	9	N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	209	7	Y	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	215		Y	Not applicable	Not recovered, but no changes expected
003013	Norway	59/M/C	Depression	うつ病	3	N	Pre	-340		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	Pre	-2	11	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	9		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	9	9	N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	17		N	None	Ongoing at study termination / withdrawal
			Urinary retention	尿閉	2	N	TE	17		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	21	1	N	Not applicable	Recovered
			Urinary tract infection	尿路感染	4	N	TE	24		N	None	Ongoing at study termination / withdrawal
			Pathological fracture	病的骨折	4	Y	TE	24		N	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	1	N	TE	25	3	N	None	Ongoing at time of death
			Nausea	悪心	3	N	TE	25		N	Not applicable	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	2	N	TE	27		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	29		N	Drug permanently withdrawn	Ongoing at time of death
			Anxiety	不安	2	N	TE	31		N	Not applicable	Ongoing at study termination / withdrawal
004002	Norway	60/M/C	Anorexia	食欲不振	2	N	Pre	1		N	None	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	9	3	N	None	Recovered
			Vomiting	嘔吐	3	Y	TE	11	10	N	None	Recovered
			Hallucination	幻覚	2	N	TE	12	8	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	2	N	TE	20		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	33	2	N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	58		N	Drug administration postponed	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	58	6	N	None	Recovered
			Anaemia	貧血	2	N	TE	83	11	Y	None	Recovered
			Bone pain	骨痛	4	Y	TE	104	4	N	Not applicable	Recovered
			Eye infection	眼感染	2	N	TE	107		N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	107		N	Not applicable	Ongoing at time of death
005003	Norway	44/M/C	Bone pain	骨痛	2	N	TE	86	58	N	None	Recovered
			Weight decreased	体重減少	3	N	TE	113		N	None	Not recovered, but no changes expected
			Lymphadenopathy	リンパ節症	1	N	TE	172		N	None	Recovered
			Bone pain	骨痛	2	N	TE	202	4	N	Not applicable	Recovered
			Bone pain	骨痛	2	Y	TE	205	9	N	Not applicable	Recovered
			Oral candidiasis	口腔カンジダ症	1	N	TE	206	15	N	Not applicable	Recovered
			Anaemia	貧血	2	N	Post	352	6	Y	Not applicable	Recovered with sequelae
006002	Norway	73/M/C	Pain	疼痛	1	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE	56	27	N	None	Recovered
			Parosmia	嗅覚錯誤	1	N	TE	56		N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	1	N	TE	82		N	None	Not recovered, but no changes expected
			Food poisoning	食中毒	2	Y	TE	102	5	N	None	Recovered
006003	Norway	73/M/C	Nausea	悪心	1	N	TE	56		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	56	41	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	96	5	N	None	Recovered
006012	Norway	81/M/C	Constipation	便秘	2	N	Pre	-1		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	28	18	N	None	Recovered
			Glaucoma	緑内障	3	Y	TE	41		Y	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	45		Y	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	Y	TE	52		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	57	3	N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	N	TE	59		N	None	Ongoing at study termination / withdrawal
006013	Norway	83/M/C	Dizziness	浮動性めまい	1	N	TE			N	Not applicable	Recovered
			Fatigue	疲労	1	N	TE	18	1	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Back pain	背部痛	1	N	TE	18	1	N	None	Recovered
			Bone pain	骨痛	2	N	TE	28	29	N	None	Recovered
			Fatigue	疲労	2	N	TE	56		N	None	Not recovered, but no changes expected
			Pathological fracture	病的骨折	2	Y	TE	137	19	N	Drug administration postponed	Recovered with sequelae
006014	Norway	81/M/C	Anorexia	食欲不振	2	N	TE	29		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	57	80	N	None	Recovered
			Cystitis	膀胱炎	2	N	TE	101	5	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	101	55	N	Drug administration postponed	Recovered
			Pneumonia	肺炎	3	N	TE	106	10	N	Drug administration postponed	Recovered
			Cystitis	膀胱炎	2	N	TE	159	8	N	None	Recovered
			Dyspnoea	呼吸困難	3	Y	TE	159	6	N	Drug administration postponed	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	175	10	N	Not applicable	Recovered with sequelae
			Cystitis	膀胱炎	2	N	TE	177	9	N	None	Recovered
			Bone pain	骨痛	1	Y	TE	184	2	N	Not applicable	Recovered with sequelae
			Death	死亡	5	Y	TE	205	1	N	Not applicable	Death
006019	Norway	70/M/C	Nausea	悪心	1	N	TE			Y	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Musculoskeletal pain	筋骨格痛	1	N	Pre	-1	10	N	None	Recovered
			Nausea	悪心	1	N	TE	2	26	Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	2	N	TE	9	4	N	None	Recovered
			Bone pain	骨痛	2	N	TE	36	15	N	None	Recovered
			Bone pain	骨痛	2	N	TE	70	8	N	None	Recovered
			Constipation	便秘	2	N	TE	75	95	N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	84	29	Y	Drug administration postponed	Recovered with sequelae
			Weight decreased	体重減少	1	N	TE	84	57	N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	99	8	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	99	8	N	None	Recovered
			Anaemia	貧血	3	Y	TE	112	2	Y	Drug administration postponed	Recovered with sequelae
			Anaemia	貧血	2	N	TE	113	57	Y	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	131	6	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	140		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	140		N	None	Not recovered, but no changes expected
			Anaemia	貧血	3	Y	TE	169	2	Y	Not applicable	Recovered with sequelae
			Constipation	便秘	1	N	TE	169		N	None	Not recovered, but no changes expected
			Fatigue	疲労	2	N	TE	169	3	N	None	Recovered
			Pyrexia	発熱	1	N	TE	169	2	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	N	TE	169	3	Y	None	Recovered
			Anaemia	貧血	2	N	TE	170	2	Y	-	

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	170	56	N	None	Recovered
			Anaemia	貧血	1	N	TE	171	33	Y	-	
			Pyrexia	発熱	2	Y	TE	202	7	Y	Not applicable	Recovered
			Arthralgia	関節痛	2	Y	TE	202	7	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	203	3	Y	-	
			Fatigue	疲労	2	N	TE	203	6	N	None	Recovered
			Anaemia	貧血	1	N	TE	205	36	Y	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	240	8	Y	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	1	N	TE	247		Y	Not applicable	Not recovered, but no changes expected
006029	Norway	77/M/C	Diarrhoea	下痢	1	N	TE	2	5	Y	None	Recovered
			Fatigue	疲労	1	N	TE	2	5	N	None	Recovered
			Anaemia	貧血	2	N	TE	35	39	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	56		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	68	12	N	None	Recovered with sequelae
			Dysphagia	嚥下障害	2	N	TE	69	5	N	None	Recovered
			Pyrexia	発熱	1	N	TE	69	2	Y	None	Recovered
			Infection	感染	3	N	TE	69	10	N	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	3	N	TE	69	9	N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	72	4	N	None	Recovered
			Anaemia	貧血	1	N	TE	73		N	None	Ongoing at time of death
			Psoriasis	乾癬	2	N	TE	75		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary retention	尿閉	2	N	TE	76	1	N	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	1	N	TE	77		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	79		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	4	Y	TE	96	3	N	Not applicable	Death
			Dyspnoea	呼吸困難	5	Y	TE	98	1	N	Not applicable	Death
006043	Norway	68/M/C	Dysgeusia	味覚異常	1	N	TE	4	61	N	None	Recovered
			Bone pain	骨痛	2	N	TE	64	92	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	99		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	99	85	N	None	Recovered
			Constipation	便秘	1	N	TE	127	100	N	None	Recovered
			Anorexia	食欲不振	2	N	TE	127		N	None	Not recovered, but no changes expected
			Urinary retention	尿閉	2	N	TE	127	1	N	None	Recovered
			Haematuria	血尿	2	Y	TE	128	2	N	None	Recovered
			Bone pain	骨痛	1	N	TE	155	29	N	None	Recovered
006045	Norway	63/M/C	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2	N	Pre	-1	63	N	None	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1	N	Pre	-1	91	N	None	Recovered
			Fatigue	疲労	2	N	TE	8	83	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	20	2	N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	21	70	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	TE	28	35	N	None	Recovered
			Fatigue	疲労	1	N	TE	90	156	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	90	114	N	None	Recovered
			Femoral neck fracture	大腿骨頚部骨折	3	Y	TE	121	7	N	Drug administration postponed	Recovered
			Bone pain	骨痛	2	N	TE	203	43	N	Not applicable	Recovered
			Fatigue	疲労	2	N	TE	245		N	None	Not recovered, but no changes expected
006048	Norway	69/M/C	Cough	咳嗽	1	N	TE			N	Not applicable	Recovered
			Dyspnoea	呼吸困難	1	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	Pre	-1	29	N	None	Not recovered, but no changes expected
			Urinary retention	尿閉	2	Y	TE	10	7	N	None	Recovered
			Musculoskeletal pain	筋骨格痛	2	N	TE	17	82	N	None	Recovered with sequelae
			Bone pain	骨痛	3	N	TE	28	29	N	None	Not recovered, but no changes expected
			Localised oedema	限局性浮腫	1	N	TE	56		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	56		N	None	Not recovered, but no changes expected
			Musculoskeletal pain	筋骨格痛	3	Y	TE	98	5	N	None	Recovered with sequelae
			Musculoskeletal pain	筋骨格痛	2	N	TE	102		N	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neoplasm	新生物	2	N	TE	114		N	None	Not recovered, but no changes expected
			Oedema peripheral	末梢性浮腫	2	Y	TE	170	2	N	Not applicable	Recovered
006051	Norway	86/M/C	Nasopharyngitis	鼻咽頭炎	2	N	TE			N	None	Recovered
			Flushing	潮紅	1	N	TE			Y	None	Recovered
			Bone pain	骨痛	1	N	TE	37	3	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	63		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	63		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	93	4	N	None	Recovered
			Bone pain	骨痛	1	N	TE	120	8	N	None	Recovered
			Bone pain	骨痛	1	N	TE	184	3	N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	194	8	N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	201	2	N	Not applicable	Recovered
007003	Norway	65/M/C	Pleural effusion	胸水	2	Y	TE	1	11	N	None	Recovered
			Pneumonia	肺炎	2	N	TE	26	4	N	Drug administration postponed	Recovered
			Pneumonia	肺炎	3	Y	TE	29	9	N	Drug administration postponed	Recovered
			Bone pain	骨痛	3	N	TE	36		N	None	Ongoing at time of death
			Confusional state	錯乱状態	1	N	TE	53	3	Y	None	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	54		N	None	Ongoing at time of death
			Dizziness	浮動性めまい	1	N	TE	54	2	N	None	Recovered
			Pneumonia	肺炎	2	Y	TE	55	19	Y	Drug administration postponed	Recovered
			Confusional state	錯乱状態	2	Y	TE	55	19	Y	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	57	15	N	None	Recovered
			Metastases to meninges	髄膜転移	3	Y	TE	64	30	N	None	Death
			Thrombocytopenia	血小板減少症	4	Y	TE	86		Y	None	Ongoing at time of death
			Metastases to meninges	髄膜転移	5	Y	TE	93	1	N	None	Death
007004	Norway	64/M/C	Bone pain	骨痛	2	N	TE	29	17	N	None	Recovered
			Bone pain	骨痛	1	N	TE	113		N	None	Ongoing at study termination / withdrawal
			Pain in extremity	四肢痛	1	N	TE	113		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	122		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	Y	TE	122	2	N	None	Recovered
			Constipation	便秘	2	Y	TE	126	9	N	None	Recovered
			Nausea	悪心	1	N	TE	126		N	None	Not recovered, but no changes expected
			Hypokalaemia	低カリウム血症	1	N	TE	132	3	N	None	Recovered
007006	Norway	78/M/C	Night sweats	寝汗	2	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	29		N	None	Ongoing at time of death
			Joint stiffness	関節硬直	1	N	TE	57	57	N	None	Recovered
			Influenza	インフルエンザ	1	N	TE	70	4	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	96	60	N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	103		N	None	Ongoing at time of death
			Hyperhidrosis	多汗症	1	N	TE	113	59	N	None	Recovered
			Stomatitis	口内炎	1	N	TE	128	29	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	1	N	TE	155		N	None	Ongoing at time of death
			Fatigue	疲労	3	Y	TE	211	11	N	Not applicable	Recovered with sequelae
007007	Norway	67/M/C	Oedema genital	性器浮腫	2	N	TE			N	None	Not recovered, but no changes expected
			Rash	発疹	1	N	Pre	-7	64	N	None	Not recovered, but no changes expected
			Cardiac murmur	心雑音	1	N	TE	29	29	N	None	Recovered
			Bone pain	骨痛	1	N	TE	39	15	N	None	Recovered
			Rash	発疹	2	N	TE	57		N	None	Not recovered, but no changes expected
			Metastases to skin	皮膚転移	3	N	TE	80		N	None	Not recovered, but no changes expected
			Diarrhoea	下痢	1	N	TE	134	4	N	None	Recovered
			Nausea	悪心	1	N	TE	134	15	N	None	Recovered
			Mucosal inflammation	粘膜の炎症	2	N	TE	141	7	N	None	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	141	18	N	Drug permanently withdrawn	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	145		N	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hydronephrosis	水腎症	3	Y	TE	148	3	N	Drug permanently withdrawn	Recovered with sequelae
			Anaemia	貧血	2	N	TE	151	6	Y	None	Recovered
			Blood urea increased	血中尿素増加	1	N	TE	151		N	Not applicable	Not recovered, but no changes expected
			Hypercreatininaemia	高クレアチニン血症	1	N	TE	151		N	Not applicable	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	157		N	Not applicable	Not recovered, but no changes expected
			Erysipelas	丹毒	1	N	TE	158	9	N	Not applicable	Recovered
			Dyspepsia	消化不良	1	N	TE	187		N	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	187		N	Not applicable	Ongoing at time of death
007008	Norway	64/M/C	Arthralgia	関節痛	1	N	TE	26	32	N	None	Recovered
			Bone pain	骨痛	1	N	TE	26		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	60	26	N	None	Recovered
			Bone pain	骨痛	2	N	TE	85	36	N	None	Recovered
			Pneumonia	肺炎	2	Y	TE	111	10	N	None	Recovered
			Anaemia	貧血	2	N	TE	112	2	Y	None	Recovered
			Nausea	悪心	1	N	TE	127		N	Not applicable	Not recovered, but no changes expected
			Insomnia	不眠症	1	N	TE	127		N	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	2	Y	TE	134	10	N	Not applicable	Recovered
			Suicide attempt	自殺企図	4	Y	TE	152	7	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pneumonia aspiration	嚥下性肺炎	1	N	TE	152		N	Not applicable	Recovered
			Anaemia	貧血	3	Y	TE	162	5	N	Not applicable	Recovered
			Tooth infection	歯感染	3	N	TE	162	5	N	Not applicable	Recovered
007009	Norway	67/M/C	Thrombocytopenia	血小板減少症	1	N	Pre	1	2	N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	4	Y	Pre	1		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	2	4	N	None	Ongoing at time of death
			Myocardial infarction	心筋梗塞	2	Y	TE	3	14	N	None	Death
			Hyperglycaemia	高血糖	4	Y	TE	4		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	5	8	N	None	Ongoing at time of death
			Localised oedema	限局性浮腫	1	N	TE	11		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	12		N	None	Ongoing at time of death
			Myocardial infarction	心筋梗塞	5	Y	TE	16	1	N	None	Death
008014	Norway	77/M/C	Oedema peripheral	末梢性浮腫	1	N	TE			N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE			N	None	Ongoing at time of death
			Anaemia	貧血	1	N	Pre	1	3	N	-	
			Anaemia	貧血	2	N	TE	3	27	N	-	
			Cystitis	膀胱炎	2	N	TE	3	11	N	None	Recovered
			Myalgia	筋痛	2	Y	TE	3	4	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	29	42	N	-	
			Respiratory tract infection	気道感染	2	N	TE	48		N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	69	12	N	None	Recovered
			Anaemia	貧血	2	N	TE	70	4	N	None	Ongoing at time of death
			Atrial fibrillation	心房細動	2	N	TE	70	2	N	None	Recovered
			Anaemia	貧血	1	N	TE	73	37	N	None	Ongoing at time of death
			Weight decreased	体重減少	2	N	TE	85		N	None	Ongoing at time of death
			Gastroenteritis norovirus	ノロウイルス性胃腸炎	2	Y	TE	93	5	N	None	Recovered
			Post procedural infection	処置後感染	2	N	TE	93	17	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	109		N	None	Ongoing at time of death
			Post procedural infection	処置後感染	2	Y	TE	109	8	N	Drug administration postponed	Recovered
			Syncope	失神	2	N	TE	110	1	N	None	Recovered
			Syncope	失神	2	N	TE	111	1	N	None	Recovered
			Syncope	失神	2	N	TE	112	1	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	113	3	N	None	Recovered
			Pneumonia	肺炎	2	N	TE	114		N	Drug administration postponed	Recovered
			Dyspnoea	呼吸困難	3	Y	TE	152		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	155	16	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	170	1	N	Not applicable	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
009001	Czech Republic	66/M/C	Oedema peripheral	末梢性浮腫	2	N	TE	30		N	None	Not recovered, but no changes expected
			Micturition urgency	尿意切迫	2	N	TE	62	135	N	None	Recovered
			Anaemia	貧血	2	N	TE	183	44	Y	None	Recovered
			Generalised oedema	全身性浮腫	3	N	TE	183	36	Y	Not applicable	Ongoing at time of death
			Cardiac failure	心不全	3	Y	TE	196	23	Y	Not applicable	Recovered with sequelae
010001	Czech Republic	60/M/C	Anaemia	貧血	2	Y	TE	165	5	Y	Not applicable	Recovered
			Bone pain	骨痛	2	Y	TE	165	5	Y	Not applicable	Recovered
			Anaemia	貧血	3	Y	TE	213	4	Y	Not applicable	Recovered
			Anaemia	貧血	3	Y	Post	231	4	Y	Not applicable	Recovered
010003	Czech Republic	70/M/C	Bronchitis	気管支炎	1	N	TE	68	7	N	None	Recovered
			Dermatitis	皮膚炎	1	N	TE	70	27	N	None	Recovered
			Thrombosis	血栓症	2	N	TE	118	52	Y	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	170	9	N	Not applicable	Recovered
010005	Czech Republic	83/M/C	Cachexia	悪液質	5	Y	TE	147	1	N	Not applicable	Death
011003	Czech Republic	63/M/C	Bone pain	骨痛	1	N	TE	2	5	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	37	4	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	78	2	N	None	Recovered
011007	Czech Republic	60/M/C	Anaemia	貧血	1	N	TE	29	29	N	None	Recovered
			Anaemia	貧血	3	Y	TE	57	8	N	None	Recovered
			Anaemia	貧血	1	N	TE	64		N	None	Ongoing at time of death
016001	Czech Republic	72/M/C	Malignant neoplasm progression	悪性新生物進行	3	Y	TE	78	10	N	None	Not recovered, but no changes expected
			Thrombocytopenia	血小板減少症	3	N	TE	84		Y	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	98	3	N	None	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	100	1	N	None	Death
017009	Czech Republic	64/M/C	Spinal cord compression	脊髄圧迫	3	Y	TE	72	21	N	Drug administration postponed	Recovered with sequelae
			Urinary tract infection	尿路感染	2	N	TE	133	7	N	None	Recovered
017010	Czech Republic	69/M/C	Bursitis	滑液包炎	2	Y	TE	37	13	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	52	32	N	None	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	83	1	N	None	Death
017013	Czech Republic	78/M/C	Dyspepsia	消化不良	1	Y	Pre	-17	5	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	1	N	Pre	-1		N	None	Ongoing at time of death
			Cerebral ischaemia	脳虚血	4	Y	TE	85	7	N	None	Death
			Cerebral ischaemia	脳虚血	5	Y	TE	91	1	N	None	Death
017014	Czech Republic	63/M/C	Bone pain	骨痛	2	N	TE	15		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	98	1	N	None	Death
017016	Czech Republic	79/M/C	Urinary tract infection	尿路感染	3	Y	TE	80	6	N	None	Death
			Urinary tract infection	尿路感染	5	Y	TE	85	1	N	None	Death
017028	Czech Republic	63/M/C	Insomnia	不眠症	1	N	TE	113	29	N	None	Recovered
			Bone pain	骨痛	2	N	TE	141	29	N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	169	64	N	Not applicable	Ongoing at time of death
			Venous thrombosis	静脈血栓症	3	Y	TE	184	8	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	191	42	N	Not applicable	Ongoing at time of death
			Renal failure	腎不全	3	Y	TE	191	42	N	Not applicable	Death
			Staphylococcal infection	ブドウ球菌感染	3	Y	TE	200		N	Not applicable	Ongoing at time of death
			Renal failure	腎不全	5	Y	TE	232	1	N	Not applicable	Death
020001	Sweden	67/M/C	Food poisoning	食中毒	1	N	TE			N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	46	26	N	Drug administration postponed	Recovered with sequelae
			Bone pain	骨痛	1	N	TE	56	157	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	71	16	N	Drug administration postponed	Recovered with sequelae
			Gastritis	胃炎	1	N	TE	72		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	72		Y	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	1	N	TE	72	106	N	Drug administration postponed	Not recovered, but no changes expected
			Thrombophlebitis	血栓性静脈炎	2	N	TE	77	10	N	None	Recovered
			Dry mouth	口内乾燥	1	N	TE	84		N	None	Not recovered, but no changes expected
			Urinary tract infection	尿路感染	1	N	TE	88	16	N	None	Recovered
			Increased upper airway secretion	上気道分泌増加	2	N	TE	122		N	None	Not recovered, but no changes expected
			Spinal cord compression	脊髄圧迫	2	N	TE	177		N	Drug administration postponed	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	212	49	N	None	Recovered
			Dysphagia	嚥下障害	2	N	TE	239	22	N	None	Recovered
020003	Sweden	71/M/C	Hypoaesthesia	感覚鈍麻	1	N	Pre	-1	1	N	None	Recovered
			Sinus tachycardia	洞性頻脈	1	N	TE	2	4	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	2	4	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	2	78	Y	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	26	9	N	None	Recovered
			Fatigue	疲労	2	N	TE	61		N	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE	64	47	N	None	Recovered
			Headache	頭痛	1	N	TE	64	47	N	None	Recovered
			Anaemia	貧血	2	Y	TE	77	12	Y	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	3	Y	TE	77	12	Y	Drug permanently withdrawn	Recovered with sequelae
			Nausea	悪心	2	N	TE	77		N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	80		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	88		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	88		Y	Drug permanently withdrawn	Not recovered, but no changes expected
020010	Sweden	63/M/C	Constipation	便秘	1	N	TE			N	None	Ongoing at time of death
			Pathological fracture	病的骨折	2	N	TE			N	Drug permanently withdrawn	Ongoing at time of death
			Hypotension	低血圧	1	N	Pre	1		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	29		Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	29		Y	Drug permanently withdrawn	Ongoing at time of death
			Pathological fracture	病的骨折	3	N	TE	29		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

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			Bone pain	骨痛	3	Y	TE	30	7	N	Drug permanently withdrawn	Recovered
			Bone pain	骨痛	2	N	TE	36		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
021001	Sweden	65/M/C	Anorexia	食欲不振	1	N	TE			N	None	Ongoing at time of death
			Gastritis	胃炎	2	N	Pre	-1	65	N	None	Recovered
			Pain	疼痛	1	N	TE	2	2	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	17	28	N	None	Recovered
			Pyrexia	発熱	1	N	TE	33	2	Y	None	Recovered
			Infection	感染	3	Y	TE	52	4	N	Drug administration postponed	Recovered
			Infection	感染	1	N	TE	55	11	N	Drug administration postponed	Recovered
			Pyrexia	発熱	1	N	TE	101	7	Y	None	Recovered
			Procedural pain	処置による疼痛	2	Y	TE	103	2	N	None	Recovered
			Abdominal pain	腹痛	1	N	TE	108	1	N	None	Recovered
			Pyrexia	発熱	1	N	TE	108	1	N	None	Recovered
			Bone pain	骨痛	2	N	TE	110	9	N	None	Recovered
			Bone pain	骨痛	2	N	TE	126		N	None	Ongoing at time of death
			Abdominal pain	腹痛	1	N	TE	130	26	N	None	Recovered
			Hypercreatininaemia	高クレアチニン血症	2	N	TE	148	44	N	None	Recovered
			Bone pain	骨痛	2	N	TE	157	5	N	None	Recovered
			Pyrexia	発熱	2	N	TE	165	2	N	None	Recovered
			Bone pain	骨痛	1	N	TE	165	2	N	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	171	3	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pain	疼痛	2	N	TE	174	2	N	None	Recovered
			Pyrexia	発熱	1	N	TE	174	2	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	179	6	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	3	N	TE	179	19	N	Not applicable	Recovered
			Bone pain	骨痛	4	N	TE	194	46	N	Not applicable	Recovered
			Pyrexia	発熱	1	N	TE	196	2	N	Not applicable	Recovered
			Bone pain	骨痛	3	N	TE	201		N	Not applicable	Not recovered, but no changes expected
			Muscle spasms	筋痙縮	1	N	TE	205		N	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	209	5	N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	224		N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	224		N	None	Ongoing at time of death
022002	Sweden	64/M/C	Fatigue	疲労	1	N	TE	29	66	N	None	Recovered
			Bone pain	骨痛	2	N	TE	57	32	N	None	Recovered
			Bone pain	骨痛	2	N	TE	81	32	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	117	5	N	None	Recovered
			Diarrhoea	下痢	3	Y	TE	121	2	N	None	Recovered
			Nephrolithiasis	腎結石症	1	N	TE	168	8	N	Not applicable	Recovered
			Dizziness	浮動性めまい	1	N	TE	200		N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
022003	Sweden	78/M/C	Anaemia	貧血	1	N	TE	22	92	N	None	Recovered
			Bone pain	骨痛	2	N	TE	27	146	N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	33	1	N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	51	1	N	None	Recovered
			Cognitive disorder	認知障害	1	N	TE	140		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	175	1	N	None	Recovered
			Infection	感染	2	Y	TE	203	6	N	Not applicable	Recovered
022005	Sweden	62/M/C	Dizziness	浮動性めまい	1	N	TE			N	None	Recovered
			Nausea	悪心	2	Y	TE	17	7	N	None	Recovered
			Vomiting	嘔吐	2	Y	TE	17	7	N	None	Recovered
			Dehydration	脱水	2	Y	TE	17	7	N	None	Recovered
			Bone pain	骨痛	2	N	TE	18	12	N	None	Recovered
			Fatigue	疲労	2	Y	TE	37	2	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	57		Y	None	Ongoing at time of death
			Sepsis	敗血症	4	Y	TE	57	5	N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	84	53	N	Not applicable	Death
			Anaemia	貧血	3	N	TE	85	14	N	None	Recovered with sequelae
			Anaemia	貧血	3	Y	TE	98	14	N	None	Recovered with sequelae
			Constipation	便秘	3	Y	TE	99	13	N	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	99	13	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	113	2	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	136	1	N	Not applicable	Death
022008	Sweden	67/M/C	Fatigue	疲労	1	N	TE	29		N	None	Ongoing at time of death
			Haematuria	血尿	1	Y	TE	60	2	N	None	Recovered
			Haematuria	血尿	2	N	TE	61	49	N	None	Recovered
			Haematuria	血尿	2	N	TE	61	49	N	None	Recovered
			Bone pain	骨痛	3	N	TE	88	9	N	None	Recovered with sequelae
			Anaemia	貧血	1	N	TE	116	1	N	None	Recovered
022010	Sweden	76/M/C	Rash	発疹	1	N	TE			N	Not applicable	Recovered
			Fatigue	疲労	2	N	TE	32	8	Y	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	32	1	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	46	56	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	59	12	N	Drug permanently withdrawn	Recovered
			Bone pain	骨痛	2	N	TE	60		N	Not applicable	Ongoing at time of death
			Erythema	紅斑	1	N	TE	70	74	N	Not applicable	Recovered
			Diarrhoea	下痢	1	N	TE	77	15	N	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	77	38	N	None	Recovered
			Mucosal inflammation	粘膜の炎症	2	Y	TE	91	15	N	Not applicable	Recovered
			Pneumonia	肺炎	2	N	TE	91	24	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dizziness	浮動性めまい	1	N	TE	95	1	N	Not applicable	Recovered
023002	Sweden	79/M/C	Bone pain	骨痛	2	N	TE	2	27	N	None	Recovered
			Fall	転倒・転落	1	N	TE	42	1	N	None	Recovered
			Amnesia	健忘	2	N	TE	42		N	None	Ongoing at time of death
			Balance disorder	平衡障害	3	N	TE	42		N	None	Ongoing at time of death
			Urinary incontinence	尿失禁	1	N	TE	42		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	56	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	85	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	113	2	Y	None	Recovered
			Fatigue	疲労	1	N	TE	131		N	None	Ongoing at time of death
			Post-traumatic pain	外傷後疼痛	2	N	TE	168		N	None	Ongoing at time of death
			Hydrocephalus	水頭症	2	Y	TE	168	62	N	Not applicable	Recovered with sequelae
			Dizziness	浮動性めまい	1	N	TE	169		N	None	Ongoing at time of death
			Urinary retention	尿閉	1	N	TE	169		N	None	Ongoing at time of death
			Insomnia	不眠症	2	N	TE	170		N	None	Ongoing at time of death
			Erythema	紅斑	1	N	TE	171	4	N	None	Recovered
			Constipation	便秘	1	N	TE	172		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	172		N	None	Ongoing at time of death
			Medical device pain	医療機器による疼痛	1	N	TE	173	2	N	None	Recovered
			Cystitis	膀胱炎	2	N	TE	177	4	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Medical device pain	医療機器による疼痛	1	N	TE	187	2	N	None	Recovered
			Haematuria	血尿	1	N	TE	187		N	None	Not recovered, but no changes expected
			Nausea	悪心	2	N	TE	188		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	1	N	TE	188		N	None	Not recovered, but no changes expected
			Apraxia	失行症	1	N	TE	190		N	None	Not recovered, but no changes expected
			Gastritis	胃炎	1	N	TE	202		N	None	Not recovered, but no changes expected
			Anxiety	不安	1	N	TE	202		N	None	Ongoing at time of death
024003	Sweden	71/M/C	Upper respiratory tract infection	上気道感染	2	N	TE	36	8	N	None	Recovered
			Anaemia	貧血	2	N	TE	56	30	N	None	Recovered
			Neutropenia	好中球減少症	2	N	TE	84	8	Y	Drug administration postponed	Recovered
			Neutropenia	好中球減少症	3	Y	TE	112		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	119	1	Y	Not applicable	Recovered
			Dry mouth	口内乾燥	2	N	TE	141	35	N	None	Recovered
			Infection	感染	2	N	TE	141		N	Not applicable	Ongoing at study termination / withdrawal
024005	Sweden	69/M/C	Anaemia	貧血	2	N	TE	57	3	Y	None	Recovered
			Infection	感染	2	N	TE	103	11	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	113	2	Y	None	Recovered
			General physical health deterioration	全身健康状態低下	3	N	TE	113		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	113	23	N	None	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	135	1	N	None	Death
024009	Sweden	73/M/C	Pathological fracture	病的骨折	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	11	50	N	None	Recovered
			Arrhythmia	不整脈	1	N	TE	29		N	None	Not recovered, but no changes expected
			Chills	悪寒	1	N	TE	29		Y	None	Recovered
			Oedema	浮腫	3	N	TE	29		N	Not applicable	Ongoing at time of death
			Magnesium deficiency	マグネシウム欠乏	1	N	TE	29	29	N	None	Recovered
			General physical health deterioration	全身健康状態低下	3	N	TE	57		N	None	Not recovered, but no changes expected
			Pathological fracture	病的骨折	2	N	TE	61		N	None	Not recovered, but no changes expected
			Dyspepsia	消化不良	2	N	TE	65		N	None	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	Y	TE	65	15	N	None	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	3	N	TE	66		N	None	Not recovered, but no changes expected
			Metastases to liver	肝転移	2	N	TE	86		N	None	Not recovered, but no changes expected
			Metastases to liver	肝転移	2	N	TE	86		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	91	5	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary tract infection	尿路感染	2	N	TE	92		N	Not applicable	Ongoing at time of death
			Anxiety	不安	2	N	TE	93		N	Not applicable	Ongoing at time of death
			Myocardial infarction	心筋梗塞	3	Y	TE	95		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	97	1	N	Drug permanently withdrawn	Death
024014	Sweden	74/M/C	Dry eye	眼乾燥	1	N	TE	15		N	None	Ongoing at time of death
			Skin infection	皮膚感染	2	N	TE	53	9	N	None	Recovered
			Metastases to bone	骨転移	1	N	TE	53		N	None	Not recovered, but no changes expected
			Micturition urgency	尿意切迫	1	N	TE	53		N	None	Not recovered, but no changes expected
			Hypoaesthesia	感覚鈍麻	2	N	TE	61		N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	81		N	None	Not recovered, but no changes expected
			Dizziness	浮動性めまい	2	N	TE	81	27	N	None	Recovered
			Viral skin infection	皮膚ウイルス感染	2	N	TE	100		N	None	Ongoing at time of death
			Atrial fibrillation	心房細動	2	Y	TE	101	7	N	None	Recovered
			Oral fungal infection	口腔真菌感染	2	N	TE	103		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	126	1	N	Drug permanently withdrawn	Death

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
024022	Sweden	84/M/C	Constipation	便秘	2	N	TE			N	Not applicable	Recovered
			Pneumonia	肺炎	4	Y	TE			N	Drug permanently withdrawn	Ongoing at time of death
			Hip fracture	股関節部骨折	3	Y	Pre			N	Drug administration postponed	Recovered
			Pulmonary oedema	肺水腫	4	Y	TE			N	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	Y	Pre	-33	14	N	Drug administration postponed	Recovered with sequelae
			Urinary retention	尿閉	2	Y	Pre	-33	14	N	Drug administration postponed	Recovered with sequelae
			Vomiting	嘔吐	3	N	Pre	-18	10	N	Not applicable	Recovered
			Pyrexia	発熱	3	N	Pre	-18	10	N	Not applicable	Recovered
			Dislocation of joint prosthesis	人工骨頭関節脱臼	3	Y	Pre	-18	10	N	Not applicable	Recovered
			Bone pain	骨痛	3	N	Pre	-18	10	N	Not applicable	Recovered
			Pathological fracture	病的骨折	3	Y	TE	6		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	6	43	N	Drug permanently withdrawn	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Sepsis	敗血症	3	Y	TE	15		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	48	1	N	Drug permanently withdrawn	Death
024024	Sweden	82/M/C	Fatigue	疲労	2	N	TE	59	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	112		N	None	Not recovered, but no changes expected
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	132	16	N	Drug permanently withdrawn	Not recovered, but no changes expected
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	148	14	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	161	1	N	Not applicable	Death
024026	Sweden	68/M/C	Nausea	悪心	2	N	TE			Y	None	Recovered
			Infection	感染	3	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE			N	Drug administration postponed	Death
			Restless legs syndrome	下肢静止不能症候群	1	N	TE	31	27	N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	57	30	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	57		N	None	Lost to follow-up
			Restless legs syndrome	下肢静止不能症候群	2	N	TE	57		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	79	8	N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	86		N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	86		N	None	Ongoing at time of death
			Fatigue	疲労	3	Y	TE	102	12	N	Drug administration postponed	Recovered
			Pyrexia	発熱	3	Y	TE	102	12	N	Drug administration postponed	Recovered
			Bone pain	骨痛	3	Y	TE	102	12	N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	126	1	N	Drug administration postponed	Death
025002	Sweden	64/M/C	Nausea	悪心	1	N	TE	60	149	Y	None	Recovered
			Tremor	振戦	1	N	TE	88		N	None	Ongoing at time of death
			Listeriosis	リステリア症	2	Y	TE	92	26	N	Drug administration postponed	Recovered
			Fatigue	疲労	2	N	TE	155		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Haematuria	血尿	1	N	TE	185		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	204	5	N	Not applicable	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	208	1	N	Not applicable	Death
026009	Sweden	71/M/C	Constipation	便秘	2	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE			Y	None	Not recovered, but no changes expected
			Nausea	悪心	2	N	TE			Y	None	Not recovered, but no changes expected
			Pathological fracture	病的骨折	2	N	TE			N	Not applicable	Ongoing at time of death
			Nausea	悪心	1	N	TE	1	1	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	3		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	29	1	Y	None	Recovered
			Fibroma	線維腫	1	N	TE	56		N	Not applicable	Ongoing at time of death
			Pyrexia	発熱	2	Y	TE	65	4	N	None	Recovered
			Myalgia	筋痛	2	Y	TE	65	5	N	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	68		N	Not applicable	Ongoing at time of death
			Pyrexia	発熱	2	Y	TE	85	27	N	Drug permanently withdrawn	Recovered with sequelae
			Anaemia	貧血	2	N	TE	103	1	N	Not applicable	Recovered
			Pyrexia	発熱	1	N	TE	111		N	Drug permanently withdrawn	Not recovered, but no changes expected
026017	Sweden	76/M/C	Fatigue	疲労	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			N	Not applicable	Not recovered, but no changes expected

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Diarrhoea	下痢	1	N	TE	2	2	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	28	2	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	56	2	N	None	Recovered
			Pyrexia	発熱	2	Y	TE	113	8	N	Drug administration postponed	Recovered
			Urinary tract infection	尿路感染	3	N	TE	113	8	N	None	Recovered
			Hypotension	低血圧	2	N	TE	114	7	N	None	Recovered
			Bone pain	骨痛	2	N	TE	132	57	N	None	Recovered
			Hypoaesthesia	感覚鈍麻	1	N	TE	160		N	None	Not recovered, but no changes expected
			Painful defaecation	排便痛	1	N	TE	188	70	N	None	Recovered
			Nausea	悪心	2	N	TE	207	220	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	207	220	N	Not applicable	Recovered
			Anorexia	食欲不振	1	N	TE	207	220	N	Not applicable	Recovered
			Deafness	難聴	3	N	TE	221		N	Not applicable	Not recovered, but no changes expected
028005	Belgium	70/M/C	Radiculitis	神経根炎	2	N	Pre	-8		N	None	Ongoing at time of death
			Pathological fracture	病的骨折	3	Y	TE	21	3	N	None	Recovered
			Anaemia	貧血	3	N	TE	22	1	N	None	Recovered
			General physical health deterioration	全身健康状態低下	3	Y	TE	26	14	Y	None	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	82	12	N	Drug permanently withdrawn	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	93	1	N	Drug permanently withdrawn	Death
029001	Belgium	56/M/C	Sciatica	坐骨神経痛	2	N	TE	4		N	None	Ongoing at study termination / withdrawal
			Constipation	便秘	1	N	TE	41		N	None	Ongoing at study termination / withdrawal
			Dysuria	排尿困難	1	N	TE	41	15	N	Drug administration postponed	Ongoing at study termination / withdrawal
			Dysuria	排尿困難	2	N	TE	55		N	Drug administration postponed	Ongoing at study termination / withdrawal
			Urinary retention	尿閉	2	N	TE	62	22	N	Not applicable	Recovered with sequelae
			Urinary retention	尿閉	3	Y	TE	83	4	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	3	N	TE	110		N	Not applicable	Ongoing at study termination / withdrawal
			General physical health deterioration	全身健康状態低下	3	Y	TE	110	44	N	Not applicable	Recovered
			Campylobacter infection	カンピロバクター感染	3	N	TE	110	44	N	Not applicable	Recovered
029002	Belgium	81/M/C	Fatigue	疲労	1	N	TE	41	32	N	None	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	1	N	TE	41	30	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Depression	うつ病	1	N	TE	59		N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	2	N	TE	72		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	105	2	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	106		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	Y	TE	106	12	N	None	Recovered
			Muscular weakness	筋力低下	1	N	TE	109		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	117		N	Not applicable	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	128	31	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	158	1	N	Not applicable	Death
033001	UK	84/M/C	Oedema peripheral	末梢性浮腫	1	N	Pre	1		N	None	Ongoing at time of death
			Lymphadenopathy	リンパ節症	1	N	TE	25		N	None	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	2	N	TE	25		N	None	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	25	14	N	None	Ongoing at time of death
			Muscular weakness	筋力低下	2	N	TE	29		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	2	N	TE	29		N	None	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	N	TE	38		N	None	Ongoing at time of death
			Pulmonary embolism	肺塞栓症	5	Y	TE	59	1	N	None	Death
033002	UK	72/M/B	Non-cardiac chest pain	非心臓性胸痛	2	N	TE			N	None	Recovered
			Weight decreased	体重減少	1	N	TE			N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE			N	None	Not recovered, but no changes expected
			Muscular weakness	筋力低下	2	N	TE			N	None	Ongoing at time of death
			Lethargy	嗜眠	2	N	TE			N	None	Not recovered, but no changes expected
			Mood altered	気分変化	1	N	TE			N	None	Not recovered, but no changes expected
			Cough	咳嗽	1	N	TE			N	None	Recovered
			Atrial fibrillation	心房細動	3	Y	Pre	-67	4	N	Not applicable	Recovered
			Urinary tract infection	尿路感染	2	Y	Pre	-67	4	N	Not applicable	Recovered
			Eyelid ptosis	眼瞼下垂	1	N	TE	3	7	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	46	8	N	None	Recovered
			Constipation	便秘	1	N	TE	56		Y	Drug administration postponed	Recovered
			Fatigue	疲労	1	N	TE	59		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	93	8	Y	None	Recovered
			Bone pain	骨痛	2	Y	TE	93	2	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	2	N	TE	113		N	None	Ongoing at time of death
033014	UK	73/M/C	Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Pitting oedema	圧痕浮腫	2	N	TE			N	None	Ongoing at time of death
			Weight increased	体重増加	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			Y	None	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	1	N	TE			N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	112		Y	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	112	2	N	None	Recovered
			Nausea	悪心	1	N	TE	177	3	Y	None	Recovered
			Dysphasia	不全失語症	3	N	TE	177	3	N	None	Recovered
			Pleuritic pain	胸膜痛	3	Y	TE	177	3	N	Not applicable	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	184	1	N	Not applicable	Death
033017	UK	80/M/C	Abdominal pain lower	下腹部痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			Y	None	Recovered
			Dysuria	排尿困難	1	N	TE			N	None	Recovered
			Pollakiuria	頻尿	2	N	TE			N	None	Recovered with sequelae
			Pollakiuria	頻尿	2	N	TE			N	None	Recovered
			Urine flow decreased	尿流量減少	2	N	TE			N	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Skin lesion	皮膚病変	1	N	TE			N	None	Not recovered, but no changes expected
			Pulmonary embolism	肺塞栓症	5	Y	TE	124	1	N	None	Death
033025	UK	66/M/C	Fatigue	疲労	2	N	TE			N	None	Not recovered, but no changes expected
			Tooth fracture	歯牙破折	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			Y	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	Pre	-35		Y	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	4	14	Y	None	Recovered
			Anaemia	貧血	2	N	TE	29	64	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	85	2	Y	None	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE	88		N	None	Recovered
			Anaemia	貧血	3	N	TE	116	19	Y	None	Recovered
			Anaemia	貧血	2	N	TE	134	29	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	162	5	Y	None	Recovered
			Disseminated intravascular coagulation	播種性血管内凝固	4	Y	TE	165		N	Not applicable	Ongoing at time of death
			Respiratory failure	呼吸不全	4	Y	TE	168		N	Not applicable	Ongoing at time of death
			Haemorrhage intracranial	頭蓋内出血	5	Y	TE	169	1	N	Not applicable	Death
033026	UK	68/M/C	Constipation	便秘	1	N	TE			Y	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	1	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE			Y	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			Y	None	Recovered
			Bone pain	骨痛	2	N	TE	106		N	None	Recovered
			Constipation	便秘	1	N	TE	128		Y	None	Not recovered, but no changes expected
			Gynaecomastia	女性化乳房	2	N	TE	128		N	None	Not recovered, but no changes expected
			Hot flush	ほてり	1	N	TE	128		N	None	Not recovered, but no changes expected
			Arrhythmia	不整脈	1	N	TE	171		N	None	Not recovered, but no changes expected
			Hypokalaemia	低カリウム血症	1	N	TE	178	15	N	Not applicable	Recovered
			Haemoptysis	喀血	1	N	TE	209	2	N	Not applicable	Recovered
			Lower respiratory tract infection	下気道感染	3	Y	TE	210	4	N	Not applicable	Recovered
			Pneumonia	肺炎	2	N	TE	213	19	N	None	Recovered
			Bone pain	骨痛	2	N	TE	215	3	N	Not applicable	Recovered with sequelae
			Musculoskeletal pain	筋骨格痛	3	Y	TE	217	10	N	Not applicable	Recovered
			Hyponatraemia	低ナトリウム血症	1	N	TE	220	14	N	Not applicable	Recovered
			Pyrexia	発熱	1	N	TE	221	6	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	221	6	N	Not applicable	Recovered
			Lymphopenia	リンパ球減少症	3	N	TE	223	11	Y	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	1	N	TE	223	1	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	223	1	N	Not applicable	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	223	2	N	Not applicable	Recovered
033031	UK	78/M/C	Constipation	便秘	1	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE			Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE			N	None	Not recovered, but no changes expected
			Lethargy	嗜眠	2	N	TE			N	Not applicable	Not recovered, but no changes expected
			Dyspnoea exertional	労作性呼吸困難	1	N	TE			N	None	Not recovered, but no changes expected
			Back pain	背部痛	1	N	Pre	-7	20	N	None	Recovered
			Anaemia	貧血	2	N	Pre	-1	29	N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	Pre	-1		N	None	Not recovered, but no changes expected
			Vomiting	嘔吐	1	N	TE	11	7	Y	None	Recovered
			Back pain	背部痛	3	N	TE	13	8	N	None	Recovered
			Urinary retention	尿閉	2	Y	TE	13	7	N	Drug administration postponed	Recovered
			Urinary retention	尿閉	2	N	TE	19	60	N	None	Recovered
			Anaemia	貧血	1	N	Pre	28	9	N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	Pre	36		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	60	32	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	91	29	Y	None	Recovered
			Dysgeusia	味覚異常	1	N	TE	106		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	147	4	Y	Not applicable	Recovered
			Anaemia	貧血	2	Y	TE	150	2	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	224		Y	Not applicable	Not recovered, but no changes expected
034016	UK	66/M/C	Pain	疼痛	3	N	TE	8	4	N	None	Recovered
			Bone pain	骨痛	2	N	TE	8		N	None	Ongoing at time of death
			Pain	疼痛	2	N	TE	11	4	N	None	Recovered
			Lethargy	嗜眠	3	N	TE	11	4	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	14	2	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	22	10	N	None	Recovered
			Bone pain	骨痛	1	N	TE	22	10	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	33	12	N	None	Recovered
			Bone pain	骨痛	2	N	TE	33	10	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	51	3	N	None	Recovered
			Bone pain	骨痛	3	N	TE	54	17	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	61		N	None	Ongoing at time of death
			Pain	疼痛	3	N	TE	69		N	None	Ongoing at time of death
			Dysgeusia	味覚異常	2	N	TE	69	15	Y	None	Recovered
			Lethargy	嗜眠	2	N	TE	69		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	101		N	None	Ongoing at study termination / withdrawal
			Abdominal pain	腹痛	3	N	TE	140	8	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	2	N	TE	141	6	N	None	Recovered
			Pyonephrosis	膿腎症	3	Y	TE	141	18	N	Drug administration postponed	Recovered with sequelae
			Nausea	悪心	1	N	TE	144	14	N	None	Recovered
			Lobar pneumonia	大葉性肺炎	3	Y	TE	162	3	N	Drug permanently withdrawn	Recovered
			Stent occlusion	ステント閉塞	3	Y	TE	175	5	N	Not applicable	Recovered with sequelae
			Mobility decreased	運動性低下	3	N	TE	193		N	Not applicable	Ongoing at time of death
035011	UK	58/M/C	Bone pain	骨痛	1	N	TE	85	28	N	None	Recovered
			Large intestine perforation	大腸穿孔	3	Y	TE	167		N	Not applicable	Ongoing at study termination / withdrawal
035013	UK	71/M/C	Bone pain	骨痛	3	N	TE	6	24	N	None	Recovered
			Bone pain	骨痛	3	N	TE	28	2	N	None	Recovered
			Nausea	悪心	3	Y	TE	49	8	Y	None	Recovered
			Dehydration	脱水	3	N	TE	49	4	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	49	9	N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	50	1	N	None	Recovered
035015	UK	79/M/C	Vomiting	嘔吐	1	N	TE	58	11	N	None	Recovered
			Pain in extremity	四肢痛	1	N	TE	86	55	Y	None	Recovered
			Confusional state	錯乱状態	1	N	TE	122	4	Y	None	Recovered
			Transient ischaemic attack	一過性脳虚血発作	1	N	TE	160	1	N	None	Recovered
			Bone pain	骨痛	2	N	TE	212	9	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	220	8	N	Not applicable	Recovered
035017	UK	75/M/C	Diarrhoea	下痢	1	N	TE			Y	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE	106	8	N	None	Recovered
			Constipation	便秘	2	N	TE	127	10	N	None	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	135	7	N	None	Recovered
			Faecal incontinence	便失禁	2	N	TE	169	1	Y	Not applicable	Recovered
			Diarrhoea	下痢	2	N	TE	175		Y	None	Recovered
035022	UK	83/M/C	Bone pain	骨痛	2	N	TE	56	29	N	None	Recovered
			Asthenia	無力症	1	N	TE	66		N	None	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	TE	68	7	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	68	40	N	None	Recovered
			Constipation	便秘	2	N	TE	71		N	None	Ongoing at time of death
			Abdominal pain	腹痛	1	N	TE	77	4	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	77	16	N	None	Recovered
			Haemorrhoids	痔核	1	N	TE	77		N	None	Ongoing at time of death
			Hypoaesthesia facial	顔面感覚鈍麻	2	N	TE	86		N	None	Recovered
			Myalgia	筋痛	2	N	TE	97		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	101	4	N	None	Recovered
			Hypotension	低血圧	1	N	TE	107		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	Post	143	4	Y	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
035029	UK	64/M/C	Anaemia	貧血	2	N	TE			N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE			N	None	Not recovered, but no changes expected
			Fatigue	疲労	1	N	TE	1	28	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	1	28	Y	None	Recovered
			Constipation	便秘	1	N	TE	29		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	77	16	Y	None	Recovered
			Asthenia	無力症	1	N	TE	191		N	None	Not recovered, but no changes expected
035030	UK	63/M/C	Lower respiratory tract infection	下気道感染	2	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE			N	None	Not recovered, but no changes expected
			Toothache	歯痛	1	N	TE	23	41	N	None	Recovered
			Toothache	歯痛	2	N	TE	63	21	N	None	Recovered
			Spinal cord compression	脊髄圧迫	2	Y	TE	92	9	N	None	Recovered
			Tooth infection	歯感染	1	N	TE	107		N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	112		N	None	Recovered
035037	UK	70/M/C	Bone pain	骨痛	2	N	Pre			N	None	Recovered
			Anaemia	貧血	3	N	TE	28	43	Y	Drug administration postponed	Ongoing at time of death

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	1	N	TE	39	116	N	None	Not recovered, but no changes expected
			Oedema peripheral	末梢性浮腫	1	N	TE	39		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	154	3	Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	154		N	None	Not recovered, but no changes expected
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	185	9	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	193	1	N	Not applicable	Death
036003	UK	67/M/C	Dysuria	排尿困難	1	N	Pre			N	None	Ongoing at study termination / withdrawal
			Metastases to bone	骨転移	1	N	TE	29		N	None	Not recovered, but no changes expected
			Headache	頭痛	1	N	TE	29	30	N	None	Recovered
			Hypercalcaemia	高カルシウム血症	1	N	TE	58		Y	None	Ongoing at study termination / withdrawal
			Headache	頭痛	2	N	TE	58	123	N	None	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	212	13	N	Not applicable	Recovered
036004	UK	84/M/C	Pulmonary embolism	肺塞栓症	3	Y	TE	32		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
036011	UK	64/M/C	Nausea	悪心	1	N	Pre	-8		N	None	Ongoing at study termination / withdrawal
			Back pain	背部痛	1	N	Pre	-8		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	29		N	None	Ongoing at study termination / withdrawal
			Paraesthesia	錯感覚	1	N	TE	29		N	None	Ongoing at study termination / withdrawal
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	46		N	None	Ongoing at study termination / withdrawal
			Constipation	便秘	3	Y	TE	104	7	N	Not applicable	Recovered
037018	UK	68/M/C	Somnolence	傾眠	1	N	TE			N	None	Recovered
			Tachycardia	頻脈	1	N	Pre	1	29	N	None	Recovered
			Muscle atrophy	筋萎縮	1	N	Pre	1		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	28	49	N	Drug administration postponed	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	63		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	76	4	N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	Y	TE	76		N	Drug administration postponed	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	76	30	N	None	Death
			Herpes zoster	帯状疱疹	2	Y	TE	78	8	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	79		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	79	9	N	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	79		N	None	Ongoing at time of death
			Fall	転倒・転落	1	N	TE	80	1	N	None	Recovered
			Bone pain	骨痛	2	N	TE	81		N	None	Ongoing at time of death
			Hypotension	低血圧	1	N	TE	85	2	N	None	Recovered
			Muscular weakness	筋力低下	1	N	TE	88	2	N	None	Recovered
			Cough	咳嗽	1	N	TE	90	4	N	None	Recovered
			Dyspnoea	呼吸困難	3	N	TE	92		N	None	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	3	Y	TE	93	6	N	None	Recovered
			Somnolence	傾眠	1	N	TE	96		N	None	Ongoing at time of death
			Dry mouth	口内乾燥	1	N	TE	103		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	105	1	N	None	Death
039011	UK	65/M/C	Bone pain	骨痛	3	Y	Pre	-37	3	N	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	1	N	TE	3		N	None	Ongoing at time of death
			Nausea	悪心	3	Y	TE	4	4	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dizziness	浮動性めまい	3	N	TE	5	17	Y	None	Ongoing at time of death
			Vomiting	嘔吐	3	N	TE	8		Y	None	Recovered
			Nausea	悪心	3	Y	TE	10		Y	Drug administration postponed	Ongoing at time of death
			Retching	レッチング	3	N	TE	10	12	Y	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	10	12	Y	None	Ongoing at time of death
			Paraesthesia	錯感覚	3	N	TE	10	12	N	None	Ongoing at time of death
			Somnolence	傾眠	1	N	TE	12		N	None	Ongoing at time of death
			Somnolence	傾眠	1	N	TE	12		N	None	Ongoing at time of death
			Tachycardia	頻脈	2	N	TE	13	9	N	None	Ongoing at time of death
			Abdominal pain	腹痛	2	N	TE	13	9	N	None	Ongoing at time of death
			Pleural effusion	胸水	2	N	TE	13	9	N	None	Ongoing at time of death
			Pleural effusion	胸水	3	N	TE	14	5	N	Drug administration postponed	Death
			Sepsis	敗血症	2	N	TE	15	7	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	15	7	N	None	Ongoing at time of death
			Rash	発疹	2	N	TE	15	7	N	None	Ongoing at time of death
			Chest pain	胸痛	3	N	TE	17	5	N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Depressed mood	抑うつ気分	2	N	TE	17	5	N	None	Ongoing at time of death
			Vomiting	嘔吐	3	N	TE	18		N	None	Ongoing at time of death
			Pleural effusion	胸水	4	Y	TE	18	4	N	Drug administration postponed	Death
			Constipation	便秘	3	N	TE	19	3	N	None	Ongoing at time of death
			Abdominal pain lower	下腹部痛	1	N	TE	20	2	N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	3	N	TE	20	2	N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	20	2	N	None	Ongoing at time of death
			Pleural effusion	胸水	5	Y	TE	21	1	N	Drug administration postponed	Death
039020	UK	80/M/C	Bone pain	骨痛	3	N	Pre			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at time of death
			Sleep disorder	睡眠障害	2	N	Pre			N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	N	TE	18		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	1	N	TE	28		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pleural effusion	胸水	2	Y	TE	51	6	N	Drug permanently withdrawn	Recovered
039028	UK	84/M/C	Vomiting	嘔吐	2	N	Pre	-1	1	N	None	Recovered
			Syncope	失神	3	N	Pre	-1	1	N	None	Recovered
			Syncope	失神	3	Y	TE	27	2	N	Drug permanently withdrawn	Recovered
040006	UK	81/M/C	Bone pain	骨痛	1	N	Pre			N	None	Recovered
			Bone pain	骨痛	1	N	Pre			N	None	Ongoing at study termination / withdrawal
			Atrioventricular block complete	完全房室ブロック	4	Y	TE	39	2	N	None	Recovered
			Bone pain	骨痛	1	N	TE	81		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	95	4	N	None	Recovered
			Atrial fibrillation	心房細動	3	Y	TE	129	18	N	Drug permanently withdrawn	Recovered with sequelae
			Cardiac failure	心不全	3	N	TE	146	21	N	Not applicable	Recovered with sequelae
			Cardiac failure	心不全	3	Y	TE	166	11	N	Not applicable	Recovered with sequelae
			Cardiac failure	心不全	3	N	TE	176	159	N	Not applicable	Ongoing at time of death
041007	UK	62/M/C	Lymphadenopathy	リンパ節症	1	N	Pre	1		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	2	N	TE	7		Y	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	7		N	None	Ongoing at time of death
			Eyelid function disorder	眼瞼機能障害	2	N	TE	12	19	N	None	Recovered
			Vision blurred	霧視	1	N	TE	12		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	29		Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	29		Y	None	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	29		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	60	6	N	None	Death
			Muscular weakness	筋力低下	2	N	TE	61		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	65	1	N	None	Death
042002	UK	64/M/C	Nausea	悪心	1	N	TE			Y	None	Recovered
			Vomiting	嘔吐	1	N	TE			Y	None	Recovered
			Peripheral coldness	末梢冷感	1	N	TE			N	None	Recovered
			Anorexia	食欲不振	1	N	TE			Y	None	Recovered
			Constipation	便秘	1	N	TE	3		Y	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	4	6	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	4	6	N	None	Recovered
			Bone pain	骨痛	2	N	TE	8	22	N	None	Recovered
			Tachycardia	頻脈	1	N	TE	28		N	None	Ongoing at time of death
			Hypotension	低血圧	1	N	TE	55	1	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	57	57	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	57	57	N	None	Recovered
			Spinal cord compression	脊髄圧迫	2	N	TE	58	56	N	None	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	164	12	N	Not applicable	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	192	1	N	Not applicable	Death
042003	UK	66/M/C	Anaemia	貧血	2	Y	TE	17	2	Y	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	17	7	N	None	Recovered
			Anaemia	貧血	3	N	TE	34	3	N	Not applicable	Recovered
			Cardiac failure congestive	うっ血性心不全	3	Y	TE	34	8	N	None	Death
			Constipation	便秘	2	N	TE	34		N	Not applicable	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	34	4	N	Not applicable	Recovered
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	2	N	TE	34		N	Not applicable	Ongoing at time of death
			Hypokalaemia	低カリウム血症	3	N	TE	35	3	N	Not applicable	Recovered
			Rectal haemorrhage	直腸出血	1	N	TE	37	1	N	Not applicable	Recovered
			Neuropathy peripheral	末梢性ニューロパチー	2	N	TE	38		N	Not applicable	Ongoing at time of death
			Urinary tract obstruction	尿路閉塞	3	N	TE	38		N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	39		N	Not applicable	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	2	Y	TE	39		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	1	N	TE	40	2	N	Not applicable	Recovered
			Pneumonia	肺炎	3	N	TE	40		N	Not applicable	Ongoing at time of death
			Confusional state	錯乱状態	1	N	TE	40		N	Not applicable	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	5	Y	TE	41	1	N	None	Death
042004	UK	74/M/C	Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Cough	咳嗽	1	N	TE			N	None	Ongoing at time of death
			Dysphonia	発声障害	1	N	TE			N	None	Ongoing at time of death
			Small intestinal obstruction	小腸閉塞	2	Y	Pre	-35	9	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	3	27	N	None	Recovered
			Epistaxis	鼻出血	1	N	TE	5	1	N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	30	8	N	None	Recovered
			Lethargy	嗜眠	1	N	TE	30	140	Y	None	Ongoing at time of death
			Dysgeusia	味覚異常	2	N	TE	41	3	N	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	45	2	N	None	Recovered
			Pathological fracture	病的骨折	2	Y	TE	55	9	N	None	Recovered
			Nausea	悪心	1	N	TE	56		N	None	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	58	6	Y	None	Recovered
			Eye pain	眼痛	1	N	TE	80	3	N	None	Recovered
			Bone pain	骨痛	1	N	TE	106	1	N	None	Recovered
			Bone pain	骨痛	1	N	TE	112	1	N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	1	N	TE	113		N	None	Ongoing at time of death
			Oral pain	口腔内痛	1	N	TE	119	1	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Palpitations	動悸	1	N	TE	121	1	N	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	141		N	None	Ongoing at time of death
			Contusion	挫傷	1	N	TE	141		N	None	Ongoing at time of death
			Lethargy	嗜眠	2	N	TE	169		Y	None	Ongoing at time of death
			Pleural effusion	胸水	1	N	TE	169		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	198	1	N	Not applicable	Death
042010	UK	61/M/C	Rectal haemorrhage	直腸出血	1	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Malaise	倦怠感	2	Y	Pre	-15	2	N	Not applicable	Recovered
			Venous thrombosis limb	四肢静脈血栓症	2	N	TE	19		N	None	Ongoing at time of death
			Arthritis infective	感染性関節炎	1	N	TE	64		Y	None	Recovered
			Gynaecomastia	女性化乳房	1	N	TE	64		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	152		N	None	Ongoing at time of death
			Neuralgia	神経痛	2	Y	TE	152	10	N	None	Recovered
			Muscle spasms	筋痙縮	1	N	TE	153		N	None	Ongoing at time of death
042024	UK	62/M/C	Fatigue	疲労	1	N	TE			N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Confusional state	錯乱状態	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	1	29	Y	None	Recovered
			Anxiety	不安	1	N	TE	2	28	N	None	Recovered
			Hyperhidrosis	多汗症	2	N	TE	2		N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	8		N	None	Ongoing at time of death
			Pyrexia	発熱	1	N	TE	62	1	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	64		N	None	Ongoing at time of death
			Dysuria	排尿困難	2	N	TE	80	6	N	Not applicable	Recovered
			Vomiting	嘔吐	3	Y	TE	83	6	N	None	Recovered
			Pyrexia	発熱	3	Y	TE	83	6	N	None	Recovered
			Confusional state	錯乱状態	3	Y	TE	83	1	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	99	23	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	121	1	N	Not applicable	Death
042025	UK	57/M/C	Nausea	悪心	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	1	85	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	29	85	N	None	Recovered
			Urinary retention	尿閉	3	Y	TE	51	2	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	52	4	N	None	Recovered
			Bone pain	骨痛	2	N	TE	58	8	Y	None	Recovered
			Fatigue	疲労	1	N	TE	85		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	134	92	N	None	Recovered
			Anaemia	貧血	2	N	TE	141		Y	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	142		N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	169	57	N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	169		N	None	Ongoing at time of death
			Weight decreased	体重減少	2	N	TE	225		N	None	Ongoing at time of death
042028	UK	70/M/C	Bone pain	骨痛	2	N	TE	15	155	Y	None	Recovered
			Nocturia	夜間頻尿	1	N	TE	23		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	35	3	N	None	Recovered
			Bone pain	骨痛	1	N	TE	85	57	N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	88	18	Y	None	Recovered
			Viral infection	ウイルス感染	1	N	TE	88	18	N	None	Recovered
			Lethargy	嗜眠	1	N	TE	113		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	141		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	169	64	Y	None	Recovered
042031	UK	73/M/C	Depression	うつ病	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	-10	115	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	18	40	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	29	85	N	None	Recovered
			Decreased appetite	食欲減退	2	N	TE	29	85	N	None	Recovered
			Constipation	便秘	1	N	TE	53		N	None	Ongoing at time of death
			Cough	咳嗽	2	N	TE	53	8	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	105	22	N	None	Recovered
			Bone pain	骨痛	3	N	TE	126	16	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	142		N	Drug administration postponed	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	142	24	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	165	1	N	Drug permanently withdrawn	Death
042038	UK	74/M/C	Vision blurred	霧視	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	2	N	TE	14	17	N	None	Recovered
			Acute myocardial infarction	急性心筋梗塞	3	Y	TE	31	12	N	None	Recovered
			Angina pectoris	狭心症	2	N	TE	31		N	None	Ongoing at study termination / withdrawal
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	3	Y	TE	46	18	N	Drug administration postponed	Recovered
			Pulmonary embolism	肺塞栓症	3	Y	TE	46	18	N	Drug administration postponed	Recovered
			Bone pain	骨痛	2	N	TE	70	16	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	85	148	N	None	Recovered
042039	UK	67/M/C	Decreased appetite	食欲減退	1	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Pathological fracture	病的骨折	1	N	TE			N	Not applicable	Ongoing at time of death
			Lethargy	嗜眠	1	N	TE			N	None	Ongoing at time of death
			Depressed mood	抑うつ気分	1	N	TE			N	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE			N	None	Ongoing at time of death
			Pallor	蒼白	1	N	TE			N	None	Ongoing at time of death
			Lethargy	嗜眠	1	N	TE	1		Y	None	Recovered
			Gastrointestinal motility disorder	消化管運動障害	1	N	TE	29		Y	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	131		N	None	Ongoing at time of death
			Urinary retention	尿閉	2	N	TE	131		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	141	57	N	None	Ongoing at time of death
			Fall	転倒・転落	1	N	TE	170	1	N	None	Recovered
			Pyelonephritis	腎盂腎炎	1	N	TE	195	40	N	Not applicable	Recovered
			Dehydration	脱水	1	N	TE	195		N	Not applicable	Recovered
			Haematuria	血尿	1	N	TE	195	40	N	Not applicable	Recovered
			Emphysema	肺気腫	3	Y	TE	195	40	N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	197		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
043015	UK	74/M/C	Ligament rupture	靭帯断裂	2	N	Pre			N	None	Recovered
			Arthralgia	関節痛	2	N	Pre	-4	64	N	None	
			Fatigue	疲労	2	N	Pre	1	35	N	None	Recovered
			Bone pain	骨痛	1	N	Pre	1		Y	None	Not recovered, but no changes expected
			Toothache	歯痛	1	N	TE	24	5	N	None	Recovered
			Fatigue	疲労	1	N	TE	29	148	Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	29		Y	None	Not recovered, but no changes expected
			Phlebitis	静脈炎	1	N	TE	41	15	N	None	Recovered
			Dysuria	排尿困難	2	N	TE	85	26	N	None	Recovered
			Haematuria	血尿	1	N	TE	86	90	N	None	Recovered
			Urethral obstruction	尿道閉塞	3	N	TE	86	50	N	Drug administration postponed	Recovered
			Urinary tract infection	尿路感染	2	N	TE	109		N	None	Recovered
			Genital pain	生殖器痛	3	N	TE	113		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	122	1	Y	None	Recovered
			Urinary retention	尿閉	3	Y	TE	122	4	N	None	Recovered
			Pelvic pain	骨盤痛	2	N	TE	126	2	N	None	Recovered
			Fatigue	疲労	1	N	TE	141		Y	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	151		Y	None	Not recovered, but no changes expected
			Myalgia	筋痛	1	N	TE	154		Y	None	Not recovered, but no changes expected
			Myalgia	筋痛	1	N	TE	154		Y	None	Not recovered, but no changes expected
			Dysuria	排尿困難	1	N	TE	155		N	None	Recovered
			Swollen tongue	舌腫脹	1	N	TE	164	1	N	None	Recovered
			Haemorrhoids	痔核	1	N	TE	171	7	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	176		Y	None	Not recovered, but no changes expected
			Oedema peripheral	末梢性浮腫	1	N	TE	196		Y	None	Not recovered, but no changes expected
043016	UK	74/M/A	Fatigue	疲労	1	N	TE	2	8	Y	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	71		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	116	15	N	None	Recovered
			Bone pain	骨痛	2	N	TE	116	4	N	None	Recovered
			Bone pain	骨痛	1	N	TE	134		N	None	Not recovered, but no changes expected
			Paraesthesia	錯感覚	1	N	TE	134	15	N	None	Recovered
			Stress urinary incontinence	腹圧性尿失禁	1	N	TE	148		N	None	Not recovered, but no changes expected
			Abdominal pain upper	上腹部痛	1	N	TE	180	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	180		N	Not applicable	Not recovered, but no changes expected
			Paraplegia	対麻痺	3	Y	TE	190	231	N	Not applicable	Not recovered, but no changes expected
			Spinal cord compression	脊髄圧迫	4	Y	TE	190	36	N	Not applicable	Recovered with sequelae
043017	UK	85/M/C	Deafness unilateral	片耳難聴	3	N	TE			N	None	Not recovered, but no changes expected
			Urinary tract infection	尿路感染	1	N	TE			N	None	Recovered
			Anorexia	食欲不振	2	N	TE			N	None	Recovered
			Urinary retention	尿閉	3	Y	Pre	-13	4	N	None	Recovered
			Bone pain	骨痛	1	N	Pre	1		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	Pre	1		N	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary tract infection	尿路感染	1	N	TE	29		N	None	Recovered
			Joint lock	関節ロック	1	N	TE	42		N	None	Not recovered, but no changes expected
			Post procedural infection	処置後感染	1	N	TE	43	16	N	Drug administration postponed	Recovered
			Nausea	悪心	1	N	TE	71		Y	None	Recovered
			Facial palsy	顔面神経麻痺	3	N	TE	71		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	99		N	None	Not recovered, but no changes expected
043018	UK	63/M/C	Neuropathy peripheral	末梢性ニューロパチー	3	N	Pre	-3		N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	4	4	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	23	9	N	None	Recovered
			Contusion	挫傷	2	N	TE	50		N	None	Ongoing at time of death
			Skin disorder	皮膚障害	2	N	TE	50	8	N	None	Recovered
			Hypoaesthesia	感覚鈍麻	2	N	TE	76		N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	90	25	Y	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	90	25	Y	None	Ongoing at time of death
			Metastases to central nervous system	中枢神経系転移	4	Y	TE	106	9	N	Drug permanently withdrawn	Death
			Metastases to central nervous system	中枢神経系転移	5	Y	TE	114	1	N	Drug permanently withdrawn	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
045001	UK	74/M/C	Haematuria	血尿	3	Y	TE	6	5	N	None	Recovered
			Haematuria	血尿	3	N	TE	10	26	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	21	20	N	None	Recovered
			Haematuria	血尿	3	Y	TE	35	2	N	None	Recovered
			Hypoalbuminaemia	低アルブミン血症	2	N	TE	56		N	Not applicable	Ongoing at study termination / withdrawal
046008	UK	67/M/C	Urinary tract obstruction	尿路閉塞		N	TE			N	None	Ongoing at time of death
			Thrombophlebitis	血栓性静脈炎		N	TE			N	None	Recovered
			Brain oedema	脳浮腫	1	Y	TE	40	5	N	None	Recovered
			Pulmonary embolism	肺塞栓症	4	Y	TE	152		N	Not applicable	Not recovered, but no changes expected
047006	UK	73/M/C	Cardiac arrest	心停止	5	Y	TE	25	1	N	Drug permanently withdrawn	Death
048012	UK	68/M/C	Anorexia	食欲不振	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	8	76	N	None	Ongoing at time of death
			Asthenia	無力症	1	N	TE	41		Y	None	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE	51		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	57	2	N	None	Recovered
			Vision blurred	霧視	1	N	TE	69		N	None	Ongoing at time of death
			Headache	頭痛	2	N	TE	73	10	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE	83		N	None	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	103	5	N	None	Recovered
			Anaemia	貧血	2	N	TE	112	3	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	189	1	N	Not applicable	Death
050001	UK	80/M/C	Anaemia	貧血	3	N	TE			N	Not applicable	Recovered with sequelae
			Fatigue	疲労	2	N	TE			Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Ear infection	耳感染	2	N	TE			N	None	Recovered
			Anorexia	食欲不振	1	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at study termination / withdrawal
			Upper respiratory tract infection	上気道感染	2	N	Pre	-14	8	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	1	29	Y	-	
			Nausea	悪心	2	N	TE	2	2	Y	None	Recovered
			Fatigue	疲労	2	N	TE	8	14	Y	None	Recovered
			Muscular weakness	筋力低下	2	N	TE	8	14	N	None	Recovered
			Myalgia	筋痛	2	N	TE	8	22	N	None	Recovered
			Fatigue	疲労	3	N	TE	21	4	Y	None	Recovered
			Muscular weakness	筋力低下	3	N	TE	21	9	N	None	Recovered
			Fatigue	疲労	1	N	TE	24	37	Y	None	Recovered
			Anaemia	貧血	1	N	TE	29	29	Y	-	

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	2	N	TE	30	1	Y	None	Recovered
			Hot flush	ほてり	2	N	TE	30		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	34	1	Y	None	Recovered
			Anaemia	貧血	3	N	TE	57	5	Y	-	
			Anaemia	貧血	1	N	TE	61	12	Y	-	
			Urinary tract infection	尿路感染	2	N	TE	61	6	N	None	Recovered
			Urinary retention	尿閉	3	Y	TE	61	2	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	72	70	Y	-	
			Haemorrhage urinary tract	尿路出血	2	N	TE	80	2	N	None	Recovered
			Urinary retention	尿閉	1	N	TE	84		N	None	Ongoing at study termination / withdrawal
			Urinary retention	尿閉	1	N	TE	84	3	N	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	85	57	N	None	Ongoing at study termination / withdrawal
			Urinary retention	尿閉	2	N	TE	86		N	None	Ongoing at study termination / withdrawal
			Insomnia	不眠症	2	N	TE	101	5	N	None	Recovered
			Fatigue	疲労	3	N	TE	113		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Muscular weakness	筋力低下	2	N	TE	113		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	N	TE	141	9	Y	-	

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	1	N	TE	141		Y	Not applicable	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	2	N	TE	141		N	None	Ongoing at study termination / withdrawal
			Muscular weakness	筋力低下	3	N	TE	141		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	4	N	TE	149	3	Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	151		Y	None	Ongoing at study termination / withdrawal
			Cranial neuropathy	脳ニューロパチー	2	N	TE	155		N	None	Ongoing at time of death
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	2	N	TE	155		N	None	Ongoing at time of death
			Oral candidiasis	口腔カンジダ症	2	N	TE	190		N	None	Ongoing at time of death
			Anaemia	貧血	4	Y	TE	192	5	N	Not applicable	Recovered with sequelae
			Gastric cancer	胃癌	4	Y	TE	192	28	N	Not applicable	Death
			Gastric cancer	胃癌	5	Y	TE	219	1	N	Not applicable	Death
050003	UK	60/M/C	Nausea	悪心	1	N	TE			N	None	Recovered
			Fatigue	疲労	2	N	TE			N	-	
			Fatigue	疲労	3	N	TE			N	-	
			Weight decreased	体重減少	1	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	2	N	TE			N	None	Ongoing at time of death
			Muscular weakness	筋力低下	3	N	TE			N	None	Ongoing at time of death
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE			N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	N	TE	6	10	N	-	
			Oedema genital	性器浮腫		N	TE	10		N	None	Ongoing at time of death
			Pharyngolaryngeal pain	咽喉頭疼痛	1	N	TE	13		N	None	Recovered
			Contusion	挫傷	1	N	TE	14		Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	15	9	N	-	
			Constipation	便秘	2	N	TE	16		Y	None	Ongoing at time of death
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE	16		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	18		N	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	19	3	N	-	
			Pollakiuria	頻尿	1	N	TE	19	4	N	None	Recovered
			Fatigue	疲労	3	N	TE	21		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	4	N	TE	23	8	N	-	
			Dysphagia	嚥下障害	2	N	TE	26		N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	1	N	TE	26	3	N	None	Recovered
			Oedema peripheral	末梢性浮腫	3	N	TE	29	2	N	Not applicable	Ongoing at time of death
			Abdominal pain	腹痛	3	N	TE	30	1	N	None	Recovered
			Oedema peripheral	末梢性浮腫	4	N	TE	30		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	4	N	TE	30		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	31	1	N	Drug permanently withdrawn	Death
			Agitation	激越	2	N	TE	31	1	N	Not applicable	Recovered
050016	UK	63/M/C	Constipation	便秘	1	N	TE			Y	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE			N	Not applicable	Ongoing at time of death
			Herpes zoster	帯状疱疹	2	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at time of death
			Memory impairment	記憶障害	1	N	TE			N	Not applicable	Ongoing at time of death
			Agitation	激越	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	Pre	-41	3	N	Not applicable	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	3	27	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	43	8	N	None	Recovered with sequelae
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	Y	TE	43	8	N	None	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	3	N	TE	43	16	N	None	Recovered
			Lung infection	肺感染	2	Y	TE	80	11	N	Drug administration postponed	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	99		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	99		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	100		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	134	4	Y	None	Recovered
			Nausea	悪心	2	N	TE	138		Y	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	148		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	165	4	Y	Not applicable	Recovered
			General physical health deterioration	全身健康状態低下	2	Y	TE	168	17	N	Not applicable	Death
			Oral candidiasis	口腔カンジダ症	2	N	TE	171	6	N	Not applicable	Recovered
			Epilepsy	てんかん	3	Y	TE	175	1	N	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	5	Y	TE	184	1	N	Not applicable	Death
050018	UK	70/M/C	Diarrhoea	下痢	3	N	TE			N	None	Recovered
			Diarrhoea	下痢	1	N	TE			N	Not applicable	Recovered
			Hypoaesthesia	感覚鈍麻	1	N	TE			N	Not applicable	Recovered
			Neuralgia	神経痛	2	N	TE			N	None	Recovered
			Lethargy	嗜眠	1	N	TE	2		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	2	N	TE	5	53	N	None	Ongoing at study termination / withdrawal
			Dizziness	浮動性めまい	2	N	TE	5	32	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	5		N	None	Recovered
			Bone pain	骨痛	3	N	TE	10	1	Y	-	
			Bone pain	骨痛	2	N	TE	10	103	Y	-	
			Constipation	便秘	2	N	TE	32		Y	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	46	12	N	None	Recovered
			Nausea	悪心	1	N	TE	57		N	None	Ongoing at study termination / withdrawal
			Nasopharyngitis	鼻咽頭炎	2	N	TE	85	8	N	None	Recovered
			Bone pain	骨痛	3	N	TE	112	2	Y	-	
			Bone pain	骨痛	2	N	TE	113	28	N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	120		N	None	Recovered
			Bone pain	骨痛	3	N	TE	140		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	150		N	Not applicable	Recovered
			Joint swelling	関節腫脹	1	N	TE	206		N	Not applicable	Ongoing at study termination / withdrawal
			Neuralgia	神経痛	2	Y	TE	217	1	N	Not applicable	Recovered
			Neuralgia	神経痛	2	Y	TE	217	1	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neuralgia	神経痛	2	N	TE	217		N	Not applicable	Ongoing at study termination / withdrawal
			Neuralgia	神経痛	2	N	TE	217		N	Not applicable	Ongoing at study termination / withdrawal
			Anxiety	不安	1	N	TE	227		N	Not applicable	Ongoing at study termination / withdrawal
055007	Netherlands	62/M/C	Confusional state	錯乱状態	2	Y	Pre	-13	2	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	8		N	Not applicable	Ongoing at time of death
			Nausea	悪心	2	N	TE	8		N	Not applicable	Ongoing at time of death
			Intertrigo	間擦疹	1	N	TE	8		Y	Not applicable	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	35	2	N	None	Recovered
			Anaemia	貧血	3	N	TE	36		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	85	1	N	Not applicable	Death
060008	Spain	63/M/C	Thrombocytopenia	血小板減少症	1	N	TE	29		Y	None	Ongoing at study termination / withdrawal
			Asthenia	無力症	2	N	TE	29	8	N	None	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	2	N	TE	29	8	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Asthenia	無力症	1	N	TE	36		N	None	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	1	N	TE	36	64	N	None	Recovered
			Anaemia	貧血	2	N	TE	57	43	N	None	Recovered
			Hypocalcaemia	低カルシウム血症	1	N	TE	57	43	N	None	Recovered
			Bone pain	骨痛	2	N	TE	85	39	N	None	Recovered
			Anaemia	貧血	1	N	TE	99	22	N	None	Recovered
			Cushingoid	クッシング様	2	N	TE	99	22	N	None	Recovered
			Pupils unequal	瞳孔不同	1	N	TE	99	25	N	None	Recovered
			Aphasia	失語症	2	N	TE	119	2	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	120	2	N	None	Recovered
			Eyelid ptosis	眼瞼下垂	2	N	TE	120	4	N	None	Recovered
			Pyrexia	発熱	1	N	TE	120	1	N	None	Recovered
			Aphasia	失語症	3	Y	TE	120	10	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	N	TE	121	2	N	None	Recovered
			Anaemia	貧血	1	N	TE	122	6	N	None	Recovered
			Hypertension	高血圧	1	N	TE	123	3	N	None	Ongoing at study termination / withdrawal
			Hypertension	高血圧	2	N	TE	125		N	None	Ongoing at study termination / withdrawal
			Arthralgia	関節痛	3	N	TE	134		N	None	Ongoing at study termination / withdrawal
060009	Spain	66/M/C	Asthenia	無力症	1	N	Pre	1	28	Y	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	2	N	Pre	1	116	N	None	Ongoing at time of death
			Hypophosphataemia	低リン酸血症	3	N	Pre	1	28	N	None	Recovered
			Nausea	悪心	1	N	TE	25	92	Y	None	Recovered
			Anaemia	貧血	2	N	TE	28	76	Y	-	
			Asthenia	無力症	2	N	TE	28	135	Y	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	28	61	N	None	Recovered
			Hypocalcaemia	低カルシウム血症	2	N	TE	28	5	N	-	
			Hypophosphataemia	低リン酸血症	2	N	Pre	28	61	N	None	Recovered
			Hypocalcaemia	低カルシウム血症	1	N	TE	32	120	N	-	
			Constipation	便秘	1	N	TE	57	32	N	None	Recovered
			Gastritis	胃炎	2	N	TE	88	29	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	88	149	N	None	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	101	3	N	None	Recovered
			Anaemia	貧血	3	N	TE	103	2	Y	-	
			Diarrhoea	下痢	1	Y	TE	103	2	N	None	Recovered
			Anaemia	貧血	1	N	TE	104	10	Y	-	
			Anaemia	貧血	2	N	TE	113	23	Y	-	
			Anorexia	食欲不振	1	N	Pre	116	54	N	None	Ongoing at time of death
			Asthenia	無力症	2	N	TE	131	11	N	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	131	11	N	None	Recovered
			Anaemia	貧血	1	N	TE	135	1	Y	-	
			Anaemia	貧血	2	N	TE	135	17	Y	-	
			Diarrhoea	下痢	3	N	TE	140		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	141	22	N	None	Recovered
			Acute myocardial infarction	急性心筋梗塞	4	Y	TE	143	5	N	Not applicable	Recovered
			Dysarthria	構語障害	2	N	TE	150	13	N	None	Recovered
			Facial paresis	顔面不全麻痺	2	N	TE	150	13	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	N	TE	151	11	Y	None	Ongoing at time of death
			Hypocalcaemia	低カルシウム血症	2	N	TE	151	19	N	-	
			Anaemia	貧血	2	N	TE	161		Y	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	162	36	N	None	Recovered
			Asthenia	無力症	3	N	TE	162		Y	None	Ongoing at time of death
			Facial paresis	顔面不全麻痺	1	N	TE	162	61	N	None	Recovered
			Anorexia	食欲不振	2	N	Pre	169		N	None	Ongoing at time of death
			Hypocalcaemia	低カルシウム血症	1	N	TE	169	64	N	None	Ongoing at time of death
			Hypocalcaemia	低カルシウム血症	2	N	TE	232		N	None	Ongoing at time of death
060012	Spain	73/M/C	Nausea	悪心	1	N	TE	29	75	Y	None	Recovered
			Anaemia	貧血	1	N	TE	57	22	Y	Not applicable	Recovered
			Asthenia	無力症	2	N	TE	57	18	N	Not applicable	Recovered
			Anorexia	食欲不振	2	N	TE	57	18	N	Not applicable	Recovered
			Asthenia	無力症	1	N	TE	74	30	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	78	7	Y	Not applicable	Recovered
			Leukopenia	白血球減少症	3	N	TE	83	2	N	Not applicable	Recovered
			Neutropenia	好中球減少症	2	N	TE	83	2	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	83	2	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

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			Pyrexia	発熱	1	N	TE	83	2	N	Not applicable	Recovered
			Cellulitis	蜂巣炎	3	Y	TE	83	10	N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	84	2	Y	Not applicable	Recovered
			Leukopenia	白血球減少症	2	N	TE	84	4	N	Not applicable	Recovered
			Neutropenia	好中球減少症	1	N	TE	84	4	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	84	9	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	86	1	N	Not applicable	Recovered
			Leukopenia	白血球減少症	1	N	TE	87	2	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	92	11	N	Not applicable	Recovered
			Cellulitis	蜂巣炎	2	N	TE	92	12	N	Not applicable	Recovered
062004	Spain	81/M/C	Oedema peripheral	末梢性浮腫	2	N	Pre	1	57	N	None	Recovered
			Bone pain	骨痛	1	N	TE	28	29	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	56		N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	78	2	N	None	Recovered
			Vomiting	嘔吐	1	Y	TE	80	5	N	Not applicable	Recovered
			Fatigue	疲労	1	N	TE	81	84	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	81	84	N	None	Recovered
			Anorexia	食欲不振	3	N	TE	81	32	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hypocalcaemia	低カルシウム血症	2	N	TE	81		N	Not applicable	Ongoing at time of death
063003	Spain	66/M/C	Spinal cord compression	脊髄圧迫	2	Y	TE	30	20	N	Drug permanently withdrawn	Recovered
070002	Spain	55/M/C	Anaemia	貧血	1	N	TE			Y	Not applicable	Recovered
			Bone pain	骨痛	2	N	Pre	1	85	N	Drug permanently withdrawn	Ongoing at time of death
			Nausea	悪心	2	N	TE	8	8	Y	None	Recovered
			Anorexia	食欲不振	2	N	TE	8	8	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	85	29	N	Drug permanently withdrawn	Ongoing at time of death
			Bone pain	骨痛	4	N	TE	113	112	N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	147	7	N	Not applicable	Recovered
071002	Spain	65/M/C	Bone pain	骨痛	3	N	Pre	-9	9	N	None	Recovered
			Bone pain	骨痛	2	N	Pre	-1	58	N	None	Recovered
			Dizziness	浮動性めまい	2	N	TE	28	2	N	None	Recovered
			Anxiety	不安	1	N	TE	28		N	None	Not recovered, but no changes expected
			Depression	うつ病	1	N	TE	28		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	57		N	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Spinal cord compression	脊髄圧迫	3	Y	TE	221	15	N	Not applicable	Recovered
071008	Spain	70/M/C	Rectal tenesmus	直腸しぶり	2	N	TE			N	None	Recovered with sequelae
			Dysuria	排尿困難	2	N	TE			N	None	Recovered with sequelae
			Dysaesthesia	異常感覚	2	N	Pre	-20	21	N	None	Recovered
			Bone pain	骨痛	2	N	Pre	1	93	N	None	Not recovered, but no changes expected
			Urinary retention	尿閉	2	Y	TE	89	14	N	Drug permanently withdrawn	Recovered
			Pyrexia	発熱	2	N	TE	91	8	N	Drug permanently withdrawn	Recovered
			Bone pain	骨痛	3	N	TE	93	46	N	None	Not recovered, but no changes expected
			Spinal cord compression	脊髄圧迫	3	Y	TE	97	6	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	135	9	N	None	Recovered
			Bone pain	骨痛	2	N	TE	138		N	None	Not recovered, but no changes expected
072001	Spain	78/M/C	Fatigue	疲労	1	N	Pre			N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	10		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	21	7	N	None	Recovered
			Cardiac failure	心不全	4	Y	TE	31	5	N	None	Death
			Cardiac failure	心不全	5	Y	TE	35	1	N	None	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
080001	Italy	73/M/C	Nausea	悪心	1	N	TE			Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE			Y	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	130	9	N	None	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	138	1	N	None	Death
084002	Israel	63/M/C	Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	TE	27		N	None	Not recovered, but no changes expected
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	2	N	TE	27		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	57		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	Y	TE	72	2	N	None	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	91		N	Drug permanently withdrawn	Not recovered, but no changes expected
			Nausea	悪心	2	N	TE	102	9	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	102	9	N	None	Recovered
			Anaemia	貧血	3	Y	TE	145	6	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	145	6	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	167	5	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	174	2	N	Not applicable	Recovered with sequelae
085001	Israel	58/M/C	Pyrexia	発熱	1	N	TE	31	1	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary tract infection	尿路感染	3	Y	TE	58	7	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	58	7	N	None	Recovered with sequelae
			Pneumonia	肺炎	1	Y	TE	79		N	None	Ongoing at time of death
			Respiratory failure	呼吸不全	4	Y	TE	83	2	N	None	Death
			Respiratory failure	呼吸不全	5	Y	TE	84	1	N	None	Death
085003	Israel	74/M/C	Deep vein thrombosis	深部静脈血栓症	2	Y	Pre	-16	3	N	Not applicable	Recovered with sequelae
			Dermatitis contact	接触性皮膚炎	1	N	TE	37	8	N	None	Recovered
			Asthenia	無力症	1	N	TE	49	1	N	None	Recovered
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	55		N	None	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	TE	62		N	None	Ongoing at time of death
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	3	N	TE	62		N	None	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	TE	63	11	N	None	Recovered
			Rectal haemorrhage	直腸出血	2	Y	TE	82	4	N	None	Recovered
			Haematuria	血尿	2	Y	TE	82	4	N	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	90		N	None	Ongoing at time of death
			Tremor	振戦	2	N	TE	90		N	None	Ongoing at time of death
			Hypochromic anaemia	低色素性貧血	2	N	TE	96		N	None	Ongoing at time of death
			Localised oedema	限局性浮腫	1	N	TE	104		N	None	Ongoing at time of death
			Lobar pneumonia	大葉性肺炎	3	Y	TE	104	8	N	Drug permanently withdrawn	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			General physical health deterioration	全身健康状態低下	3	Y	TE	107		N	Drug permanently withdrawn	Ongoing at time of death
			Urosepsis	尿路性敗血症	3	Y	TE	107		N	Drug permanently withdrawn	Ongoing at time of death
			Lobar pneumonia	大葉性肺炎	5	Y	TE	111	1	N	Drug permanently withdrawn	Death
085005	Israel	75/M/C	Anaemia	貧血	1	N	Pre	-9	2	N	Not applicable	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	TE	57		N	None	Not recovered, but no changes expected
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	1	N	TE	83		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	83		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	160	20	N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	Y	TE	166	4	N	Not applicable	Recovered
			Fatigue	疲労	2	Y	TE	166	4	N	Not applicable	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	167	1	N	None	Recovered
			Bone pain	骨痛	3	N	TE	179		N	None	Not recovered, but no changes expected
			Urinary tract infection	尿路感染	2	Y	TE	190	5	N	Not applicable	Recovered with sequelae
			Dermatitis	皮膚炎	1	N	TE	190	3	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			General physical health deterioration	全身健康状態低下	2	N	TE	193	26	N	Not applicable	Ongoing at study termination / withdrawal
			Asthenia	無力症	2	Y	TE	196	19	N	Not applicable	Recovered with sequelae
			Haematuria	血尿	2	Y	TE	196	19	N	Not applicable	Recovered
			General physical health deterioration	全身健康状態低下	3	Y	TE	218		N	Not applicable	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	Y	TE	219		N	Not applicable	Ongoing at study termination / withdrawal
086002	Israel	70/M/C	Bone pain	骨痛	2	N	Pre	1	30	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	30		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	58	3	N	Drug administration postponed	Recovered with sequelae
			Dysuria	排尿困難	2	N	TE	58	9	N	Drug administration postponed	Recovered
093001	Slovakia	72/M/C	Anaemia	貧血	2	N	Pre	-13	14	N	None	Recovered
			Constipation	便秘	1	N	Pre	-13	57	N	None	Recovered with sequelae
			Hyperbilirubinaemia	高ビリルビン血症	2	Y	Pre	-13	5	N	Not applicable	Recovered with sequelae
			Weight decreased	体重減少	2	Y	Pre	-13	5	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	Pre	-13	5	N	Not applicable	Recovered with sequelae
			Hyperbilirubinaemia	高ビリルビン血症	2	N	Pre	-9	3	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	1	N	Pre	-9	10	N	None	Recovered with sequelae
			Hyperbilirubinaemia	高ビリルビン血症	2	Y	Pre	-7	7	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	Y	TE	1	40	N	None	Recovered with sequelae
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	TE	35		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	35		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	35		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	44		N	None	Ongoing at time of death
			Constipation	便秘	2	Y	TE	44	11	N	None	Recovered with sequelae
			Bone pain	骨痛	2	Y	TE	44	11	N	None	Recovered with sequelae
			Pneumonia	肺炎	4	Y	TE	75		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	90	1	N	None	Death
095001	Slovakia	75/M/C	Bone pain	骨痛	4	N	TE	3	8	Y	Drug administration postponed	Recovered
			Bone pain	骨痛	2	N	TE	10	26	Y	Drug administration postponed	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	14	61	Y	Drug administration postponed	Recovered
			Nausea	悪心	1	N	TE	20	64	N	None	Recovered
			Fatigue	疲労	2	N	TE	20	118	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	35	40	Y	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	83		Y	Not applicable	Ongoing at time of death
			Cardiopulmonary failure	心肺不全	4	Y	Post	235	13	Y	Not applicable	Death
			Cardiopulmonary failure	心肺不全	5	Y	Post	247	1	Y	Not applicable	Death
097001	Slovakia	70/M/C	Anaemia	貧血	2	N	Pre	1		N	None	Ongoing at time of death
			Sudden death	突然死	5	Y	TE	9	1	N	None	Death
097004	Slovakia	80/M/C	Fatigue	疲労	3	N	TE	3		N	None	Ongoing at time of death
			Cerebral ischaemia	脳虚血	4	Y	TE	3	36	N	Drug administration postponed	Recovered with sequelae
			Micturition disorder	排尿異常	2	N	TE	112		N	None	Ongoing at time of death
			Constipation	便秘	3	N	TE	114		N	None	Ongoing at time of death
			Diarrhoea	下痢	3	Y	TE	143	29	Y	Drug permanently withdrawn	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	3	Y	TE	143	29	Y	Drug permanently withdrawn	Recovered
			Pyrexia	発熱	3	Y	TE	143	29	N	Drug permanently withdrawn	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	143	29	N	Drug permanently withdrawn	Recovered
			Disorientation	失見当識	3	N	TE	143	29	N	Not applicable	Recovered
			Cardiopulmonary failure	心肺不全	5	Y	TE	176	1	N	Not applicable	Death
097007	Slovakia	70/M/C	Bone pain	骨痛	2	N	Pre	-9	38	N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	2	56	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	29	84	N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	29	112	N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	57	56	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	112	9	Y	None	Recovered
			Anorexia	食欲不振	2	N	TE	112		N	None	Ongoing at time of death
			Sleep disorder	睡眠障害	1	N	TE	112	49	N	None	Recovered
			Mixed incontinence	混合性尿失禁	3	N	TE	112		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	120		Y	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	140		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	Pre	140		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	160	1	N	Not applicable	Death
097010	Slovakia	80/M/C	Nausea	悪心	1	N	TE	2	56	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	2		Y	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	29	58	N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	64	6	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	64	6	N	None	Recovered
			Nausea	悪心	1	N	TE	86	91	Y	None	Recovered
			Fatigue	疲労	3	Y	TE	86	5	Y	Drug administration postponed	Recovered with sequelae
			Weight decreased	体重減少	2	N	TE	86		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	90	68	Y	None	Recovered with sequelae
			Vomiting	嘔吐	2	N	TE	152	6	Y	None	Recovered
			Anaemia	貧血	2	N	TE	157	5	Y	None	Recovered
			Fatigue	疲労	3	Y	TE	157	5	Y	None	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	206	1	N	Not applicable	Death
097014	Slovakia	52/M/C	Anaemia	貧血	2	N	TE	28	29	N	None	Recovered with sequelae
			Anaemia	貧血	3	N	TE	56	3	N	None	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	58	25	N	None	Recovered with sequelae
			Haemorrhage urinary tract	尿路出血	3	Y	TE	84	3	N	Not applicable	Recovered
105003	Hong Kong	75/M/A	Cough	咳嗽	1	N	TE	4	5	N	None	Recovered
			Pharyngolaryngeal pain	咽喉頭疼痛	1	N	TE	4	5	N	None	Recovered
			Rhinorrhoea	鼻漏	1	N	TE	4	5	N	None	Recovered
			Pruritus	そう痒症	1	N	TE	8	22	N	None	Recovered
			Chromaturia	着色尿	1	N	TE	22		N	None	Ongoing at time of death
			Cough	咳嗽	1	N	TE	32	9	N	None	Recovered
			Productive cough	湿性咳嗽	1	N	TE	32	15	N	None	Recovered
			Pharyngolaryngeal pain	咽喉頭疼痛	1	N	TE	33	14	N	None	Recovered
			Rhinorrhoea	鼻漏	1	N	TE	33	8	N	None	Recovered
			Oedema	浮腫	1	N	TE	66	8	N	None	Recovered
			Rash pruritic	そう痒性皮疹	1	N	TE	66	7	N	None	Recovered
			Gastrooesophageal reflux disease	胃食道逆流性疾患	1	N	TE	71		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	71	8	N	None	Recovered
			Bone pain	骨痛	1	N	TE	85	47	N	None	Ongoing at time of death
			Chest discomfort	胸部不快感	1	N	TE	98	8	N	None	Recovered
			Pruritus	そう痒症	1	N	TE	98		N	None	Ongoing at time of death
			Pharyngolaryngeal pain	咽喉頭疼痛	1	N	TE	99	13	N	None	Recovered
			Cough	咳嗽	1	N	TE	105	7	N	None	Recovered
			Productive cough	湿性咳嗽	1	N	TE	107	5	N	None	Recovered
			Bone pain	骨痛	2	N	TE	131		N	None	Ongoing at time of death
			Bone pain	骨痛	2	Y	TE	131	50	N	Drug administration postponed	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	131		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	143		N	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	214	2	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	214		N	Not applicable	Ongoing at time of death
106001	Hong Kong	62/M/A	Bone pain	骨痛	2	N	TE	57	57	N	None	Recovered
			Urogenital disorder	尿生殖器障害	2	N	TE	57		N	None	Not recovered, but no changes expected
			Haematuria	血尿	1	N	TE	98	44	N	None	Recovered
			Hypersensitivity	過敏症	2	N	TE	101	5	N	None	Recovered
			Pharyngolaryngeal pain	咽喉頭疼痛	2	N	TE	101	5	N	None	Recovered
			Cough	咳嗽	2	N	TE	105	6	N	None	Recovered
			Nasal discomfort	鼻部不快感	2	N	TE	105	6	N	None	Recovered
			Rhinorrhoea	鼻漏	2	N	TE	105	6	N	None	Recovered
			Hyponatraemia	低ナトリウム血症	3	N	TE	113	9	N	None	Recovered
			Cystitis	膀胱炎	3	Y	TE	115	11	N	None	Recovered
			Urinary bladder haemorrhage	膀胱出血	3	Y	TE	115	11	N	None	Recovered
			Urinary retention	尿閉	3	Y	TE	115	11	N	None	Recovered
			Hyponatraemia	低ナトリウム血症	1	N	TE	121	21	N	None	Recovered
			Constipation	便秘	2	N	TE	141	28	N	None	Recovered
			Nausea	悪心	2	N	TE	141	28	N	None	Recovered
			Hyponatraemia	低ナトリウム血症	3	N	TE	141	28	N	None	Recovered
106012	Hong Kong	75/M/A	Cystitis	膀胱炎	2	N	TE	7	7	N	None	Recovered
			Anaemia	貧血	2	Y	TE	29	2	Y	None	Recovered
			Constipation	便秘	1	N	TE	29	29	Y	None	Recovered
			Faeces discoloured	変色便	1	N	TE	29	29	N	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	29	29	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	57	3	Y	Drug administration postponed	Recovered
			Hyperkalaemia	高カリウム血症	1	N	TE	57	23	N	None	Recovered
			Haematuria	血尿	1	N	TE	57	23	N	None	Recovered
			Gastroduodenal ulcer	胃十二指腸潰瘍	1	N	TE	73		N	None	Ongoing at time of death
			Haemorrhoids	痔核	1	N	TE	73	7	N	None	Recovered
			Muscular weakness	筋力低下	2	N	TE	77		N	None	Ongoing at time of death
			Sepsis	敗血症	2	N	TE	79	20	N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	79		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	79		N	Drug permanently withdrawn	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	2	N	TE	80		N	None	Ongoing at time of death
			Convulsion	痙攣	2	N	TE	85		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	4	Y	TE	90		N	Not applicable	Ongoing at time of death
			Pyrexia	発熱	2	N	TE	91	4	N	Not applicable	Recovered
			Diabetes mellitus	糖尿病	2	N	TE	91	16	N	Not applicable	Recovered
			Anxiety	不安	2	N	TE	94	13	N	Not applicable	Recovered
			Metastases to bone	骨転移	5	Y	TE	106	1	N	Not applicable	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
128005	Canada	86/M/C	Bone pain	骨痛	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Musculoskeletal chest pain	筋骨格系胸痛	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Musculoskeletal pain	筋骨格痛	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Cough	咳嗽	1	N	Pre			N	None	Recovered
			Fatigue	疲労	1	N	TE	2	3	Y	None	Recovered
			Decreased appetite	食欲減退	2	N	TE	92	8	N	None	Recovered
			Atrial fibrillation	心房細動	3	Y	TE	121	3	N	Drug permanently withdrawn	Recovered
			Left ventricular failure	左室不全	3	Y	TE	121	3	N	Drug permanently withdrawn	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	121	11	N	None	Recovered
			Pleural effusion	胸水	2	N	TE	162	8	N	Not applicable	Recovered
129002	Canada	81/M/C	Nausea	悪心	1	N	TE			N	None	Recovered
			Rectal haemorrhage	直腸出血	1	N	Pre			N	None	Recovered
			Fatigue	疲労	2	N	Pre			Y	None	Recovered
			Depression	うつ病	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	Pre	-7	22	N	None	Recovered
			Nausea	悪心	1	N	Pre	-3	7	N	None	Recovered
			Fatigue	疲労	1	N	Pre	14	99	Y	None	Recovered
			Angina pectoris	狭心症	1	N	TE	39	1	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	57	27	N	None	Recovered
			Hand fracture	手骨折	1	N	TE	106	1	N	None	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	112		Y	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	113		N	None	Ongoing at study termination / withdrawal
			Dizziness	浮動性めまい	1	N	TE	113		N	None	Recovered
			Constipation	便秘	2	N	TE	141		N	None	Ongoing at study termination / withdrawal
			Gastroenteritis radiation	放射線胃腸炎	1	N	TE	174		N	None	Ongoing at study termination / withdrawal
			Muscular weakness	筋力低下	3	Y	TE	193	7	N	Not applicable	Recovered
133010	Poland	74/M/C	General physical health deterioration	全身健康状態低下	4	Y	TE			N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	12		N	None	Ongoing at study termination / withdrawal
133013	Poland	69/M/C	Fatigue	疲労	3	Y	TE	29	11	N	Drug permanently withdrawn	Recovered
			Fatigue	疲労	2	N	TE	39	20	N	Not applicable	Recovered
133021	Poland	70/M/C	Bone pain	骨痛	2	N	TE	15	8	Y	None	Recovered
			Device dislocation	医療機器位置異常	1	Y	TE	77	3	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	171	2	N	Drug administration postponed	Recovered
			Fatigue	疲労	4	Y	TE	171		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Haematuria	血尿	2	N	TE	179		N	Not applicable	Not recovered, but no changes expected
133022	Poland	84/M/C	General physical health deterioration	全身健康状態低下	4	N	TE	77		N	None	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	3	Y	TE	77	8	N	Drug permanently withdrawn	Death
			Dyspnoea	呼吸困難	5	Y	TE	84	1	N	Drug permanently withdrawn	Death
133025	Poland	66/M/C	Decubitus ulcer	褥瘡性潰瘍	3	N	TE			N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Arteriovenous graft site haemorrhage	動静脈グラフト部位出血	2	Y	Pre	-11	7	N	Not applicable	Recovered
			Paraplegia	対麻痺	3	Y	TE	48		N	Drug administration postponed	Not recovered, but no changes expected
			Insomnia	不眠症	1	N	TE	51		N	None	Ongoing at study termination / withdrawal
			Pyrexia	発熱	2	N	TE	118	10	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	1	N	TE	118		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	Y	TE	157	6	N	Drug administration postponed	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	157		N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	2	N	TE	159	2	N	None	Recovered
133029	Poland	56/M/C	Nausea	悪心	1	N	TE	2	2	Y	None	Recovered
			Asthenia	無力症	2	N	TE	2	3	Y	None	Recovered
			Urinary retention	尿閉	2	N	TE	53	4	N	None	Recovered
			Subileus	亜イレウス	3	Y	TE	63	5	Y	Drug administration postponed	Recovered
			Renal failure	腎不全	3	Y	TE	82	10	N	Drug permanently withdrawn	Death
			Renal failure	腎不全	5	Y	TE	91	1	N	Drug permanently withdrawn	Death
135005	Poland	65/M/C	Cerebral ischaemia	脳虚血	4	Y	TE	128	8	N	Drug administration postponed	Recovered with sequelae
137001	Poland	84/M/C	Peripheral motor neuropathy	末梢性運動ニューロパチー	3	Y	TE	16	10	N	Drug permanently withdrawn	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Muscular weakness	筋力低下	2	N	TE	25		N	Not applicable	Ongoing at time of death
137008	Poland	60/M/C	Bone pain	骨痛	2	Y	TE	101	13	N	None	Recovered
137010	Poland	65/M/C	Bone pain	骨痛	2	N	TE			Y	None	Recovered with sequelae
			Bone pain	骨痛	2	Y	TE	38	3	Y	None	Recovered with sequelae
			Anaemia	貧血	3	N	TE	85	2	N	Drug administration postponed	Recovered with sequelae
			Anaemia	貧血	3	Y	TE	86	6	N	Drug administration postponed	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	86	34	N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	127	2	N	Not applicable	Recovered
			Anaemia	貧血	3	Y	TE	128	4	N	Not applicable	Recovered
			Anaemia	貧血	2	Y	TE	176	3	N	Not applicable	Recovered
137012	Poland	71/M/C	Pathological fracture	病的骨折	3	Y	TE	62	10	N	Drug administration postponed	Recovered with sequelae
			Pathological fracture	病的骨折	3	N	TE	71		N	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Depression	うつ病	3	N	TE	85		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
139002	Poland	71/M/C	Bone pain	骨痛	2	N	TE	117	47	N	None	Recovered
			Nausea	悪心	2	N	TE	217		N	Not applicable	Recovered
			Vomiting	嘔吐	2	N	TE	217		N	Not applicable	Recovered
			Dizziness	浮動性めまい	2	N	TE	217		N	Not applicable	Recovered
			Dysphasia	不全失語症	3	N	TE	217		N	Not applicable	Ongoing at time of death
			Ischaemic stroke	虚血性脳卒中	3	Y	TE	217	13	N	Not applicable	Recovered with sequelae
141002	Poland	60/M/C	Haematuria	血尿	2	Y	TE	10	27	N	None	Recovered
			Haematuria	血尿	3	Y	TE	40	11	N	None	Recovered with sequelae
			Haematuria	血尿	2	N	TE	50		N	None	Not recovered, but no changes expected
			Hydronephrosis	水腎症	2	Y	TE	56	5	N	Drug administration postponed	Recovered with sequelae
			Anaemia	貧血	3	Y	TE	90	3	N	None	Recovered with sequelae
			Thrombocytopenia	血小板減少症	2	N	TE	92		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	2	N	TE	92		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	3	Y	TE	95	5	N	Not applicable	Death
			Dyspnoea	呼吸困難	5	Y	TE	99	1	N	Not applicable	Death
141003	Poland	57/M/C	Pathological fracture	病的骨折	3	Y	TE			N	Not applicable	Lost to follow-up
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE			Y	None	Ongoing at study termination / withdrawal
148005	Germany	63/M/C	Nausea	悪心	1	N	TE	27	1	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	57	38	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	57	29	Y	None	Recovered
			Nausea	悪心	1	N	TE	59	5	Y	None	Recovered
			Fatigue	疲労	2	N	TE	64		Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	85	1	Y	None	Recovered
			Anaemia	貧血	1	Y	TE	94	2	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	112		N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	114	4	Y	None	Recovered
			Nausea	悪心	1	N	TE	114	4	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	114	4	Y	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	129	1	N	None	Death
148007	Germany	62/M/C	Anaemia	貧血	1	N	TE			N	Not applicable	Recovered
			Oesophageal pain	食道痛	1	N	Pre			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	Pre	-3	10	Y	-	

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Diarrhoea	下痢	1	N	TE	3	1	Y	None	Recovered
			Nausea	悪心	2	N	TE	3	2	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	3	6	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	3	5	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	3		Y	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	4	29	Y	None	Recovered
			Bone pain	骨痛	1	N	Pre	7	45	Y	-	
			Bone pain	骨痛	1	N	TE	7		Y	None	Recovered
			Lymphadenopathy	リンパ節症	2	N	TE	13	40	N	None	
			Bone pain	骨痛	2	N	Pre	51	7	Y	-	
			Lymphadenopathy	リンパ節症	3	N	TE	52	7	N	None	
			Bone pain	骨痛	1	N	Pre	57	2	Y	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	58		N	None	
			Bone pain	骨痛	2	N	Pre	58	2	Y	None	Recovered
			Bone pain	骨痛	1	N	Pre	59		Y	None	Recovered
			Abdominal pain upper	上腹部痛	2	N	TE	67	37	N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	102	2	Y	None	Recovered
			Abdominal pain upper	上腹部痛	1	N	TE	103		N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	111	1	Y	None	Recovered
			Diarrhoea	下痢	3	Y	TE	162	12	N	Not applicable	Recovered
			Nausea	悪心	3	Y	TE	162	12	N	Not applicable	Recovered
			Vomiting	嘔吐	3	Y	TE	162	12	N	Not applicable	Recovered
			Weight decreased	体重減少	2	N	TE	162	91	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
148015	Germany	68/M/C	Migraine with aura	前兆を伴う片頭痛	2	N	TE	3	3	Y	None	Recovered
			Metastases to lymph nodes	リンパ節転移	2	N	TE	15	115	N	None	Recovered with sequelae
			Anorexia	食欲不振	1	N	TE	113	56	Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	113	119	Y	None	Recovered
			Metastases to lymph nodes	リンパ節転移	3	Y	TE	129	2	N	None	Recovered with sequelae
			Metastases to lymph nodes	リンパ節転移	3	N	TE	130	101	N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	168		Y	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	169		N	None	Recovered
			Metastases to lymph nodes	リンパ節転移	1	N	TE	230		N	None	Not recovered, but no changes expected
			Anaemia	貧血	1	N		477	427	N	-	Recovered with sequelae
148021	Germany	73/M/C	Dysphagia	嚥下障害	3	Y	TE	43	21	N	Drug permanently withdrawn	Recovered
			Fatigue	疲労	3	Y	TE	43	21	N	Drug permanently withdrawn	Recovered
			Prostatic specific antigen increased	前立腺特異性抗原増加	3	Y	TE	43		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	3	Y	TE	43	21	N	Drug permanently withdrawn	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Gastritis	胃炎	1	N	TE	47		N	None	Ongoing at study termination / withdrawal
149004	Germany	65/M/C	Bone pain	骨痛	2	N	Pre	-7	37	N	None	Recovered
			Vomiting	嘔吐	2	N	Pre	-1	1	N	None	Recovered
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE	1	1	Y	None	Recovered
			Vertigo	回転性めまい	1	N	TE	15		N	None	Not recovered, but no changes expected
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE	31	1	Y	None	Recovered
			Anaemia	貧血	1	N	TE	51	16	Y	None	Recovered
			Depression	うつ病	1	N	TE	64		N	None	Not recovered, but no changes expected
			Hypertension	高血圧	2	N	TE	64		N	None	Not recovered, but no changes expected
			Nausea	悪心	2	N	TE	66	2	N	None	Recovered
			Bone pain	骨痛	1	N	TE	66	7	N	None	Recovered
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE	66	1	Y	None	Recovered
			Tooth infection	歯感染	1	N	TE	89	4	N	None	Recovered
			Constipation	便秘	1	N	TE	98		N	None	Ongoing at study termination / withdrawal
			Insomnia	不眠症	1	N	TE	99	10	N	None	Recovered
			Hyperhidrosis	多汗症	2	N	TE	129		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	149	3	N	None	Recovered
			Bone pain	骨痛	1	N	TE	220	19	N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	238	5	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	Post	505	2	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	Post	603	1	Y	Not applicable	Recovered
149005	Germany	73/M/C	Bone pain	骨痛	1	N	TE	13	31	Y	None	Recovered
			Abdominal pain	腹痛	1	N	TE	31	13	Y	None	Recovered
			Nausea	悪心	1	N	TE	64	3	N	None	Recovered
			Fatigue	疲労	1	N	TE	64	5	N	Drug permanently withdrawn	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	64		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	1	N	TE	64	28	N	-	
			Insomnia	不眠症	1	N	TE	64	4	N	None	Recovered
			Fatigue	疲労	2	N	TE	68	13	N	Drug permanently withdrawn	Ongoing at time of death
			Fatigue	疲労	3	N	TE	80		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	91	24	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	114	2	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	115	1	N	Not applicable	Death
149006	Germany	60/M/C	Bone pain	骨痛	1	N	TE	63	29	Y	None	Recovered with sequelae
			Urine flow decreased	尿流量減少	1	N	TE	65	7	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Insomnia	不眠症	1	N	TE	77		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	91	123	Y	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	113	3	Y	Drug administration postponed	Recovered
			Haematuria	血尿	1	N	TE	125	1	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	133	4	Y	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	133	39	N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	133		N	None	Ongoing at study termination / withdrawal
			Monoparesis	不全単麻痺	1	N	TE	133	18	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	134		N	Not applicable	Not recovered, but no changes expected
			Monoparesis	不全単麻痺	3	Y	TE	150		N	Not applicable	Ongoing at time of death
			Monoparesis	不全単麻痺	3	N	TE	150	29	N	Not applicable	Recovered
			Pleural effusion	胸水	1	N	TE	150		N	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	163	5	Y	Not applicable	Recovered
			Stomatitis radiation	放射線口内炎	2	N	TE	168	4	N	Not applicable	Recovered
			Stomatitis radiation	放射線口内炎	1	N	TE	171	8	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dysaesthesia	異常感覚	1	N	TE	171		N	Not applicable	Not recovered, but no changes expected
			Thrombocytopenia	血小板減少症	2	N	TE	178	29	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	TE	183	11	Y	Not applicable	Recovered
			Ureteric obstruction	尿管閉塞	1	N	TE	190		N	Not applicable	Not recovered, but no changes expected
			Gastritis	胃炎	3	Y	TE	191	11	N	Not applicable	Recovered
			General physical health deterioration	全身健康状態低下	3	Y	TE	191	11	N	Not applicable	Recovered
151002	Germany	69/M/C	Vomiting	嘔吐	1	N	TE	5	12	N	None	Recovered
			VIth nerve paralysis	第６脳神経麻痺	2	N	TE	7	30	N	None	Recovered
			Hypotension	低血圧	2	N	TE	16	7	N	None	Recovered
			Metastases to soft tissue	軟部組織転移	3	N	TE	19		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	22		N	None	Ongoing at study termination / withdrawal
			Pain in jaw	顎痛	2	N	TE	22	91	N	None	Ongoing at study termination / withdrawal
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	TE	29	28	N	None	Ongoing at study termination / withdrawal
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	56	81	N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Visual disturbance	視覚障害	3	N	TE	92	8	N	None	Ongoing at study termination / withdrawal
			Visual disturbance	視覚障害	4	N	TE	99		N	None	Ongoing at study termination / withdrawal
			Pain in jaw	顎痛	3	N	TE	112	43	N	None	Ongoing at study termination / withdrawal
			Urinary retention	尿閉	3	Y	TE	129	5	N	Not applicable	Recovered with sequelae
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	TE	136		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	Y	TE	137	4	N	Not applicable	Recovered
			Pain in jaw	顎痛	2	N	TE	154		N	None	Ongoing at study termination / withdrawal
			Abscess jaw	顎膿瘍	3	Y	TE	163	22	N	Not applicable	Recovered with sequelae
155006	Germany	70/M/C	Chills	悪寒	1	N	Pre			N	None	Recovered
			Nausea	悪心	1	N	TE	2		N	None	Not recovered, but no changes expected
			Device related infection	医療機器関連感染	3	Y	TE	92	25	N	Drug administration postponed	Recovered with sequelae
			Bone pain	骨痛	3	N	TE	175		N	Not applicable	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
155007	Germany	63/M/C	Metastases to bone	骨転移	3	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	Pre	-10		N	None	Not recovered, but no changes expected
			Benign urinary tract neoplasm	尿路の良性新生物	2	Y	TE	73	6	N	None	Recovered
			Metastases to liver	肝転移	2	N	TE	163		N	None	Not recovered, but no changes expected
155010	Germany	80/M/C	Gastritis	胃炎	1	N	TE			N	None	Recovered
			General physical health deterioration	全身健康状態低下	1	N	TE	1	86	N	None	Recovered
			Gastritis	胃炎	2	N	TE	54		N	None	Recovered
			Anaemia	貧血	2	N	TE	120		N	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	1	N	TE	120		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	135		N	Not applicable	Ongoing at time of death
			Atrial fibrillation	心房細動	4	N	TE	203		N	Not applicable	Ongoing at time of death
			Sinusitis	副鼻腔炎	1	N	TE	203		N	Not applicable	Ongoing at time of death
			Cerebral haemorrhage	脳出血	4	Y	TE	203		N	Not applicable	Ongoing at time of death
			Epilepsy	てんかん	2	N	TE	203	2	N	Not applicable	Ongoing at time of death
			Pneumonia aspiration	嚥下性肺炎	4	Y	TE	203	2	N	Not applicable	Death
			Pneumonia aspiration	嚥下性肺炎	5	Y	TE	204	1	N	Not applicable	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
172001	Brazil	75/M/C	Fatigue	疲労	2	N	TE	31		N	None	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	1	N	TE	31	29	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	36	4	N	None	Recovered
			Nasal congestion	鼻閉	1	N	TE	38	22	N	None	Recovered
			Cachexia	悪液質	3	N	TE	59		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	86	2	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	86	28	N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	87		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	113		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	212	1	N	Not applicable	Death
174003	Brazil	71/M/A	Weight decreased	体重減少	1	N	Pre	1	76	N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	4	15	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	41	17	N	None	Recovered
			Bone pain	骨痛	3	N	TE	41	4	N	None	Recovered
			Bone pain	骨痛	3	N	TE	41	17	N	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	2	N	TE	44		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	44	14	N	None	Recovered
			Constipation	便秘	2	N	TE	48	10	N	None	Recovered
			Nausea	悪心	2	N	TE	51	7	N	None	Recovered
			Bone pain	骨痛	2	N	TE	57		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	57		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	57		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	63	28	N	None	Recovered
			Nausea	悪心	1	N	TE	63	156	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	76	116	N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	99	43	N	None	Recovered
			Bone pain	骨痛	1	N	TE	105	1	N	None	Recovered
			Anaemia	貧血	3	N	TE	106	29	Y	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	106	29	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	134		Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	162	30	Y	None	Recovered
			Weight decreased	体重減少	3	N	TE	191		N	None	Ongoing at time of death
			Pneumonia	肺炎		N	TE	225		N	Not applicable	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	4	Y	TE	240	8	N	Not applicable	Death
			General physical health deterioration	全身健康状態低下	5	Y	TE	247	1	N	Not applicable	Death
179005	Brazil	77/M/C	Monoparesis	不全単麻痺	1	N	Pre			N	Not applicable	Ongoing at study termination / withdrawal
			Urinary tract infection	尿路感染	3	Y	Pre	-67	9	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neutropenia	好中球減少症	3	N	TE	31	33	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	42		N	Not applicable	Recovered
			Asthenia	無力症	1	N	TE	42		N	Not applicable	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	1	N	TE	42	22	N	Not applicable	Recovered
			Diarrhoea	下痢	1	N	TE	44		N	Not applicable	Recovered
			Gait disturbance	歩行障害	1	N	TE	63		N	Not applicable	Lost to follow-up
			Neutropenia	好中球減少症	3	N	TE	78	14	N	Not applicable	Recovered
181006	Brazil	75/M/B	Sepsis	敗血症	4	Y	TE	146	11	N	None	Death
			Hypernatraemia	高ナトリウム血症	4	N	TE	146		N	Drug administration postponed	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	146		N	None	Ongoing at time of death
			Renal failure acute	急性腎不全	4	N	TE	146		N	Drug permanently withdrawn	Ongoing at time of death
			Respiratory failure	呼吸不全	4	N	TE	146		N	Drug permanently withdrawn	Ongoing at time of death
			Sepsis	敗血症	5	Y	TE	156	1	N	None	Death
191006	Singapore	71/M/A	Hypoaesthesia	感覚鈍麻	1	N	Pre	-5		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Musculoskeletal pain	筋骨格痛	1	N	Pre	-4		N	None	Ongoing at time of death
			Myopathy	ミオパチー	1	N	Pre	-4		N	None	Ongoing at time of death
			Insomnia	不眠症	1	N	Pre	-4		N	None	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	Pre	1	7	N	None	Recovered
			Hyperkalaemia	高カリウム血症	2	N	Pre	1	28	N	None	Recovered
			Constipation	便秘	1	N	TE	16		Y	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	16		Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	24	46	N	None	Recovered
			Headache	頭痛	1	N	TE	24		Y	None	Ongoing at time of death
			Urinary incontinence	尿失禁	2	N	TE	69		N	None	Ongoing at time of death
			Anal sphincter atony	肛門括約筋無緊張症	3	N	TE	118	59	N	Not applicable	Ongoing at time of death
			Somnolence	傾眠	3	N	TE	169		N	Not applicable	Ongoing at time of death
			Intestinal perforation	腸管穿孔	4	Y	TE	174		N	Not applicable	Ongoing at time of death
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	3	Y	TE	174		N	Not applicable	Ongoing at time of death
			Myocardial infarction	心筋梗塞	5	Y	TE	176	1	N	Not applicable	Death
200002	Australia	57/M/C	Arthralgia	関節痛	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			N	None	Recovered
			Osteoarthritis	骨関節炎	1	N	Pre			N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Synovial cyst	滑液嚢腫	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Non-cardiac chest pain	非心臓性胸痛	3	Y	Pre	-17	3	N	None	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	57	57	N	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	1	N	TE	92		N	None	Ongoing at study termination / withdrawal
			Constipation	便秘	1	N	TE	94	6	N	Not applicable	Recovered
			Insomnia	不眠症	1	N	TE	95		N	Not applicable	Recovered
			Dizziness	浮動性めまい	1	N	TE	99	1	N	Not applicable	Recovered
			Upper respiratory tract infection	上気道感染	1	N	TE	110	8	N	Not applicable	Recovered
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE	110		N	Not applicable	Ongoing at study termination / withdrawal
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	TE	113	22	N	None	Recovered
			Cytokine release syndrome	サイトカイン放出症候群	2	N	TE	114	1	N	Not applicable	Recovered
			Pneumonia	肺炎	2	N	TE	172		N	Not applicable	Recovered
202003	Australia	64/M/C	Nausea	悪心	2	N	TE	11	18	N	None	Recovered
			Bone pain	骨痛	3	N	TE	11	2	Y	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	57	7	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Diplopia	複視	1	N	TE	104	21	N	Not applicable	Recovered
203006	Australia	72/M/C	Anorexia	食欲不振	1	N	TE			N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	-1		N	None	
			Constipation	便秘	1	N	TE	10	50	N	None	Recovered
			Bone pain	骨痛	1	N	TE	20	24	N	None	Recovered
			Bone pain	骨痛	2	N	TE	26	18	N	None	Recovered
			Fatigue	疲労	1	N	TE	28	12	N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	39	194	N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	39	11	N	Drug permanently withdrawn	Recovered
			Bone pain	骨痛	2	N	TE	39	5	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	43		N	Not applicable	Ongoing at time of death
			Nausea	悪心	1	N	TE	44	1	N	Not applicable	Recovered
			Mobility decreased	運動性低下	1	Y	TE	51	13	N	Not applicable	Recovered
			Diarrhoea	下痢	1	N	TE	57	7	N	Not applicable	Recovered
			Asthenia	無力症	2	N	TE	62	15	N	Not applicable	Recovered
			Constipation	便秘	1	N	TE	63	175	N	Not applicable	Ongoing at time of death
			Gastrooesophageal reflux disease	胃食道逆流性疾患	1	N	TE	63		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Mucosal inflammation	粘膜の炎症	1	N	TE	63	153	N	Not applicable	Recovered
			Agitation	激越	1	N	TE	63	66	N	Not applicable	Recovered
			Fatigue	疲労	4	N	TE	232		N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	237		N	Not applicable	Ongoing at time of death
207002	Australia	81/M/C	Anorexia	食欲不振	2	N	TE			N	None	Lost to follow-up
			Urinary incontinence	尿失禁	2	N	TE			N	None	Lost to follow-up
			Oedema peripheral	末梢性浮腫	1	N	TE	58		N	None	Lost to follow-up
			Swelling face	顔面腫脹	1	N	TE	58		N	None	Lost to follow-up
			Faecal incontinence	便失禁	1	N	TE	104		N	None	Ongoing at time of death
			Dementia	認知症	3	Y	TE	104	7	N	Drug permanently withdrawn	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	137	1	N	Not applicable	Death
212001	Australia	81/M/C	Thrombocytopenia	血小板減少症	1	N	TE	30	50	N	None	Recovered
			Atrial fibrillation	心房細動	2	Y	TE	38	11	N	None	Recovered
			Abdominal pain	腹痛	3	N	TE	59	8	N	Drug administration postponed	Recovered
			Nausea	悪心	3	N	TE	59		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	59	21	N	Drug administration postponed	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	59		N	Drug administration postponed	Ongoing at time of death
			Dyspnoea	呼吸困難	3	N	TE	59	21	N	Drug administration postponed	Recovered
			Tachycardia	頻脈	3	N	TE	198	68	N	Not applicable	Ongoing at time of death
			Nausea	悪心	2	N	TE	198	68	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	198	68	N	None	Ongoing at time of death
			Muscular weakness	筋力低下	3	N	TE	198	68	N	None	Ongoing at time of death
			Fatigue	疲労	3	Y	TE	205		N	Not applicable	Ongoing at time of death
			Dehydration	脱水	3	Y	TE	205	3	N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	205	3	N	Not applicable	Recovered
			Weight decreased	体重減少	1	N	TE	247	19	N	None	Ongoing at time of death
213006	Australia	72/M/C	Constipation	便秘	1	N	TE			N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			N	None	Recovered
			Fatigue	疲労	1	N	TE	1	2	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	3	55	N	None	Recovered
			Ingrowing nail	嵌入爪	1	N	TE	18		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	29	3	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	1	N	TE	57	3	Y	None	Recovered
			Constipation	便秘	1	N	TE	59	7	N	None	Recovered
			Fatigue	疲労	1	N	TE	85		Y	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	142		N	None	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	4	Y	TE	185	30	N	Not applicable	Recovered with sequelae
			Pneumonia	肺炎	3	Y	TE	188	5	N	Not applicable	Recovered
			Gastrointestinal haemorrhage	胃腸出血	3	Y	TE	196	2	N	Not applicable	Recovered
			Oral candidiasis	口腔カンジダ症	2	N	TE	200		N	Not applicable	Ongoing at time of death
			Postoperative wound infection	術後創感染	3	Y	TE	201	14	N	Not applicable	Recovered with sequelae
			Postoperative wound infection	術後創感染	2	N	TE	214		N	Not applicable	Ongoing at time of death
			Pulmonary embolism	肺塞栓症	4	Y	TE	220	5	N	Not applicable	Death
			Pulmonary embolism	肺塞栓症	5	Y	TE	224	1	N	Not applicable	Death
213009	Australia	76/M/C	Fatigue	疲労	1	N	TE	5	27	Y	None	Not recovered, but no changes expected
			Arthralgia	関節痛	1	N	TE	21	2	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	23	2	N	None	Recovered
			Fatigue	疲労	2	N	TE	31	26	Y	None	Not recovered, but no changes expected
			Lower respiratory tract infection	下気道感染	2	N	TE	32	26	N	None	Recovered
			Fatigue	疲労	1	N	TE	56		Y	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	2	N	TE	105	4	N	Not applicable	Recovered
			Febrile neutropenia	発熱性好中球減少症	3	Y	TE	107	7	N	Not applicable	Recovered
			Abdominal pain	腹痛	2	N	TE	107		N	None	Not recovered, but no changes expected
			Diarrhoea	下痢	2	N	TE	108		N	Not applicable	Not recovered, but no changes expected
			Hypophosphataemia	低リン酸血症	3	N	TE	110	4	N	Not applicable	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	111	5	N	Not applicable	Recovered
			Thrombosis	血栓症	2	N	TE	138		N	Not applicable	Not recovered, but no changes expected
233003	UK	61/M/C	Anorexia	食欲不振	1	N	Pre	-13	22	N	None	Recovered with sequelae
			Fatigue	疲労	2	N	Pre	1	163	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre	1	29	N	None	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	29	36	Y	None	Recovered
			Bone pain	骨痛	2	N	Pre	29	36	N	None	Ongoing at time of death
			Ageusia	味覚消失	2	N	TE	29	36	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	58	4	N	None	Recovered
			Constipation	便秘	2	N	TE	60		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	64	25	N	None	Recovered
			Bone pain	骨痛	3	N	Pre	64		N	None	Ongoing at time of death
			Muscular weakness	筋力低下	3	N	TE	64		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	92	17	N	None	Recovered
			Tachycardia	頻脈	1	N	TE	92		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	92		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	104	60	N	None	Recovered
			Anaemia	貧血	3	Y	TE	135	3	N	Drug administration postponed	Recovered
			Asthenia	無力症	3	N	TE	135	3	Y	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	138		N	Drug administration postponed	Ongoing at study termination / withdrawal
			Dysarthria	構語障害	1	N	TE	145		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	3	N	TE	152	12	N	None	Death
			Cardiac failure	心不全	4	Y	TE	152		N	Drug permanently withdrawn	Ongoing at time of death
			Pleural effusion	胸水	2	N	TE	152		N	Not applicable	Ongoing at time of death
			Nausea	悪心	2	N	TE	159	5	N	Not applicable	Ongoing at time of death
			Anaemia	貧血	5	Y	TE	163	1	N	None	Death
240010	USA	67/M/B	Nausea	悪心	1	N	TE	28	35	N	None	Recovered
			Arthralgia	関節痛	2	N	TE	28	35	N	None	Recovered
			Bone pain	骨痛	2	N	TE	28	35	N	None	Recovered
			Bone pain	骨痛	2	N	TE	28	35	N	None	Recovered
			Pain in extremity	四肢痛	2	N	TE	28	35	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary tract obstruction	尿路閉塞	2	N	TE	49		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	N	TE	56	3	Y	Drug administration postponed	Recovered
			Pericardial effusion	心嚢液貯留	1	N	TE	56		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	56	4	N	None	Recovered
			Gait disturbance	歩行障害	2	N	TE	56		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	56		N	None	Ongoing at study termination / withdrawal
			Urinary tract infection	尿路感染	1	N	TE	56	7	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	56		N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	56	4	N	Drug permanently withdrawn	Recovered
			Muscular weakness	筋力低下	1	N	TE	56		N	None	Ongoing at time of death
			Atelectasis	無気肺	1	N	TE	56		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	58	64	Y	Drug administration postponed	Recovered
			Bone pain	骨痛	1	N	TE	59		N	Not applicable	Ongoing at time of death
			Bronchitis	気管支炎	1	N	TE	68	15	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Productive cough	湿性咳嗽	1	N	TE	68	15	N	Not applicable	Recovered
			Pain in extremity	四肢痛	3	N	TE	82		N	Not applicable	Ongoing at time of death
			Decubitus ulcer	褥瘡性潰瘍	1	N	TE	82		N	Not applicable	Ongoing at time of death
251003	USA	83/M/O	Dyspnoea	呼吸困難	3	N	Pre	-7	2	N	None	Recovered
			Pleural effusion	胸水	2	Y	Pre	-6	1	N	None	Recovered
			Anaemia	貧血	2	N	Pre	-4	3	N	None	Recovered
			Oedema	浮腫	2	N	Pre	-4		N	None	Ongoing at study termination / withdrawal
			Pleural effusion	胸水	1	N	Pre	-4		N	None	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	3	Y	Pre	-3	4	N	Not applicable	Recovered
			Fatigue	疲労	1	N	Pre	-3	2	N	None	Recovered
			Fatigue	疲労	3	N	Pre	-3	4	N	None	Recovered
			Fluid retention	体液貯留	2	N	Pre	-3	4	N	None	Recovered
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	3	Y	Pre	-3	4	N	None	Recovered
			Tachypnoea	頻呼吸	2	N	Pre	-3	1	N	None	Recovered
			Hypotension	低血圧	1	N	Pre	-3		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	Pre	-2	3	N	None	Recovered
			Left ventricular hypertrophy	左室肥大	1	N	Pre	-1		N	None	Ongoing at time of death
			Mitral valve incompetence	僧帽弁閉鎖不全症	1	N	Pre	-1		N	None	Ongoing at time of death
			Lymphopenia	リンパ球減少症	4	Y	Pre	1	6	N	None	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dizziness	浮動性めまい	2	N	TE	4		N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	23		N	Not applicable	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	23	2	N	Drug administration postponed	Recovered
			Abdominal pain	腹痛	2	N	TE	24		N	None	Recovered
			Gastritis	胃炎	2	N	TE	24		N	Drug administration postponed	Recovered
			Epigastric discomfort	心窩部不快感	2	N	TE	25	9	N	None	Recovered
			Chills	悪寒	1	N	TE	25	2	N	Drug administration postponed	Recovered
			Pyrexia	発熱	1	N	TE	25	1	N	Drug administration postponed	Recovered
			Dyspnoea	呼吸困難	3	N	TE	25	1	N	None	Recovered
			Acute myocardial infarction	急性心筋梗塞	4	Y	TE	26	9	N	Drug administration postponed	Recovered
			Cardiac failure congestive	うっ血性心不全	2	N	TE	26	24	N	Drug administration postponed	Recovered
			Tachycardia	頻脈	3	N	TE	26	1	N	Drug administration postponed	Recovered
			Vomiting	嘔吐	1	N	TE	26		N	Drug administration postponed	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pyrexia	発熱	1	N	TE	26	2	Y	Drug administration postponed	Recovered
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	3	Y	TE	26	9	N	Drug administration postponed	Recovered
			Hypoxia	低酸素症	3	N	TE	26		N	Drug administration postponed	Ongoing at study termination / withdrawal
			Tachypnoea	頻呼吸	3	N	TE	26		N	Drug administration postponed	Ongoing at time of death
			Diabetes mellitus	糖尿病	2	N	TE	27		N	Drug administration postponed	Ongoing at time of death
			Anxiety	不安	2	N	TE	30		N	None	Ongoing at study termination / withdrawal
			Asthenia	無力症	3	N	TE	43		N	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	43		N	Not applicable	Ongoing at study termination / withdrawal
			Haematuria	血尿	2	N	TE	43	2	N	Not applicable	Recovered
			Epistaxis	鼻出血	2	Y	TE	43	4	N	None	Recovered
			Anaemia	貧血	3	N	TE	44	2	N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	49		N	Not applicable	Ongoing at study termination / withdrawal

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cardiac failure congestive	うっ血性心不全	3	Y	TE	49		N	Not applicable	Ongoing at study termination / withdrawal
			Pneumonia	肺炎	3	N	TE	49		N	Not applicable	Ongoing at study termination / withdrawal
			Dizziness	浮動性めまい	3	N	TE	49		N	Not applicable	Ongoing at study termination / withdrawal
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	3	Y	TE	49		N	Not applicable	Ongoing at study termination / withdrawal
			Chronic respiratory failure	慢性呼吸不全	3	Y	TE	49		N	Not applicable	Ongoing at study termination / withdrawal
			Orthostatic hypotension	起立性低血圧	3	Y	TE	49		N	Not applicable	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
001003	Norway	67/M/C	Nausea	悪心	1	N	TE	23	1	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	23	1	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	28	29	Y	None	Not recovered, but no changes expected
			Nausea	悪心	2	N	TE	31	12	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	31	12	Y	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	35	11	Y	None	Recovered
			Nausea	悪心	2	N	TE	56	8	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	56	8	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	56		Y	None	Not recovered, but no changes expected
			Weight decreased	体重減少	2	N	TE	84		Y	None	Not recovered, but no changes expected
			Nausea	悪心	2	N	TE	87	8	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	87	8	Y	None	Recovered
			Nausea	悪心	2	N	TE	114	40	Y	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	2	N	TE	114	40	Y	Not applicable	Recovered with sequelae
			Pathological fracture	病的骨折	2	N	TE	115		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	Y	TE	127	15	N	None	Recovered
			Nausea	悪心	3	Y	TE	153	6	Y	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	3	Y	TE	153	6	Y	Not applicable	Recovered with sequelae
			Nausea	悪心	2	N	TE	158	17	Y	None	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	174	5	Y	Not applicable	Recovered with sequelae
			Nausea	悪心	3	Y	TE	174	5	Y	Not applicable	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	3	Y	TE	174	5	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	3	N	TE	174	5	Y	Not applicable	Ongoing at study termination / withdrawal
			Infection	感染	1	Y	TE	174	5	Y	Not applicable	Recovered
			Bone pain	骨痛	2	Y	TE	174	5	Y	Not applicable	Recovered
			Nausea	悪心	2	N	TE	178		Y	None	Ongoing at study termination / withdrawal
			General physical health deterioration	全身健康状態低下	2	N	TE	178		Y	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	Y	TE	192	2	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	197	14	Y	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	2	Y	TE	197	14	N	Not applicable	Recovered with sequelae
			Infection	感染	2	Y	TE	197	14	N	Not applicable	Recovered
001012	Norway	52/M/C	Bone pain	骨痛	2	Y	TE	105	2	N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	106		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	Y	TE	141	4	N	Not applicable	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	2	N	TE	166	57	N	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	Y	TE	184	3	N	Not applicable	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	TE	222		N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	2	N	TE	222		N	Not applicable	Not recovered, but no changes expected
001019	Norway	70/M/C	Ankle fracture	足関節部骨折	2	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE	118	56	Y	None	Recovered
			Chest pain	胸痛	2	Y	TE	133	2	Y	None	Recovered
			Anaemia	貧血	2	N	TE	145	63	Y	Not applicable	Recovered with sequelae
			Dysgeusia	味覚異常	2	N	TE	145	29	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	207	4	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	TE	210		Y	Not applicable	Ongoing at study termination / withdrawal
001021	Norway	66/M/C	Lung infection	肺感染	2	Y	Pre	-13	5	N	Not applicable	Recovered
			Anaemia	貧血	2	N	Pre	1		Y	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	57	1	Y	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	57		Y	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	112	6	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	2	N	TE	148		Y	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	148		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	156		Y	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	2	N	TE	183		Y	None	Ongoing at study termination / withdrawal
001023	Norway	62/M/C	Bone pain	骨痛	2	N	Pre	1		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	29		Y	None	Ongoing at study termination / withdrawal
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	57		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	TE	57		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	57		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	57	19	N	Drug permanently withdrawn	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Metastases to liver	肝転移	3	Y	TE	57		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	75	1	N	Drug permanently withdrawn	Death
001025	Norway	77/M/C	Bone pain	骨痛	2	Y	Pre	-14	2	N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	57	16	N	None	Recovered
			Nausea	悪心	2	N	TE	69		Y	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	2	N	TE	85		Y	None	Ongoing at study termination / withdrawal
001029	Norway	66/M/C	Diarrhoea	下痢	1	N	TE	3	8	Y	None	Recovered
			Nausea	悪心	2	N	TE	3	4	Y	None	Recovered
			Fatigue	疲労	1	N	TE	57		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	57		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	87	7	Y	Drug administration postponed	Recovered
			Anaemia	貧血	3	Y	TE	90	4	Y	Drug administration postponed	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	2	N	TE	90	4	Y	Drug administration postponed	Recovered
			Dehydration	脱水	2	Y	TE	90	4	Y	Drug administration postponed	Recovered
			Weight decreased	体重減少	2	N	TE	106	29	Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	Y	TE	134	2	Y	Drug permanently withdrawn	Recovered with sequelae
			Leukopenia	白血球減少症	2	Y	TE	134		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	3	Y	TE	134		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	3	N	TE	134		Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	135		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
001035	Norway	75/M/C	Anaemia	貧血	2	N	TE	3	8	Y	None	Recovered
			Nausea	悪心	2	N	TE	3	8	Y	None	Recovered
			Infection	感染	2	Y	TE	3	8	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	66	12	N	None	Recovered with sequelae
			Mobility decreased	運動性低下	2	N	TE	77		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	85		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	Y	TE	141	10	Y	Drug administration postponed	Recovered with sequelae
			Medical device complication	医療機器合併症	3	Y	TE	141	10	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	Y	TE	156	10	Y	Drug administration postponed	Recovered with sequelae
			Urinary tract infection	尿路感染	3	Y	TE	156	10	Y	Drug administration postponed	Recovered
			Urinary retention	尿閉	3	Y	TE	189		N	Drug permanently withdrawn	Ongoing at time of death
001041	Norway	63/M/C	Bone pain	骨痛	1	N	TE	29	71	Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	85	29	Y	Drug permanently withdrawn	Recovered with sequelae
			Pyrexia	発熱	2	N	TE	85	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	99		Y	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	107	5	Y	None	Recovered
			Pneumonia	肺炎	2	N	TE	111	17	N	None	Recovered
			Anaemia	貧血	1	N	TE	113	32	Y	Drug permanently withdrawn	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	2	N	TE	113		Y	None	Ongoing at study termination / withdrawal
			Dehydration	脱水	3	Y	TE	115	8	Y	None	Recovered
			Tumour associated fever	腫瘍熱	1	N	TE	115		N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	141	4	Y	Drug permanently withdrawn	Recovered with sequelae
			Metastases to lung	肺転移	3	N	TE	141		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Cough	咳嗽	1	N	TE	141		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	Y	TE	144	6	Y	Drug permanently withdrawn	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	2	Y	TE	144	6	Y	Drug permanently withdrawn	Recovered with sequelae
			Dehydration	脱水	2	Y	TE	144	6	Y	Drug permanently withdrawn	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	149		Y	None	Ongoing at study termination / withdrawal
002006	Norway	66/M/C	Bone pain	骨痛	2	N	Pre			N	None	Ongoing at study termination / withdrawal
			Urinary tract infection	尿路感染	3	N	TE	10	10	N	None	Recovered
			Anaemia	貧血	2	N	TE	29	34	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	Pre	29	29	N	None	Ongoing at study termination / withdrawal
			Ascites	腹水	1	N	TE	57	6	N	None	Recovered
			Bone pain	骨痛	2	N	Pre	57		N	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	Y	TE	62	18	N	Drug permanently withdrawn	Recovered with sequelae
			Fungal infection	真菌感染	2	N	TE	76	5	N	None	Recovered
			Anxiety	不安	2	N	TE	77		N	None	Not recovered, but no changes expected
			Sepsis	敗血症	4	Y	TE	79	5	N	Not applicable	Death
			Anaemia	貧血	2	N	TE	81	2	N	None	Recovered
			Sepsis	敗血症	5	Y	TE	83	1	N	Not applicable	Death
002008	Norway	69/M/C	Nausea	悪心	1	N	TE	29	3	N	None	Recovered
			Nausea	悪心	1	N	TE	34		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	105	21	N	None	Recovered
			Constipation	便秘	1	N	TE	120		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	Y	TE	125	5	N	None	Recovered
			Hyperglycaemia	高血糖	4	Y	TE	159	4	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	161	3	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Ascites	腹水	1	N	TE	176		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	183	2	N	Not applicable	Recovered
			Infection	感染	2	N	TE	183	3	N	Not applicable	Recovered
			Infection	感染	3	Y	TE	185	5	N	Not applicable	Recovered
			Anaemia	貧血	4	Y	TE	216	2	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	4	Y	TE	216		Y	Not applicable	Ongoing at time of death
002009	Norway	73/M/C	Diarrhoea	下痢	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	2	N	TE	2	3	Y	None	Recovered
			Osteoporosis	骨粗鬆症	3	Y	TE	39	6	N	None	Recovered with sequelae
			Atrial fibrillation	心房細動	2	N	TE	71	2	N	None	Recovered
			Pneumonia	肺炎	2	N	TE	71	14	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	71	14	N	None	Recovered with sequelae
			Urinary retention	尿閉	2	N	TE	71	14	N	None	Recovered
			Oral infection	口腔感染	2	N	TE	79	5	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	79	2	N	None	Recovered
			Bone pain	骨痛	3	N	TE	113		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	132	47	N	None	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	2	N	TE	225		N	None	Not recovered, but no changes expected
002013	Norway	69/M/C	Vision blurred	霧視	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	2	5	Y	None	Recovered
			Metastases to skin	皮膚転移	1	N	TE	57		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	85		N	None	Ongoing at study termination / withdrawal
			Metastases to soft tissue	軟部組織転移	1	N	TE	86		N	None	Ongoing at time of death
			Cerebral haemorrhage	脳出血	3	Y	TE	100	38	Y	Drug permanently withdrawn	Death
			Anaemia	貧血	2	N	TE	110		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	111		Y	Not applicable	Ongoing at time of death
			Cerebral haemorrhage	脳出血	5	Y	TE	137	1	Y	Drug permanently withdrawn	Death
002017	Norway	79/M/C	Nausea	悪心	1	N	TE	4	2	Y	None	Recovered
			Nausea	悪心	2	N	TE	28	4	Y	None	Recovered
			Dizziness	浮動性めまい	2	N	TE	28	4	Y	None	Recovered
			Localised infection	限局性感染	2	N	TE	54	116	N	None	Recovered
			Nausea	悪心	2	N	TE	57	4	Y	None	Recovered
			Dizziness	浮動性めまい	2	N	TE	57	4	Y	None	Recovered
			Wound	創傷	2	N	TE	68	122	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Supraventricular tachycardia	上室性頻脈	3	Y	TE	176	7	N	Not applicable	Recovered
			Urinary tract infection	尿路感染	2	N	TE	177	7	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	N	TE	178	4	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	205	10	N	None	Recovered
			Atrial flutter	心房粗動	2	Y	TE	230	4	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	N	TE	230	3	N	Not applicable	Recovered
003001	Norway	64/M/C	Dizziness	浮動性めまい	1	N	TE			Y	None	Ongoing at study termination / withdrawal
			Constipation	便秘	1	N	TE	1	21	Y	None	Recovered
			Nausea	悪心	1	N	TE	2	82	Y	None	Recovered
			Insomnia	不眠症	2	N	TE	2		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	8	18	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	28	98	N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	Y	TE	84		Y	Not applicable	Ongoing at time of death
			Leukopenia	白血球減少症	1	N	TE	84		Y	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	1	N	TE	84		Y	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	N	TE	112	2	Y	Drug administration postponed	Recovered
			Neutropenia	好中球減少症	3	Y	TE	112	3	Y	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	112		Y	Drug administration postponed	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	125	52	Y	Drug permanently withdrawn	Recovered with sequelae
			Leukopenia	白血球減少症	1	N	TE	125		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	1	N	TE	125		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	3	N	TE	125		N	None	Ongoing at study termination / withdrawal
			Pyrexia	発熱	2	N	TE	131	5	Y	Not applicable	Recovered
003005	Norway	58/M/C	Spinal cord compression	脊髄圧迫	2	N	TE			N	Not applicable	Ongoing at time of death
			Nasopharyngitis	鼻咽頭炎	2	N	Pre	-1	9	N	None	Recovered
			Bone pain	骨痛	1	N	Pre	-1	9	N	None	Recovered
			Nausea	悪心	1	N	TE	29	30	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	64	84	Y	None	Recovered
			Nausea	悪心	1	N	TE	87	33	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	119	123	Y	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	1	N	TE	119		Y	None	Ongoing at study termination / withdrawal
			Muscular weakness	筋力低下	2	N	TE	147		N	None	Ongoing at study termination / withdrawal
			Pneumonia	肺炎	3	Y	TE	187	3	N	Not applicable	Recovered
			Pneumonia	肺炎	1	N	TE	189	25	N	Not applicable	Recovered with sequelae
			Pleural effusion	胸水	3	N	TE	209	5	N	Not applicable	Recovered with sequelae
			Hypovitaminosis	ビタミン欠乏症	1	N	TE	211		N	Not applicable	Ongoing at time of death
			Pleural effusion	胸水	3	Y	TE	213	6	N	Not applicable	Recovered with sequelae
			Insomnia	不眠症	1	N	TE	221		N	Not applicable	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	221		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	1	N	TE	241		Y	None	Ongoing at study termination / withdrawal
003007	Norway	51/M/C	Anxiety	不安	1	N	Pre			N	None	Ongoing at study termination / withdrawal
			Radiation associated pain	放射線関連痛	2	N	TE	17	4	N	None	Recovered
			Hypoaesthesia	感覚鈍麻	2	N	TE	20	123	N	None	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Radiation associated pain	放射線関連痛	3	N	TE	32	55	N	None	Ongoing at study termination / withdrawal
			Radiation associated pain	放射線関連痛	2	N	TE	86		N	None	Ongoing at study termination / withdrawal
			Hypoaesthesia	感覚鈍麻	1	N	TE	86	60	N	None	Recovered
			Neuralgia	神経痛	1	N	TE	86	29	N	None	Recovered
			Micturition urgency	尿意切迫	2	N	TE	144	2	N	Not applicable	Recovered
			Micturition urgency	尿意切迫	1	Y	TE	145	5	N	Not applicable	Recovered
			Hydronephrosis	水腎症	3	N	TE	195	39	N	Not applicable	Recovered
003014	Norway	55/M/C	Diarrhoea	下痢	1	N	TE	1		Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	27	86	Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	2	N	TE	126	49	N	Not applicable	Recovered with sequelae
			Nausea	悪心	2	N	TE	140	5	N	None	Recovered
			Nausea	悪心	3	N	TE	144	5	N	None	Recovered
			Nausea	悪心	1	N	TE	148	25	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	174	1	N	Not applicable	Recovered
			Musculoskeletal pain	筋骨格痛	3	Y	TE	174	21	N	Not applicable	Recovered with sequelae
			Insomnia	不眠症	2	N	TE	174		N	Not applicable	Ongoing at time of death
			Tooth extraction	抜歯	2	N	TE	176	1	N	Not applicable	Recovered
			Thrombosis	血栓症	3	N	TE	187		N	Not applicable	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Musculoskeletal pain	筋骨格痛	3	Y	TE	201	17	N	Not applicable	Recovered with sequelae
			Depression	うつ病	2	N	TE	209		N	Not applicable	Ongoing at study termination / withdrawal
003015	Norway	72/M/C	Constipation	便秘	2	N				N	None	Recovered
			Oral candidiasis	口腔カンジダ症	1	N	TE	15	43	N	None	Recovered
			Sinus tachycardia	洞性頻脈	3	N	TE	57	29	N	None	Not recovered, but no changes expected
			Rib fracture	肋骨骨折	2	Y	TE	82	4	N	None	Recovered with sequelae
			Sinus tachycardia	洞性頻脈	1	N	TE	85		N	None	Not recovered, but no changes expected
			Herpes zoster	帯状疱疹	3	N	TE	98	9	N	None	Recovered
			Herpes zoster	帯状疱疹	1	N	TE	106	36	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	141		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	1	N	TE	160	9	N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	168	9	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	168	9	N	Not applicable	Recovered
			Cough	咳嗽	1	N	TE	176		N	Not applicable	Ongoing at study termination / withdrawal
003016	Norway	77/M/C	Spinal compression fracture	脊椎圧迫骨折	1	N	TE	95	5	N	None	Recovered
			Constipation	便秘	3	Y	TE	99	2	Y	None	Recovered
			Nausea	悪心	2	N	TE	99	49	N	None	Recovered
			Spinal compression fracture	脊椎圧迫骨折	3	Y	TE	99	7	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Insomnia	不眠症	1	N	TE	99		N	None	Not recovered, but no changes expected
			Constipation	便秘	1	N	TE	100	1	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	105	38	N	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	142	6	N	None	Recovered with sequelae
			Osteoporosis	骨粗鬆症	2	N	TE	143		N	Not applicable	Not recovered, but no changes expected
			Musculoskeletal pain	筋骨格痛	1	N	TE	147		N	None	
			Constipation	便秘	2	N	TE	197		N	Not applicable	Ongoing at study termination / withdrawal
003017	Norway	63/M/C	Nausea	悪心	1	N	TE	4	54	Y	None	Recovered
			Constipation	便秘	2	N	TE	10	48	Y	None	Recovered
			Hyperchlorhydria	胃酸過多	1	N	TE	29		Y	None	Ongoing at study termination / withdrawal
			Constipation	便秘	3	N	TE	57	110	Y	None	Recovered
			Nausea	悪心	2	N	TE	57	110	Y	None	Recovered
			Fatigue	疲労	2	N	TE	84	83	N	Not applicable	Recovered
			Musculoskeletal pain	筋骨格痛	2	N	TE	84	23	N	None	Recovered with sequelae
			Cystitis	膀胱炎	2	N	TE	106	11	N	None	Recovered
			Musculoskeletal pain	筋骨格痛	2	Y	TE	106	4	N	None	Recovered with sequelae
			Musculoskeletal pain	筋骨格痛	2	N	TE	109	4	N	None	Recovered
			Musculoskeletal pain	筋骨格痛	3	Y	TE	112	8	N	None	Recovered
			Depression	うつ病	2	N	TE	112	50	N	None	Recovered
			Nausea	悪心	1	N	TE	116	4	Y	None	Recovered
			Anaemia	貧血	2	N	TE	137	1	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	2	N	TE	166		N	None	Ongoing at study termination / withdrawal
			Femoral neck fracture	大腿骨頚部骨折	3	Y	TE	191	7	N	Not applicable	Recovered
003018	Norway	71/M/C	Constipation	便秘	2	N	TE			N	Not applicable	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	2	N	TE	2	134	N	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	1	N	TE	57	102	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	116	57	N	Not applicable	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	3	N	TE	135	24	N	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	2	N	TE	147	72	N	Not applicable	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	3	Y	TE	158	5	N	Not applicable	Recovered with sequelae
			Pelvic pain	骨盤痛	3	N	TE	162		Y	Not applicable	Ongoing at time of death
			Nausea	悪心	2	N	TE	172		N	Not applicable	Ongoing at time of death
			Weight decreased	体重減少	3	N	TE	172		N	Not applicable	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	3	Y	TE	172	38	N	Not applicable	Recovered with sequelae
			Gastric ulcer	胃潰瘍	3	N	TE	181		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	187	1	Y	Not applicable	Recovered
			Depression	うつ病	3	N	TE	208		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	218	1	N	Not applicable	Death
004001	Norway	60/M/C	Dysgeusia	味覚異常	1	N	TE	2	28	Y	None	Recovered
			Anaemia	貧血	1	N	TE	92	24	Y	None	Recovered
			Anaemia	貧血	1	N	TE	92	24	Y	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	92	113	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	120		Y	None	Ongoing at time of death
			Respiratory tract infection viral	ウイルス性気道感染	2	N	TE	134	11	N	None	Recovered
			Anaemia	貧血	2	N	TE	144		Y	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	2	N	TE	148	37	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	148	12	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	148	12	Y	None	Recovered with sequelae
			Pancytopenia	汎血球減少症	3	N	TE	155	5	Y	Not applicable	Recovered with sequelae
			Pancytopenia	汎血球減少症	3	Y	TE	159	11	Y	Not applicable	Recovered with sequelae
			Oedema	浮腫	2	Y	TE	159	11	Y	Not applicable	Recovered with sequelae
			Dyspnoea	呼吸困難	3	Y	TE	159	11	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	Y	TE	159	11	Y	Not applicable	Recovered with sequelae
			Pancytopenia	汎血球減少症	2	N	TE	169	16	Y	Not applicable	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	2	N	TE	169	16	Y	Not applicable	Recovered
			Pleural effusion	胸水	1	N	TE	170	15	Y	Not applicable	Recovered
			Pancytopenia	汎血球減少症	3	Y	TE	184	15	Y	Not applicable	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	3	Y	TE	184	15	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	Y	TE	184	15	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	Y	TE	184	15	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	198	7	Y	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	198	7	Y	Not applicable	Recovered with sequelae
			Pancytopenia	汎血球減少症	4	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	204		Y	Not applicable	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	3	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Pleural effusion	胸水	2	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Renal failure	腎不全	5	Y	TE	208	1	N	Not applicable	Death
005002	Norway	75/M/C	Bone pain	骨痛	1	N	TE			N	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	85		N	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	162	36	N	Not applicable	Recovered
			Pneumonia	肺炎	3	Y	TE	169	15	N	Not applicable	Recovered
			Atrial fibrillation	心房細動	2	Y	TE	180	1	N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	197	7	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	198	6	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	1	N	TE	203		Y	Not applicable	Ongoing at time of death
			Pulmonary embolism	肺塞栓症	4	Y	TE	222	5	Y	Not applicable	Death
			Pulmonary embolism	肺塞栓症	5	Y	TE	226	1	Y	Not applicable	Death
006001	Norway	76/M/C	Bone pain	骨痛	2	N	TE	75	20	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	82	13	N	None	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	82	13	N	Drug administration postponed	Recovered
			Bone pain	骨痛	3	N	TE	113	27	N	None	Recovered
			Renal failure	腎不全	3	Y	TE	113	8	N	None	Recovered
			Reflux gastritis	逆流性胃炎	1	N	TE	114		N	None	Recovered
			Anaemia	貧血	2	N	TE	167	2	N	Not applicable	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	167	86	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	167	3	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	1	N	TE	168		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hypomagnesaemia	低マグネシウム血症	2	N	TE	191	62	N	None	Not recovered, but no changes expected
			Hypomagnesaemia	低マグネシウム血症	1	N	TE	252		N	None	Not recovered, but no changes expected
006004	Norway	53/M/C	Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE			Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	2	15	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	2	4	Y	None	Recovered
			Nausea	悪心	2	N	TE	15	68	Y	None	Recovered
			Anorexia	食欲不振	2	N	TE	56		N	None	Not recovered, but no changes expected
			Insomnia	不眠症	2	N	TE	166		N	None	Not recovered, but no changes expected
			Upper respiratory tract infection	上気道感染	2	Y	TE	180	10	N	Not applicable	Recovered
			Oesophagitis	食道炎	2	N	TE	217		N	Not applicable	Not recovered, but no changes expected
006005	Norway	72/M/C	Diarrhoea	下痢	1	N	TE	3	1	Y	None	Recovered
			Pyrexia	発熱	2	Y	TE	22	7	N	None	Recovered
			Dehydration	脱水	2	Y	TE	22	7	N	None	Recovered
			Vomiting	嘔吐	1	Y	TE	38	1	N	None	Recovered
			Pyrexia	発熱	2	Y	TE	38	1	Y	None	Recovered
			Dehydration	脱水	2	Y	TE	38	6	Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	2	Y	TE	38	6	N	None	Recovered
			Vomiting	嘔吐	2	Y	TE	62	11	Y	None	Recovered
			Dehydration	脱水	2	Y	TE	62	11	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	62	11	N	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	85	15	N	None	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspepsia	消化不良	2	N	TE	86		N	None	Ongoing at time of death
			Depression	うつ病	2	N	TE	99		N	None	Ongoing at time of death
			Pneumonia	肺炎	3	Y	TE	176	2	N	Not applicable	Death
			Bone pain	骨痛	3	Y	TE	176		N	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	5	Y	TE	177	1	N	Not applicable	Death
006008	Norway	70/M/C	Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	Pre	-1	29	N	None	Ongoing at time of death
			Hydronephrosis	水腎症	3	Y	Pre	-1	3	N	None	Recovered
			Constipation	便秘	2	N	TE	2	25	Y	None	Recovered
			Nausea	悪心	1	N	TE	2	6	Y	None	Recovered
			Fatigue	疲労	2	N	TE	2	6	N	None	Recovered
			Hyperhidrosis	多汗症	2	N	TE	2	6	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	17	11	N	None	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	Pre	28		N	None	Ongoing at time of death
			Small intestinal obstruction	小腸閉塞	3	Y	TE	55	3	N	Drug administration postponed	Recovered
			Death	死亡	5	Y	TE	60	1	N	Drug permanently withdrawn	Death
006009	Norway	75/M/C	Dizziness	浮動性めまい	1	N	TE			N	None	Recovered
			Diarrhoea	下痢	1	N	TE	2	1	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	2	2	Y	None	Recovered
			Fatigue	疲労	3	Y	TE	16	9	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dehydration	脱水	2	N	TE	19	6	Y	None	Recovered
			Influenza	インフルエンザ	1	N	TE	43	8	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	73	12	Y	None	Recovered
			Nausea	悪心	1	N	TE	84	37	N	None	Recovered
			Fatigue	疲労	2	N	TE	84		Y	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	84	29	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	84	29	Y	None	Ongoing at study termination / withdrawal
			Mood altered	気分変化	1	N	TE	84		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	107		N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	112	5	Y	None	Recovered
			Anorexia	食欲不振	2	N	TE	112		Y	None	Ongoing at study termination / withdrawal
			Cachexia	悪液質	2	N	TE	112		N	Not applicable	Ongoing at study termination / withdrawal
006011	Norway	68/M/C	Weight decreased	体重減少	2	N	TE	2		Y	None	Not recovered, but no changes expected
			Diarrhoea	下痢	1	N	TE	8	10	N	None	Recovered
			Nausea	悪心	1	N	TE	8	10	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	8	10	N	None	Recovered
			Bone pain	骨痛	2	N	TE	28	29	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	36	10	N	None	Recovered
			Nausea	悪心	1	N	TE	36	10	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	1	N	TE	36	10	N	None	Recovered
			Bone pain	骨痛	2	N	TE	103	6	N	None	Recovered
			Nausea	悪心	1	N	TE	114	27	Y	None	Recovered
			Fatigue	疲労	1	N	TE	114		Y	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	114	27	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	140	16	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	Y	TE	155	13	N	Not applicable	Recovered with sequelae
			Nausea	悪心	2	N	TE	157	11	N	None	Recovered
			Anaemia	貧血	2	N	TE	225		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	225	64	N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	225	4	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	4	N	TE	288		N	Not applicable	Ongoing at time of death
006016	Norway	59/M/C	Thrombocytopenia	血小板減少症	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	92	8	N	None	Recovered
			Venous thrombosis	静脈血栓症	2	N	TE	105		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	132		N	None	Ongoing at time of death
			Prostatic haemorrhage	前立腺出血	3	Y	TE	132	29	N	Drug administration postponed	Recovered
			Bone pain	骨痛	2	N	TE	141		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Catheter related infection	カテーテル関連感染	3	Y	TE	166		N	Drug permanently withdrawn	Recovered
006017	Norway	59/M/C	Nausea	悪心	1	N	TE	10	3	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	10	1	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	10	75	N	None	Recovered
			Bone pain	骨痛	2	N	TE	10	75	N	None	Recovered
			Anaemia	貧血	3	Y	TE	84	6	Y	-	
			Thrombocytopenia	血小板減少症	4	Y	TE	84	58	Y	Drug permanently withdrawn	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	84		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	Y	TE	89	3	Y	-	
			Anaemia	貧血	2	Y	TE	91	8	Y	-	
			Anaemia	貧血	3	Y	TE	98	13	Y	-	
			Anaemia	貧血	2	Y	TE	110	2	Y	-	
			Anaemia	貧血	3	Y	TE	111	2	Y	-	
			Anaemia	貧血	2	Y	TE	112	2	Y	-	
			Anaemia	貧血	1	Y	TE	113	2	Y	-	
			Cerebral haemorrhage	脳出血	2	Y	TE	113		Y	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	114	19	Y	-	
			Anaemia	貧血	1	Y	TE	132	3	Y	-	
			Anaemia	貧血	2	Y	TE	134	2	Y	-	
			Anaemia	貧血	1	Y	TE	135	2	Y	-	
			Anaemia	貧血	2	Y	TE	136	3	Y	Drug permanently withdrawn	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	Y	TE	138	3	Y	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	140		Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	Y	TE	141	2	Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	Y	TE	142		Y	Drug permanently withdrawn	Ongoing at time of death
006018	Norway	62/M/C	Pyrexia	発熱	2	N	TE	25	2	Y	None	Recovered
			Pyrexia	発熱	1	N	TE	26	2	Y	None	Recovered
			Weight decreased	体重減少	1	N	TE	33	29	N	None	Not recovered, but no changes expected
			Nausea	悪心	2	N	TE	37	2	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	37	2	N	None	Recovered
			Pyrexia	発熱	2	Y	TE	37	8	Y	None	Recovered
			Anaemia	貧血	2	N	TE	40	3	Y	None	Recovered
			Nausea	悪心	2	N	TE	48	29	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	48	2	N	None	Recovered
			Pyrexia	発熱	2	Y	TE	49	21	Y	None	Recovered
			Anaemia	貧血	2	N	TE	59	2	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	61		N	None	Not recovered, but no changes expected
			Pyrexia	発熱	2	Y	TE	76	2	Y	None	Recovered with sequelae
			Dyspnoea	呼吸困難	1	N	TE	76	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	89	2	N	None	Recovered
			Bone pain	骨痛	2	N	TE	89	26	N	None	Recovered
			Anaemia	貧血	2	N	TE	114	20	N	-	

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pyrexia	発熱	2	N	TE	114	4	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	114	7	N	None	Recovered
			Pyrexia	発熱	2	N	TE	120		Y	None	Recovered
			Spinal cord compression	脊髄圧迫	2	Y	TE	132	7	N	None	Recovered
			Anaemia	貧血	1	N	TE	133	1	N	-	
			Anaemia	貧血	2	N	TE	133	9	N	-	
			Anaemia	貧血	1	N	TE	141	28	N	-	
			Anaemia	貧血	2	N	TE	168	9	N	-	
			Leukopenia	白血球減少症	2	N	TE	168	15	N	None	Recovered
			Neutropenia	好中球減少症	1	N	TE	168	14	N	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	168	31	N	None	Recovered
			Anaemia	貧血	1	N	TE	176	7	N	-	
			Anorexia	食欲不振	1	N	TE	176	14	N	None	Recovered
			Bone pain	骨痛	2	N	TE	176	14	N	None	Recovered
			Bone pain	骨痛	2	N	TE	176	54	N	None	Recovered
			Diplopia	複視	2	N	TE	177	53	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	181	10	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	TE	182	8	N	-	
			Leukopenia	白血球減少症	1	N	TE	182	8	N	None	Recovered
			Pyrexia	発熱	2	N	TE	182	1	Y	None	Recovered
			Pyrexia	発熱	1	N	TE	182	5	Y	None	Recovered
			Anaemia	貧血	1	N	TE	189	10	N	-	
			Leukopenia	白血球減少症	3	N	TE	189	41	N	None	Recovered
			Neutropenia	好中球減少症	2	N	TE	189	10	N	None	Recovered
			Bone pain	骨痛	1	N	TE	190	40	N	None	Recovered
			Anaemia	貧血	2	N	TE	198	35	N	None	Not recovered, but no changes expected
			Neutropenia	好中球減少症	3	N	TE	198	32	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	198	32	N	None	Recovered
			Diplopia	複視	1	N	TE	229		N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	232		N	None	Not recovered, but no changes expected
006020	Norway	77/M/C	Nausea	悪心	1	N	TE			N	None	Recovered
			Anorexia	食欲不振	1	N	TE	28	134	N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	64	36	N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	2	N	TE	99		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	161		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	198	22	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	TE	205	6	N	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	1	N	TE	210		N	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	219		N	None	Not recovered, but no changes expected
			Constipation	便秘	2	N	TE	232	3	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	232	4	N	Not applicable	Recovered with sequelae
006024	Norway	67/M/C	Gastrointestinal pain	消化器痛	3	Y	Pre	-9	2	N	None	Recovered
			Constipation	便秘	2	N	Pre	-1	29	N	None	Recovered
			Fatigue	疲労	2	N	TE	28	92	N	None	Recovered
			Arthralgia	関節痛	1	N	TE	91	29	N	None	Not recovered, but no changes expected
			Paraesthesia	錯感覚	1	N	TE	91	29	N	None	Recovered
			Arthralgia	関節痛	2	N	TE	119	36	N	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Arthralgia	関節痛	1	N	TE	154		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	182	64	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	245		N	None	Not recovered, but no changes expected
006026	Norway	71/M/C	Nausea	悪心	1	N	TE			Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	2	8	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	55	10	N	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	64	11	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	70	3	Y	-	Ongoing at study termination / withdrawal
			Insomnia	不眠症	2	N	TE	71		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	72		Y	-	Ongoing at study termination / withdrawal
			Accidental overdose	偶発的過量投与	2	Y	TE	75	2	N	None	Recovered
			Infection	感染	3	N	TE	87		N	Not applicable	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	Y	TE	87		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Confusional state	錯乱状態	2	N	TE	87		N	None	Ongoing at study termination / withdrawal
006030	Norway	64/M/C	Insomnia	不眠症	1	N	TE			N	None	Lost to follow-up
			Spinal cord compression	脊髄圧迫	3	Y	TE	12	7	N	Drug administration postponed	Recovered
			Weight decreased	体重減少	2	N	TE	47	57	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	62	14	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	103	29	N	None	Recovered
			Bone pain	骨痛	1	N	TE	103		Y	None	Ongoing at study termination / withdrawal
			Leukopenia	白血球減少症	2	N	TE	131	29	Y	None	Recovered
			Neutropenia	好中球減少症	2	N	TE	131	29	Y	None	Recovered
			Leukopenia	白血球減少症	1	N	TE	159	92	Y	None	Recovered
			Neutropenia	好中球減少症	1	N	TE	159	31	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	159		Y	None	Ongoing at study termination / withdrawal
			Metastases to central nervous system	中枢神経系転移	3	Y	TE	184	27	N	Not applicable	Recovered with sequelae
			Nausea	悪心	2	N	TE	195		N	Not applicable	Recovered
			Vomiting	嘔吐	2	N	TE	195		N	Not applicable	Recovered
			Dysarthria	構語障害	2	N	TE	195	16	N	Not applicable	Recovered
006032	Norway	77/M/C	Musculoskeletal pain	筋骨格痛	1	Y	Pre	-5	2	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	Pre	-1	29	N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	28		N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	1	N	TE	30	62	N	None	Recovered
			Nausea	悪心	1	N	TE	31	4	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	31	4	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	91		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	91	65	N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	92	64	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	119	37	N	None	Recovered
			Urinary retention	尿閉	2	N	TE	119		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	155		N	None	Ongoing at time of death
006036	Norway	76/M/C	Patella fracture	膝蓋骨骨折	2	Y	TE	12	2	N	None	Recovered with sequelae
			Patella fracture	膝蓋骨骨折	2	N	TE	13	16	N	None	Recovered
			Anaemia	貧血	1	N	TE	28	85	N	-	
			Neutropenia	好中球減少症	1	N	TE	28	113	N	None	Recovered
			Nausea	悪心	2	N	TE	28	29	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	28	57	N	None	Recovered
			Anorexia	食欲不振	2	N	TE	28	85	N	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	56		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	56	85	N	None	Recovered with sequelae
			Oedema genital	性器浮腫	2	N	TE	80	5	N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	84	57	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema genital	性器浮腫	1	N	TE	84	57	N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	112	72	N	-	
			Nausea	悪心	1	N	TE	140		N	None	Ongoing at time of death
			Localised oedema	限局性浮腫	1	N	TE	140	18	N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	140	18	N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	140		N	None	Ongoing at time of death
			Oedema genital	性器浮腫	2	N	TE	140		N	None	Ongoing at time of death
			Lymphadenopathy mediastinal	縦隔リンパ節腫脹	2	N	TE	154		N	None	Ongoing at time of death
			Metastases to lung	肺転移	2	N	TE	154		N	None	Ongoing at time of death
			Localised oedema	限局性浮腫	2	N	TE	157		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	157		N	None	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	TE	170	8	N	None	Recovered
			Anaemia	貧血	1	N	TE	183	15	N	-	
			Pleural effusion	胸水	2	N	TE	196	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	197	5	N	-	
			Haematuria	血尿	3	Y	TE	197	21	N	Not applicable	Recovered
			Pneumonia	肺炎	2	N	TE	200	19	N	None	Recovered
			Anaemia	貧血	1	N	TE	201	2	N	-	
			Anaemia	貧血	2	N	TE	202	2	N	-	
			Anaemia	貧血	1	N	TE	203	4	N	-	
			Anaemia	貧血	2	N	TE	206	3	N	-	
			Anaemia	貧血	1	N	TE	208	5	N	-	

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	212	2	N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	213		N	None	Ongoing at time of death
006038	Norway	60/M/C	Bone pain	骨痛	3	Y	Pre	-46	3	N	Not applicable	Recovered
			Pyelonephritis	腎盂腎炎	3	Y	TE	61	10	N	None	Recovered
			Constipation	便秘	2	N	TE	63		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	64	2	N	-	
			Anaemia	貧血	1	N	TE	65	13	N	-	
			Anaemia	貧血	2	N	TE	77	28	N	-	
			Vomiting	嘔吐	2	N	TE	77	3	Y	None	Recovered
			General physical health deterioration	全身健康状態低下	3	Y	TE	77	16	N	Drug administration postponed	Recovered with sequelae
			Infection	感染	3	Y	TE	77	16	N	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	78	18	N	Not applicable	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	78	18	N	None	Recovered with sequelae
			Pyrexia	発熱	1	N	TE	79	8	Y	None	Recovered
			Pyrexia	発熱	2	N	TE	86	2	Y	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	90		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	2	N	TE	95	7	N	Not applicable	Ongoing at study termination / withdrawal
			Pyrexia	発熱	1	N	TE	95	3	Y	None	Recovered
			Bone pain	骨痛	3	Y	TE	95	11	N	None	Recovered with sequelae
			Pyrexia	発熱	2	N	TE	97	4	Y	None	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	101		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	N	TE	104		N	Not applicable	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	105		N	None	Ongoing at study termination / withdrawal
006039	Norway	72/M/C	Nausea	悪心	1	N	TE	2	8	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	72	36	N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	82	26	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	99	34	N	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	2	N	TE	99		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	111	11	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	111	11	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	111	11	N	None	Recovered
			Constipation	便秘	2	N	TE	131	7	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	N	TE	131		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Spinal cord compression	脊髄圧迫	3	Y	TE	131		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Urinary retention	尿閉	2	N	TE	131		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	N	TE	132	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	133	9	N	None	Recovered
006040	Norway	72/M/C	Pain	疼痛	1	N	Pre	-1	29	N	None	Recovered
			Bone pain	骨痛	2	N	TE	84	14	N	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	97	4	N	None	Recovered with sequelae
			Insomnia	不眠症	2	N	TE	97		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	98	5	N	None	Recovered
			Bone pain	骨痛	2	N	TE	99	9	Y	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	102	5	N	None	Recovered
			Vomiting	嘔吐	2	Y	TE	102	10	N	None	Recovered
			Infection	感染	3	N	TE	102	6	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	105	7	N	None	Recovered
			Nausea	悪心	1	N	TE	106	6	N	None	Recovered
			Infection	感染	2	N	TE	107	3	N	None	Recovered
			Bone pain	骨痛	1	N	TE	107		Y	None	Ongoing at study termination / withdrawal
			Infection	感染	1	N	TE	109	3	N	None	Recovered
			Nausea	悪心	2	N	TE	117	5	Y	None	Recovered
			Vomiting	嘔吐	2	Y	TE	117	8	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Infection	感染	3	N	TE	117	5	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	119		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	121	9	Y	None	Recovered
			Infection	感染	2	N	TE	121	11	Y	None	Recovered
			Duodenitis	十二指腸炎	1	N	TE	124		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	129	3	Y	None	Recovered
			Vomiting	嘔吐	2	Y	TE	129	3	N	None	Recovered
			Nausea	悪心	2	N	TE	136		Y	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	3	Y	TE	136		N	None	Ongoing at study termination / withdrawal
			Infection	感染	2	N	TE	136		N	None	Ongoing at study termination / withdrawal
			Hypomagnesaemia	低マグネシウム血症	1	N	TE	138		N	None	Ongoing at study termination / withdrawal
			Constipation	便秘	2	N	TE	140		Y	None	Ongoing at study termination / withdrawal
			Pulmonary oedema	肺水腫	2	N	TE	141	3	N	None	Recovered
006041	Norway	56/M/C	Nausea	悪心	1	N	TE	1	8	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	8	161	Y	None	Recovered
			Nausea	悪心	1	N	TE	29	19	Y	None	Recovered
			Nausea	悪心	1	N	TE	65	14	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	65	14	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	98	71	Y	None	Recovered
			Nausea	悪心	1	N	TE	99	4	Y	None	Recovered
			Pneumonia	肺炎	2	Y	TE	104	6	N	None	Recovered
			Nausea	悪心	1	N	TE	135	59	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	135	35	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	169	25	Y	None	Recovered
			Pyrexia	発熱	1	N	TE	173	4	Y	Not applicable	Recovered
			Infection	感染	2	Y	TE	173	8	N	Not applicable	Recovered
			Bone pain	骨痛	3	N	TE	173	4	N	Not applicable	Recovered
			Leukopenia	白血球減少症	2	N	TE	176	21	Y	Not applicable	Recovered
			Neutropenia	好中球減少症	1	N	TE	177	2	Y	Not applicable	Recovered
			Neutropenia	好中球減少症	2	N	TE	178	19	Y	Not applicable	Recovered
			Leukopenia	白血球減少症	1	N	TE	196	48	Y	Not applicable	Recovered
			Neutropenia	好中球減少症	1	N	TE	196	48	Y	Not applicable	Recovered
			Pyrexia	発熱	1	N	TE	243	4	N	Not applicable	Recovered
			Infection	感染	3	Y	TE	243	38	N	Not applicable	Recovered
			Cough	咳嗽	1	N	TE	243	4	N	Not applicable	Recovered
			Hypotension	低血圧	2	N	TE	243	1	N	Not applicable	Recovered
006046	Norway	76/M/C	Dizziness	浮動性めまい	1	N	TE			N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	Pre	-1	59	N	None	
			Bone pain	骨痛	1	N	TE	28	57	N	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	56	3	Y	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	58	5	N	None	
			Leukopenia	白血球減少症	2	N	TE	58	3	Y	None	Recovered
			Nausea	悪心	2	N	TE	58	3	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	58	2	Y	None	Recovered
			Pyrexia	発熱	3	Y	TE	58	3	Y	None	Recovered
			Pyrexia	発熱	1	N	TE	58	2	N	None	Recovered
			Dyspnoea	呼吸困難	2	Y	TE	58	3	Y	None	Recovered with sequelae
			Cardiomegaly	心拡大	2	N	TE	59	39	N	None	Recovered
			Leukopenia	白血球減少症	3	N	TE	60	3	Y	None	Recovered
			Neutropenia	好中球減少症	3	Y	TE	60	3	Y	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	60	25	N	None	Recovered
			Anaemia	貧血	1	N	TE	62	126	N	None	
			Leukopenia	白血球減少症	1	N	TE	62	23	Y	None	Recovered
			Hypertension	高血圧	2	N	TE	97	77	N	None	Recovered
			Anaemia	貧血	2	N	TE	187	2	N	-	
			Abdominal pain	腹痛	3	Y	TE	187	4	N	Not applicable	Recovered
			Diarrhoea	下痢	2	N	TE	187	3	N	Not applicable	Recovered
			Rectal haemorrhage	直腸出血	2	N	TE	187	4	N	Not applicable	Recovered
			Vomiting	嘔吐	2	N	TE	187	3	N	Not applicable	Recovered
			Chills	悪寒	2	N	TE	187	3	N	Not applicable	Recovered
			Anaemia	貧血	1	N	TE	188	1	N	-	
			Anaemia	貧血	2	N	TE	188	2	N	-	

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Infection	感染	2	N	TE	188	3	N	Not applicable	Recovered
			Anaemia	貧血	1	N	TE	189		N	Not applicable	Not recovered, but no changes expected
			Diarrhoea	下痢	1	N	TE	189	2	N	Not applicable	Recovered
			Pyrexia	発熱	2	N	TE	193	4	N	Not applicable	Recovered
			Infection	感染	3	Y	TE	193	19	N	Not applicable	Recovered
			Pyrexia	発熱	1	N	TE	196	3	N	Not applicable	Recovered
			Pyrexia	発熱	2	N	TE	202		N	Not applicable	Recovered
006047	Norway	73/M/C	Nausea	悪心	1	N	TE	2	23	N	None	Recovered
			Nausea	悪心	1	N	TE	28	21	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	55	22	Y	-	
			Nausea	悪心	1	N	TE	57	27	Y	None	Recovered
			Nerve root compression	神経根圧迫	3	Y	TE	76	6	N	None	Recovered
			Bone pain	骨痛	1	N	TE	81		N	None	Not recovered, but no changes expected
			Oedema peripheral	末梢性浮腫	1	N	TE	111		N	None	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	1	N	TE	111	57	N	None	Recovered
			Epigastric discomfort	心窩部不快感	1	N	TE	167	43	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	167	43	Y	Not applicable	Recovered
006052	Norway	73/M/C	Constipation	便秘	2	N	TE	14	2	N	None	Recovered
			Hydronephrosis	水腎症	3	Y	TE	14	5	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary retention	尿閉	2	N	TE	27	1	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	70	6	N	None	Recovered
			Nausea	悪心	2	N	TE	70	4	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	70	4	N	None	Recovered
			Pyrexia	発熱	1	N	TE	70	4	N	None	Recovered
			Sepsis	敗血症	3	Y	TE	70	6	N	None	Recovered
			Anaemia	貧血	2	N	TE	71	2	Y	None	
			Thrombocytopenia	血小板減少症	1	N	TE	71	3	Y	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	71	4	N	None	Recovered
			Anaemia	貧血	1	N	TE	72	40	Y	None	
			Weight decreased	体重減少	2	N	TE	83	29	N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	111	29	Y	None	
			Thrombocytopenia	血小板減少症	1	N	TE	111	85	N	None	Not recovered, but no changes expected
			Oedema peripheral	末梢性浮腫	1	N	TE	111	83	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	111	29	N	None	Not recovered, but no changes expected
			Urinary retention	尿閉	3	Y	TE	131	4	N	None	Recovered
			Anaemia	貧血	1	N	TE	139	28	Y	None	
			Weight decreased	体重減少	2	N	TE	139		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	166	28	Y	None	
			Bone pain	骨痛	1	N	TE	167	21	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	187	18	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	3	N	TE	193	3	Y	None	
			Leukopenia	白血球減少症	3	N	TE	193	3	Y	Not applicable	Recovered
			Neutropenia	好中球減少症	2	N	TE	193	3	Y	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Chills	悪寒	2	N	TE	193	1	N	Not applicable	Recovered
			Fatigue	疲労	3	N	TE	193	2	N	Not applicable	Not recovered, but no changes expected
			Pyrexia	発熱	3	N	TE	193	1	N	Not applicable	Recovered
			Pyrexia	発熱	2	N	TE	193	5	N	Not applicable	Recovered
			Urosepsis	尿路性敗血症	3	Y	TE	193	12	N	Not applicable	Recovered
			Fatigue	疲労	2	N	TE	194		N	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	195	3	N	Not applicable	Not recovered, but no changes expected
			Leukopenia	白血球減少症	1	N	TE	195	3	Y	Not applicable	Recovered
			Neutropenia	好中球減少症	1	N	TE	195	3	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	195	11	N	None	Not recovered, but no changes expected
			Anaemia	貧血	1	N	TE	197		N	Not applicable	Not recovered, but no changes expected
			Pyrexia	発熱	1	N	TE	197		N	Not applicable	Recovered
			Bone pain	骨痛	2	Y	TE	204	5	N	Not applicable	Recovered with sequelae
			Thrombocytopenia	血小板減少症	1	N	TE	205		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	208		N	Not applicable	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
006055	Norway	63/M/C	Petechiae	点状出血	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Nerve root compression	神経根圧迫	3	Y	Pre	-33	4	N	None	Recovered
			Groin pain	鼠径部痛	2	N	Pre	-2	3	N	None	Recovered
			Nerve root compression	神経根圧迫	3	Y	TE	1	4	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	1	4	N	None	Recovered
			Pyrexia	発熱	1	N	TE	23	3	N	None	Recovered
			Oedema peripheral	末梢性浮腫	3	Y	TE	24	4	N	None	Recovered with sequelae
			Hypoalbuminaemia	低アルブミン血症	2	N	TE	24	4	N	None	Ongoing at study termination / withdrawal
			Hypoaesthesia	感覚鈍麻	1	N	TE	24		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	27	8	N	None	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	2	N	TE	27	8	N	None	Ongoing at study termination / withdrawal
			Hypoalbuminaemia	低アルブミン血症	1	N	TE	27		N	None	Ongoing at study termination / withdrawal
			Cardiac failure	心不全	2	N	TE	28		N	None	Ongoing at study termination / withdrawal
			Pyrexia	発熱	1	N	TE	28	2	N	None	Recovered
			Pneumonia	肺炎	3	Y	TE	28	6	N	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	28	7	N	None	Recovered
			Pleural effusion	胸水	2	N	TE	28	7	N	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	30	3	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pulmonary hypertension	肺高血圧症	2	N	TE	32		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	34	5	N	None	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	1	N	TE	34		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	38	31	N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	52	18	N	None	Ongoing at study termination / withdrawal
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	Y	TE	52	3	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	53	11	N	None	Recovered
			Thrombocytopenia	血小板減少症	4	Y	TE	66	2	Y	Drug administration postponed	Recovered with sequelae
			Hypokalaemia	低カリウム血症	1	N	TE	66		N	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	Y	TE	66		N	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	3	N	TE	67	4	N	None	Ongoing at study termination / withdrawal
			Urinary tract infection	尿路感染	1	N	TE	67		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	N	TE	68		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE	69		N	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	3	N	TE	70		N	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	4	N	TE	70	1	N	None	Ongoing at study termination / withdrawal
			General physical health deterioration	全身健康状態低下	3	N	TE	71		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	84	1	N	Not applicable	Death
008001	Norway	66/M/C	Haemorrhoids	痔核	1	N	TE			N	None	Recovered
			Decreased appetite	食欲減退	2	N	TE			N	None	Ongoing at time of death
			Depressed mood	抑うつ気分	2	N	TE			N	None	Ongoing at time of death
			Pathological fracture	病的骨折	3	Y	Pre	-48	14	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	Pre	-26	15	Y	-	
			Post procedural infection	処置後感染	3	Y	Pre	-26	29	N	Drug administration postponed	Recovered
			Nausea	悪心	1	N	Pre	-20	77	N	None	Recovered
			Vomiting	嘔吐	1	N	Pre	-20	77	N	None	Recovered
			Anaemia	貧血	1	N	Pre	-12	4	Y	-	
			Anaemia	貧血	2	N	Pre	-9	86	Y	-	
			Soft tissue infection	軟部組織感染	2	N	TE	3		N	None	Recovered
			Nausea	悪心	2	N	TE	57	14	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	57		N	None	Ongoing at time of death
			Nausea	悪心	2	Y	TE	70	11	N	None	Recovered
			Anaemia	貧血	1	N	Pre	77	51	Y	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	86	7	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	92		N	Not applicable	Ongoing at time of death
			Pyrexia	発熱	2	N	TE	112	1	N	None	Recovered
			Anaemia	貧血	2	N	Pre	127		Y	None	Ongoing at time of death
008003	Norway	79/M/C	Nausea	悪心	2	N	Pre	1	25	N	None	Recovered
			Nausea	悪心	2	Y	TE	25	4	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	25		N	None	Ongoing at time of death
			Hypercalcaemia	高カルシウム血症	1	N	TE	25	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	27	2	Y	None	Recovered
			Nausea	悪心	2	N	TE	28		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	35	25	N	Drug permanently withdrawn	Recovered
			Dehydration	脱水	2	N	TE	51		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	59	1	N	Not applicable	Death
008007	Norway	62/M/C	Fatigue	疲労	1	N	TE			N	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	1	N	TE			N	Not applicable	Recovered
			Anaemia	貧血	1	N	Pre	1	85	Y	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	21	78	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	85	16	Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	98		N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	98	13	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	99	1	N	Not applicable	Recovered
			Anaemia	貧血	1	N	TE	100		Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	106		N	Not applicable	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	106	1	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	110		N	Not applicable	Ongoing at time of death
			Infection	感染	3	Y	TE	112	6	N	Not applicable	Recovered
008008	Norway	74/M/C	Anorexia	食欲不振	1	N	TE			Y	None	Not recovered, but no changes expected
			Fatigue	疲労	2	N	Pre	-1		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	1		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	29	40	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	2	N	TE	29		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	3	Y	TE	68	1	Y	None	Recovered
			Anaemia	貧血	2	N	TE	68	78	Y	-	
			Atrial fibrillation	心房細動	3	N	TE	68	1	Y	None	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	131	38	Y	-	
			Leukopenia	白血球減少症	2	N	TE	141	14	Y	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	145	1	Y	-	
			Anaemia	貧血	2	N	TE	145	16	Y	-	
			Leukopenia	白血球減少症	1	N	TE	154	7	Y	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	160	7	Y	-	
			Leukopenia	白血球減少症	2	N	TE	160	35	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	166	18	Y	-	
			Thrombocytopenia	血小板減少症	4	N	TE	168	7	Y	-	
			General physical health deterioration	全身健康状態低下	2	Y	TE	168	2	Y	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	169		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	174	28	Y	-	
			Anaemia	貧血	3	N	TE	183	7	Y	-	
			Anaemia	貧血	2	N	TE	189	13	Y	-	
			Anaemia	貧血	1	N	TE	201	8	Y	-	
			Thrombocytopenia	血小板減少症	4	N	TE	201	39	Y	-	
			Anaemia	貧血	2	N	TE	208	31	Y	-	
			Leukopenia	白血球減少症	3	N	Post	236	2	Y	-	
			Leukopenia	白血球減少症	2	N	Post	237	17	Y	-	
			Anaemia	貧血	1	N	TE	238	2	Y	-	
			Anaemia	貧血	2	N	TE	239	15	Y	-	
			Thrombocytopenia	血小板減少症	3	N	TE	239	7	Y	-	
			Thrombocytopenia	血小板減少症	4	N	TE	245	16	Y	-	

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	253	5	Y	-	
			Leukopenia	白血球減少症	3	N	Post	253	11	Y	-	
			Anaemia	貧血	2	N	TE	257	2	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	258	13	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	260	3	Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	262		Y	Drug permanently withdrawn	Ongoing at time of death
			Leukopenia	白血球減少症	4	N	Post	263	5	Y	Not applicable	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	Post	267	4	Y	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	270		Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	Post	270		Y	Not applicable	Ongoing at time of death
008011	Norway	69/M/C	Nausea	悪心	1	N	TE			N	None	Recovered
			Vomiting	嘔吐	1	N	TE			N	None	Recovered
			Fatigue	疲労	1	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE	2	2	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	2	2	N	None	Recovered
			Tendonitis	腱炎	2	N	TE	35		N	None	Recovered
			Constipation	便秘	1	N	TE	37		N	None	Recovered
			Nausea	悪心	1	N	TE	37	5	N	None	Recovered
			Musculoskeletal stiffness	筋骨格硬直	2	N	TE	99	15	N	None	Recovered
			Pharyngitis	咽頭炎	1	N	TE	138	3	N	None	Recovered
			Pathological fracture	病的骨折	2	N	TE	149		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Spinal cord compression	脊髄圧迫	3	Y	TE	149	9	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	2	N	TE	157	10	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	166	6	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	167	22	N	None	Recovered
			Spinal cord compression	脊髄圧迫	3	N	TE	171	42	N	Not applicable	Ongoing at time of death
			Subileus	亜イレウス	2	Y	TE	181	4	N	Not applicable	Recovered
			Oesophageal pain	食道痛	1	N	TE	198	1	N	Not applicable	Recovered
			Cystitis	膀胱炎	1	N	TE	201	11	N	Not applicable	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	212	1	N	Not applicable	Death
008013	Norway	77/M/C	Weight decreased	体重減少	2	N	TE	15		Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	1	N	TE	29		N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	29	50	N	None	Recovered
			Nausea	悪心	1	N	TE	57	22	N	None	Recovered
			Pathological fracture	病的骨折	2	N	TE	73		N	None	Not recovered, but no changes expected
			Atrial fibrillation	心房細動	3	Y	TE	221	5	N	Not applicable	Recovered
008015	Norway	63/M/C	Vomiting	嘔吐	1	N	TE			N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	2	N	TE			N	None	Not recovered, but no changes expected
			Diarrhoea	下痢	1	N	TE	1	9	Y	None	Recovered
			Nausea	悪心	1	N	TE	1	9	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Skin laceration	皮膚裂傷	2	N	TE	28	1	N	None	Recovered
			Anaemia	貧血	1	N	TE	29		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	74	45	N	None	Not recovered, but no changes expected
			Constipation	便秘	2	N	TE	114		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	116	3	N	None	Recovered
			Nausea	悪心	2	N	TE	117	29	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	118	8	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	125		N	None	Not recovered, but no changes expected
			Nausea	悪心	3	Y	TE	145	10	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	154		N	Not applicable	Not recovered, but no changes expected
			Urinary retention	尿閉	1	N	TE	180	1	N	Not applicable	Recovered
010008	Czech Republic	75/M/C	Viral infection	ウイルス感染	1	N	TE	84	8	N	None	Recovered
			Anaemia	貧血	3	N	TE	91	13	N	Drug permanently withdrawn	Recovered with sequelae
			Leukopenia	白血球減少症	2	N	TE	91	127	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	98	52	N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	2	N	TE	98	21	N	Not applicable	Recovered
			Anaemia	貧血	3	Y	TE	103	12	N	Drug permanently withdrawn	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	114	266	N	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	149	69	N	None	Recovered
			Anaemia	貧血	3	N	TE	379		N	Not applicable	Ongoing at time of death
011006	Czech Republic	68/M/C	Diarrhoea	下痢	1	N	TE	2	11	Y	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	150	256	Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	Y	TE	405		Y	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	4	Y	Post	405	2	Y	Not applicable	Death
			Pneumonia	肺炎	5	Y	Post	406	1	Y	Not applicable	Death
012001	Czech Republic	60/M/C	Blood testosterone abnormal	血中テストステロン異常	1	Y	Pre	-35	4	N	None	Recovered
			Anaemia	貧血	3	Y	TE	169	2	Y	Not applicable	Recovered
017003	Czech Republic	80/M/C	Cachexia	悪液質	4	Y	TE	115	10	N	None	Death
			Pneumonitis	肺臓炎	3	N	TE	115		N	None	Ongoing at time of death
			Cachexia	悪液質	5	Y	TE	124	1	N	None	Death
017004	Czech Republic	83/M/C	Angina pectoris	狭心症	3	Y	TE	105	15	N	None	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Depression	うつ病	2	N	TE	105	8	N	Drug administration postponed	Recovered
			Angina pectoris	狭心症	2	N	TE	119	184	N	None	Death
			Hypokalaemia	低カリウム血症	1	N	TE	119		N	None	Not recovered, but no changes expected
			Angina pectoris	狭心症	5	Y	TE	302	1	N	None	Death
017005	Czech Republic	80/M/C	Anaemia	貧血	4	Y	TE	168	7	N	Not applicable	Recovered
			Anorexia	食欲不振	1	N	TE	174		N	None	Not recovered, but no changes expected
017007	Czech Republic	80/M/C	Malignant neoplasm progression	悪性新生物進行	4	Y	TE	178	3	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	180	1	N	Not applicable	Death
017017	Czech Republic	77/M/C	General physical health deterioration	全身健康状態低下	4	Y	TE	151	2	N	Not applicable	Death
			General physical health deterioration	全身健康状態低下	5	Y	TE	152	1	N	Not applicable	Death
017018	Czech Republic	76/M/C	Bone pain	骨痛	1	Y	Pre	-61	10	N	None	Recovered
			Myocardial ischaemia	心筋虚血	4	Y	TE	146		N	Not applicable	Ongoing at time of death
			Myocardial infarction	心筋梗塞	5	Y	TE	154	1	N	Not applicable	Death
017027	Czech Republic	60/M/C	Anaemia	貧血	2	N	TE	79	43	N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	116	6	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	121	1	N	Drug permanently withdrawn	Death
017030	Czech Republic	86/M/C	Leukopenia	白血球減少症			TE			N	None	Recovered
			Anaemia	貧血	2	N	Pre	1		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	28		N	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	Y	TE	50	8	N	None	Recovered
			Thrombocytopenia	血小板減少症	3	Y	TE	50	8	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	Y	TE	57		N	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	5	Y	TE	59	1	N	None	Death
017031	Czech Republic	71/M/C	Duodenal ulcer	十二指腸潰瘍	2	Y	TE	155	6	N	Not applicable	Recovered
			Intervertebral disc disorder	椎間板障害	2	N	TE	202	16	N	Not applicable	Not recovered, but no changes expected
			Intervertebral disc disorder	椎間板障害	3	N	TE	217		N	Not applicable	Not recovered, but no changes expected
017032	Czech Republic	57/M/C	Malignant neoplasm progression	悪性新生物進行	5	Y	TE	97	1	N	None	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
018004	Czech Republic	62/M/C	Bone pain	骨痛	2	N	TE	19	18	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	1	N	TE	19		N	None	Ongoing at time of death
			Gastritis	胃炎	1	Y	TE	127	4	N	None	Recovered
			Pancytopenia	汎血球減少症	4	Y	TE	169	44	Y	Not applicable	Recovered
			Gastritis	胃炎	1	N	TE	169		N	None	Ongoing at time of death
			Metastases to central nervous system	中枢神経系転移	3	N	TE	178		N	None	Ongoing at time of death
020005	Sweden	71/M/C	Anorexia	食欲不振	2	N	TE			N	None	Ongoing at time of death
			Micturition urgency	尿意切迫	2	N	Pre			N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	1	4	Y	None	Recovered
			Fatigue	疲労	2	N	TE	1		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	1		Y	None	Not recovered, but no changes expected
			Musculoskeletal pain	筋骨格痛	1	N	TE	1	4	Y	None	Recovered
			Haematuria	血尿	2	N	TE	11		N	None	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	17	3	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	33	5	Y	None	Recovered
			Constipation	便秘	3	N	TE	39		N	None	Ongoing at study termination / withdrawal
			Chills	悪寒	1	N	TE	54		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	Y	TE	75	14	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	91	22	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	112	1	N	Drug permanently withdrawn	Death
020015	Sweden	74/M/C	Nausea	悪心	1	N	Pre			N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE			N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	N	TE			Y	None	Ongoing at time of death
			Myalgia	筋痛	1	N	Pre			N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE			Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	19		Y	None	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	3	Y	TE	28	15	Y	Drug administration postponed	Recovered with sequelae
			Constipation	便秘	2	N	TE	28		Y	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	28	15	Y	None	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	1	N	TE	42		Y	None	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE	42		Y	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	106	5	N	Drug permanently withdrawn	Death
021002	Sweden	63/M/C	Vomiting	嘔吐	1	N	TE	2	49	N	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	26	10	N	None	Recovered
			Cough	咳嗽	1	N	TE	26		N	None	Recovered
			Nausea	悪心	2	N	TE	30	21	N	None	Recovered
			Erosive duodenitis	びらん性十二指腸炎	3	Y	TE	32	6	Y	None	Recovered
			Erosive duodenitis	びらん性十二指腸炎	2	N	TE	38	16	Y	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	44		N	None	Ongoing at time of death
			Nausea	悪心	3	Y	TE	50	4	N	None	Recovered
			Vomiting	嘔吐	3	Y	TE	50	4	N	None	Recovered
			Anorexia	食欲不振	3	Y	TE	50	4	N	None	Recovered
			Dehydration	脱水	3	Y	TE	50	4	N	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	50	4	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	57	29	N	None	Recovered
			Anxiety	不安	1	N	TE	57		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	63	79	N	None	Recovered
			Bone pain	骨痛	2	N	TE	96	5	N	None	Recovered
			Bone pain	骨痛	2	N	TE	100	42	N	None	Recovered
			Abdominal pain	腹痛	2	N	TE	130	32	N	None	Recovered
			Nausea	悪心	2	N	TE	130	32	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	147	15	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	204	6	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	209	4	N	Not applicable	Recovered
			Oedema peripheral	末梢性浮腫	3	N	TE	210		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	210	3	N	Not applicable	Recovered with sequelae
			Hypoaesthesia	感覚鈍麻	2	N	TE	210		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	212		N	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	213	42	N	None	Recovered
021003	Sweden	63/M/C	Bone pain	骨痛	2	N	Pre	-10	40	N	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	Pre	-7	5	N	None	Recovered
			Weight decreased	体重減少	3	N	Pre	-2		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	Pre	-2	149	N	None	Recovered
			Nausea	悪心	1	N	TE	1		N	None	Recovered
			Paraesthesia	錯感覚	1	N	Pre	1		N	None	Recovered
			Fatigue	疲労	2	N	TE	15	42	N	None	Recovered
			Diarrhoea	下痢	2	Y	TE	29	5	N	None	Recovered
			Myasthenia gravis	重症筋無力症	2	N	TE	29	442	N	None	Recovered
			Myasthenia gravis	重症筋無力症	1	N	TE	29	29	N	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	29		N	None	Recovered
			Pyrexia	発熱	2	Y	TE	44	13	Y	None	Recovered
			Headache	頭痛	1	N	TE	44	11	N	None	Recovered
			Dysphagia	嚥下障害	1	N	TE	57	57	N	None	Recovered
			Pyrexia	発熱	1	N	TE	59	3	N	None	Recovered
			Myalgia	筋痛	1	N	TE	66	4	N	None	Recovered
			Bone pain	骨痛	2	N	TE	72		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	138	12	N	None	Recovered
			Respiratory tract infection	気道感染	1	N	TE	142	12	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	2	N	TE	216	82	N	Not applicable	Recovered
022004	Sweden	84/M/C	Weight decreased	体重減少	1	N	TE	25	151	N	None	Recovered
			Increased upper airway secretion	上気道分泌増加	1	N	TE	98	15	N	None	Recovered
			Nausea	悪心	1	N	TE	101	75	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	116	60	N	None	Recovered with sequelae
			Cystitis	膀胱炎	2	N	TE	141	35	N	None	Recovered
			Sternal fracture	胸骨骨折	2	Y	TE	190	7	N	Not applicable	Recovered
			Anaemia	貧血	1	N	TE	226		N	None	Not recovered, but no changes expected
022009	Sweden	75/M/C	Fatigue	疲労	1	N	TE	116		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	116		N	None	Not recovered, but no changes expected
			Spinal cord compression	脊髄圧迫	3	N	TE	176	67	N	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	178	7	N	Not applicable	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	2	N	TE	242	137	N	Not applicable	Not recovered, but no changes expected
			Spinal cord compression	脊髄圧迫	3	N	TE	378		N	Not applicable	Not recovered, but no changes expected
023003	Sweden	57/M/C	Anorexia	食欲不振	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Haematuria	血尿	2	N	Pre	-7		N	None	Ongoing at time of death
			Cushing's syndrome	クッシング症候群	1	N	TE	29		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	149	82	N	None	Recovered
			Bacterial sepsis	細菌性敗血症	4	Y	TE	149	21	Y	Not applicable	Recovered with sequelae
			Renal failure	腎不全	1	N	TE	150	3	N	None	Recovered
			Oral candidiasis	口腔カンジダ症	2	N	TE	151	18	N	None	Recovered
			Fatigue	疲労	2	N	TE	155		N	None	Ongoing at time of death
024007	Sweden	63/M/C	Insomnia	不眠症	1	N	Pre	-2		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	Pre	-1		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	1	2	Y	None	Recovered
			Cystitis	膀胱炎	2	N	TE	30	41	N	None	Recovered
			Oedema	浮腫	2	N	TE	63	106	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	75		N	None	Not recovered, but no changes expected
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	114		N	None	Not recovered, but no changes expected
			Erysipelas	丹毒	2	N	TE	128		N	None	Recovered
			Thrombophlebitis	血栓性静脈炎	1	N	TE	128		N	None	Recovered
			Bone pain	骨痛	3	Y	TE	138		N	None	Ongoing at time of death
			Metastases to liver	肝転移	3	N	TE	141	28	N	Not applicable	Death
			Anaemia	貧血	2	N	TE	158	4	Y	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Metastases to liver	肝転移	5	Y	TE	168	1	N	Not applicable	Death
024010	Sweden	75/M/C	Anaemia	貧血	2	N	TE			N	Not applicable	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	Y	Pre	1	12	N	None	Recovered with sequelae
			Pathological fracture	病的骨折	2	N	TE	5	145	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	31		Y	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	59		N	None	Not recovered, but no changes expected
			Rash	発疹	1	N	TE	66	84	N	None	Recovered
			Abdominal pain upper	上腹部痛	2	N	TE	78	38	N	None	Recovered
			Anaemia	貧血	1	N	TE	114	37	Y	None	Recovered
			Nausea	悪心	2	N	TE	131		N	None	Recovered
			Oedema genital	性器浮腫	1	N	TE	150		N	None	Not recovered, but no changes expected
			Metastases to central nervous system	中枢神経系転移	3	N	TE	198		N	None	Not recovered, but no changes expected
			Pathological fracture	病的骨折	3	N	TE	213		N	None	Not recovered, but no changes expected
024011	Sweden	87/M/C	Diarrhoea	下痢	1	N	Pre	-5	2	N	None	Recovered
			Anaemia	貧血	2	N	Pre	-1	30	N	None	Recovered
			Bone pain	骨痛	3	N	Pre	-1	30	N	None	Recovered
			Dysgeusia	味覚異常	1	N	Pre	1		N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	49		N	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	2	N	TE	60		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	63	18	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	Y	TE	82	11	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	91		N	None	Ongoing at study termination / withdrawal
			Dry mouth	口内乾燥	1	N	TE	91		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	135		N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	2	N	TE	135		N	None	Ongoing at study termination / withdrawal
024016	Sweden	73/M/C	Injury	損傷	3	Y	TE			N	-	Recovered with sequelae
			Post-traumatic pain	外傷後疼痛	3	Y	TE			N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	3	N	TE			N	None	Not recovered, but no changes expected
			Fatigue	疲労	1	N	TE	29		N	None	Not recovered, but no changes expected
			Cushingoid	クッシング様	2	N	TE	57		N	None	Not recovered, but no changes expected
			Oedema peripheral	末梢性浮腫	2	N	TE	57		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	113	29	N	None	Recovered
024017	Sweden	73/M/C	Bone pain	骨痛	2	N	TE	34		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	64	27	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	64		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	117	30	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	204	1	N	Not applicable	Death
024023	Sweden	81/M/C	Bone pain	骨痛	2	Y	TE	16	2	N	None	Recovered
			Bone pain	骨痛	3	N	TE	28		N	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	2	N	TE	29		N	None	Ongoing at study termination / withdrawal
			Rash	発疹	2	N	TE	29		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	57		N	None	Ongoing at study termination / withdrawal
025001	Sweden	66/M/C	Pyrexia	発熱	2	N	TE			N	Not applicable	Recovered
			Cough	咳嗽	1	N	TE			N	Not applicable	Recovered
			Arrhythmia	不整脈	1	N	Pre	-1		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	4	6	N	None	Recovered
			Anaemia	貧血	3	Y	TE	57	4	Y	Drug permanently withdrawn	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	2	Y	TE	57	4	Y	None	Recovered with sequelae
			Dyspnoea	呼吸困難	2	N	TE	57	4	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	59	39	N	Not applicable	Recovered
			Polyneuropathy	多発ニューロパチー	2	N	TE	94		N	Not applicable	Not recovered, but no changes expected
025004	Sweden	63/M/C	Fatigue	疲労	1	N	TE	31	-1	Y	None	Recovered
			Upper respiratory tract infection bacterial	細菌性上気道感染	1	N	TE	48	12	N	None	Recovered
			Haematuria	血尿	3	Y	TE	82		N	Drug administration postponed	Ongoing at time of death
			Cardiac failure	心不全	4	Y	TE	90	2	N	Drug permanently withdrawn	Death
			Cardiac failure	心不全	5	Y	TE	91	1	N	Drug permanently withdrawn	Death
025012	Sweden	74/M/C	Vomiting	嘔吐	2	N	TE	53	1	N	None	Recovered
			Hydronephrosis	水腎症	2	Y	TE	172	7	N	Not applicable	Recovered
			Hypercreatininaemia	高クレアチニン血症	2	N	TE	175		N	None	Ongoing at time of death
			Ureteric obstruction	尿管閉塞	3	N	TE	175		N	Not applicable	Not recovered, but no changes expected
025013	Sweden	71/M/C	Dry mouth	口内乾燥	1	N	TE			N	None	Recovered
			Increased bronchial secretion	気管支分泌増加	1	N	TE			N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	Pre	1		N	None	Ongoing at study termination / withdrawal
			Pyrexia	発熱	1	N	TE	79	12	N	None	Recovered
			Leukopenia	白血球減少症	2	N	TE	102	104	N	None	Recovered
			Anaemia	貧血	2	N	TE	121		N	None	Ongoing at time of death
			Infection	感染	2	N	TE	137	2	N	Drug administration postponed	Recovered
			Infection	感染	3	Y	TE	138	4	N	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	148	29	N	Drug administration postponed	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	176	57	N	Drug administration postponed	Ongoing at time of death
			Pyrexia	発熱	2	Y	TE	185	6	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	4	N	TE	232		N	Drug administration postponed	Ongoing at time of death
025014	Sweden	82/M/C	Haematuria	血尿	2	N	Pre			N	None	Recovered
			Fatigue	疲労	3	N	TE	29		N	Drug permanently withdrawn	Ongoing at time of death
			Hepatic failure	肝不全	3	Y	TE	29	9	N	Drug permanently withdrawn	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	Y	TE	29		N	Drug permanently withdrawn	Ongoing at time of death
			Hepatic failure	肝不全	5	Y	TE	37	1	N	Drug permanently withdrawn	Death
025015	Sweden	72/M/C	Fatigue	疲労	2	N	TE	57		N	None	Ongoing at study termination / withdrawal
			Lymphadenopathy	リンパ節症	2	N	TE	62		N	None	Ongoing at time of death
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	TE	62		N	None	Ongoing at study termination / withdrawal
			Metastases to liver	肝転移	5	Y	TE	88	1	N	Not applicable	Death
025020	Sweden	61/M/C	Bone pain	骨痛	2	Y	TE	42	3	N	None	Recovered
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE	70	71	N	None	Recovered
			Bone pain	骨痛	1	N	TE	127		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	132	8	N	None	Recovered
			Sepsis	敗血症	4	Y	TE	160	11	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	4	Y	TE	160	14	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	166		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	220	1	N	Not applicable	Death
025022	Sweden	61/M/C	Anorexia	食欲不振	1	N	TE			N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	25	2	Y	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	30	9	Y	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	3	N	TE	30	9	Y	None	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	TE	30	9	Y	None	Recovered
			Chills	悪寒	1	N	TE	32		N	None	Ongoing at study termination / withdrawal
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	2	N	TE	38	20	Y	None	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	2	N	TE	38	20	Y	None	Recovered
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	2	N	TE	38	20	N	None	Recovered
			Bone pain	骨痛	2	N	TE	42	44	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	85	7	N	Drug administration postponed	Recovered
			Bone pain	骨痛	1	N	TE	86	64	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	91	30	N	Drug administration postponed	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	149		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	150		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	177		Y	Not applicable	Ongoing at time of death
			Nausea	悪心	2	N	TE	177	3	N	Not applicable	Recovered
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	177	3	N	Not applicable	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	179		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	233	8	Y	Not applicable	
026001	Sweden	78/M/C	Bone pain	骨痛	3	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	3		N	None	Not recovered, but no changes expected
			Haematuria	血尿	1	N	TE	106	4	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	114		N	None	Ongoing at time of death
			Dehydration	脱水	2	Y	TE	117	12	N	None	Recovered
			Confusional state	錯乱状態	2	Y	TE	117	12	N	None	Recovered with sequelae
			Urinary retention	尿閉	2	N	TE	118		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	137	2	N	Drug permanently withdrawn	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	138	1	N	Drug permanently withdrawn	Death
026002	Sweden	66/M/C	Oesophageal spasm	食道痙攣	1	N	TE			N	None	Recovered
			Bone pain	骨痛	3	Y	Pre	-2	8	N	Not applicable	Recovered with sequelae
			Polyneuropathy	多発ニューロパチー	1	Y	TE	91	4	N	None	Recovered with sequelae
			Faecal incontinence	便失禁	3	Y	TE	108	8	N	None	Recovered with sequelae
			Hyperglycaemia	高血糖	3	Y	TE	108	8	N	None	Recovered with sequelae
			Urinary incontinence	尿失禁	3	Y	TE	108	8	N	None	Recovered with sequelae
			Pancytopenia	汎血球減少症	2	N	TE	124	6	N	Drug permanently withdrawn	Ongoing at time of death
			Fall	転倒・転落	3	Y	TE	124		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	124	13	N	None	Death
			Urinary retention	尿閉	2	N	TE	124		N	Not applicable	Ongoing at time of death
			Mouth ulceration	口腔内潰瘍形成	2	N	TE	125		N	Not applicable	Ongoing at time of death
			Pancytopenia	汎血球減少症	3	Y	TE	129		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	136	1	N	None	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
026003	Sweden	55/M/C	Nausea	悪心	1	N	TE			Y	None	Not recovered, but no changes expected
			Fatigue	疲労	1	N	TE			N	None	Not recovered, but no changes expected
			Pneumonia	肺炎	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			Y	None	Not recovered, but no changes expected
			Sciatica	坐骨神経痛	2	N	TE			N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	2	2	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	2	2	Y	None	Recovered
			Nausea	悪心	1	N	TE	31	2	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	31	2	Y	None	Recovered
			Anorexia	食欲不振	2	N	TE	116	119	N	None	Recovered
			Anaemia	貧血	2	N	TE	197		Y	None	
			General physical health deterioration	全身健康状態低下	2	Y	TE	219	5	N	Not applicable	Recovered
			Pneumonia	肺炎	3	Y	TE	219	15	N	Not applicable	Recovered
			Compression fracture	圧迫骨折	1	N	TE	220		N	Not applicable	Not recovered, but no changes expected
026005	Sweden	66/M/C	Lymphadenopathy	リンパ節症	1	N	Pre			N	Not applicable	Ongoing at time of death
			Toothache	歯痛	1	N	TE			N	None	Recovered
			Dizziness	浮動性めまい	1	N	TE			N	Not applicable	Recovered
			Insomnia	不眠症	2	N	Pre	1		N	Not applicable	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	TE	109		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	127		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hydronephrosis	水腎症	3	Y	TE	136	5	N	None	Recovered with sequelae
			Weight decreased	体重減少	1	N	TE	147		N	Not applicable	Ongoing at time of death
			Anxiety	不安	2	N	TE	147		N	None	Ongoing at time of death
			Hyponatraemia	低ナトリウム血症	1	N	TE	161	26	N	None	Recovered
			Depression	うつ病	2	N	TE	161		N	None	Recovered with sequelae
			Rectal haemorrhage	直腸出血	3	Y	TE	167	4	N	Not applicable	Recovered
			General physical health deterioration	全身健康状態低下	1	Y	TE	167	4	N	Not applicable	Recovered
			Lymphadenopathy	リンパ節症	2	N	TE	171		N	Not applicable	Ongoing at time of death
			Oral fungal infection	口腔真菌感染	1	N	TE	186		N	Not applicable	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	186	6	N	Not applicable	Recovered
			Dehydration	脱水	2	Y	TE	199	3	N	Not applicable	Recovered
			Bone pain	骨痛	2	Y	TE	199	3	N	Not applicable	Recovered
026007	Sweden	66/M/C	Nausea	悪心	1	N	TE			Y	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE			Y	Not applicable	Recovered
			Upper respiratory tract infection	上気道感染	1	N	TE			N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			N	None	Recovered
			Stent occlusion	ステント閉塞	2	Y	Pre	-10	5	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Herpes zoster	帯状疱疹	2	N	TE	6	10	N	None	Recovered
			Lymphadenopathy	リンパ節症	2	N	TE	119	43	N	None	Recovered with sequelae
026010	Sweden	66/M/C	Bone pain	骨痛	2	N	TE	3	4	Y	None	Recovered
			Anaemia	貧血	2	N	TE	170		Y	None	Not recovered, but no changes expected
			Convulsion	痙攣	4	Y	TE	193	3	N	Not applicable	Recovered with sequelae
			Metastases to nervous system	神経系転移	2	N	TE	195		N	Not applicable	Ongoing at time of death
026016	Sweden	72/M/C	Fatigue	疲労	1	N	TE			N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Nocturia	夜間頻尿	1	N	TE			N	None	Ongoing at time of death
			Hyperhidrosis	多汗症	2	N	TE			N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	2	11	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	2	11	Y	None	Recovered
			Anaemia	貧血	2	N	TE	29		Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	68		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	Y	TE	83	24	Y	Drug permanently withdrawn	Recovered with sequelae
			Thrombocytopenia	血小板減少症	3	N	TE	83	25	Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Mucosal inflammation	粘膜の炎症	2	N	TE	83	18	N	None	Recovered
			Pneumonia	肺炎	3	Y	TE	83	24	N	Drug administration postponed	Recovered
			Petechiae	点状出血	2	N	TE	83		N	None	Ongoing at time of death
			Epistaxis	鼻出血	1	N	TE	84	1	N	None	Recovered
			Thrombocytopenia	血小板減少症	4	N	TE	107		Y	Not applicable	Ongoing at time of death
027001	Sweden	72/M/C	Dry mouth	口内乾燥	1	N	TE	29	204	Y	None	Recovered
			Fatigue	疲労	1	N	TE	29	204	Y	None	Recovered with sequelae
			Anorexia	食欲不振	2	N	TE	29	141	Y	None	Recovered
			Arthralgia	関節痛	2	N	TE	29	56	N	None	Not recovered, but no changes expected
			Arthralgia	関節痛	1	N	TE	84		N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	113	120	Y	None	Recovered
			Circulatory collapse	循環虚脱	4	Y	TE	176	9	N	Not applicable	Recovered
027002	Sweden	67/M/C	Hypertension	高血圧	2	N	TE	29		N	None	Not recovered, but no changes expected
			Onycholysis	爪甲離床症	2	N	TE	78	64	N	None	Recovered with sequelae
			Constipation	便秘	4	Y	Post	684	9	Y	Not applicable	Death
			Constipation	便秘	5	Y	Post	692	1	Y	Not applicable	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Multi-organ failure	多臓器不全	5	Y	Post	692	1	Y	Not applicable	Death
028001	Belgium	63/M/C	Bone pain	骨痛	2	N	Pre	-102	103	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	Pre	1		N	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	2	N	TE	18	103	Y	None	Recovered with sequelae
			Sinus tachycardia	洞性頻脈	1	N	TE	26	73	N	None	Recovered
			Hepatic function abnormal	肝機能異常	2	N	TE	28		N	None	Ongoing at time of death
			Jaundice	黄疸	3	N	TE	28	10	N	None	Recovered
			Jaundice	黄疸	1	N	TE	37	48	N	None	Recovered
			Hypotension	低血圧	2	N	TE	37	62	N	None	Recovered
			Anaemia	貧血	2	N	TE	56	29	Y	Drug permanently withdrawn	Recovered with sequelae
			Leukopenia	白血球減少症	1	N	TE	56	29	Y	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	56	29	Y	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	56	29	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	56	65	N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	56	29	N	None	Recovered with sequelae
			Dyspnoea	呼吸困難	2	N	TE	72	13	N	None	Recovered with sequelae
			Vomiting	嘔吐	2	N	TE	77	8	N	None	Recovered
			Anaemia	貧血	4	Y	TE	84	15	Y	Drug permanently withdrawn	Recovered with sequelae
			Leukopenia	白血球減少症	2	N	TE	84	49	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	3	N	TE	84	15	Y	None	Ongoing at time of death
			Vomiting	嘔吐	1	Y	TE	84	2	N	None	Recovered
			Anorexia	食欲不振	1	Y	TE	84	2	N	None	Recovered with sequelae
			Dyspnoea	呼吸困難	2	Y	TE	84	2	N	None	Recovered with sequelae
			Anorexia	食欲不振	1	N	TE	85		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	98	23	Y	Not applicable	Recovered with sequelae
			Thrombocytopenia	血小板減少症	4	N	TE	98		Y	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	120	2	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	3	Y	TE	120	2	Y	Not applicable	Recovered with sequelae
			Weight decreased	体重減少	2	N	TE	120		N	None	Ongoing at time of death
			Cough	咳嗽	1	N	TE	120		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	121	12	Y	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	2	N	TE	121	12	Y	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	132		Y	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	3	Y	TE	132	4	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	2	N	TE	135	8	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	3	Y	TE	142	2	Y	Not applicable	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			General physical health deterioration	全身健康状態低下	2	N	TE	143	10	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	3	Y	TE	152	4	Y	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	2	N	Post	155		Y	Not applicable	Ongoing at time of death
028002	Belgium	72/M/C	General physical health deterioration	全身健康状態低下	2	Y	Pre	-9	19	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	Y	Pre	-9	19	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	3	N	Pre	-1	2	N	None	Recovered
			Anal ulcer	肛門潰瘍	2	N	Pre	-1	88	N	None	Recovered
			General physical health deterioration	全身健康状態低下	1	N	Pre	10		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	Pre	10		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	3	Y	TE	29	7	Y	Drug administration postponed	Recovered
			Weight decreased	体重減少	2	N	TE	29	28	N	None	Recovered
			Anorexia	食欲不振	3	N	TE	56	28	N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	56		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	Y	TE	83		Y	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	3	Y	TE	83	24	N	Drug permanently withdrawn	Death
			Anorexia	食欲不振	1	N	TE	83		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	87	20	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pathological fracture	病的骨折	3	Y	TE	91		N	Drug permanently withdrawn	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	105		N	Not applicable	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	5	Y	TE	106	1	N	Drug permanently withdrawn	Death
028003	Belgium	83/M/C	Nausea	悪心	1	N	TE	2	1	Y	None	Recovered
			Fatigue	疲労	1	N	TE	29		N	None	Ongoing at time of death
			Skin irritation	皮膚刺激	2	N	TE	50	15	N	None	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	55		Y	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	4	Y	TE	55		N	None	Ongoing at time of death
			Renal failure	腎不全	4	Y	TE	55		N	Drug permanently withdrawn	Ongoing at time of death
			Pulmonary oedema	肺水腫	4	Y	TE	55		N	None	Ongoing at time of death
			Multi-organ failure	多臓器不全	4	Y	TE	59	6	N	None	Death
			Multi-organ failure	多臓器不全	5	Y	TE	64	1	N	None	Death
028004	Belgium	84/M/C	Transient ischaemic attack	一過性脳虚血発作	2	Y	Pre	-13	55	N	Not applicable	Recovered
			Urinary retention	尿閉	2	N	Pre	-7	6	N	None	Recovered
			Pruritus	そう痒症	1	N	TE	8	7	N	None	Recovered with sequelae
			Pruritus	そう痒症	1	N	TE	8	27	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	1	N	TE	14	48	N	None	Recovered
			Urinary tract infection	尿路感染	1	N	TE	28	29	N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	30		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	51		N	None	Ongoing at time of death
			Hypercholesterolaemia	高コレステロール血症	2	N	TE	51		N	None	Ongoing at time of death
			Inguinal hernia	鼠径ヘルニア	1	N	TE	55	14	N	None	Recovered
			Bone pain	骨痛	3	N	TE	57		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	93	1	N	Not applicable	Death
028007	Belgium	65/M/C	Fatigue	疲労	1	N	TE	28		Y	None	Ongoing at study termination / withdrawal
			Feeling cold	冷感	1	N	TE	28	36	Y	None	Recovered
			Pallor	蒼白	1	N	TE	28		Y	None	Ongoing at study termination / withdrawal
			Pyrexia	発熱	2	N	TE	50	6	N	None	Recovered
			Urinary retention	尿閉	3	Y	TE	50	2	N	None	Recovered with sequelae
			Anaemia	貧血	3	N	TE	55	9	Y	None	Recovered with sequelae
			Pleurisy	胸膜炎	2	N	TE	56	23	N	None	Recovered
			Anaemia	貧血	2	N	TE	63		Y	None	Ongoing at study termination / withdrawal
			Tachycardia	頻脈	2	N	TE	91	15	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pleural effusion	胸水	2	N	TE	167	15	N	Not applicable	Recovered
			Paraesthesia	錯感覚	2	N	TE	168		N	None	Ongoing at study termination / withdrawal
			Lymphangiosis carcinomatosa	癌性リンパ管症	4	Y	TE	181	19	N	Not applicable	Recovered with sequelae
			Pleural effusion	胸水	4	Y	TE	181	2	N	Not applicable	Recovered
			Lymphangiosis carcinomatosa	癌性リンパ管症	4	N	TE	199	5	N	Not applicable	Recovered with sequelae
			Lymphangiosis carcinomatosa	癌性リンパ管症	5	Y	TE	203	1	N	Not applicable	Death
033005	UK	83/M/C	Bone pain	骨痛	1	N	TE	1	3	Y	None	Recovered
			Myocardial infarction	心筋梗塞	4	Y	TE	82	3	N	None	Death
			Myocardial infarction	心筋梗塞	5	Y	TE	84	1	N	None	Death
033006	UK	76/M/C	Bone pain	骨痛	2	N	TE			N	None	Not recovered, but no changes expected
			Constipation	便秘	3	Y	TE	77	10	N	Drug administration postponed	Recovered
			Cellulitis	蜂巣炎	3	Y	TE	77	10	N	Drug administration postponed	Recovered
			Pneumonia	肺炎	3	Y	TE	89		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pathological fracture	病的骨折	3	Y	TE	89		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
033011	UK	84/M/C	Abdominal distension	腹部膨満	2	N	TE			N	None	Recovered
			Fatigue	疲労	1	N	TE			Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE			N	None	Recovered with sequelae
			Contusion	挫傷	1	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Balance disorder	平衡障害	1	N	TE			N	None	Not recovered, but no changes expected
			Hallucination	幻覚	1	N	TE			N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	2	N	TE			N	None	Not recovered, but no changes expected
			Orthostatic hypotension	起立性低血圧	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	71	43	N	None	Recovered with sequelae
			Haematemesis	吐血	3	Y	TE	195	5	N	Not applicable	Recovered
			Hyperaesthesia	知覚過敏	2	N	TE	214		N	None	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	214		N	None	Ongoing at time of death
033012	UK	72/M/C	Constipation	便秘	2	N	TE			N	None	Recovered
			Mouth ulceration	口腔内潰瘍形成	2	N	TE			N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Mobility decreased	運動性低下	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Dizziness	浮動性めまい	2	N	TE	11	1	N	None	Recovered
			Dizziness	浮動性めまい	2	N	TE	47	1	N	None	Recovered
			Bone pain	骨痛	3	N	TE	55		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	106	16	N	Drug administration postponed	Recovered
			Hypokalaemia	低カリウム血症	3	N	TE	111	3	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	142		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	144	15	N	None	Recovered with sequelae
			Nausea	悪心	1	N	TE	158		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	158	8	N	None	Recovered with sequelae
033019	UK	71/M/C	Oedema peripheral	末梢性浮腫	1	N	TE			N	None	Not recovered, but no changes expected
			Spinal compression fracture	脊椎圧迫骨折	2	N	TE			Y	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Not recovered, but no changes expected
			Paraesthesia	錯感覚	1	N	TE			N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	2	N	Pre			N	None	Not recovered, but no changes expected
			Pleuritic pain	胸膜痛	1	N	TE			N	None	Recovered
			Spinal cord compression	脊髄圧迫	3	N	Pre	-6	13	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	2	181	Y	None	Not recovered, but no changes expected
			Deep vein thrombosis	深部静脈血栓症	2	Y	TE	26	4	N	Drug administration postponed	Recovered with sequelae
			Deep vein thrombosis	深部静脈血栓症	1	N	TE	29		N	Drug administration postponed	Recovered with sequelae
			Deep vein thrombosis	深部静脈血栓症	1	N	TE	29		N	None	Not recovered, but no changes expected
			Pulmonary embolism	肺塞栓症	3	Y	TE	59	79	N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	3	N	TE	169		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	182	65	Y	None	Recovered
033022	UK	82/M/C	Constipation	便秘	2	N	TE			N	None	Recovered
			Nausea	悪心	2	N	TE			N	None	Recovered
			Vomiting	嘔吐	2	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			N	Drug permanently withdrawn	Recovered with sequelae
			Bone pain	骨痛	3	N	TE	77	15	N	Drug permanently withdrawn	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	77	15	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	91		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
033023	UK	69/M/C	Post-traumatic pain	外傷後疼痛	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at time of death
			Muscular weakness	筋力低下	3	N	TE			N	None	Ongoing at time of death
			Pathological fracture	病的骨折	2	N	TE			N	None	Not recovered, but no changes expected
			Constipation	便秘	1	N	Pre	-673	882	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	28		N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	85	65	N	None	Recovered with sequelae
			Pathological fracture	病的骨折	3	Y	TE	149	20	Y	Drug administration postponed	Recovered
			Mobility decreased	運動性低下	2	N	TE	168	42	N	None	Ongoing at time of death
			Pathological fracture	病的骨折	2	N	TE	168		Y	None	Not recovered, but no changes expected
			Paraesthesia	錯感覚	1	Y	TE	175	5	N	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	178	7	N	None	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	178	32	N	None	Ongoing at time of death
			Upper limb fracture	上肢骨折	3	Y	TE	202		Y	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	5	Y	TE	209	1	N	Not applicable	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
033027	UK	58/M/C	Diarrhoea	下痢	1	N	TE			Y	None	Recovered
			Nausea	悪心	1	N	TE			Y	None	Recovered
			Gingival infection	歯肉感染	1	N	TE			N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			N	None	Not recovered, but no changes expected
			Pain in jaw	顎痛	1	N	TE			Y	None	Recovered
			Hypoaesthesia	感覚鈍麻	1	N	TE			N	None	Not recovered, but no changes expected
			Depression	うつ病	1	N	TE			N	None	Not recovered, but no changes expected
			Palpitations	動悸	2	N	TE	40	1	N	None	Recovered
			Dyspepsia	消化不良	2	N	TE	40		N	None	Ongoing at time of death
			Hyperhidrosis	多汗症	2	N	TE	40	1	N	None	Recovered
			Vomiting	嘔吐	3	Y	TE	44	3	N	None	Recovered
			Nausea	悪心	1	N	TE	57		N	None	Recovered
			Diarrhoea	下痢	1	N	TE	60	10	Y	None	Recovered
			Osteonecrosis	骨壊死	2	N	TE	100		Y	None	Not recovered, but no changes expected
			Defaecation urgency	便意切迫	3	N	TE	120	1	Y	None	Recovered
			Defaecation urgency	便意切迫	3	N	TE	120	2	Y	None	Recovered
			Faecal incontinence	便失禁	3	N	TE	120	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	193		N	None	Recovered
			Diarrhoea	下痢	3	Y	TE	196	8	N	Not applicable	Recovered
			Vomiting	嘔吐	3	Y	TE	196	8	N	Not applicable	Recovered
			Intervertebral disc degeneration	椎間板変性症	3	Y	TE	196	8	N	Not applicable	Recovered
			Paraesthesia	錯感覚	2	N	TE	196	8	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
034004	UK	63/M/C	Nausea	悪心	1	N	TE	8		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	8		Y	None	Ongoing at time of death
			Oral candidiasis	口腔カンジダ症	1	N	TE	8		N	None	Ongoing at time of death
			Dizziness	浮動性めまい	1	N	TE	8		N	None	Ongoing at time of death
			Cerebral ischaemia	脳虚血	4	Y	TE	43	5	N	None	Recovered with sequelae
			Anorexia	食欲不振	3	N	TE	53		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	92	9	N	Not applicable	Recovered
			Diarrhoea	下痢	3	N	TE	95	6	Y	Not applicable	Recovered
			Vomiting	嘔吐	3	N	TE	95	6	N	Not applicable	Recovered
			Anaemia	貧血	4	N	TE	98	2	N	Not applicable	Recovered
			Bone marrow failure	骨髄機能不全	4	Y	TE	98	9	N	Not applicable	Death
			Sinus tachycardia	洞性頻脈	1	N	TE	98		N	Not applicable	Ongoing at time of death
			Confusional state	錯乱状態	3	N	TE	98	2	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	98	2	N	Not applicable	Recovered
			Rash	発疹	2	N	TE	98		N	None	Ongoing at time of death
			Haematemesis	吐血	3	N	TE	99	2	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oesophagitis	食道炎	2	N	TE	99		N	Not applicable	Ongoing at time of death
			Bone marrow failure	骨髄機能不全	5	Y	TE	106	1	N	Not applicable	Death
034017	UK	83/M/C	Rash	発疹	1	N	TE			N	None	Recovered
			Vision blurred	霧視	3	N	TE	25	2	N	None	Ongoing at time of death
			Vision blurred	霧視	2	N	TE	26		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	42	57	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	42	57	N	None	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	2	N	TE	42		N	None	Ongoing at time of death
			Oral candidiasis	口腔カンジダ症	2	N	TE	70	29	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	95	1	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	98		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	114		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
035006	UK	62/M/C	Fatigue	疲労	1	N	Pre	-22	23	N	None	Recovered
			Conjunctivitis	結膜炎	1	N	TE	13	15	N	None	Recovered
			Polyneuropathy	多発ニューロパチー	1	N	TE	27	28	N	None	Recovered
			Paresis cranial nerve	脳神経不全麻痺	3	Y	TE	30		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	84	35	N	None	Recovered
			Constipation	便秘	1	N	TE	85		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oral candidiasis	口腔カンジダ症	2	N	TE	86		N	None	Recovered
			Respiratory tract infection	気道感染	1	N	TE	86		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	87		N	None	Ongoing at time of death
			Urinary tract obstruction	尿路閉塞	2	N	TE	101		N	None	Recovered with sequelae
			Decreased appetite	食欲減退	1	N	TE	111	2	N	None	Recovered
035016	UK	62/M/C	Diarrhoea	下痢	2	N	TE	3	11	N	None	Recovered
			Nausea	悪心	2	N	TE	3	11	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	109	9	N	None	Recovered
			Constipation	便秘	1	N	TE	111	8	N	None	Recovered
			Oral candidiasis	口腔カンジダ症	2	N	TE	112	42	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	112	7	N	Drug administration postponed	Recovered
			Dyspepsia	消化不良	1	N	TE	113	3	N	None	Recovered
			Nausea	悪心	1	N	TE	113	3	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	113		N	None	Recovered
			Bone pain	骨痛	3	N	TE	118	36	N	None	Not recovered, but no changes expected
			Diarrhoea	下痢	3	Y	TE	150	4	Y	Not applicable	Recovered
			Vomiting	嘔吐	3	Y	TE	150	4	Y	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	153		N	None	Not recovered, but no changes expected
			Diarrhoea	下痢	3	Y	Post	337	10	Y	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
035019	UK	67/M/C	Nausea	悪心	2	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	Pre	1	4	Y	None	Recovered
			Bone pain	骨痛	2	Y	TE	106	5	N	None	Recovered with sequelae
			Urinary tract infection	尿路感染	1	N	TE	128	11	N	None	Recovered
			Constipation	便秘	1	N	TE	132	5	N	None	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	152	6	Y	Not applicable	Recovered
			Nausea	悪心	1	N	TE	158	46	N	Not applicable	Recovered
			Fatigue	疲労	1	N	TE	163		N	Not applicable	Not recovered, but no changes expected
035023	UK	70/M/C	Fatigue	疲労	1	N	TE	66		Y	None	Not recovered, but no changes expected
			Fatigue	疲労	2	N	TE	66		Y	None	Not recovered, but no changes expected
			Dyspepsia	消化不良	2	N	TE	70		N	None	Not recovered, but no changes expected
			Decreased appetite	食欲減退	2	N	TE	70		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	84		Y	None	Not recovered, but no changes expected
			Gastrointestinal haemorrhage	胃腸出血	3	Y	TE	94	8	N	None	Recovered
			Electrocardiogram QT prolonged	心電図ＱＴ延長	1	N	TE	105		N	Not applicable	Not recovered, but no changes expected
			Clostridium difficile colitis	クロストリジウム・ディフィシレ大腸炎	2	Y	TE	110	9	N	Not applicable	Recovered
			Clostridium difficile colitis	クロストリジウム・ディフィシレ大腸炎	1	N	TE	150	9	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
035027	UK	68/M/C	Decreased appetite	食欲減退	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	1	3	Y	None	Recovered
			Constipation	便秘	2	N	TE	44		Y	None	Ongoing at time of death
			Intestinal obstruction	腸閉塞	4	Y	TE	54	2	Y	None	Death
			Intestinal obstruction	腸閉塞	5	Y	TE	55	1	Y	None	Death
035028	UK	70/M/C	Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Recovered
			Urine flow decreased	尿流量減少	1	N	TE	11	19	N	None	Recovered
			Bone pain	骨痛	2	N	TE	29		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	44	18	N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	44		N	None	Recovered
			Constipation	便秘	2	Y	TE	66	6	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	71	79	N	Not applicable	Death
			Constipation	便秘	1	N	TE	72	42	N	None	Recovered
			Anaemia	貧血	2	N	TE	141		Y	None	Ongoing at time of death
			Confusional state	錯乱状態	3	Y	TE	150	11	N	Not applicable	Death
			Confusional state	錯乱状態	5	Y	TE	160	1	N	Not applicable	Death
035031	UK	63/M/C	Pollakiuria	頻尿	1	N	TE	2	2	Y	None	Recovered
			Sepsis	敗血症	4	Y	TE	50	19	N	Drug permanently withdrawn	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	4	Y	TE	50	24	N	Drug permanently withdrawn	Recovered
			Haematuria	血尿	3	N	TE	50		N	Not applicable	Not recovered, but no changes expected
			Herpes zoster	帯状疱疹	2	N	TE	86	6	N	Not applicable	Recovered
			Renal impairment	腎機能障害	2	N	TE	86	5	N	Not applicable	Recovered
035033	UK	63/M/C	Angina pectoris	狭心症	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			N	None	Ongoing at time of death
			Blood urea increased	血中尿素増加	1	N	TE	41	57	N	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	87	1	N	None	Recovered
			Constipation	便秘	2	N	TE	159	3	N	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	202	1	N	None	Recovered
			Myocardial ischaemia	心筋虚血	4	Y	TE	203	3	N	Not applicable	Recovered
036001	UK	82/M/C	Bone pain	骨痛	1	N	TE	43		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	56	8	N	None	Recovered
			Bone pain	骨痛	4	Y	TE	63	11	N	None	Recovered
			Arrhythmia	不整脈	3	Y	TE	111	16	N	None	Recovered
			Anaemia	貧血	2	N	TE	149		Y	Not applicable	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	149		N	None	Ongoing at study termination / withdrawal
036005	UK	63/M/C	Dysphagia	嚥下障害	1	N	Pre			N	None	Ongoing at study termination / withdrawal
			Dizziness	浮動性めまい	1	N	TE			N	None	Recovered
			Diarrhoea	下痢	2	N	TE	24	6	N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE	24		N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	3	N	TE	36	28	Y	None	Recovered
			Disturbance in attention	注意力障害	1	N	TE	63		N	None	Ongoing at study termination / withdrawal
			Tremor	振戦	2	N	TE	63		N	None	Not recovered, but no changes expected
			Hyperhidrosis	多汗症	1	N	TE	63		N	None	Ongoing at study termination / withdrawal
			Wheezing	喘鳴	2	N	TE	91		N	None	Not recovered, but no changes expected
			Lower respiratory tract infection	下気道感染	2	N	TE	182		N	None	Ongoing at study termination / withdrawal
			Pneumonia	肺炎	3	Y	TE	182		N	Not applicable	Recovered with sequelae
			Pneumonia	肺炎	3	Y	TE	205	14	N	Not applicable	Recovered
037007	UK	72/M/C	Constipation	便秘	1	N	TE			Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	1	N	TE			N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE			N	None	Recovered
			Muscle spasms	筋痙縮	2	N	TE			N	None	Not recovered, but no changes expected
			Hypertension	高血圧	1	N	TE			Y	None	Not recovered, but no changes expected
			Diarrhoea	下痢	3	N	TE	2	3	Y	None	Recovered
			Nausea	悪心	1	N	TE	2	8	Y	None	Recovered
			Fatigue	疲労	1	N	TE	2	7	Y	None	Recovered
			Influenza	インフルエンザ	2	N	TE	11	8	Y	None	Recovered
			Cough	咳嗽	1	N	TE	18	12	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	54	4	Y	None	Recovered
			Chills	悪寒	1	N	TE	54	1	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	54	10	N	None	Recovered
			Cough	咳嗽	1	N	TE	64	9	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	68	3	Y	None	Recovered
			Urge incontinence	切迫性尿失禁	1	N	TE	68	1	N	None	Recovered
			Nausea	悪心	1	Y	TE	72	1	Y	None	Recovered
			Vomiting	嘔吐	1	Y	TE	72	1	Y	None	Recovered
			Hydronephrosis	水腎症	3	Y	TE	72	12	N	None	Recovered with sequelae
			Renal failure	腎不全	3	Y	TE	72	4	N	Drug administration postponed	Recovered with sequelae
			Renal failure	腎不全	2	N	TE	75		N	None	Not recovered, but no changes expected
			Catheter related infection	カテーテル関連感染	2	N	TE	152	40	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	160	3	N	None	Recovered
			Gynaecomastia	女性化乳房	1	N	TE	162	30	N	None	Recovered
037008	UK	81/M/C	Mobility decreased	運動性低下	2	N	TE			N	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE	2	1	N	None	Recovered
			Musculoskeletal pain	筋骨格痛	1	N	TE	2	1	N	None	Recovered
			Constipation	便秘	1	N	TE	63		N	None	Not recovered, but no changes expected
			Eye infection	眼感染	2	N	TE	99	19	N	None	Recovered
			Gastritis	胃炎	2	N	TE	221	3	N	Not applicable	Recovered
			Gastritis	胃炎	3	Y	TE	223	2	N	Not applicable	Recovered
037012	UK	67/M/C	Abdominal pain	腹痛	1	N	TE			N	None	Not recovered, but no changes expected
			Hiatus hernia	裂孔ヘルニア	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			N	None	Recovered
			Pain in jaw	顎痛	1	N	TE			N	None	Ongoing at time of death
			Deep vein thrombosis	深部静脈血栓症	3	N	TE			Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	28	2	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	113		N	None	Ongoing at time of death
			Osteoarthritis	骨関節炎	1	N	TE	163		N	None	Not recovered, but no changes expected
			Dyspnoea exertional	労作性呼吸困難	1	N	TE	171		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	198		N	None	Ongoing at time of death
			Head injury	頭部損傷	3	N	TE	212	1	N	None	Recovered with sequelae
			Disseminated intravascular coagulation	播種性血管内凝固	3	N	TE	214		N	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	3	Y	TE	214		N	Not applicable	Ongoing at time of death
			Extradural haematoma	硬膜外血腫	5	Y	TE	214	1	N	Not applicable	Death
037013	UK	70/M/C	Anorexia	食欲不振	1	N	TE			Y	None	Recovered
			Dysarthria	構語障害	1	N	TE			N	None	Not recovered, but no changes expected
			Non-cardiac chest pain	非心臓性胸痛	1	N	TE	3	8	N	None	Recovered
			Non-cardiac chest pain	非心臓性胸痛	2	N	TE	10	24	N	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	19	6	N	None	Recovered
			Bursitis infective	感染性滑液包炎	1	N	TE	30	8	N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	30		N	None	Not recovered, but no changes expected
			Bursitis infective	感染性滑液包炎	2	Y	TE	37	3	N	None	Recovered
			Nausea	悪心	1	N	TE	46	4	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	48	2	Y	None	Recovered
			Lethargy	嗜眠	1	N	TE	59		Y	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	61	4	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	118	9	Y	None	Recovered
			Rectal haemorrhage	直腸出血	1	N	TE	118	1	Y	None	Recovered
			Nausea	悪心	1	N	TE	141		Y	None	Not recovered, but no changes expected
			Diarrhoea	下痢	1	N	TE	143	3	Y	None	Recovered
			Anaemia	貧血	3	N	TE	190	44	Y	None	Recovered
038003	UK	80/M/C	Vomiting	嘔吐	3	N	TE	1	2	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	2	7	Y	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	4	4	N	None	Recovered
			Haematuria	血尿	2	N	TE	4	6	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	1	N	TE	8	2	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	16	6	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	28	2	Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	2	N	TE	28		Y	None	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	29	2	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	35	2	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	56		N	None	Ongoing at time of death
			Muscular weakness	筋力低下	4	Y	TE	56		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	57	2	Y	None	Recovered
039005	UK	72/M/C	Constipation	便秘	3	N	TE	4	38	N	None	Recovered
			Nausea	悪心	3	N	TE	13	29	N	None	Recovered
			Nausea	悪心	3	N	TE	35	7	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	35		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	N	TE	35	8	N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	42	1	N	None	Death
039007	UK	68/M/C	Bone pain	骨痛	1	N	Pre			N	None	Ongoing at time of death
			Anaemia	貧血	1	Y	Pre	-23	2	N	Drug administration postponed	Recovered
			Decreased appetite	食欲減退	1	N	Pre	-11		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	Pre	-11		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	-11	5	N	None	Recovered
			Nausea	悪心	1	N	Pre	-4		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	Pre	-4		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	4	23	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	27		Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	29	36	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	60		Y	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	70	1	N	None	Recovered
			Anaemia	貧血	2	N	TE	92		Y	Drug administration postponed	Ongoing at time of death
			Joint injury	関節損傷	2	N	TE	94		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	95		Y	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	118	2	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	180	2	Y	Not applicable	Recovered
			Skin lesion	皮膚病変	3	N	TE	183		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	214	1	N	Not applicable	Death
039012	UK	82/M/C	Anaemia	貧血	3	N	TE			N	None	Recovered
			Hyperchlorhydria	胃酸過多	2	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	2	N	Pre	-2	26	N	None	Recovered
			Hypoaesthesia	感覚鈍麻	2	N	Pre	-2		N	None	Ongoing at study termination / withdrawal
			Hypoaesthesia	感覚鈍麻	2	N	TE	8		N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	2	N	TE	8		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	24		N	None	Ongoing at time of death
			Pathological fracture	病的骨折	3	Y	TE	35	33	N	Drug administration postponed	Recovered
			Nausea	悪心	2	N	TE	71	86	Y	None	Ongoing at time of death
			Dry mouth	口内乾燥	3	N	TE	87	70	N	None	Ongoing at time of death
			Back injury	背部損傷	3	N	TE	91	66	N	None	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	125		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	156	1	N	None	Death
039015	UK	79/M/C	Abdominal distension	腹部膨満	2	N	TE			N	None	Recovered
			Nausea	悪心	2	N	TE			Y	None	Recovered
			Fatigue	疲労	3	N	TE			N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	Pre	1	85	N	None	Recovered
			Bone pain	骨痛	2	N	Pre	1	85	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	Pre	1	111	N	None	Recovered
			Incontinence	失禁	2	N	Pre	1	85	N	None	Recovered
			Decreased appetite	食欲減退	2	N	TE	29		N	None	Ongoing at study termination / withdrawal
			Haematuria	血尿	3	Y	TE	85	7	N	Drug administration postponed	Recovered
			Cystitis radiation	放射線性膀胱炎	3	Y	TE	93	5	N	Drug administration postponed	Recovered
			Cystitis radiation	放射線性膀胱炎	2	N	TE	97		N	None	Recovered
			Urinary tract infection	尿路感染	3	N	TE	146	18	N	None	Recovered
			Urinary tract infection	尿路感染	3	N	TE	167		N	None	Recovered
			Oesophageal obstruction	食道閉塞症	3	N	TE	176		N	None	Ongoing at study termination / withdrawal
			Hyperchlorhydria	胃酸過多	2	N	TE	179		N	None	Ongoing at time of death
039016	UK	69/M/C	Fatigue	疲労	2	N	TE			Y	None	Recovered
			Cellulitis	蜂巣炎	3	N	Pre			N	None	Recovered
			Rhinitis	鼻炎	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	Pre			N	None	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	7	9	N	None	Recovered
			Oedema peripheral	末梢性浮腫	3	N	TE	25	296	N	None	Recovered
			Dyspnoea	呼吸困難	2	N	TE	146		N	None	Not recovered, but no changes expected
039025	UK	78/M/C	Asthenia	無力症	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	Pre	1	57	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	Pre	1	29	N	None	Recovered
			Bone pain	骨痛	2	N	TE	83		N	None	Ongoing at time of death
			Metastases to central nervous system	中枢神経系転移	3	Y	TE	109		N	Drug permanently withdrawn	Ongoing at time of death
			Dysphasia	不全失語症	2	N	TE	109		N	None	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	113		N	Not applicable	Ongoing at time of death
039027	UK	74/M/C	Nausea	悪心	2	N	TE	1		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	1		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	2	N	Pre	1		N	None	Ongoing at time of death
			Dizziness	浮動性めまい	2	N	TE	1		N	None	Ongoing at time of death
			Headache	頭痛	1	N	TE	1		N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	1	N	TE	1		N	None	Ongoing at time of death
			Dehydration	脱水	3	Y	TE	8	7	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	18	20	N	Drug administration postponed	Death
			Renal failure	腎不全	3	Y	TE	18	1	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	N	TE	19	4	N	Drug administration postponed	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	37	1	N	Drug administration postponed	Death
040004	UK	67/M/C	Nausea	悪心	1	N	Pre			N	None	Recovered
			Vomiting	嘔吐	1	N	Pre			N	None	Recovered
			Upper respiratory tract infection	上気道感染	2	N	TE	29	8	N	None	Recovered
			Nausea	悪心	2	Y	TE	70	2	Y	None	Recovered
			Vomiting	嘔吐	2	Y	TE	70	2	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	105		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	142		Y	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	1	N	TE	142		Y	None	Ongoing at study termination / withdrawal
040005	UK	67/M/C	Bone pain	骨痛	3	N	TE			N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	2	3	Y	None	Recovered
			Malaise	倦怠感	2	N	TE	2	3	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	2		N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	29	4	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	29	4	N	None	Recovered
			Lower respiratory tract infection	下気道感染	3	N	TE	49	13	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	57	56	Y	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	68	60	N	Drug permanently withdrawn	Death
			Anaemia	貧血	3	Y	TE	112	3	Y	None	Recovered
			Fatigue	疲労	3	Y	TE	112	3	Y	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	N	TE	114		Y	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	2	N	TE	114		Y	Not applicable	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	127	1	N	Drug permanently withdrawn	Death
040007	UK	68/M/C	Breast tenderness	乳房圧痛	1	N	Pre			N	None	Recovered
			Breast tenderness	乳房圧痛	1	N	TE			Y	None	Recovered
			Nausea	悪心	1	N	TE	4	16	Y	None	Recovered
			Fatigue	疲労	1	N	TE	4	16	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	67	29	Y	None	Recovered
			Bone pain	骨痛	3	Y	TE	84	2	N	None	Recovered
			Fatigue	疲労	2	N	TE	132		N	None	Ongoing at study termination / withdrawal
			Dyspnoea	呼吸困難	1	N	TE	132		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Joint swelling	関節腫脹	1	N	TE	139		N	None	Ongoing at study termination / withdrawal
040008	UK	75/M/C	Bone pain	骨痛	2	N	Pre	-10	8	N	None	Recovered
			Headache	頭痛	1	N	Pre	-10	8	N	None	Recovered
			Nausea	悪心	2	N	Pre	-8	40	N	None	Recovered
			Anorexia	食欲不振	2	N	Pre	-8	5	N	None	Recovered
			Vomiting	嘔吐	1	N	Pre	-5	1	N	None	Recovered
			Fatigue	疲労	1	N	Pre	-5		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	Pre	1	79	N	None	Recovered
			Bone pain	骨痛	1	N	Pre	1	79	N	None	Recovered
			Bone pain	骨痛	1	N	Pre	1	79	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	33	30	Y	None	Recovered
			Dyspepsia	消化不良	2	N	TE	67		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	72	1	N	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	85	30	Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	3	N	TE	114		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Mouth haemorrhage	口腔内出血	3	Y	TE	135		Y	Not applicable	Ongoing at study termination / withdrawal
041001	UK	56/M/C	Pulmonary embolism	肺塞栓症	4	Y	Pre	-39	8	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Intertrigo	間擦疹	2	N	Pre	-33	30	N	None	Recovered
			Nausea	悪心	1	N	Pre	1	57	N	None	Recovered
			Decreased appetite	食欲減退	1	N	Pre	1	113	N	None	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	2	4	Y	None	Recovered
			Fatigue	疲労	1	N	TE	2	15	N	None	Recovered
			Bone pain	骨痛	2	N	TE	2	112	Y	None	Recovered
			Weight decreased	体重減少	1	N	TE	29	85	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	46	96	N	None	Recovered
			Pain in extremity	四肢痛	2	N	TE	46		N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	57	203	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	57		N	None	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	3	Y	TE	81	5	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	113		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	3	N	TE	113	57	N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	141	8	N	None	Recovered
			Bone pain	骨痛	3	N	TE	148	21	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	168		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	169		N	None	Ongoing at time of death
			Night sweats	寝汗	2	N	TE	192		N	None	Ongoing at time of death
			Oral candidiasis	口腔カンジダ症	2	N	TE	202		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Abdominal pain upper	上腹部痛	1	N	TE	223		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	223		N	None	Ongoing at time of death
041003	UK	59/M/C	Dry mouth	口内乾燥	1	N	TE			N	None	Ongoing at time of death
			Abdominal distension	腹部膨満	1	N	Pre	-13	52	N	None	Recovered
			Bone pain	骨痛	3	N	Pre	-13	4	N	None	Recovered
			Joint swelling	関節腫脹	1	N	Pre	-13		N	None	Ongoing at time of death
			Hot flush	ほてり	1	N	Pre	-13		N	None	Ongoing at time of death
			Pitting oedema	圧痕浮腫	1	N	Pre	1	39	N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	1	N	Pre	1		N	None	Ongoing at time of death
			Lethargy	嗜眠	2	N	TE	2	52	Y	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	4	50	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	30	140	N	None	Recovered
			Insomnia	不眠症	1	N	TE	30	124	N	None	Ongoing at time of death
			Depressed mood	抑うつ気分	1	N	TE	42		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	43	15	Y	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	43	69	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	44	126	N	None	Recovered
			Pain in jaw	顎痛	1	N	TE	44	4	N	None	Recovered
			Bone pain	骨痛	2	N	TE	50	8	N	None	Recovered
			Lethargy	嗜眠	3	N	TE	53		Y	None	Ongoing at time of death
			Musculoskeletal stiffness	筋骨格硬直	1	N	TE	55	57	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	1	N	TE	57	55	N	None	Ongoing at time of death
			Ligament injury	靭帯損傷	2	N	TE	74	38	N	None	Recovered
			Lower limb fracture	下肢骨折	2	N	TE	74		N	None	Ongoing at time of death
			Dysgeusia	味覚異常	1	N	TE	83		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	103	3	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	105	2	Y	None	Recovered
			Oral herpes	口腔ヘルペス	2	N	TE	107		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	111	16	Y	-	
			Weight decreased	体重減少	2	N	TE	111		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	2	N	TE	111	59	N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	124	1	Y	None	Recovered
			Anaemia	貧血	2	N	TE	126	12	Y	-	
			Vomiting	嘔吐	1	N	TE	126	1	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	129	1	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	136	1	Y	None	Recovered
			Anaemia	貧血	3	N	TE	137	5	Y	-	
			Anaemia	貧血	2	N	TE	141		Y	None	Ongoing at time of death
			Insomnia	不眠症	2	N	TE	153		N	None	Ongoing at time of death
			Restless legs syndrome	下肢静止不能症候群	2	N	TE	165		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	169		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	169	50	N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	218		N	None	Ongoing at time of death
			Epistaxis	鼻出血	1	N	TE	218		N	None	Ongoing at time of death
041005	UK	76/M/C	Bone pain	骨痛	2	N	TE	7	191	N	None	Not recovered, but no changes expected
			Defaecation urgency	便意切迫	1	N	TE	8	21	Y	None	Recovered
			Frequent bowel movements	排便回数増加	1	N	TE	8	21	Y	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	78	5	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	80	1	Y	None	Recovered
			Pathological fracture	病的骨折	2	Y	TE	118	51	N	None	Recovered
			Bone pain	骨痛	3	N	TE	197		N	None	Not recovered, but no changes expected
			Musculoskeletal stiffness	筋骨格硬直	1	N	TE	197		N	None	Not recovered, but no changes expected
			Pain in extremity	四肢痛	1	N	TE	197		N	None	Not recovered, but no changes expected
			Soft tissue infection	軟部組織感染	2	N	TE	222		N	None	Not recovered, but no changes expected
041006	UK	64/M/C	Lower respiratory tract infection	下気道感染	2	Y	Pre	-65	8	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	2	2	Y	None	Recovered
			Contusion	挫傷	1	N	TE	39	110	N	None	Recovered
			Joint sprain	関節捻挫	1	N	TE	39	110	N	None	Recovered
			Skin laceration	皮膚裂傷	1	N	TE	39	110	N	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	60	7	N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	Y	TE	66	20	N	None	Recovered
			Therapeutic agent toxicity	治療薬毒性	4	Y	TE	73	1	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	2	N	TE	92	6	Y	None	Recovered
			Bone pain	骨痛	3	Y	TE	100	17	N	None	Recovered
			Bone pain	骨痛	3	N	TE	116	2	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	117	25	N	None	Recovered
			Bone pain	骨痛	2	N	TE	141		N	None	Not recovered, but no changes expected
041008	UK	74/M/C	Anaemia	貧血	2	N	Pre	1	29	N	Drug administration postponed	Recovered
			Nausea	悪心	2	N	TE	1	3	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	1	3	N	None	Recovered
			Anaemia	貧血	2	Y	TE	29	4	N	Drug administration postponed	Recovered
			Acute myocardial infarction	急性心筋梗塞	4	Y	TE	29	4	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	32	19	N	Drug administration postponed	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE	35	13	N	None	Recovered
			Anaemia	貧血	3	Y	TE	50	4	N	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	50	3	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	52		N	None	Ongoing at time of death
			Anaemia	貧血		Y	TE	76		N	Drug administration postponed	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Lower respiratory tract infection	下気道感染	5	Y	TE	79	1	N	None	Death
041011	UK	58/M/C	Oral candidiasis	口腔カンジダ症	2	N	Pre	1		N	None	Recovered
			Metastases to bone	骨転移	2	N	TE	27	6	N	None	Recovered
			Anaemia	貧血	2	N	TE	29	84	Y	None	Ongoing at time of death
			Metastases to bone	骨転移	2	Y	TE	32	18	N	None	Recovered
			Metastases to bone	骨転移	2	N	TE	49		N	None	Not recovered, but no changes expected
			Oedema peripheral	末梢性浮腫	2	N	TE	57	57	N	None	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	3	Y	TE	63	6	N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	63	6	N	Drug administration postponed	Recovered
			Diabetes mellitus	糖尿病	2	N	TE	71	56	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	84	58	Y	Drug administration postponed	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	85	79	N	Drug permanently withdrawn	Death
			Anaemia	貧血	1	N	TE	112	30	Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	113	38	N	None	Ongoing at time of death
			Memory impairment	記憶障害	1	N	TE	113		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Rales	ラ音	1	N	TE	113		N	None	Ongoing at time of death
			Dizziness postural	体位性めまい	2	N	TE	116		N	None	Ongoing at time of death
			Diabetes mellitus	糖尿病	1	N	TE	126		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	141		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	141	5	Y	Drug administration postponed	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	145		Y	Drug administration postponed	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	Y	TE	150		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	163	1	N	Drug permanently withdrawn	Death
041012	UK	62/M/C	Nausea	悪心	1	N	TE			N	None	Recovered
			Ingrowing nail	嵌入爪	2	N	Pre			N	Not applicable	Recovered
			Lower respiratory tract infection	下気道感染	2	N	Pre	-2		N	None	Recovered
			Bone pain	骨痛	2	N	TE	1	5	Y	None	Recovered
			Nightmare	悪夢	2	N	TE	1	20	N	None	Recovered
			Skin odour abnormal	皮膚異常臭	2	N	TE	1	57	Y	None	Recovered
			Nail infection	爪感染	2	N	TE	5	1	N	None	Recovered
			Anaemia	貧血	2	N	TE	29	29	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	29	3	Y	None	Recovered
			Fatigue	疲労	2	N	TE	40		Y	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Insomnia	不眠症	2	N	TE	40	176	N	None	Recovered
			Anaemia	貧血	1	N	TE	57	29	Y	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	1	N	TE	57	57	Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	61	4	Y	None	Recovered
			Dry skin	皮膚乾燥	2	N	TE	80	154	N	None	Recovered
			Skin exfoliation	皮膚剥脱	2	N	TE	80	153	N	None	Recovered
			Anaemia	貧血	2	N	TE	85	85	Y	None	Recovered
			Nasopharyngitis	鼻咽頭炎	2	N	TE	110	32	N	None	Recovered
			Odynophagia	嚥下痛	1	N	TE	113	6	N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	2	N	TE	113		Y	None	Not recovered, but no changes expected
			Pharyngolaryngeal pain	咽喉頭疼痛	2	N	TE	113	6	N	None	Recovered
			Oral candidiasis	口腔カンジダ症	2	Y	TE	118	2	N	None	Recovered
			Oral candidiasis	口腔カンジダ症	1	N	TE	119	7	N	None	Recovered
			Pain of skin	皮膚疼痛	1	N	TE	120	113	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	133	2	N	None	Recovered
			Stomach discomfort	胃不快感	2	N	TE	148	22	N	Not applicable	Recovered
			Decreased appetite	食欲減退	2	N	TE	148	17	N	Not applicable	Recovered
			Oral candidiasis	口腔カンジダ症	2	N	TE	154		N	Not applicable	Recovered
			Decreased appetite	食欲減退	1	N	TE	164	53	N	Not applicable	Recovered
			Anaemia	貧血	3	Y	TE	169	2	Y	Not applicable	Recovered
			Leukopenia	白血球減少症	3	N	TE	169		N	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	1	N	TE	169	21	Y	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	1	N	TE	169		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	N	TE	170	11	Y	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	180	16	Y	Not applicable	Not recovered, but no changes expected
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	189	13	N	Not applicable	Recovered
			Anaemia	貧血	1	N	TE	195		Y	Not applicable	Not recovered, but no changes expected
042015	UK	72/M/C	Increased appetite	食欲亢進	1	N	TE			N	None	Recovered
			Somnolence	傾眠	2	N	TE			N	None	Recovered
			Diplopia	複視	3	N	TE	14	10	Y	None	Recovered
			Balance disorder	平衡障害	1	N	TE	14	10	N	None	Recovered
			Confusional state	錯乱状態	3	N	TE	14	10	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	15	15	Y	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	53	6	N	None	Recovered
			Agitation	激越	2	N	TE	114	2	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	115	1	N	None	Death
			Increased bronchial secretion	気管支分泌増加	2	N	TE	115	1	N	None	Recovered
042020	UK	73/M/C	Aphthous stomatitis	アフタ性口内炎	1	N	TE			N	None	Recovered
			Diarrhoea	下痢	1	N	TE	4	6	Y	None	Recovered
			Decreased appetite	食欲減退	2	N	TE	4	150	N	None	Ongoing at time of death
			Lethargy	嗜眠	2	N	TE	4	146	N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	1	N	TE	23		N	None	Ongoing at time of death
			Radius fracture	橈骨骨折	3	N	TE	48	33	N	None	Recovered
			Bone pain	骨痛	2	N	TE	63		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	67	122	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	89	71	N	None	Recovered
			Melaena	メレナ	1	N	TE	99		N	None	Ongoing at time of death
			Haematuria	血尿	1	Y	TE	125	2	N	None	Recovered
			Haematuria	血尿	2	N	TE	140	4	N	Drug administration postponed	Recovered
			Haematuria	血尿	2	Y	TE	143	2	N	Drug administration postponed	Recovered
			Lethargy	嗜眠	1	N	TE	149		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	153		N	None	Ongoing at time of death
			Renal tubular necrosis	腎尿細管壊死	3	Y	TE	210	89	N	Not applicable	Recovered
042030	UK	61/M/C	Proctalgia	肛門周囲痛	2	N	TE			N	None	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	TE			N	None	Ongoing at time of death
			Depressed mood	抑うつ気分	1	N	TE			N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	1		N	None	
			Vomiting	嘔吐	1	N	TE	1		N	None	Recovered
			Bone pain	骨痛	1	N	TE	2	28	Y	None	Recovered
			Haematuria	血尿	3	Y	TE	12	5	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	1	N	TE	29	39	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	52		N	None	Recovered
			Renal failure acute	急性腎不全	3	Y	TE	52	8	N	Drug administration postponed	Recovered
			Hypotension	低血圧	2	N	TE	52		N	None	Recovered
			Constipation	便秘	3	Y	TE	67	6	N	Drug administration postponed	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	132	3	N	None	Recovered
			Deep vein thrombosis	深部静脈血栓症	2	N	TE	177		N	Drug permanently withdrawn	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	207		N	None	Ongoing at time of death
042034	UK	75/M/C	Oedema peripheral	末梢性浮腫	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	141		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	141		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	172	1	N	Not applicable	Death
042041	UK	80/M/C	Fatigue	疲労	2	N	TE			N	None	Recovered
			Cauda equina syndrome	馬尾症候群	3	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	5		Y	None	Recovered
			Urinary incontinence	尿失禁	1	N	TE	29	115	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	41	22	N	Drug administration postponed	Recovered with sequelae
			Bone pain	骨痛	3	N	TE	42	93	N	None	Recovered
			Pathological fracture	病的骨折	2	N	TE	62	73	N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	84	6	N	None	Recovered
			Cellulitis	蜂巣炎	2	N	TE	85	7	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	85	59	N	None	Recovered
			Bone pain	骨痛	2	N	TE	87		N	None	Ongoing at time of death
			Urine flow decreased	尿流量減少	1	N	TE	127	17	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	134	57	N	None	Recovered
			Haematuria	血尿	1	N	TE	142		N	Not applicable	Ongoing at time of death
			Dysarthria	構語障害	2	Y	TE	143	9	N	None	Recovered
			Aggression	攻撃性	2	Y	TE	143	5	N	None	Recovered
			Confusional state	錯乱状態	2	Y	TE	143	9	N	None	Recovered
			Urinary retention	尿閉	2	Y	TE	143	5	N	None	Recovered with sequelae
			Confusional state	錯乱状態	1	N	TE	151	40	N	None	Recovered
			Urinary retention	尿閉	3	N	TE	151		N	Not applicable	Ongoing at time of death
043003	UK	64/M/C	Anaemia	貧血	1	N	Pre	-5	99	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	1	29	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	1	6	Y	None	Recovered
			Mouth ulceration	口腔内潰瘍形成	2	N	TE	73	29	N	None	Recovered
			Bone pain	骨痛	2	N	TE	75	6	N	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	96	6	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	96		Y	None	Not recovered, but no changes expected
			Lower respiratory tract infection	下気道感染	3	Y	TE	101	3	N	None	Recovered
			Metastases to central nervous system	中枢神経系転移	4	Y	TE	121	9	N	Drug permanently withdrawn	Recovered
			Fatigue	疲労	1	N	TE	175	6	Y	None	Recovered
043005	UK	66/M/C	Bone pain	骨痛	2	N	Pre	-5	29	N	Not applicable	Recovered
			Myalgia	筋痛	1	N	TE	52	29	N	None	Recovered
			Myalgia	筋痛	1	N	TE	52	29	N	None	Recovered
			Fatigue	疲労	1	N	TE	108	42	N	None	Recovered
			Myalgia	筋痛	1	N	TE	148		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	216	3	N	Not applicable	Recovered
043007	UK	60/M/A	Urinary retention	尿閉	2	N	TE			N	Not applicable	Recovered
			Diarrhoea	下痢	2	N	TE	1		Y	None	Recovered
			Fatigue	疲労	1	N	TE	1		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	Pre	1	9	N	None	Recovered
			Bone pain	骨痛	2	N	TE	29	1	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	47	3	Y	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	85	29	N	None	Recovered
			Skin nodule	皮膚小結節	1	N	TE	85	29	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	94	4	Y	None	Recovered
			Cough	咳嗽	1	N	TE	94	7	Y	None	Recovered
			Skin discolouration	皮膚変色	1	N	TE	107		Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE	113		N	None	Not recovered, but no changes expected
			Dysuria	排尿困難	3	N	TE	122		N	None	Recovered with sequelae
			Urinary retention	尿閉	3	Y	TE	152	4	N	Not applicable	Recovered
			Micturition disorder	排尿異常	2	N	TE	156		N	Not applicable	Not recovered, but no changes expected
			Vertigo	回転性めまい	2	N	TE	198	41	N	None	Recovered
			Bone pain	骨痛	2	N	TE	198		N	None	Not recovered, but no changes expected
043011	UK	77/M/A	Vision blurred	霧視	1	N	TE			N	None	Recovered
			Diarrhoea	下痢	1	N	TE			Y	None	Recovered
			Paraesthesia	錯感覚	1	N	TE			N	None	Not recovered, but no changes expected
			Fatigue	疲労	2	N	TE	1		Y	None	Not recovered, but no changes expected
			Hypocalcaemia	低カルシウム血症	2	N	TE	10		N	None	Not recovered, but no changes expected
			Dizziness	浮動性めまい	2	Y	TE	36	2	N	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	56	29	N	None	Recovered
			Dizziness	浮動性めまい	2	N	TE	84	6	N	None	Recovered
			Skin discolouration	皮膚変色	1	N	TE	86		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	2	Y	TE	88	2	Y	None	Recovered
			Vertigo	回転性めまい	1	N	TE	106	3	N	None	Recovered
			Fatigue	疲労	3	N	TE	120		Y	None	Not recovered, but no changes expected
043012	UK	55/M/C	Diarrhoea	下痢	1	N	TE			Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nocturia	夜間頻尿	1	N	TE			N	None	Not recovered, but no changes expected
			Myalgia	筋痛	1	N	Pre	-6	64	N	None	Recovered
			Paraesthesia	錯感覚	1	N	TE	30	29	Y	None	Recovered
			Abdominal pain	腹痛	1	N	TE	86		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	135	14	N	None	Recovered
			Hydronephrosis	水腎症	3	Y	TE	135	14	N	None	Recovered
			Renal failure acute	急性腎不全	3	Y	TE	135	14	N	Drug permanently withdrawn	Recovered
			Nausea	悪心	2	N	TE	137		N	None	Recovered
			Pulmonary embolism	肺塞栓症	4	Y	TE	142	7	N	Drug permanently withdrawn	Recovered
			Constipation	便秘	2	N	TE	173		N	Not applicable	Recovered
044004	UK	76/M/C	Vomiting	嘔吐	1	N	TE			Y	None	
			Haematuria	血尿	1	N	TE			N	None	Recovered
			Ataxia	運動失調	2	N	TE	23		N	None	
			Speech disorder	会話障害	3	N	TE	23	29	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	23		N	None	
			Deafness	難聴	2	N	TE	51		N	None	
			Tinnitus	耳鳴	2	N	TE	51		N	None	
			Fatigue	疲労	1	N	TE	71		Y	None	
			Radiation skin injury	放射線皮膚損傷	1	N	TE	71		N	None	
			Arthralgia	関節痛	2	N	TE	71		Y	None	
			Alopecia	脱毛症	1	N	TE	71		N	None	
			Faecal incontinence	便失禁	1	N	TE	75	1	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	76	1	N	None	Recovered
			Urinary tract infection	尿路感染	1	N	TE	76		N	None	Recovered
			Aphasia	失語症	3	Y	TE	76	4	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE	78	2	N	None	Recovered
			Bone pain	骨痛	1	N	TE	99		Y	None	
			Bone pain	骨痛	2	N	TE	121		N	None	Not recovered, but no changes expected
			Confusional state	錯乱状態	2	N	TE	121	15	N	None	Recovered
			Mobility decreased	運動性低下	2	N	TE	135		N	None	Ongoing at time of death
			Haematuria	血尿	2	N	TE	154	88	N	Not applicable	Recovered
			Mania	躁病	2	N	TE	159		N	None	Ongoing at study termination / withdrawal
			Haematuria	血尿	2	Y	TE	227	14	N	Not applicable	Recovered
			Urinary retention	尿閉	3	Y	TE	227	15	N	Not applicable	Recovered with sequelae
044005	UK	76/M/C	Cardiac failure congestive	うっ血性心不全	4	N	TE			N	Drug administration postponed	Death
			Fatigue	疲労	2	N	TE			Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	7	1	Y	None	Recovered
			Left ventricular dysfunction	左室機能不全	3	N	TE	54	73	N	Drug administration postponed	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	54	73	N	Drug administration postponed	Ongoing at time of death
			Dyspnoea	呼吸困難	3	N	TE	54	17	N	Drug administration postponed	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Troponin T increased	トロポニンＴ増加	4	N	TE	57	70	N	Drug administration postponed	Ongoing at time of death
			Pleural effusion	胸水	2	N	TE	57	70	N	Drug administration postponed	Ongoing at time of death
			Pulmonary embolism	肺塞栓症	3	Y	TE	57	3	N	Drug permanently withdrawn	Recovered with sequelae
			Pulmonary oedema	肺水腫	1	N	TE	58	69	N	Drug administration postponed	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	70	57	N	Drug administration postponed	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	5	Y	TE	126	1	N	Drug administration postponed	Death
044009	UK	67/M/C	Diarrhoea	下痢	1	N	TE			Y	None	Recovered
			Bone pain	骨痛	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Haematuria	血尿	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	2		Y	None	Recovered
			Pelvic pain	骨盤痛	2	N	TE	56		N	None	Recovered
			Deep vein thrombosis	深部静脈血栓症	3	Y	TE	107	8	N	Drug administration postponed	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Intestinal perforation	腸管穿孔	4	Y	TE	167	10	N	Drug administration postponed	Recovered
			Anorexia	食欲不振	2	Y	TE	167	10	N	Drug administration postponed	Recovered
			Dehydration	脱水	3	Y	TE	167	10	N	Drug administration postponed	Recovered
			Deep vein thrombosis	深部静脈血栓症	3	Y	TE	167	11	N	Drug permanently withdrawn	Recovered with sequelae
			Pathological fracture	病的骨折	2	Y	TE	173	5	N	Drug administration postponed	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	173		N	Drug permanently withdrawn	Not recovered, but no changes expected
			Cellulitis	蜂巣炎	3	Y	TE	200	7	N	Not applicable	Recovered
045009	UK	57/M/C	Neutropenia	好中球減少症	4	N	TE	154	15	Y	Drug administration postponed	Recovered
			Bone pain	骨痛	2	N	TE	169	37	Y	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	176	31	N	Not applicable	Recovered
046002	UK	78/M/C	Urinary tract infection	尿路感染	2	N	TE			N	None	Recovered
			Urinary incontinence	尿失禁	1	N	TE			N	None	Recovered
			Anaemia	貧血	2	N	Post	250	138	Y	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	Post	387	2	Y	Not applicable	Recovered
046004	UK	64/M/C	Nausea	悪心		N	TE			Y	None	Recovered
			Vomiting	嘔吐		N	TE			Y	None	Recovered
			Bone pain	骨痛	3	N	TE			Y	None	Ongoing at study termination / withdrawal
			Night sweats	寝汗		N	TE			N	None	Recovered
			Nausea	悪心	2	N	TE	2	1	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	3	2	Y	None	Recovered
			Diarrhoea	下痢	2	N	TE	28	19	Y	None	Recovered
			Diarrhoea	下痢	2	N	TE	28	16	N	None	Recovered
			Bone pain	骨痛	2	N	TE	33	25	N	None	Recovered
			Anaemia	貧血	2	N	TE	56	108	Y	Not applicable	Recovered
			Diarrhoea	下痢	2	N	TE	57	2	N	None	Recovered
			Cough	咳嗽	1	N	TE	83	64	N	None	Recovered
			Anaemia	貧血	2	N	TE	107	57	Y	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	163	39	Y	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	163	39	Y	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	201	22	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	201	103	Y	Not applicable	Ongoing at time of death
			Anaemia	貧血	3	N	TE	222	11	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	232	3	Y	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	234	18	Y	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	251	14	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	264	31	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	294	10	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	303	21	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	303	76	Y	Not applicable	Ongoing at time of death
			Anaemia	貧血	3	N	TE	323	8	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	330	30	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	359	20	Y	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	378	9	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	378	77	Y	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	386		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	Post	454	23	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	Post	476		Y	None	Ongoing at time of death
047002	UK	81/M/C	Anaemia	貧血	3	N	TE	2	1	Y	None	Recovered
			Anaemia	貧血	3	N	TE	39	1	Y	None	Recovered
			Anaemia	貧血	3	N	TE	73	1	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	3	N	TE	85		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	2	N	TE	136		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	154	1	N	Not applicable	Death
047003	UK	75/M/C	Urinary tract infection	尿路感染	2	N	TE	14	8	N	None	Recovered with sequelae
			Urinary tract infection	尿路感染	2	N	TE	64	10	N	None	Recovered with sequelae
			Urinary retention	尿閉	3	Y	TE	98	3	N	None	Recovered with sequelae
			Infection	感染	2	N	TE	142	14	N	None	Recovered with sequelae
			Anaemia	貧血	3	N	TE	155	1	Y	None	Recovered
048001	UK	59/M/C	Decreased appetite	食欲減退	1	N	TE			N	None	Recovered
			Anaemia	貧血	1	N	Pre	-35	71	N	None	Recovered
			Constipation	便秘	2	N	Pre	-12	11	N	None	Recovered
			Musculoskeletal pain	筋骨格痛	3	Y	Pre	-4	12	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	3	1	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	6	1	N	None	Recovered
			Bone pain	骨痛	2	N	TE	8	97	N	None	Ongoing at time of death
			Hypocalcaemia	低カルシウム血症	2	N	TE	29	6	N	None	Recovered
			Vomiting	嘔吐	3	N	TE	33	1	N	None	Recovered
			Hypocalcaemia	低カルシウム血症	3	Y	TE	34	4	N	None	Recovered
			Anaemia	貧血	2	N	TE	36	34	N	None	Recovered
			Hypocalcaemia	低カルシウム血症	2	N	TE	37	21	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Lower respiratory tract infection	下気道感染	2	N	TE	58	6	N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE	58	13	N	None	Recovered
			Constipation	便秘	2	N	TE	62	24	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	62	1	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	62	1	N	None	Recovered
			Decreased appetite	食欲減退	2	N	TE	62	17	N	None	Recovered
			Lower respiratory tract infection	下気道感染	3	Y	TE	63	3	N	None	Recovered
			Depression	うつ病	2	N	TE	70		N	None	Ongoing at time of death
			Lymphadenopathy	リンパ節症	1	N	TE	85		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	104	37	N	None	Ongoing at time of death
			Decreased appetite	食欲減退	2	N	TE	113		N	None	Recovered
			Neutropenia	好中球減少症	2	N	TE	129	13	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	134	1	N	None	Recovered
			Bone pain	骨痛	2	N	TE	140		N	None	Ongoing at time of death
			Neutropenia	好中球減少症	3	N	TE	141	15	N	Drug administration postponed	Recovered
			Amnesia	健忘	1	N	TE	141		N	None	Ongoing at time of death
			Headache	頭痛	2	N	TE	141		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	145		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anxiety	不安	2	N	TE	147		N	None	Ongoing at time of death
			Oral candidiasis	口腔カンジダ症	1	N	TE	155		N	None	Ongoing at study termination / withdrawal
048003	UK	60/M/C	Anaemia	貧血	3	N	TE			N	Not applicable	Recovered
			Abdominal distension	腹部膨満	2	N	TE			N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE			N	Not applicable	Recovered
			Oral candidiasis	口腔カンジダ症	1	N	TE			N	Not applicable	Recovered
			Fatigue	疲労	1	N	TE	2	8	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	6	6	N	None	Recovered
			Asthenopia	眼精疲労	1	N	TE	29		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	60		N	None	Ongoing at time of death
			Myalgia	筋痛	2	N	TE	115		N	None	Ongoing at time of death
			Lethargy	嗜眠	1	N	TE	148		N	None	Ongoing at time of death
			Metastases to central nervous system	中枢神経系転移	4	Y	TE	164	19	N	Not applicable	Recovered with sequelae
048004	UK	71/M/C	Diarrhoea	下痢	2	N	TE			N	None	Recovered
			Nausea	悪心	2	N	TE			N	None	Recovered
			Vomiting	嘔吐	2	N	TE			N	None	Recovered
			Constipation	便秘	2	N	Pre	-2	4	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	4	2	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Diarrhoea	下痢	1	N	TE	8	3	N	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	37	107	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	109	3	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	109	3	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	168	16	N	Not applicable	Recovered
			Dyspepsia	消化不良	1	N	TE	169	4	N	Not applicable	Recovered
			Faecal incontinence	便失禁	2	N	TE	194	1	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	195	5	N	Not applicable	Recovered with sequelae
048007	UK	79/M/C	Bone pain	骨痛	2	N	Pre	1	31	N	Drug administration postponed	Recovered
			Constipation	便秘	2	N	TE	29		N	None	Recovered
			Bone pain	骨痛	2	N	TE	29		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	31	29	N	Drug administration postponed	Recovered
048010	UK	77/M/C	Decreased appetite	食欲減退	1	N	TE	4	2	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	6	3	N	None	Recovered
			Hot flush	ほてり	1	N	TE	6		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	8	62	N	-	
			Nausea	悪心	1	N	TE	25	4	N	None	Recovered
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2	N	TE	29	29	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	TE	29	29	Y	None	Recovered
			Nail avulsion	爪裂離	2	N	TE	52		N	None	Recovered with sequelae
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	3	N	TE	57	29	Y	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	57	29	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	69	144	N	Not applicable	Recovered
			Constipation	便秘	1	N	TE	70		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	72		N	None	Ongoing at time of death
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2	N	TE	85	29	Y	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	TE	85	29	Y	None	Recovered
			Paraesthesia	錯感覚	1	N	TE	127		N	None	Ongoing at time of death
			Bone pain	骨痛	2	Y	TE	212	8	N	Not applicable	Recovered
			Urinary incontinence	尿失禁	2	N	TE	212	8	N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	219		N	Not applicable	Ongoing at time of death
049002	UK	73/M/C	Lower respiratory tract infection	下気道感染	3	Y	TE	9	11	N	None	Recovered
			Oral candidiasis	口腔カンジダ症	2	N	TE	57	53	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Paraesthesia	錯感覚	1	N	TE	100	30	N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	Y	TE	109	3	N	Drug administration postponed	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	4	Y	TE	129		N	None	Ongoing at time of death
			Pneumonia	肺炎	4	Y	TE	135	7	N	Drug permanently withdrawn	Death
			Pneumonia	肺炎	5	Y	TE	141	1	N	Drug permanently withdrawn	Death
049007	UK	80/M/C	Nausea	悪心	2	N	TE	3		Y	None	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	3		Y	None	Ongoing at time of death
			Mucosal inflammation	粘膜の炎症	2	N	TE	29		Y	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	29		Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	120		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	128		N	None	Ongoing at time of death
			Headache	頭痛	2	N	TE	148	51	N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	176	3	N	Not applicable	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	198		N	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	3	Y	TE	198		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	198	12	N	Not applicable	Death
			Headache	頭痛	4	N	TE	198		N	None	Ongoing at time of death
			Urinary retention	尿閉	2	N	TE	204		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	209	1	N	Not applicable	Death
049008	UK	72/M/C	Decreased appetite	食欲減退	2	N	TE			N	None	Ongoing at time of death
			Lymphoedema	リンパ浮腫	1	N	Pre			N	None	Recovered
			Ear pain	耳痛	1	N	Pre	-7		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre	-3	5	N	None	Recovered
			Fatigue	疲労	2	N	TE	29		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	29	50	Y	None	Recovered
			Constipation	便秘	2	N	TE	40		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	40	2	N	None	Recovered with sequelae
			Palpitations	動悸	1	N	TE	54	4	N	Not applicable	Recovered
			Depressed mood	抑うつ気分	1	N	TE	54		N	None	Ongoing at time of death
			Vomiting	嘔吐	2	Y	TE	57	6	N	Drug administration postponed	Recovered
			Pyrexia	発熱	1	Y	TE	61	2	N	Drug administration postponed	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	2	Y	TE	65	6	N	Drug administration postponed	Recovered with sequelae
			Vomiting	嘔吐	2	Y	TE	65	6	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	N	TE	67	1	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	89	1	N	Not applicable	Recovered
			Abdominal pain	腹痛	3	Y	TE	111		N	Not applicable	Ongoing at time of death
			Nausea	悪心	3	Y	TE	111		N	Not applicable	Ongoing at time of death
			Vomiting	嘔吐	3	Y	TE	111		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	111	11	N	Not applicable	Death
			Anaemia	貧血	2	N	TE	113		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	121	1	N	Not applicable	Death
050005	UK	77/M/C	Diarrhoea	下痢	1	N	TE	3	2	N	None	Recovered
			Bone pain	骨痛	3	N	TE	18		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	18	29	N	None	Recovered
			Muscular weakness	筋力低下	1	N	TE	29	26	N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	46		N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Muscular weakness	筋力低下	2	N	TE	54	5	N	None	Ongoing at study termination / withdrawal
			Muscular weakness	筋力低下	3	N	TE	58		N	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	2	Y	TE	60	13	N	None	Recovered with sequelae
			Cerebrovascular accident	脳血管発作	4	Y	TE	64	9	N	Drug administration postponed	Recovered with sequelae
			Eye infection	眼感染	2	N	TE	70		N	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	2	N	TE	72	12	N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	82	2	N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	Y	TE	83		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	2	Y	TE	83	2	N	None	Recovered
			Spinal cord compression	脊髄圧迫	2	Y	TE	83		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
050019	UK	70/M/C	Urine output increased	尿量増加	1	N	TE			N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Night sweats	寝汗	1	N	TE			N	Not applicable	Recovered
			Dehydration	脱水	2	Y	Pre	-6	2	N	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	1	N	TE	55	3	N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	55	3	N	None	Recovered
			Infection	感染	3	Y	TE	60	3	N	None	Recovered with sequelae
			Gout	痛風	2	N	TE	74	14	N	None	Recovered
			Bone pain	骨痛	1	N	TE	99		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	113		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE	141		N	None	Ongoing at time of death
			Transient ischaemic attack	一過性脳虚血発作	2	Y	TE	189	4	N	Not applicable	Recovered
			Confusional state	錯乱状態	3	Y	TE	195	9	N	Not applicable	Recovered
			Urinary retention	尿閉	2	N	TE	195	6	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	196	4	N	Not applicable	Recovered
			Rash	発疹	1	N	TE	200	89	N	Not applicable	Recovered
051003	UK	65/M/C	Bone pain	骨痛	2	N	TE	3		Y	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	1	N	TE	5		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	2	N	TE	5		N	None	Ongoing at time of death
			Dysgeusia	味覚異常	1	N	TE	5		Y	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	12		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	42		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	4	Y	TE	42		N	Drug permanently withdrawn	Ongoing at time of death
051007	UK	75/M/C	Bone pain	骨痛	2	N	Pre	-8	59	N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	2	1	Y	None	Recovered
			Bone pain	骨痛	1	N	Pre	51		N	None	Ongoing at time of death
			Dyspepsia	消化不良	1	N	TE	63	25	Y	None	Ongoing at time of death
			Dyspepsia	消化不良	3	N	TE	87	2	Y	None	Ongoing at time of death
			Dyspepsia	消化不良	1	N	TE	88		Y	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	90	80	Y	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	106	26	N	None	Recovered
			Nerve root compression	神経根圧迫	4	Y	TE	119	2	N	Drug administration postponed	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Night sweats	寝汗	1	N	TE	119	35	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	147		N	Drug administration postponed	Ongoing at time of death
			Night sweats	寝汗	2	N	TE	153		N	None	Ongoing at time of death
			Oedema	浮腫	1	N	TE	159		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	169		Y	None	Ongoing at time of death
			Metastases to central nervous system	中枢神経系転移	2	Y	TE	174		N	Not applicable	Not recovered, but no changes expected
051010	UK	68/M/C	Bone pain	骨痛	2	N	TE	21		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	47		N	None	Not recovered, but no changes expected
			Urinary bladder haemorrhage	膀胱出血	1	N	TE	47	49	N	Drug administration postponed	Not recovered, but no changes expected
			Fatigue	疲労	2	N	TE	58		N	None	Ongoing at time of death
			Pilonidal cyst	毛巣嚢胞	2	N	TE	64	65	N	None	Recovered
			Bone pain	骨痛	2	N	TE	83	23	N	None	Recovered
			Urinary bladder haemorrhage	膀胱出血	3	N	TE	95		N	Drug administration postponed	Not recovered, but no changes expected
			Renal failure acute	急性腎不全	3	Y	TE	204	10	N	Not applicable	Recovered with sequelae
051011	UK	77/M/C	Bone pain	骨痛	2	N	TE	2	5	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	30	4	N	None	Recovered
			Bone pain	骨痛	2	N	TE	30	2	Y	None	Recovered
			Nausea	悪心	1	N	TE	44		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	44	32	N	None	Recovered
			Bone pain	骨痛	2	N	TE	75	39	N	None	Recovered
			Bile duct obstruction	胆管閉塞	2	Y	TE	166	12	N	Not applicable	Recovered with sequelae
			Bile duct obstruction	胆管閉塞	2	Y	TE	177		N	Not applicable	Not recovered, but no changes expected
			Insomnia	不眠症	1	N	TE	219		N	None	Ongoing at time of death
051012	UK	73/M/C	Decreased appetite	食欲減退	1	N	TE	30		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	108	1	N	None	Death
051021	UK	74/M/C	Gastric ulcer	胃潰瘍	1	N	TE			N	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE			N	None	Recovered
			Pulmonary embolism	肺塞栓症	4	N	TE			N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	8	41	Y	None	Recovered
			Intervertebral disc protrusion	椎間板突出	1	N	TE	8		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	42	7	N	None	Recovered with sequelae
			Anorexia	食欲不振	2	N	TE	94		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	120	211	N	None	Recovered
			Constipation	便秘	2	N	TE	125		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dehydration	脱水	2	Y	TE	125	8	N	None	Recovered
			Helicobacter infection	ヘリコバクター感染	2	N	TE	131	7	N	None	Recovered
053002	Netherlands	79/M/C	Balance disorder	平衡障害	1	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	Pre	-9	19	N	None	Recovered
			Fatigue	疲労	2	N	TE	1	224	Y	None	Recovered with sequelae
			Nausea	悪心	2	N	TE	2	6	Y	None	Recovered
			Nausea	悪心	1	N	TE	7	232	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	7	1	Y	None	Recovered
			Increased tendency to bruise	挫傷発生の増加傾向	1	N	TE	29		Y	None	Not recovered, but no changes expected
			Gastrointestinal pain	消化器痛	1	N	TE	113	1	N	None	Recovered
			Bone pain	骨痛	2	N	TE	116	54	N	None	Recovered with sequelae
			Eructation	おくび	1	N	TE	149		N	None	Not recovered, but no changes expected
			Vomiting	嘔吐	2	N	TE	149	6	Y	Not applicable	Recovered
			Dizziness postural	体位性めまい	1	N	TE	162		N	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	169		N	None	Not recovered, but no changes expected
			Thrombocytopenia	血小板減少症	2	N	TE	176		N	Not applicable	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	176		N	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	3	Y	TE	177	2	Y	Not applicable	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	3	N	TE	224		Y	None	Not recovered, but no changes expected
053004	Netherlands	72/M/C	Bone pain	骨痛	1	N	Pre	-1	4	N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	3	22	Y	None	Recovered with sequelae
			Headache	頭痛	1	N	TE	3	22	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	24		N	None	Not recovered, but no changes expected
			Chills	悪寒	1	N	TE	31	4	Y	None	Recovered
			Pruritus	そう痒症	1	N	TE	31	4	Y	None	Recovered
			Nausea	悪心	2	N	TE	32	3	Y	None	Recovered
			Myalgia	筋痛	1	N	TE	32	3	Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	1	N	TE	38	70	N	None	Recovered
			Bone pain	骨痛	1	N	TE	79	15	N	None	Recovered with sequelae
			Faecal incontinence	便失禁	1	N	TE	81	31	N	None	Not recovered, but no changes expected
			Back pain	背部痛	2	N	TE	93	12	N	None	Recovered
			Back pain	背部痛	3	N	TE	104	38	N	None	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	104		N	None	Not recovered, but no changes expected
			Faecal incontinence	便失禁	2	N	TE	111		N	None	Not recovered, but no changes expected
			Faecal incontinence	便失禁	2	N	TE	111	60	N	None	Recovered
			Gastritis	胃炎	1	N	TE	113	24	N	None	Recovered
			Rash pruritic	そう痒性皮疹	1	N	TE	130	7	Y	None	Recovered
			Nausea	悪心	2	N	TE	141	7	Y	Not applicable	Recovered
			Fatigue	疲労	3	N	TE	141	7	Y	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

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Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	1	N	TE	150	8	N	Not applicable	Recovered
			Radicular syndrome	根症候群	3	Y	TE	150	8	N	Not applicable	Recovered with sequelae
			Haematuria	血尿	1	N	TE	153	5	N	Not applicable	Recovered
			Radicular syndrome	根症候群	2	N	TE	157		N	Not applicable	Not recovered, but no changes expected
054001	Netherlands	75/M/C	Upper respiratory tract infection	上気道感染	1	N	Pre	-15	8	N	Drug administration postponed	Recovered
			Diarrhoea	下痢	1	N	TE	3		Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	57	7	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	63	2	Y	None	Recovered
			Colitis	大腸炎	2	N	TE	86		Y	None	Ongoing at study termination / withdrawal
055002	Netherlands	66/M/C	Lung infection	肺感染	2	N	TE	18	27	N	None	Recovered
			Anorexia	食欲不振	2	N	TE	54		Y	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	54		Y	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	59		Y	None	Ongoing at time of death
			Drug intolerance	薬物不耐性	4	Y	TE	71	3	N	None	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pulmonary embolism	肺塞栓症	4	Y	TE	71		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	74	1	N	None	Death
060002	Spain	84/M/C	Anorexia	食欲不振	2	N	TE	29		N	None	Ongoing at time of death
			Cardiac failure	心不全	3	N	TE	100		N	None	Ongoing at study termination / withdrawal
			Dyspnoea	呼吸困難	2	N	TE	100		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	101	31	N	Not applicable	Ongoing at time of death
			Bronchitis	気管支炎	2	N	TE	107	2	N	None	Recovered
			Renal failure	腎不全	2	N	TE	107	3	N	None	Recovered
			Bronchitis	気管支炎	3	Y	TE	108		N	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	N	TE	109	5	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	113	11	Y	None	Ongoing at time of death
			Hyperuricaemia	高尿酸血症	1	N	TE	113		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	123		Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	129	1	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	131		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Death	死亡	5	Y	TE	137	1	N	Not applicable	Death
060003	Spain	85/M/C	Bone pain	骨痛	3	N	TE	31	26	N	None	Ongoing at time of death
			Weight decreased	体重減少	2	N	TE	56	6	N	None	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	2	N	TE	56	11	N	None	Recovered
			Bone pain	骨痛	2	N	TE	56		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	57		N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	61		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	111	1	N	Not applicable	Death
060007	Spain	79/M/C	Nausea	悪心	1	N	Pre	-20	28	N	None	Recovered
			Anorexia	食欲不振	2	N	Pre	-20		N	None	Ongoing at time of death
			Haematuria	血尿	2	N	TE	5		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	6	4	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	6	12	N	Drug permanently withdrawn	Death
			Pyrexia	発熱	1	N	TE	7	2	N	None	Recovered
			Respiratory tract infection	気道感染	2	N	TE	7		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	3	N	TE	8		N	None	Ongoing at time of death
			Asthenia	無力症	1	N	TE	12	2	N	None	Ongoing at time of death
			Asthenia	無力症	3	N	TE	13		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	17	1	N	Drug permanently withdrawn	Death
060010	Spain	75/M/C	Pruritus	そう痒症	1	N	TE	1	37	N	None	Recovered
			Anaemia	貧血	1	N	TE	29	2	Y	None	Recovered
			Cholestasis	胆汁うっ滞	3	Y	TE	29	9	N	Drug permanently withdrawn	Recovered
			Hyperbilirubinaemia	高ビリルビン血症	3	N	TE	29	3	N	None	Recovered
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	3	N	TE	29	3	N	-	
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	29	3	N	-	
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	TE	29	60	N	None	Not recovered, but no changes expected
			Pollakiuria	頻尿	1	N	TE	29	29	N	None	Recovered
			Anaemia	貧血	1	N	TE	31	80	Y	None	Recovered
			Hyperbilirubinaemia	高ビリルビン血症	2	N	TE	31	6	N	None	Recovered
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2	N	TE	31	6	N	-	
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	TE	31	3	N	-	

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1	N	TE	33	22	N	-	
			Hyperbilirubinaemia	高ビリルビン血症	1	N	TE	36	19	N	None	Recovered
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	1	N	TE	36	19	N	-	
			Cholestasis	胆汁うっ滞	1	N	TE	37	35	N	None	Recovered
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2	N	TE	54	18	N	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	TE	54	18	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	57	57	N	None	Recovered
			Cholestasis	胆汁うっ滞	3	Y	TE	71	3	N	Not applicable	Recovered
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	1	N	TE	71	34	N	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1	N	TE	71	40	N	None	Recovered
			Cholestasis	胆汁うっ滞	1	N	TE	73	30	N	None	Recovered
			Hyperbilirubinaemia	高ビリルビン血症	2	N	TE	88	17	N	None	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	4	N	TE	88	23	N	None	Not recovered, but no changes expected
			Chromaturia	着色尿	1	N	TE	88	26	N	None	Recovered
			Cholestasis	胆汁うっ滞	3	Y	TE	102	3	N	Not applicable	Recovered
			Hyperbilirubinaemia	高ビリルビン血症	3	N	TE	104	7	N	None	Recovered
			Hyperbilirubinaemia	高ビリルビン血症	1	N	TE	110	13	N	None	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	TE	110		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	122	41	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	162	64	Y	None	Recovered
063002	Spain	64/M/C	Dizziness	浮動性めまい	1	N	Pre			N	None	Recovered
			Respiratory tract infection	気道感染	2	N	TE	16	9	N	None	Recovered
			Muscle spasms	筋痙縮	1	N	TE	29	29	N	None	Recovered
			Discomfort	不快感	1	N	TE	57	3	Y	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	143	29	N	None	Recovered
			Gastroenteritis	胃腸炎	2	Y	TE	183	4	N	Not applicable	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	226	34	N	Not applicable	Recovered
063004	Spain	74/M/C	Abdominal pain upper	上腹部痛	1	N	TE	32	55	N	None	Recovered
			Somnolence	傾眠	2	N	TE	32	55	N	None	Recovered
			Anaemia	貧血	3	N	TE	58	29	N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	86		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	86	29	N	Not applicable	Ongoing at time of death
			Asthenia	無力症	1	N	TE	86		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	86		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	114		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	128	8	N	Drug permanently withdrawn	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	135	1	N	Drug permanently withdrawn	Death
066004	Spain	78/M/C	Asthenia	無力症	1	N	TE	30	58	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	30	28	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	87	27	N	None	Recovered
			Toothache	歯痛	1	N	TE	113	32	N	None	Recovered
			Pancytopenia	汎血球減少症	4	Y	TE	144		Y	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	144	44	Y	None	Ongoing at time of death
			Asthenia	無力症	1	N	TE	177	78	N	Not applicable	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	177	51	N	None	Recovered
070003	Spain	74/M/C	Constipation	便秘	2	N	TE	57	29	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	85	50	N	None	Recovered
			Dyspepsia	消化不良	1	N	TE	85	50	N	None	Recovered
			Nausea	悪心	2	N	TE	85	50	Y	None	Recovered
			Anorexia	食欲不振	2	N	TE	85	50	N	None	Recovered
			Cardiac failure	心不全	3	Y	TE	105	15	N	Drug administration postponed	Recovered
			Renal failure	腎不全	3	Y	TE	105	3	N	Drug administration postponed	Recovered
			Constipation	便秘	1	N	TE	218	29	N	None	Recovered
071006	Spain	76/M/C	Oedema peripheral	末梢性浮腫	1	N	Pre	1	29	N	None	Recovered
			Constipation	便秘	2	Y	TE	35	19	N	None	Recovered
			Asthenia	無力症	2	Y	TE	35	19	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	2	Y	TE	35	19	N	None	Recovered
			Renal failure	腎不全	2	Y	TE	52	2	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	80	37	N	None	Recovered
			Bone pain	骨痛	2	N	TE	199	155	N	Not applicable	Recovered
			Headache	頭痛	2	N	TE	199	59	N	None	Recovered
074002	Italy	79/M/C	Muscle spasms	筋痙縮	1	N	Pre	-10	11	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	28	8	N	None	Recovered
			Asthenia	無力症	2	N	TE	33	3	N	None	Recovered
			Pyrexia	発熱	1	N	TE	33	15	N	Drug administration postponed	Recovered
			Urinary tract infection	尿路感染	2	N	TE	46	39	N	None	Recovered
			Dry skin	皮膚乾燥	1	N	TE	75	10	Y	None	Recovered
			Asthenia	無力症	1	N	TE	84	83	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	131	29	Y	None	Recovered
			Neutropenia	好中球減少症	2	N	TE	131	29	Y	Drug permanently withdrawn	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	131	29	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	159	18	Y	None	Recovered
			Leukopenia	白血球減少症	4	N	TE	159	4	Y	None	Recovered
			Neutropenia	好中球減少症	4	N	TE	159	4	Y	Drug permanently withdrawn	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	159	15	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	162	5	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neutropenia	好中球減少症	1	N	TE	162	5	Y	Drug permanently withdrawn	Recovered
			Blood urea increased	血中尿素増加	1	N	TE	162	43	N	None	Recovered
			Asthenia	無力症	2	N	TE	166		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	173	8	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	180	8	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	183	5	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	187	32	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	187	8	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	194	11	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	204	15	Y	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	218	5	Y	None	Recovered
			Thrombocytopenia	血小板減少症	4	N	TE	218	5	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	222	2	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	222	2	Y	None	Ongoing at time of death
			Bone marrow tumour cell infiltration	腫瘍細胞の骨髄浸潤	3	Y	TE	222	37	N	Not applicable	Death
			Anaemia	貧血	3	N	TE	223	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	223	2	Y	None	

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neutropenia	好中球減少症	1	N	TE	223	5	Y	Not applicable	
			Thrombocytopenia	血小板減少症	4	N	TE	223	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	1	N	TE	224	2	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	225	8	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	225	1	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	1	N	TE	225	3	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	225	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	227	3	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	2	N	TE	227	3	Y	Not applicable	
			Thrombocytopenia	血小板減少症	4	N	TE	227	4	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	229	2	Y	None	
			Neutropenia	好中球減少症	3	N	TE	229	2	Y	Not applicable	
			Leukopenia	白血球減少症	2	N	TE	230	4	Y	None	
			Neutropenia	好中球減少症	2	N	TE	230	2	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	230	3	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	1	N	TE	231	3	Y	Not applicable	Recovered
			Anaemia	貧血	1	N	TE	232	4	Y	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	4	N	TE	232	4	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	233	2	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	2	N	TE	233	2	Y	Not applicable	Recovered
			Leukopenia	白血球減少症	2	N	TE	234	4	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	235	7	Y	None	Recovered
			Neutropenia	好中球減少症	1	N	Post	235	3	Y	-	
			Thrombocytopenia	血小板減少症	3	N	TE	235	2	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	236	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	237	7	Y	None	
			Neutropenia	好中球減少症	2	N	Post	237	2	Y	-	
			Neutropenia	好中球減少症	3	N	Post	238	5	Y	-	
			Thrombocytopenia	血小板減少症	3	N	TE	238	4	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	241	2	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	241	3	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	242	8	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	2	N	Post	242	4	Y	Not applicable	Recovered
			Leukopenia	白血球減少症	2	N	TE	243	3	Y	None	
			Thrombocytopenia	血小板減少症	3	N	TE	243	2	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	244		Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	1	N	TE	245	9	Y	None	

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	249		Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	253	2	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	1	N	Post	253	4	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	1	N	TE	254	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	256		Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	2	N	Post	256		Y	None	Ongoing at time of death
			Bone marrow tumour cell infiltration	腫瘍細胞の骨髄浸潤	5	Y	TE	258	1	N	Not applicable	Death
075001	Italy	59/M/C	Strangury	有痛性排尿困難		N	TE	2	2	N	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	14	28	N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	33	10	Y	Drug administration postponed	Recovered
			Vomiting	嘔吐	1	N	TE	33	10	Y	Drug administration postponed	Recovered
			Anorexia	食欲不振	1	N	TE	33	10	Y	Drug administration postponed	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	41		N	None	Ongoing at time of death
			Strangury	有痛性排尿困難	2	N	TE	78	1	N	None	Recovered
			Death	死亡	5	Y	TE	93	1	N	None	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
078001	Italy	76/M/C	Constipation	便秘	1	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE			N	None	Recovered
			Pyrexia	発熱	1	N	TE			N	None	Recovered
			Confusional state	錯乱状態	1	N	TE			N	None	Recovered
			Hyperhidrosis	多汗症	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE	2	11	Y	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	38	21	N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	58	21	N	None	Ongoing at time of death
			Asthenia	無力症	2	N	TE	78	37	Y	None	Recovered
			Pyrexia	発熱	1	N	TE	78	29	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	78		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	78	37	N	None	Recovered
			Fatigue	疲労	2	N	TE	127	14	N	None	Ongoing at time of death
			Depression	うつ病	2	N	TE	127		N	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	141		N	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	147	2	Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	Y	TE	147	2	Y	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	149	14	Y	Drug permanently withdrawn	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	4	Y	TE	149	11	Y	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	1	Y	TE	163		Y	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	163	15	N	Not applicable	Death
078003	Italy	74/M/C	Somnolence	傾眠	2	N	Pre	1		N	None	Ongoing at time of death
			Confusional state	錯乱状態	2	N	Pre	1		N	None	Ongoing at time of death
			Upper limb fracture	上肢骨折	2	N	TE	20	25	N	None	Recovered
			Asthenia	無力症	2	N	TE	49		Y	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	187		N	Not applicable	Ongoing at time of death
			Amnesia	健忘	2	N	TE	198		N	Not applicable	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	3	Y	TE	213	8	N	Not applicable	Death
			General physical health deterioration	全身健康状態低下	5	Y	TE	220	1	N	Not applicable	Death
078006	Italy	77/M/C	Pyrexia	発熱	1	N	TE	39	34	N	None	Recovered
			Pyrexia	発熱	1	N	TE	91	14	N	None	Recovered
			Anaemia	貧血	2	N	TE	104		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	104		Y	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	104	28	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	131	1	N	Drug permanently withdrawn	Death
080004	Italy	72/M/C	Weight decreased	体重減少	1	N	Pre	-13	13	N	None	Ongoing at time of death
			Weight decreased	体重減少	2	N	Pre	-1		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	Pre	-1	50	N	None	Recovered
			Bone pain	骨痛	3	N	TE	49	85	N	None	Recovered
			Fatigue	疲労	3	N	TE	133		N	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	133		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	161	1	N	Not applicable	Death
085004	Israel	61/M/C	Asthenia	無力症	1	N	Pre	-4	1	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	Pre	1	30	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	10	3	N	None	Recovered
			Pyrexia	発熱	1	N	TE	36	8	N	None	Recovered
			Arthralgia	関節痛	1	N	TE	100	16	N	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	2	N	TE	115		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	148		N	None	Not recovered, but no changes expected
			Anaemia	貧血	3	N	TE	167	3	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Spinal cord compression	脊髄圧迫	2	Y	TE	167	4	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	TE	220	7	N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	Y	TE	220	7	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	220	7	N	Not applicable	Recovered with sequelae
			Oral fungal infection	口腔真菌感染	1	N	TE	222	6	N	Not applicable	Recovered
087002	Israel	69/M/C	Dysgeusia	味覚異常	1	N	TE	29	28	Y	None	Recovered
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	2	N	TE	29	13	N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	33		N	None	Ongoing at study termination / withdrawal
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	3	N	TE	41		N	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	3	Y	TE	44	2	N	None	Recovered with sequelae
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	44	68	N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Haematoma	血腫	1	N	TE	44		N	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	3	N	TE	45		N	None	Ongoing at study termination / withdrawal
			Oral candidiasis	口腔カンジダ症	1	N	TE	56	36	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Blood urea increased	血中尿素増加	1	N	TE	56		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	56	36	N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	3	N	TE	91		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	91		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	91		N	None	Ongoing at study termination / withdrawal
			Decubitus ulcer	褥瘡性潰瘍	3	N	TE	111		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
093002	Slovakia	81/M/C	Anaemia	貧血	2	N	TE	29	48	N	-	
			Nausea	悪心	2	N	TE	29	85	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	29	6	Y	None	Recovered
			Constipation	便秘	1	N	TE	56	58	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	56	4	Y	None	Recovered
			Anaemia	貧血	3	N	TE	76	10	N	-	
			Bone pain	骨痛	3	Y	TE	76	8	N	None	Recovered with sequelae
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	76		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	85	29	N	-	
			Diarrhoea	下痢	2	N	TE	85	5	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	113	31	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	Y	TE	143	5	N	Drug administration postponed	Recovered
			Bronchopneumonia	気管支肺炎	3	N	TE	150		N	None	Ongoing at time of death
			Cardiopulmonary failure	心肺不全	5	Y	TE	160	1	N	Not applicable	Death
096002	Slovakia	84/M/C	Anaemia	貧血	1	N	TE	58	29	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	86	112	Y	Not applicable	Recovered
			Haematuria	血尿	1	N	TE	90	9	N	None	Recovered
			Anaemia	貧血	3	Y	TE	197	4	Y	Not applicable	Recovered
097002	Slovakia	73/M/C	Pyrexia	発熱	1	N	TE	50	3	N	None	Recovered
			Pyrexia	発熱	1	N	TE	59	8	N	None	Recovered
			Pyrexia	発熱	1	N	TE	59	8	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	85	57	N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	107	15	N	None	Recovered
			Fatigue	疲労	3	Y	TE	107	15	Y	None	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	2	N	TE	107		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	107	15	N	None	Recovered with sequelae
			Vomiting	嘔吐	1	N	TE	113	5	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	141	22	N	Not applicable	Recovered
			Weight decreased	体重減少	2	N	TE	141		N	None	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	162	7	N	Not applicable	Recovered
			Fatigue	疲労	3	Y	TE	162	7	Y	Not applicable	Recovered with sequelae
			Anorexia	食欲不振	3	Y	TE	162	7	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	1	N	TE	168		N	Not applicable	Ongoing at time of death
			Fatigue	疲労	2	N	TE	168		Y	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	168		N	Not applicable	Ongoing at time of death
097006	Slovakia	73/M/C	Fatigue	疲労	2	N	Pre	1	10	N	None	Recovered
			Mixed incontinence	混合性尿失禁	3	N	Pre	1		N	None	Ongoing at study termination / withdrawal
			Spinal column stenosis	脊柱管狭窄症	4	Y	TE	2	17	N	None	Recovered with sequelae
			Fatigue	疲労	3	N	TE	10	161	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	15	14	N	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	28		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	86	85	Y	None	Recovered
			Weight decreased	体重減少	1	N	TE	113	29	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	113	58	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	113	62	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	141	30	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	1	N	TE	170	57	N	None	Recovered
097015	Slovakia	75/M/C	Calculus ureteric	尿管結石	3	Y	TE	203	9	N	Not applicable	Recovered
099002	Slovakia	69/M/C	Nausea	悪心	1	N	Pre	-3	32	N	None	Recovered
			Bone pain	骨痛	1	N	Pre	-3	32	N	None	Recovered
			Nausea	悪心	1	N	Pre	29	35	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	57	58	N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	57	2	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	79		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	85		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	102	68	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	105	7	N	None	Recovered
			Urinary tract infection	尿路感染	1	N	TE	106	8	N	None	Recovered
			Anaemia	貧血	1	N	TE	107	63	N	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	2	N	TE	114		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	169		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hypocalcaemia	低カルシウム血症	1	N	TE	169		N	None	Ongoing at study termination / withdrawal
			Hypophosphataemia	低リン酸血症	2	N	TE	169	64	N	None	Recovered
			Bone pain	骨痛	2	N	TE	207	2	N	Not applicable	Recovered
			Bone pain	骨痛	2	Y	TE	208	14	N	Not applicable	Recovered
103001	Hong Kong	74/M/A	Hypoaesthesia	感覚鈍麻	1	N	Pre	-6	22	N	None	Recovered
			Fatigue	疲労	1	N	TE	5		Y	None	Ongoing at study termination / withdrawal
			Neutropenia	好中球減少症	2	N	TE	12	37	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	12	2	N	None	Recovered
			Abdominal distension	腹部膨満	1	N	TE	13	61	Y	None	Recovered
			Abdominal pain	腹痛	1	N	TE	13	17	Y	None	Recovered
			Headache	頭痛	1	N	TE	14	27	N	None	Recovered
			Constipation	便秘	1	N	TE	25		Y	None	Ongoing at study termination / withdrawal
			Abdominal pain	腹痛	2	N	TE	29	28	Y	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	40	5	N	None	Recovered
			Intentional overdose	企図的過量投与	4	Y	TE	48	7	N	Not applicable	Recovered
			Hypoalbuminaemia	低アルブミン血症	1	N	TE	48	64	N	None	Recovered
			Depression	うつ病	4	Y	TE	48	26	N	Not applicable	Recovered with sequelae
			Intentional self-injury	故意の自傷行為	4	Y	TE	48	7	N	Not applicable	Recovered
			Intentional self-injury	故意の自傷行為	2	Y	TE	48	7	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Depression	うつ病	2	N	TE	54		N	Not applicable	Ongoing at study termination / withdrawal
			Rash	発疹	1	N	TE	59	24	N	None	Recovered
103002	Hong Kong	75/M/A	Constipation	便秘	1	N	TE	28	30	N	None	Ongoing at study termination / withdrawal
			Constipation	便秘	2	N	TE	57		N	None	Ongoing at study termination / withdrawal
			Tinea pedis	足部白癬	1	N	TE	105		N	None	Ongoing at study termination / withdrawal
			Dysuria	排尿困難	1	N	TE	147	36	N	None	Recovered
			Cough	咳嗽	1	N	TE	167	10	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	194	3	N	None	Recovered
			Lower respiratory tract infection	下気道感染	3	Y	TE	196	4	N	Not applicable	Recovered
104005	Hong Kong	73/M/A	Constipation	便秘	1	N	TE	1	29	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	64	2	Y	None	Recovered
			Pneumonia	肺炎	2	N	TE	87		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	87	18	N	Drug permanently withdrawn	Death
			Spinal cord compression	脊髄圧迫	5	Y	TE	104	1	N	Drug permanently withdrawn	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
105004	Hong Kong	70/M/A	Urinary retention	尿閉	2	N	Pre	-14	15	N	Drug administration postponed	Recovered
			Malaise	倦怠感	1	N	TE	2		Y	None	Not recovered, but no changes expected
			Abdominal pain	腹痛	1	N	TE	80	23	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	80	23	N	None	Recovered
			Muscle spasms	筋痙縮	2	N	TE	85		N	None	Not recovered, but no changes expected
			Muscle spasms	筋痙縮	2	N	TE	85		N	None	Not recovered, but no changes expected
			Pyrexia	発熱	1	N	TE	89	11	N	None	Recovered
			Musculoskeletal chest pain	筋骨格系胸痛	2	Y	TE	99	4	N	None	Recovered
			Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	2	N	TE	100	19	N	None	Recovered
			Anaemia	貧血	3	Y	TE	118	2	N	None	Recovered
			Musculoskeletal chest pain	筋骨格系胸痛	2	Y	TE	118	2	N	Drug administration postponed	Recovered with sequelae
			Abdominal pain upper	上腹部痛	2	Y	TE	120	5	N	Drug administration postponed	Recovered
			Faecal incontinence	便失禁	2	Y	TE	120	5	N	Drug administration postponed	Recovered with sequelae
			Musculoskeletal chest pain	筋骨格系胸痛	2	Y	TE	120	5	N	None	Recovered
			Haematuria	血尿	2	Y	TE	120	5	N	Drug administration postponed	Recovered
			Urinary incontinence	尿失禁	2	Y	TE	120	5	N	Drug administration postponed	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Faecal incontinence	便失禁	2	N	TE	125		N	Drug administration postponed	Not recovered, but no changes expected
			Hearing impaired	聴覚障害	2	N	TE	129		N	None	Ongoing at study termination / withdrawal
			Dizziness	浮動性めまい	1	N	TE	134		N	None	Not recovered, but no changes expected
			Haematuria	血尿	2	N	TE	134	8	N	None	Recovered
			Anaemia	貧血	3	N	TE	141	8	N	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	141		N	Not applicable	Ongoing at study termination / withdrawal
			Cellulitis	蜂巣炎	3	Y	TE	148	10	N	Not applicable	Recovered
			Urinary tract infection	尿路感染	3	N	TE	148	4	N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	2	N	TE	148	3	N	None	Recovered
			Anaemia	貧血	3	Y	TE	170	4	N	Not applicable	Recovered
			Haematuria	血尿	2	Y	TE	170	4	N	Not applicable	Recovered
106002	Hong Kong	76/M/A	Hypoaesthesia	感覚鈍麻	1	N	TE	29	57	N	None	Recovered
			Pathological fracture	病的骨折	2	N	TE	85		N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	1	N	TE	113	3	N	None	Recovered
			Sleep disorder	睡眠障害	1	N	TE	113	29	N	None	Recovered
			Constipation	便秘	1	N	TE	141	29	Y	None	Recovered
			Cough	咳嗽	1	N	TE	169		N	None	Ongoing at time of death
			Haemophilus infection	ヘモフィルス感染	2	N	TE	178	14	N	None	Recovered
			Cardiac failure congestive	うっ血性心不全	3	Y	TE	221	26	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Musculoskeletal pain	筋骨格痛	3	Y	TE	221	26	N	Not applicable	Recovered
			Insomnia	不眠症	2	N	TE	221	3	N	None	Recovered
106005	Hong Kong	79/M/A	Decreased appetite	食欲減退	1	N	TE	29	85	Y	None	Recovered
			Dysuria	排尿困難	1	N	TE	29		N	None	Ongoing at time of death
			Nocturia	夜間頻尿	2	N	TE	29	57	N	None	Recovered
			Anaemia	貧血	3	Y	TE	113	3	Y	Drug administration postponed	Recovered with sequelae
			Constipation	便秘	2	N	TE	113	29	N	None	Recovered
			Sleep disorder	睡眠障害	1	N	TE	113	3	N	None	Recovered
			Spinal compression fracture	脊椎圧迫骨折	3	N	TE	115		N	None	Ongoing at time of death
			Sepsis	敗血症	3	Y	TE	155		N	Not applicable	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	3	N	TE	156		N	Not applicable	Ongoing at time of death
			Haematuria	血尿	3	Y	TE	159		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	165	1	N	Not applicable	Death
106007	Hong Kong	61/M/A	Nerve root compression	神経根圧迫	3	Y	Pre	-17	18	N	Not applicable	Recovered
			Constipation	便秘	1	N	TE	57	29	Y	None	Recovered
			Hypoaesthesia	感覚鈍麻	1	N	TE	113		N	None	Not recovered, but no changes expected
			Lymphadenopathy	リンパ節症	3	N	TE	225	64	N	None	Recovered
106011	Hong Kong	79/M/A	Decreased appetite	食欲減退	1	N	TE	29	29	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Abdominal pain upper	上腹部痛	1	N	TE	57	29	N	None	Recovered
			Liver function test abnormal	肝機能検査異常	3	Y	TE	57	13	N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	218	1	N	Not applicable	Death
106016	Hong Kong	75/M/A	Constipation	便秘	2	N	TE	29	126	Y	None	Recovered
			Dyspepsia	消化不良	2	N	TE	29	84	N	None	Recovered
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	3	Y	TE	41	3	N	None	Recovered
			Cough	咳嗽	1	N	TE	41	150	N	None	Recovered
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	1	N	TE	57	29	N	None	Recovered
			Headache	頭痛	1	N	TE	127	36	N	None	Recovered
			Dry skin	皮膚乾燥	2	N	TE	127	28	N	None	Recovered
110002	France	79/M/C	Hypertension	高血圧	2	N	TE			N	None	Recovered
			Somnolence	傾眠	2	N	Pre	-11	4	N	None	Recovered
			Neuralgia	神経痛	3	N	Pre	-5	34	N	None	Recovered
			Depression	うつ病	1	N	Pre	1	141	N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	Y	TE	3	5	Y	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	50	8	N	None	Recovered
			Bone pain	骨痛	3	N	TE	141		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Depression	うつ病	2	N	TE	141		N	None	Ongoing at study termination / withdrawal
111001	France	70/M/C	Nausea	悪心	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Headache	頭痛	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	Pre	1	55	N	Drug administration postponed	Recovered
			Pyrexia	発熱	2	N	TE	9		N	None	Not recovered, but no changes expected
			Anaemia	貧血	3	N	TE	55	4	N	Drug administration postponed	Recovered
			Malnutrition	栄養障害	2	N	TE	56		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	4	N	TE	87	1	N	Drug administration postponed	Recovered
			Lymphopenia	リンパ球減少症	3	N	TE	87	2	N	None	Recovered
			Anaemia	貧血	3	Y	TE	113	1	N	Drug administration postponed	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Confusional state	錯乱状態	3	Y	TE	113		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Cerebral haemorrhage	脳出血	3	Y	TE	114		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
111002	France	72/M/C	Abdominal pain upper	上腹部痛	2	N	TE			N	None	Recovered
			Anorexia	食欲不振	2	N	TE	51	195	N	None	Recovered
			Pleural effusion	胸水	2	Y	TE	51	2	N	None	Recovered
			Pleural effusion	胸水	2	Y	TE	65	5	N	None	Recovered
			Pulmonary embolism	肺塞栓症	4	Y	TE	120	6	N	None	Recovered
			Deep vein thrombosis	深部静脈血栓症	3	Y	TE	120	6	N	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	146	29	N	None	Recovered
			Dyspnoea	呼吸困難	2	Y	TE	146	4	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	150	96	N	Not applicable	Recovered
			Pleural effusion	胸水	2	N	TE	174	1	N	None	Recovered
			Pleural effusion	胸水	2	Y	TE	218	2	N	Not applicable	Recovered
			Pleural effusion	胸水	1	N	TE	220	26	N	None	Recovered
117008	France	82/M/C	Weight decreased	体重減少	1	N	TE			N	Not applicable	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	Pre	1	29	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	29		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	29		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dementia Alzheimer's type	アルツハイマー型認知症	2	Y	TE	45	11	N	None	Recovered
			Lung infection	肺感染	2	N	TE	60	58	N	Not applicable	Recovered
			Leukocytosis	白血球増加症	1	N	TE	88	5	N	None	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	88		N	None	Ongoing at study termination / withdrawal
			Asthenia	無力症	1	N	TE	111		N	Not applicable	Ongoing at study termination / withdrawal
129006	Canada	88/M/C	Vomiting	嘔吐	2	N	Pre			N	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	Pre			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre			N	None	Recovered
			Bone pain	骨痛	1	N	Pre			N	Drug administration postponed	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			N	None	Ongoing at time of death
			Headache	頭痛	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE			N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Somnolence	傾眠	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Confusional state	錯乱状態	1	N	TE			N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Depression	うつ病	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Dysphonia	発声障害	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	Pre	-8		N	Not applicable	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	Pre	-8	25	N	None	Recovered with sequelae
			Bone pain	骨痛	4	N	TE	29		N	Drug administration postponed	Ongoing at time of death
			Bone pain	骨痛	4	N	TE	29		N	Drug administration postponed	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	4	Y	TE	29		N	Drug permanently withdrawn	Ongoing at time of death
			Confusional state	錯乱状態	2	N	TE	29		N	Drug permanently withdrawn	Ongoing at time of death
			Cough	咳嗽	1	N	TE	29		N	None	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	TE	30		N	None	Ongoing at study termination / withdrawal
			Excoriation	擦過傷	1	N	TE	30		N	Not applicable	Ongoing at time of death
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	31		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Herpes simplex	単純ヘルペス	2	N	TE	33		N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	36		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	36		N	Not applicable	Ongoing at time of death
			Dysphagia	嚥下障害	2	N	TE	37		N	Not applicable	Ongoing at study termination / withdrawal
			Oral candidiasis	口腔カンジダ症	2	N	TE	37		N	Not applicable	Ongoing at study termination / withdrawal
			Oral candidiasis	口腔カンジダ症	2	N	TE	38		N	None	Ongoing at time of death
129007	Canada	81/M/O	Anaemia	貧血			TE			N	Not applicable	Recovered with sequelae
			Abdominal distension	腹部膨満	1	N	TE			N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE			Y	None	Not recovered, but no changes expected
			Weight decreased	体重減少	2	N	Pre	1		N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	2		Y	None	Not recovered, but no changes expected
			Stomatitis	口内炎	1	N	TE	9		N	None	Recovered
			Anaemia	貧血	3	Y	TE	119	3	N	Drug administration postponed	Recovered with sequelae
			Anaemia	貧血	2	N	TE	121	27	N	None	Recovered
			Anaemia	貧血	3	Y	TE	147	4	Y	Drug administration postponed	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	150	26	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	3	Y	TE	175	10	N	Not applicable	Recovered with sequelae
			Thrombocytopenia	血小板減少症	1	N	TE	175	9	N	None	Recovered
			Fall	転倒・転落	1	N	TE	181	1	N	None	Recovered
			Anxiety	不安	1	N	TE	181		N	None	Not recovered, but no changes expected
			Thrombocytopenia	血小板減少症	3	N	TE	183	51	N	None	Recovered
			Thrombocytopenia	血小板減少症	4	N	TE	233	12	N	None	Recovered
			Asthenia	無力症	1	N	TE	234		N	None	Ongoing at time of death
130004	Canada	82/M/C	Hip fracture	股関節部骨折	3	Y	TE	32		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
130009	Canada	72/M/C	Diarrhoea	下痢	1	N	TE			Y	None	Recovered
			Fatigue	疲労	2	N	TE			Y	None	Ongoing at study termination / withdrawal
			Decreased appetite	食欲減退	1	N	TE			Y	None	Recovered
			Bone pain	骨痛	1	N	TE			Y	None	Recovered
			Bone pain	骨痛	1	N	TE			Y	None	Recovered
			Anaemia	貧血	2	N	Pre	1	86	Y	-	
			Lymphopenia	リンパ球減少症	3	N	Pre	1	29	N	None	Ongoing at study termination / withdrawal
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	Pre	1	57	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Lymphopenia	リンパ球減少症	2	N	Pre	29	29	N	None	Ongoing at study termination / withdrawal
			Injection site reaction	注射部位反応	1	N	TE	31	3	Y	None	Recovered
			Lymphopenia	リンパ球減少症	3	N	Pre	57		N	None	Ongoing at study termination / withdrawal
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	Pre	57	86	N	None	Recovered
			Gynaecomastia	女性化乳房	2	N	TE	57	114	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	62	1	Y	None	Recovered
			Cough	咳嗽	1	N	TE	65		Y	None	Recovered
			Anaemia	貧血	1	N	Pre	86	29	Y	-	
			Anaemia	貧血	2	N	Pre	114	29	Y	-	
			Anaemia	貧血	1	N	Pre	142	29	Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	Pre	170		Y	None	Ongoing at study termination / withdrawal
			Blood urea increased	血中尿素増加	1	N	TE	170		Y	None	Ongoing at study termination / withdrawal
			Hypercreatininaemia	高クレアチニン血症	1	N	TE	170	23	Y	None	Recovered
			Bone pain	骨痛	3	Y	TE	191	7	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	1	N	Post	228	82	Y	None	Recovered
133002	Poland	78/M/C	Pyrexia	発熱	1	N	TE	3	14	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	3	6	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	8	44	Y	None	Recovered
			Pathological fracture	病的骨折	2	Y	TE	43		N	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	51	53	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	72	34	N	None	Recovered
			Fatigue	疲労	3	N	TE	88	26	N	Drug permanently withdrawn	Ongoing at time of death
			Fatigue	疲労	4	N	TE	113		N	Drug permanently withdrawn	Ongoing at time of death
			Weight decreased	体重減少	2	N	TE	113		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	162	1	N	Not applicable	Death
133003	Poland	77/M/C	Arthralgia	関節痛	2	N	TE	3	3	Y	None	Recovered
			Neutropenia	好中球減少症	3	N	TE	56	9	Y	Drug administration postponed	Recovered
			Anaemia	貧血	3	Y	TE	65	2	Y	None	Recovered
			Anaemia	貧血	2	N	TE	85	5	Y	Drug permanently withdrawn	Recovered
			Anaemia	貧血	3	Y	TE	89	5	Y	Drug permanently withdrawn	Recovered
			Neutropenia	好中球減少症	3	N	TE	89	5	Y	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	89	2	Y	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	3	N	TE	90		Y	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fibrin D dimer increased	フィブリンDダイマー増加	2	N	TE	99		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	4	Y	TE	130	2	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	N	TE	131		N	None	Ongoing at study termination / withdrawal
133005	Poland	62/M/C	Nausea	悪心	1	N	TE			Y	None	Recovered
			Paraparesis	不全対麻痺	3	Y	TE	14		N	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	141		N	None	Ongoing at study termination / withdrawal
133006	Poland	53/M/C	Bone pain	骨痛	2	N	TE	2	10	Y	None	Recovered
			Hypertension	高血圧	2	N	TE	29	29	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	50		N	None	Recovered
			Abdominal pain	腹痛	2	N	TE	71		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	140	29	N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	168		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	168		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	184	2	N	Not applicable	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	185	1	N	Not applicable	Death
133009	Poland	75/M/C	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2	N	TE	85	29	N	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1	N	TE	85	29	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	141	29	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	198	1	N	Not applicable	Death
133011	Poland	66/M/C	Anaemia	貧血	2	N	Pre	1		N	None	Ongoing at time of death
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	Pre	1		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre	1		N	None	Not recovered, but no changes expected
			Tremor	振戦	4	Y	TE	25	1	Y	None	Recovered
			Confusional state	錯乱状態	4	Y	TE	25		Y	None	Ongoing at time of death
			Death	死亡	5	Y	TE	29	1	Y	None	Death
133012	Poland	67/M/C	Spinal cord compression	脊髄圧迫	3	Y	Pre	-35		N	Drug administration postponed	Ongoing at time of death
			Dyspnoea	呼吸困難	4	Y	TE	2	1	N	None	Death
			Dyspnoea	呼吸困難	5	Y	TE	2	1	N	None	Death
133017	Poland	61/M/C	Hyperthyroidism	甲状腺機能亢進症	1	N	TE	3		N	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Upper gastrointestinal haemorrhage	上部消化管出血	2	Y	TE	3		N	None	Ongoing at study termination / withdrawal
133018	Poland	72/M/C	Diarrhoea	下痢	1	N	TE	39	5	Y	None	Recovered
			Dehydration	脱水	1	N	TE	57	3	N	None	Recovered
			Leukopenia	白血球減少症	3	N	TE	106		Y	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	3	N	TE	106		Y	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	4	Y	TE	106		N	Drug permanently withdrawn	Not recovered, but no changes expected
133020	Poland	76/M/C	Nausea	悪心	3	N	TE	1		Y	None	Not recovered, but no changes expected
			Vomiting	嘔吐	3	N	TE	1		Y	None	Not recovered, but no changes expected
			Dehydration	脱水	3	Y	TE	8	4	Y	Drug permanently withdrawn	Recovered
			Anaemia	貧血	2	N	TE	9	1	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	25		N	None	Ongoing at study termination / withdrawal
			Dehydration	脱水	2	N	TE	36		N	Not applicable	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	2	N	TE	36	1	N	None	Recovered
133026	Poland	50/M/C	Neutropenia	好中球減少症	2	N	TE	57	15	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary tract infection	尿路感染	2	N	TE	57	15	Y	Drug administration postponed	Recovered
			Pollakiuria	頻尿	1	N	TE	99	53	N	None	
			Urinary retention	尿閉	2	N	TE	151	1	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	155		N	None	Recovered
			Haematuria	血尿	2	Y	TE	200	6	N	Not applicable	Recovered
134001	Poland	57/M/C	Paralysis	麻痺	4	Y	Pre	-10		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	20	1	N	None	Death
135003	Poland	62/M/C	Bone pain	骨痛	3	N	TE			N	None	Recovered
			Anaemia	貧血	3	Y	TE	114	3	Y	None	Recovered
			Anaemia	貧血	2	N	TE	115	2	Y	None	Recovered
137006	Poland	71/M/C	Anaemia	貧血	3	Y	TE	139	8	N	Not applicable	Recovered with sequelae
			Urinary tract infection	尿路感染	2	N	TE	157	8	N	Not applicable	Recovered
			Haematuria	血尿	3	Y	TE	197	7	N	Not applicable	Recovered
			Anaemia	貧血	4	Y	TE	203		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	213	1	N	Not applicable	Death
139001	Poland	76/M/C	Anaemia	貧血	1	N	TE	29		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malaise	倦怠感	3	N	TE	29		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	46	1	N	None	Death
139005	Poland	71/M/C	Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre			N	None	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	57	5	Y	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	120	1	N	None	Death
139006	Poland	76/M/C	Oedema peripheral	末梢性浮腫	3	N	TE			N	None	Not recovered, but no changes expected
			Vomiting	嘔吐	2	N	TE	31	3	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	88	5	Y	None	Recovered with sequelae
			Renal failure	腎不全	2	N	TE	119	26	N	None	Ongoing at study termination / withdrawal
			General physical health deterioration	全身健康状態低下	3	N	TE	144		Y	Drug permanently withdrawn	Not recovered, but no changes expected
			Renal failure	腎不全	1	N	TE	144		N	None	Ongoing at study termination / withdrawal
139009	Poland	57/M/C	Pancytopenia	汎血球減少症	3	Y	TE	117	8	Y	Drug administration postponed	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Leukopenia	白血球減少症	3	Y	TE	172	10	Y	Drug administration postponed	Recovered with sequelae
			Leukopenia	白血球減少症	2	N	TE	181		Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	181	1	Y	None	Ongoing at time of death
139012	Poland	67/M/C	Thrombophlebitis	血栓性静脈炎	2	Y	Pre	-26	12	N	Drug administration postponed	Recovered with sequelae
			Thrombophlebitis	血栓性静脈炎	1	N	Pre	-15		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	29	8	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	29	8	Y	None	Recovered
			Nausea	悪心	1	N	TE	57	8	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	57	8	Y	None	Recovered
			Nausea	悪心	1	N	TE	85	7	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	85	7	Y	None	Recovered
144002	Germany	77/M/C	Hyperthyroidism	甲状腺機能亢進症	1	N	TE			Y	None	Recovered
			Dysgeusia	味覚異常	1	N	TE			Y	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	2	4	Y	None	Recovered
			Fatigue	疲労	2	N	TE	3	3	Y	None	Recovered with sequelae
			Urinary retention	尿閉	1	N	TE	47	37	N	None	Recovered with sequelae
			Benign neoplasm of bladder	膀胱の良性新生物	3	Y	TE	77	7	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	101	4	N	None	Recovered
			Haematuria	血尿	1	N	TE	158	6	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Haematuria	血尿	1	N	TE	216	3	N	None	Recovered
144004	Germany	68/M/C	Pneumonia	肺炎	3	Y	TE	59	6	N	None	Recovered
146001	Germany	70/M/C	Paraesthesia	錯感覚	2	N	TE	73		N	None	Recovered with sequelae
			Herpes zoster	帯状疱疹	2	Y	TE	169	12	N	Not applicable	Recovered with sequelae
			Urinary incontinence	尿失禁	1	N	TE	174		N	Not applicable	Ongoing at study termination / withdrawal
146004	Germany	77/M/C	Anaemia	貧血	2	N	TE	17	5	N	Drug administration postponed	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	17		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Multi-organ failure	多臓器不全	4	Y	TE	17	12	N	None	Death
			Anaemia	貧血	4	N	TE	21		N	Drug administration postponed	Ongoing at time of death
			Multi-organ failure	多臓器不全	5	Y	TE	28	1	N	None	Death
148009	Germany	71/M/C	Nasopharyngitis	鼻咽頭炎	1	N	Pre	-14	15	N	None	Recovered
			Anaemia	貧血	2	N	Pre	1	57	Y	Drug administration postponed	Recovered
			Fatigue	疲労	2	N	TE	8		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	29	4	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	57	4	Y	Drug administration postponed	Recovered
			Anaemia	貧血	1	N	TE	60	31	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	60	1	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	60	2	Y	None	Recovered
			Herpes zoster	帯状疱疹	3	Y	TE	96	12	Y	Drug administration postponed	Recovered
			Anaemia	貧血	2	Y	TE	98	1	Y	None	Recovered
			Anaemia	貧血	4	Y	TE	125	3	Y	Drug administration postponed	Recovered
			Syncope	失神	3	Y	TE	125	1	Y	Drug administration postponed	Recovered
			Pancytopenia	汎血球減少症		N	TE	140		Y	None	Ongoing at time of death
			Metastases to liver	肝転移	3	Y	TE	140	10	N	Drug permanently withdrawn	Death
			Epistaxis	鼻出血	2	N	TE	140	1	N	Not applicable	Recovered
			Metastases to liver	肝転移	5	Y	TE	149	1	N	Drug permanently withdrawn	Death
148012	Germany	72/M/C	Acute coronary syndrome	急性冠動脈症候群	3	Y	TE	6	3	N	None	Recovered
			Angina pectoris	狭心症	2	N	TE	76	15	N	None	Recovered
			Angina pectoris	狭心症	3	Y	TE	90	3	N	None	Recovered
			Anaemia	貧血	3	N	TE	141	15	Y	Drug administration postponed	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	155		Y	Drug administration postponed	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	155	29	Y	None	Recovered
			Arthralgia	関節痛	2	N	TE	169		N	None	Ongoing at study termination / withdrawal
			Pigmentation disorder	色素沈着障害	1	N	TE	183		N	None	Recovered
148014	Germany	62/M/C	Nausea	悪心	1	N	TE	29	1	Y	None	Recovered
			Ageusia	味覚消失	1	N	TE	29	1	Y	None	Recovered
			Cataract	白内障	3	Y	TE	154	3	N	Not applicable	Recovered
148019	Germany	65/M/C	Conjunctivitis	結膜炎	2	N	TE	2	8	N	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	29	1	Y	None	Recovered
			Nausea	悪心	1	N	TE	31	4	Y	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	32	1	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	32	1	Y	None	Recovered
			Pleural effusion	胸水	1	N	TE	93		N	None	Ongoing at time of death
			Blood urea increased	血中尿素増加	2	N	TE	109	11	N	None	Recovered
			Blood creatinine increased	血中クレアチニン増加	2	N	TE	113	7	N	None	Recovered
			Hydronephrosis	水腎症	3	Y	TE	113	2	N	None	Recovered
			Dyspnoea	呼吸困難	2	N	TE	113		N	None	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	119	4	N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	119		N	None	Ongoing at time of death
			Blood creatinine increased	血中クレアチニン増加	3	N	TE	119	4	N	None	Recovered
			Blood urea increased	血中尿素増加	3	N	TE	119	4	N	None	Recovered
			Hydronephrosis	水腎症	3	Y	TE	119	4	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	143	1	N	Drug permanently withdrawn	Death
149009	Germany	72/M/C	Bone pain	骨痛	1	N	TE	1	3	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	29	3	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	36	21	Y	None	Recovered
			Insomnia	不眠症	1	N	TE	56		N	None	Not recovered, but no changes expected
			Diarrhoea	下痢	1	N	TE	58	18	Y	None	Recovered
			Anaemia	貧血	1	N	TE	82	2	Y	Drug administration postponed	Recovered
			Bone pain	骨痛	1	N	TE	83	87	Y	None	Recovered with sequelae
			Pancytopenia	汎血球減少症	2	N	TE	140		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	169	27	Y	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	176		Y	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	208	2	Y	Not applicable	Recovered
			Anaemia	貧血	3	N	Post	251	3	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	Post	265	2	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	Post	279	9	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	Post	307	4	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	Post	356	2	Y	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	Post	371	14	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	Post	412	17	Y	Not applicable	Recovered
			Anaemia	貧血	3	N	Post	470	7	Y	Not applicable	Recovered
			Aplastic anaemia	再生不良性貧血	3	Y	Post	526		Y	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	Post	540	2	Y	Not applicable	Recovered
			Anaemia	貧血	2	N	Post	575	2	Y	Not applicable	Recovered
150002	Germany	72/M/C	Nausea	悪心	2	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE			N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	23	4	N	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	26	8	N	None	Recovered with sequelae
			Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	4	N	TE	29	26	N	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	4	N	TE	29	2	N	None	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	TE	29	2	N	None	Recovered
			Neuralgia	神経痛	2	N	TE	29	5	N	None	Recovered with sequelae
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	30	25	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	2	N	TE	30	25	N	None	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1	N	TE	54	13	N	None	Recovered
			Nerve root compression	神経根圧迫	2	Y	TE	66	3	N	None	Recovered with sequelae
			Nausea	悪心	2	N	TE	69	11	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	69	11	N	None	Recovered
			Fatigue	疲労	1	N	TE	69	11	N	None	Recovered
			Urinary retention	尿閉	2	Y	TE	69	11	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	177	11	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	178	1	N	None	Recovered
			Headache	頭痛	2	N	TE	180	1	N	None	Recovered
150003	Germany	70/M/C	Nausea	悪心	1	N	TE	72		N	None	Ongoing at time of death
			Hydronephrosis	水腎症	2	Y	TE	100	2	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	141	5	N	None	Recovered
			Hypercreatininaemia	高クレアチニン血症	2	N	TE	141	16	N	None	Recovered
			Hydronephrosis	水腎症	2	Y	TE	141	6	N	None	Recovered with sequelae
			Anaemia	貧血	3	N	TE	143		N	None	Ongoing at time of death
			Hypercreatininaemia	高クレアチニン血症	1	N	TE	156	32	N	None	Recovered
151005	Germany	83/M/C	Diarrhoea	下痢	1	N	TE			N	None	Recovered
			Cystitis	膀胱炎	3	N	TE	44	5	Y	None	Recovered
			Urinary retention	尿閉	3	Y	TE	130	7	N	None	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	131		Y	None	Ongoing at time of death
			Hypoglycaemia	低血糖症	3	Y	TE	214	4	N	Not applicable	Recovered
			Urinary tract infection	尿路感染	1	N	TE	215	8	N	None	Recovered
152003	Germany	49/M/C	Nausea	悪心	1	N	TE			N	Not applicable	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE			N	Not applicable	Recovered with sequelae
			Escherichia urinary tract infection	大腸菌性尿路感染	1	N	TE			N	Not applicable	Recovered
			Depression	うつ病	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	1	85	N	Drug administration postponed	Recovered with sequelae
			Productive cough	湿性咳嗽	1	N	TE	22	11	N	None	Recovered
			Injection site swelling	注射部位腫脹	1	N	TE	34		Y	None	Recovered
			Injection site swelling	注射部位腫脹	1	N	TE	58		Y	None	Recovered
			Bone pain	骨痛	3	Y	TE	85	10	N	Drug administration postponed	Recovered with sequelae
			Anaemia	貧血	2	N	TE	115	18	N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	115		N	Not applicable	Recovered with sequelae
			Dehydration	脱水	2	N	TE	115		N	None	Recovered
			Bone pain	骨痛	3	Y	TE	115	18	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
152004	Germany	75/M/C	Bone pain	骨痛	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	1	N	TE	1		N	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	1	N	TE	79		N	None	Recovered
			Bone pain	骨痛	3	Y	TE	79	14	N	Drug administration postponed	Recovered with sequelae
			Disturbance in attention	注意力障害	1	N	TE	79		N	None	Ongoing at study termination / withdrawal
			Insomnia	不眠症	1	N	TE	79		N	None	Recovered
			Pleural effusion	胸水	1	N	TE	79		N	None	Recovered
			Bone pain	骨痛	2	N	TE	92	37	N	None	Recovered with sequelae
			Pancytopenia	汎血球減少症	2	N	TE	128		N	None	Recovered with sequelae
			Nausea	悪心	1	N	TE	128	8	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	128	8	N	None	Recovered
			Infection	感染	2	N	TE	128	8	N	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	128	8	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	128	8	N	None	Recovered with sequelae
			Pneumonia primary atypical	原発性異型肺炎	3	Y	TE	147	22	N	Drug administration postponed	Recovered with sequelae
			Asthenia	無力症	2	N	TE	161		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			General physical health deterioration	全身健康状態低下	5	Y	TE	195	1	N	None	Death
154001	Germany	65/M/C	Coronary artery disease	冠動脈疾患	3	Y	Pre	-12	3	N	Not applicable	Recovered
			Hypercholesterolaemia	高コレステロール血症	1	N	Pre	-12		N	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	50	32	N	None	Recovered
			Anaemia	貧血	2	N	TE	59		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	80	75	N	None	Recovered
			Coronary artery disease	冠動脈疾患	2	Y	TE	122	8	N	Not applicable	Recovered
154002	Germany	71/M/C	Nausea	悪心	1	N	Pre			N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Pain	疼痛	3	N	TE			N	None	Ongoing at study termination / withdrawal
			Angina pectoris	狭心症	1	N	TE	1	15	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	42		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	42		N	None	Ongoing at time of death
			Joint injury	関節損傷	1	N	TE	61	1	N	None	Recovered
			Anaemia	貧血	2	N	TE	85		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Gait disturbance	歩行障害	3	N	TE	94		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	123	13	N	Drug administration postponed	Recovered with sequelae
			Facial palsy	顔面神経麻痺	3	N	TE	155	15	N	Drug administration postponed	Ongoing at time of death
			Facial palsy	顔面神経麻痺	3	Y	TE	169	7	N	Drug administration postponed	Ongoing at time of death
			Facial palsy	顔面神経麻痺	2	N	TE	175		N	Drug administration postponed	Ongoing at study termination / withdrawal
154004	Germany	62/M/C	Atrial fibrillation	心房細動	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Renal failure	腎不全	2	N	TE			N	None	Recovered with sequelae
			Cystitis	膀胱炎	1	N	Pre	-3	7	N	None	Recovered
			Nausea	悪心	1	N	TE	2		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	TE	2		Y	None	Not recovered, but no changes expected
			Abdominal pain upper	上腹部痛	1	N	TE	7	23	Y	None	Recovered
			Abdominal pain	腹痛	1	N	TE	29	56	N	Not applicable	Ongoing at study termination / withdrawal
			Nocturia	夜間頻尿	2	N	TE	57		N	None	Ongoing at time of death
			Acute prerenal failure	急性腎前性腎不全	2	Y	TE	81	4	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Abdominal pain	腹痛	2	N	TE	84		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	N	TE	85		N	None	Ongoing at time of death
			Peritonitis bacterial	細菌性腹膜炎	3	Y	TE	86	22	N	Drug permanently withdrawn	Recovered
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	107	6	N	Drug permanently withdrawn	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	112		N	Drug permanently withdrawn	Not recovered, but no changes expected
155004	Germany	63/M/C	Vomiting	嘔吐	2	N	TE			Y	None	Recovered
			Vomiting	嘔吐	1	N	TE			Y	None	Recovered
			Depression	うつ病	1	N	Pre	1	217	N	None	Not recovered, but no changes expected
			Constipation	便秘	1	Y	TE	26	3	N	None	Recovered
			Reflux oesophagitis	逆流性食道炎	1	N	TE	32	46	N	None	Recovered
			Fatigue	疲労	2	N	TE	32		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	32		N	None	Not recovered, but no changes expected
			Night sweats	寝汗	1	N	TE	32	31	N	None	Recovered
			Reflux oesophagitis	逆流性食道炎	2	N	TE	77	95	N	None	Recovered
			Depression	うつ病	2	N	TE	217		N	None	Not recovered, but no changes expected
157002	Germany	76/M/C	General physical health deterioration	全身健康状態低下	2	N	TE			N	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			General physical health deterioration	全身健康状態低下	1	N	TE			N	None	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	3	Y	Pre	-10	2	N	Not applicable	Recovered
			Anaemia	貧血	2	N	Pre	1	37	Y	None	Recovered with sequelae
			Fatigue	疲労	2	N	TE	5		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	5		Y	None	Ongoing at time of death
			Night sweats	寝汗	1	N	TE	5		Y	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	37	2	Y	None	Recovered with sequelae
			Anaemia	貧血	3	N	TE	38	6	Y	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	43		Y	None	Not recovered, but no changes expected
170004	Brazil	78/M/C	Pathological fracture	病的骨折	3	N	TE	127		N	Drug administration postponed	Ongoing at time of death
			Urinary retention	尿閉	3	N	TE	156	1	N	None	Recovered
			Anaemia	貧血	2	N	TE	211		N	None	Ongoing at time of death
			Bone pain	骨痛	4	Y	TE	230		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	230	3	N	Drug permanently withdrawn	Death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	232	1	N	Drug permanently withdrawn	Death
173008	Brazil	67/M/C	Anaemia	貧血	2	N	Pre	1	33	N	Drug administration postponed	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	Pre	1	63	N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	33	2	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	34	30	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	N	TE	63	3	N	Drug administration postponed	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	Pre	63		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	65	83	N	Drug administration postponed	Recovered
			Anorexia	食欲不振	2	N	TE	87	70	N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	147	5	N	Drug administration postponed	Recovered
			Anorexia	食欲不振	3	N	TE	156		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	156		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

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Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	3	N	TE	183		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	3	N	TE	184	11	N	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	184	11	N	None	Ongoing at time of death
			Anaemia	貧血	4	N	TE	194	5	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	194	5	N	None	Ongoing at time of death
			Neutropenia	好中球減少症	4	N	TE	198		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	198		N	None	Ongoing at time of death
			Cerebrovascular accident	脳血管発作	4	Y	TE	198	4	Y	Not applicable	Death
			Cerebrovascular accident	脳血管発作	5	Y	TE	201	1	Y	Not applicable	Death
173009	Brazil	66/M/O	Bone pain	骨痛	2	N	Pre	-9		N	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	4	Y	TE	29	20	N	Drug permanently withdrawn	Death
			General physical health deterioration	全身健康状態低下	5	Y	TE	48	1	N	Drug permanently withdrawn	Death
173011	Brazil	62/M/B	Constipation	便秘	2	N	Pre	-7	13	N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	Pre	-7	8	N	None	Ongoing at time of death
			Arthralgia	関節痛	2	N	Pre	-7		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	3	N	TE	1		N	None	Ongoing at time of death
			Constipation	便秘	1	N	Pre	6		N	None	Ongoing at time of death
			Anaemia	貧血	4	N	TE	29		N	Drug permanently withdrawn	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	4	Y	TE	30		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
178007	Brazil	71/M/O	Hypercalcaemia	高カルシウム血症	3	N	Pre	1	88	Y	None	Recovered
			Neutropenia	好中球減少症	2	N	TE	29	29	Y	Drug administration postponed	Recovered
			Bone pain	骨痛	2	N	TE	48	77	N	None	Ongoing at time of death
			Neutropenia	好中球減少症	3	N	TE	57	4	Y	Drug administration postponed	Recovered
			Neutropenia	好中球減少症	2	N	TE	60	65	Y	Drug administration postponed	Recovered
			Insomnia	不眠症	2	N	TE	78		N	None	Ongoing at time of death
			Pathological fracture	病的骨折	3	Y	TE	121	28	N	Drug administration postponed	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	124		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	124	15	N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE	138	25	N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	139	7	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	141	1	N	Not applicable	Recovered
			Anaemia	貧血	3	Y	TE	147	2	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	148		N	Not applicable	Lost to follow-up
			Device dislocation	医療機器位置異常	3	Y	TE	162	3	N	Not applicable	Recovered
			Procedural pain	処置による疼痛	3	Y	TE	162	3	N	Not applicable	Recovered
			Pneumonia	肺炎	3	Y	TE	165	3	N	Not applicable	Recovered
			Pulmonary embolism	肺塞栓症	3	Y	TE	165	3	N	Not applicable	Death
			Pneumonia	肺炎	4	Y	TE	167	28	N	Not applicable	Recovered
			Pulmonary embolism	肺塞栓症	4	Y	TE	167	63	N	Not applicable	Death
			Pulmonary embolism	肺塞栓症	5	Y	TE	229	1	N	Not applicable	Death
179001	Brazil	77/M/C	Hypercreatininaemia	高クレアチニン血症	2	N	Pre	1	59	N	None	Ongoing at study termination / withdrawal
			Hypercreatininaemia	高クレアチニン血症	1	N	Pre	59	29	N	None	Ongoing at study termination / withdrawal
			Asthenia	無力症	1	N	TE	69	1	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hypercreatininaemia	高クレアチニン血症	2	N	Pre	87		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	Y	TE	93	4	N	None	Recovered
			Anaemia	貧血	2	Y	TE	114	3	N	None	Recovered
			Asthenia	無力症	2	Y	TE	126	5	N	Drug administration postponed	Recovered with sequelae
			Fatigue	疲労	3	Y	TE	146	9	N	Drug permanently withdrawn	Recovered
179006	Brazil	79/M/C	Nausea	悪心	1	N	Pre	-17	3	N	Not applicable	Recovered
			Cough	咳嗽	1	N	Pre	-6	5	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	34	99	N	None	Recovered
			Arthralgia	関節痛	1	N	TE	132		N	None	Recovered
			Bone pain	骨痛	1	N	TE	159	2	N	None	Recovered
			Myocardial infarction	心筋梗塞	5	Y	TE	244	1	N	Not applicable	Death
181005	Brazil	74/M/C	Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	Pre	1		N	None	Ongoing at time of death
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	Pre	1		N	None	Ongoing at time of death
			Hypoglycaemia	低血糖症	3	Y	TE	29	2	N	None	Recovered
			Pneumonia	肺炎	2	Y	TE	30	16	N	Not applicable	Death
			Acute pulmonary oedema	急性肺水腫	2	Y	TE	30		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pneumonia	肺炎	5	Y	TE	45	1	N	Not applicable	Death
181048	Brazil	70/M/C	Thrombosis	血栓症	2	N	Pre	-1		N	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	29		N	None	Ongoing at study termination / withdrawal
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	1	N	TE	141		N	None	Ongoing at study termination / withdrawal
			Constipation	便秘	2	N	TE	158		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	Y	TE	176	5	N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	176	5	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	209		N	Not applicable	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	4	Y	TE	209	23	N	Not applicable	Recovered with sequelae
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1	N	TE	209		N	Not applicable	Ongoing at study termination / withdrawal
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1	N	TE	209		N	Not applicable	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
201002	Australia	72/M/C	Dysphagia	嚥下障害	2	N	Pre	-7	70	N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	48	46	N	None	Recovered
			Muscle strain	筋挫傷	2	N	TE	49	15	N	None	Recovered
			Dysphagia	嚥下障害	1	N	Pre	63	71	N	None	Ongoing at time of death
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	2	N	TE	93	4	N	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	99	8	N	None	Recovered
			Anaemia	貧血	3	Y	TE	132	9	N	Not applicable	Recovered
			Supraventricular tachycardia	上室性頻脈	2	Y	TE	132	1	N	Not applicable	Recovered
			Abdominal distension	腹部膨満	3	Y	TE	132	9	N	Not applicable	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	3	N	TE	132		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	132	39	N	Not applicable	Death
			Anxiety	不安	2	N	TE	132		N	Not applicable	Ongoing at time of death
			Dysphagia	嚥下障害	2	N	Pre	133		N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	1	N	TE	137	3	N	Not applicable	Recovered
			Abdominal distension	腹部膨満	2	N	TE	140		N	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	147		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	161		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	170	1	N	Not applicable	Death
203004	Australia	70/M/C	Constipation	便秘	1	N	Pre	-7		N	None	Recovered
			Hypophosphataemia	低リン酸血症	4	N	Pre	-2	29	N	-	
			Lethargy	嗜眠	1	N	TE	4	1	Y	None	Recovered
			Hypophosphataemia	低リン酸血症	3	N	Pre	27	64	N	-	
			Hypomagnesaemia	低マグネシウム血症	1	N	TE	55	36	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	56	1	N	None	Recovered
			Lethargy	嗜眠	1	N	TE	79	69	Y	None	Ongoing at study termination / withdrawal
			Cough	咳嗽	1	N	TE	79	15	N	None	Recovered
			Dyspepsia	消化不良	1	N	TE	84	15	N	None	Recovered
			Hypophosphataemia	低リン酸血症	4	N	Pre	90	29	N	-	
			Paraesthesia	錯感覚	1	N	TE	91		N	None	Ongoing at time of death
			Hypophosphataemia	低リン酸血症	3	N	Pre	118	15	N	-	
			Dyspepsia	消化不良	1	N	TE	120		N	None	Recovered
			Hypophosphataemia	低リン酸血症	4	N	Pre	132	6	N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	132	115	N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	132	115	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	133	114	N	Not applicable	Recovered
			Hypophosphataemia	低リン酸血症	4	Y	TE	137	4	N	Not applicable	Recovered
			Hyperparathyroidism	副甲状腺機能亢進症	1	N	TE	139		N	Not applicable	Recovered
			Cachexia	悪液質	2	N	TE	139		N	Not applicable	

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Osteomalacia	骨軟化症	2	N	TE	139		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	146	20	N	Not applicable	Recovered
			Lethargy	嗜眠	2	N	TE	147		Y	None	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	1	N	TE	166		N	Not applicable	Ongoing at time of death
203007	Australia	70/M/C	Bone pain	骨痛	2	N	Pre	-7	63	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	Pre	-7	63	N	None	Recovered
			Constipation	便秘	2	Y	Pre	-1	3	N	None	Recovered
			Anorexia	食欲不振	2	N	TE	3		N	None	Ongoing at time of death
			Dysgeusia	味覚異常	1	N	TE	3		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	4	2	Y	None	Recovered
			Anaemia	貧血	2	N	TE	28	49	Y	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	28	29	N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	28	83	N	Not applicable	Death
			Fatigue	疲労	2	N	TE	35		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	53	5	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	56	3	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	56	3	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	56	3	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE	58		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	58		N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	66	8	N	Not applicable	Recovered
			Constipation	便秘	3	Y	TE	73	6	N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	76	3	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	78		Y	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	110	1	N	Not applicable	Death
204001	Australia	76/M/C	Dyspnoea	呼吸困難	1	N	Pre	-392	366	N	None	Recovered
			Nausea	悪心	1	N	TE	1		Y	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	2		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	2		Y	None	Ongoing at study termination / withdrawal
			Chills	悪寒	1	N	TE	6	1	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	8	1	Y	None	Recovered
			Constipation	便秘	1	N	TE	9		Y	None	Ongoing at study termination / withdrawal
			Contusion	挫傷	1	N	TE	10		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Gastroenteritis	胃腸炎	4	Y	TE	18	6	Y	None	Recovered with sequelae
			Renal failure acute	急性腎不全	2	Y	TE	18	6	Y	None	Recovered
			Gastroenteritis	胃腸炎	3	N	TE	21	3	Y	None	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	22	2	Y	None	Recovered
			Gastroenteritis	胃腸炎	2	N	TE	23	1	Y	None	Recovered with sequelae
			Bone pain	骨痛	1	N	TE	34		Y	None	Ongoing at time of death
			Mobility decreased	運動性低下	1	N	TE	34		Y	None	Ongoing at time of death
			Tremor	振戦	1	N	TE	34		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	43	26	N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	63	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	68	9	N	Not applicable	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	76		N	Not applicable	Ongoing at study termination / withdrawal
			Anxiety	不安	1	N	TE	79	1	Y	None	Recovered
			Anxiety	不安	1	N	TE	83	3	Y	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	116	1	N	Drug permanently withdrawn	Death
205004	Australia	82/M/C	Bone pain	骨痛	2	N	TE			Y	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	Pre	1		N	None	Ongoing at time of death
			Urinary incontinence	尿失禁	2	N	TE	6		Y	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	33		Y	None	Ongoing at time of death
			Hydrocephalus	水頭症	4	Y	TE	107	20	N	Drug permanently withdrawn	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	127	14	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	140	1	N	Drug permanently withdrawn	Death
206001	Australia	83/M/C	Meniere's disease	メニエール病	2	N	TE	78	18	Y	Drug administration postponed	Recovered with sequelae
			Deep vein thrombosis	深部静脈血栓症	3	Y	TE	90	6	Y	None	Recovered with sequelae
			Constipation	便秘	1	N	TE	91	4	N	Drug administration postponed	Recovered
			Pollakiuria	頻尿	3	N	TE	189		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	201		N	Not applicable	Ongoing at time of death
			Nausea	悪心	3	N	TE	201		N	Not applicable	Ongoing at time of death
			Pain	疼痛	3	N	TE	201		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary tract infection	尿路感染	3	N	TE	201		N	Not applicable	Ongoing at time of death
			Hydronephrosis	水腎症	3	Y	TE	201		N	Not applicable	Ongoing at time of death
			Fluid overload	水分過負荷	3	N	TE	202		N	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	4	N	TE	202		N	Not applicable	Ongoing at time of death
			Lung consolidation	肺硬化	3	N	TE	202		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	212	1	N	Not applicable	Death
209001	Australia	78/M/C	Stomatitis	口内炎	1	N	Pre	-2	17	N	None	Recovered
			Lethargy	嗜眠	1	N	TE	2	105	N	None	Recovered
			Bone pain	骨痛	1	N	TE	29	84	N	None	Recovered
			Fatigue	疲労	3	Y	TE	107	6	N	Drug administration postponed	Recovered
			Bone pain	骨痛	1	N	TE	107	3	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	107	6	N	Drug administration postponed	Recovered
			Nausea	悪心	1	N	TE	108	3	N	Not applicable	Recovered
			Headache	頭痛	1	N	TE	112	1	N	Not applicable	Recovered
			Lethargy	嗜眠	3	N	TE	113		N	Not applicable	Ongoing at study termination / withdrawal

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	126	8	N	Not applicable	Recovered
209002	Australia	78/M/C	Bone pain	骨痛	1	N	Pre	1	71	N	None	Recovered
			Rash	発疹	1	N	Pre	1	57	N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	2		N	None	Ongoing at time of death
			Neutropenia	好中球減少症	3	N	TE	29	42	N	Drug administration postponed	Recovered
			Diarrhoea	下痢	1	N	TE	29	99	N	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	29	29	N	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	57		N	None	Ongoing at time of death
			Lymphadenopathy	リンパ節症	1	N	TE	57		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	84	59	N	None	Recovered
			Hypoalbuminaemia	低アルブミン血症	1	N	TE	98		N	None	Ongoing at time of death
			Pallor	蒼白	2	N	TE	98	33	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	99		N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	99	29	N	None	Recovered
			Neutropenia	好中球減少症	4	N	TE	126	5	N	Drug permanently withdrawn	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	126		N	Not applicable	Ongoing at time of death
			Rectal tenesmus	直腸しぶり	1	N	TE	127		N	Not applicable	Ongoing at study termination / withdrawal
			Crepitations	捻髪音	1	N	TE	127		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Breath sounds abnormal	呼吸音異常	1	N	TE	127		N	Not applicable	Ongoing at time of death
			Wheezing	喘鳴	1	N	TE	127		N	Not applicable	Ongoing at time of death
			Neutropenia	好中球減少症	3	N	TE	130	15	N	Drug permanently withdrawn	Recovered
			Anaemia	貧血	2	N	TE	133	13	N	Not applicable	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	137	6	N	Not applicable	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	TE	142	22	N	Not applicable	Ongoing at time of death
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1	N	TE	142	12	N	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	3	Y	TE	143	12	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	153	61	N	Not applicable	Recovered
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	2	N	TE	153	11	N	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE	155		N	Not applicable	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	TE	163		N	Not applicable	Ongoing at time of death
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	TE	163		N	Not applicable	Ongoing at time of death
209003	Australia	56/M/C	Bone pain	骨痛	1	N	Pre	-22		N	None	Ongoing at time of death
			Oesophagitis	食道炎	1	N	TE	29		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Decreased appetite	食欲減退	1	N	TE	29		N	None	Ongoing at time of death
			Muscle spasms	筋痙縮	1	N	TE	57		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	78		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	78		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	78		N	None	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	85		N	None	Ongoing at time of death
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	1	N	TE	85		N	None	Ongoing at time of death
			Breath sounds abnormal	呼吸音異常	1	N	TE	85		N	None	Ongoing at time of death
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1	N	TE	85		N	None	Ongoing at time of death
			Neuropathy peripheral	末梢性ニューロパチー	1	N	TE	88		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	4	Y	TE	94	16	N	None	Recovered
			Burning sensation	灼熱感	1	N	TE	102	1	N	None	Recovered
			Rash	発疹	1	N	TE	103		N	None	Ongoing at time of death
			Pyrexia	発熱	1	N	TE	108	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	109		N	Not applicable	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	109		N	Not applicable	Ongoing at time of death
			Radiation skin injury	放射線皮膚損傷	1	N	TE	109		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	Y	TE	109	7	N	Drug permanently withdrawn	Recovered
			Anxiety	不安	1	N	TE	109		N	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	138		N	Not applicable	Ongoing at time of death
			Ascites	腹水	1	Y	TE	149		N	Not applicable	Ongoing at time of death
			Epistaxis	鼻出血	1	N	TE	149	18	N	Not applicable	Recovered
			Dry skin	皮膚乾燥	1	N	TE	149		N	Not applicable	Ongoing at time of death
			Pruritus	そう痒症	1	N	TE	149		N	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE	153		N	None	Ongoing at time of death
			Rectal haemorrhage	直腸出血	1	N	TE	158		N	Not applicable	Ongoing at time of death
			Pitting oedema	圧痕浮腫	1	N	TE	158		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	158	9	N	Not applicable	Death
			Confusional state	錯乱状態	1	N	TE	158		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	166	1	N	Not applicable	Death
213002	Australia	49/M/O	Cough	咳嗽	1	N	Pre	-10	31	N	None	Recovered
			Musculoskeletal pain	筋骨格痛	3	N	TE	17	2	Y	None	Recovered
			Dyspnoea	呼吸困難	3	N	TE	82		Y	None	Not recovered, but no changes expected
			Abdominal pain	腹痛	2	N	TE	85	3	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	2	N	TE	85	1	N	None	Recovered
			Pulmonary haemorrhage	肺出血	1	N	TE	85	1	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	140	29	N	None	Not recovered, but no changes expected
			Rectal haemorrhage	直腸出血	1	N	TE	159		N	None	Not recovered, but no changes expected
			Fatigue	疲労	2	N	TE	161		N	None	Not recovered, but no changes expected
			Headache	頭痛	1	N	TE	161		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	163	9	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	163	9	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	168	28	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	168	3	N	Not applicable	Recovered
			Insomnia	不眠症	1	N	TE	168		N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	195		N	None	Not recovered, but no changes expected
213008	Australia	74/M/C	Bone pain	骨痛	1	N	TE			N	None	Recovered
			Hypotension	低血圧	1	N	TE			N	Not applicable	Recovered
			Hypotension	低血圧	2	N	TE			N	Not applicable	Not recovered, but no changes expected
			Hypotension	低血圧	3	N	TE			N	Not applicable	Not recovered, but no changes expected
			Nausea	悪心	2	N	TE	2	6	Y	None	Recovered
			Fatigue	疲労	1	N	TE	2	6	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	2	10	Y	None	Recovered
			Headache	頭痛	1	N	TE	2	6	Y	None	Recovered
			Constipation	便秘	1	N	TE	4	8	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	1	N	TE	7	5	Y	None	Recovered
			Skin laceration	皮膚裂傷	3	Y	TE	25	2	N	None	Recovered
			Hypotension	低血圧	1	N	TE	45	15	N	None	Recovered
			Nausea	悪心	1	N	TE	64	29	Y	None	Recovered
			Fatigue	疲労	1	N	TE	65	8	Y	None	Recovered
			Fatigue	疲労	1	N	TE	92		Y	None	Not recovered, but no changes expected
			Paraesthesia	錯感覚	1	N	TE	92	24	N	None	Recovered
			Fatigue	疲労	1	N	TE	120		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	120		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	146	4	N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	149	28	N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	149		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	176		N	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	176		N	None	Ongoing at study termination / withdrawal
214003	Australia	68/M/C	Rash	発疹	2	N	TE	3	20	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	8	10	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	42	16	N	Drug administration postponed	Recovered
			Constipation	便秘	1	N	TE	54	4	N	None	Recovered
			Fatigue	疲労	3	N	TE	58	28	Y	None	Recovered
			Constipation	便秘	1	N	TE	60	3	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	61		Y	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	85	29	N	None	Recovered
			Hydronephrosis	水腎症	3	N	TE	85	36	N	None	Recovered
			Myositis	筋炎	2	N	TE	101	15	N	None	Recovered
			Anaemia	貧血	2	N	TE	122	3	N	None	Ongoing at time of death
			Procedural pain	処置による疼痛	3	Y	TE	122	4	N	None	Recovered
			Dysuria	排尿困難	2	N	TE	122	3	N	None	Recovered
			Haematuria	血尿	1	N	TE	122	15	N	None	Recovered
			Anaemia	貧血	1	N	TE	124		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	124	18	Y	Drug permanently withdrawn	Ongoing at time of death
			Nausea	悪心	2	N	TE	124	18	Y	None	Recovered
			Diarrhoea	下痢	2	N	TE	130	8	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	141	61	Y	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	173	5	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	201		Y	Drug permanently withdrawn	Ongoing at time of death
230002	UK	66/M/C	Muscle spasms	筋痙縮	1	N	TE			N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE	28		N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	38	8	Y	None	Recovered
			Anaemia	貧血	2	N	TE	56	29	Y	None	Recovered with sequelae
			Arthralgia	関節痛	2	N	TE	84	86	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	94	6	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	98	44	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	159		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	169	33	Y	None	Recovered
			Hypocalcaemia	低カルシウム血症	1	N	TE	169	79	N	None	Recovered
			Hypophosphataemia	低リン酸血症	4	N	TE	169		Y	None	Not recovered, but no changes expected
			Arthralgia	関節痛	3	N	TE	169		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	169	28	N	Not applicable	Recovered
			Pathological fracture	病的骨折	3	Y	TE	197	9	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	203	15	Y	None	Recovered
			Anaemia	貧血	3	N	TE	245	2	Y	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	245	11	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	1	N	TE	247	6	Y	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
230003	UK	73/M/C	Diarrhoea	下痢	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	1	N	Pre			N	None	Ongoing at study termination / withdrawal
			Scrotal swelling	陰嚢腫脹	1	N	TE			N	Not applicable	Ongoing at time of death
			Urosepsis	尿路性敗血症	3	Y	Pre	-15	4	N	Drug administration postponed	Recovered
			Hypoglycaemia	低血糖症	4	Y	Pre	-15	1	N	Drug administration postponed	Recovered
			Dizziness	浮動性めまい	1	N	TE	68		N	Not applicable	Recovered
			Rectal discharge	直腸分泌物	1	N	TE	69	10	N	Not applicable	Recovered
			Dysuria	排尿困難	1	N	TE	73		N	Not applicable	Recovered
			Groin pain	鼠径部痛	3	N	TE	75		Y	Not applicable	Recovered
			Nausea	悪心	1	N	TE	83		N	Not applicable	Ongoing at study termination / withdrawal
230005	UK	64/M/C	Bone pain	骨痛	3	N	TE	62		N	None	Not recovered, but no changes expected
			Hypoaesthesia	感覚鈍麻	2	N	TE	62		N	None	Not recovered, but no changes expected
			Pyrexia	発熱	3	N	TE	69	3	N	None	Recovered
			Infection	感染	3	Y	TE	69	3	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

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Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hyperglycaemia	高血糖	4	Y	TE	77	8	N	None	Recovered with sequelae
			Hyperglycaemia	高血糖	2	N	TE	84		Y	None	Ongoing at study termination / withdrawal
233001	UK	75/M/C	Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE			Y	None	Recovered
			Bone pain	骨痛	2	N	Pre	-2	33	N	None	Recovered
			Bone pain	骨痛	3	N	TE	85		N	Drug administration postponed	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	85		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	4	Y	TE	103	7	N	Drug administration postponed	Recovered with sequelae
			Atrial fibrillation	心房細動	3	Y	TE	116	2	Y	None	Recovered
			Cardiac failure congestive	うっ血性心不全	3	Y	TE	131		Y	Not applicable	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	N	TE	131	22	N	Not applicable	Recovered
			Hypokalaemia	低カリウム血症	3	N	TE	132	3	N	Not applicable	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	135	3	N	Not applicable	Recovered
233002	UK	70/M/C	Bone pain	骨痛	2	N	Pre	1		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	4	4	Y	None	Recovered
			Productive cough	湿性咳嗽	2	N	TE	4	4	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

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Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Sepsis	敗血症	4	Y	TE	5	11	Y	Drug permanently withdrawn	Recovered
233005	UK	78/M/C	Nausea	悪心	1	N	TE	1	209	N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	29	181	Y	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	29	29	N	None	Recovered
			Anorexia	食欲不振	3	N	TE	29	113	Y	None	Ongoing at time of death
			Dehydration	脱水	3	N	TE	29	4	Y	Drug administration postponed	Recovered
			Malaise	倦怠感	2	Y	TE	32	6	Y	Drug administration postponed	Recovered
			Dehydration	脱水	3	Y	TE	32	6	Y	Drug administration postponed	Recovered
			Dehydration	脱水	2	Y	TE	45	5	Y	Drug administration postponed	Recovered
			Anaemia	貧血	3	Y	TE	53	3	Y	None	Recovered
			Hypertension	高血圧	3	N	TE	85	125	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	134	3	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	136	3	Y	None	Recovered
			Dehydration	脱水	2	N	TE	136	3	Y	None	Recovered
			Dyspnoea	呼吸困難	3	N	TE	136	2	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	141		Y	None	Ongoing at time of death
			Abdominal pain upper	上腹部痛	1	N	TE	167	3	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	Y	TE	168	2	Y	None	Recovered
			Fatigue	疲労	2	N	TE	168		N	None	Ongoing at time of death
			Dehydration	脱水	2	Y	TE	168	2	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	176	3	Y	Not applicable	Recovered
			Cough	咳嗽	2	N	TE	176	3	N	None	Recovered
			Cough	咳嗽	1	N	TE	176	3	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	N	TE	176	3	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	190		Y	Not applicable	Ongoing at time of death
			Neutropenia	好中球減少症	2	Y	TE	190		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	Y	TE	190		Y	Not applicable	Ongoing at time of death
			Abdominal pain	腹痛	1	N	TE	190	1	Y	Not applicable	Recovered
			Decreased appetite	食欲減退	3	N	TE	190		N	None	Ongoing at time of death
			Dehydration	脱水	3	Y	TE	190	4	Y	Not applicable	Recovered
			Hyperkalaemia	高カリウム血症	2	N	TE	190	20	Y	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	190		Y	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	190	4	Y	Not applicable	Recovered
			Dizziness	浮動性めまい	2	N	TE	190		N	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	3	Y	TE	209		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bronchopneumonia	気管支肺炎	5	Y	TE	209	1	N	Not applicable	Death
			Dehydration	脱水	3	Y	TE	209		Y	Not applicable	Ongoing at time of death
			Agitation	激越	2	N	TE	209	1	N	None	Ongoing at time of death
234005	UK	58/M/C	Nausea	悪心	2	N	Pre			N	None	Recovered
			Vomiting	嘔吐	2	N	Pre			Y	None	Recovered
			Anaemia	貧血	2	N	Pre	-1	85	N	None	Recovered with sequelae
			Anaemia	貧血	3	Y	TE	84	4	Y	Drug permanently withdrawn	Recovered
			Pancytopenia	汎血球減少症	3	N	TE	87		Y	None	Ongoing at time of death
			Cerebrovascular accident	脳血管発作	4	Y	TE	94		Y	None	Ongoing at study termination / withdrawal
240002	USA	68/M/C	Anaemia	貧血	3	N	TE	33	6	Y	Drug administration postponed	Recovered with sequelae
			Pneumonia	肺炎	3	Y	TE	33	6	N	Drug administration postponed	Recovered
			Sepsis	敗血症	4	Y	TE	33	6	N	Drug administration postponed	Recovered
			Pleural effusion	胸水	2	N	TE	33	4	N	None	Recovered
			Hypotension	低血圧	3	N	TE	33	1	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	38	48	Y	None	Recovered with sequelae
			Diarrhoea	下痢	1	N	TE	62		Y	None	Ongoing at time of death
			Muscle spasms	筋痙縮	1	N	TE	72	43	N	None	Recovered
			Anaemia	貧血	2	N	TE	85	97	Y	None	Recovered with sequelae
			Nausea	悪心	1	N	TE	114	3	N	None	Recovered
			Fatigue	疲労	2	N	TE	114		Y	None	Ongoing at time of death
			Haematuria	血尿	1	N	TE	133	7	N	None	Recovered
			Leukopenia	白血球減少症	2	N	TE	139		Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	1	N	TE	139		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	139		Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	140		N	None	Ongoing at time of death
			Contusion	挫傷	1	N	TE	140		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	140		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	170		N	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	180	3	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	3	Y	TE	180	6	Y	Not applicable	Recovered
			Urinary tract infection	尿路感染	1	N	TE	180	11	N	Not applicable	Recovered
			Bone pain	骨痛	3	N	TE	180	6	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	180	62	N	Not applicable	Death
			Haematuria	血尿	2	Y	TE	180	6	Y	Not applicable	Recovered
			Urinary retention	尿閉	2	Y	TE	180	6	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	N	TE	180	24	N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	181	2	Y	None	Recovered with sequelae
			Dyspnoea	呼吸困難	1	N	TE	181	5	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	182	50	Y	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	194		N	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	199	5	Y	Not applicable	Ongoing at time of death
			Abdominal pain	腹痛	2	N	TE	199	11	N	Not applicable	Recovered
			Diarrhoea	下痢	1	N	TE	199	11	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	199	11	N	Not applicable	Recovered
			Vomiting	嘔吐	2	N	TE	199	11	N	Not applicable	Recovered
			Asthenia	無力症	2	N	TE	199		N	Not applicable	Ongoing at time of death
			Arthralgia	関節痛	1	N	TE	199	11	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	199	11	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	3	N	TE	199	5	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	203		Y	Not applicable	Ongoing at time of death
			Skin laceration	皮膚裂傷	2	N	TE	205		N	Not applicable	Ongoing at time of death
			Haemorrhoids	痔核	1	N	TE	210	6	N	Not applicable	Recovered
			Convulsion	痙攣	2	N	TE	223	1	N	Not applicable	Recovered
			Subcutaneous abscess	皮下組織膿瘍	2	N	TE	227		N	Not applicable	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	229		N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	231		Y	Not applicable	Ongoing at time of death
			Urinary retention	尿閉	2	N	TE	240	1	Y	Not applicable	Recovered
			Salivary hypersecretion	流涎過多	1	N	TE	241		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	241	1	N	Not applicable	Death
			Confusional state	錯乱状態	3	N	TE	241		N	Not applicable	Ongoing at time of death
240006	USA	75/M/C	Constipation	便秘	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	Pre	-7	100	N	None	Recovered
			Cardiac murmur	心雑音	1	N	Pre	-2	35	N	None	Recovered
			Bone pain	骨痛	1	N	TE	31	63	N	None	Recovered
			Contusion	挫傷	1	N	TE	33		N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	3	N	TE	47	11	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Abdominal pain upper	上腹部痛	1	N	TE	64	25	N	None	Recovered
			Fatigue	疲労	1	N	TE	64		Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	64	60	N	None	Recovered
			Weight increased	体重増加	1	N	TE	64		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	64	25	N	Drug administration postponed	Recovered
			Muscular weakness	筋力低下	1	N	TE	64		N	None	Ongoing at time of death
			Bone pain	骨痛	4	Y	TE	88	6	N	Drug administration postponed	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	88	115	N	Drug permanently withdrawn	Recovered
			Anaemia	貧血	2	N	TE	109	33	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	110	87	Y	Not applicable	Recovered
			Asthenia	無力症	2	N	TE	110		N	Not applicable	Ongoing at time of death
			Depression	うつ病	2	N	TE	110		N	Not applicable	Ongoing at time of death
			Fluid intake reduced	水分摂取量減少	2	N	TE	116	8	N	Not applicable	Recovered
			Cough	咳嗽	1	N	TE	118	17	N	None	Recovered
			Hypotension	低血圧	2	N	TE	120	55	N	Not applicable	Recovered
			Anorexia	食欲不振	2	N	TE	124		Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	145	203	N	Drug permanently withdrawn	Death
			Spinal cord compression	脊髄圧迫	3	N		202		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	347	1	N	Drug permanently withdrawn	Death
242001	USA	80/M/C	Vomiting	嘔吐	1	N	TE	83	1	N	None	Recovered
			Fatigue	疲労	2	N	TE	83	5	N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	83	31	N	Drug administration postponed	Recovered
			Muscular weakness	筋力低下	2	N	TE	83	5	N	Drug administration postponed	Recovered
			Pyrexia	発熱	1	N	TE	85	3	N	Drug administration postponed	Recovered
			Viral infection	ウイルス感染	2	N	TE	85	3	N	Drug administration postponed	Recovered
			Confusional state	錯乱状態	1	N	TE	85	15	N	Drug administration postponed	Recovered
			Fatigue	疲労	1	N	TE	87	13	N	None	Not recovered, but no changes expected
			Pyrexia	発熱	1	N	TE	88	6	N	None	Recovered
			Dyspepsia	消化不良	1	N	TE	89	116	N	None	Recovered
			Eructation	おくび	1	N	TE	89	116	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	1	N	TE	99	40	N	Not applicable	Recovered
			Fatigue	疲労	2	N	TE	99		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	109	31	N	None	Not recovered, but no changes expected
			Diarrhoea	下痢	1	N	TE	135	7	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	135	4	N	Not applicable	Recovered
			Asthenia	無力症	2	N	TE	137	16	N	Not applicable	Recovered
			Chills	悪寒	1	N	TE	137	2	N	Not applicable	Recovered
			Dehydration	脱水	3	Y	TE	137	5	N	Not applicable	Recovered
			Dizziness	浮動性めまい	1	N	TE	137	2	N	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	139	14	N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	147	4	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	150	5	N	Not applicable	Recovered
			Vomiting	嘔吐	2	N	TE	150	5	N	Not applicable	Recovered
			Angina pectoris	狭心症	1	N	TE	152	4	N	Not applicable	Recovered
			Abdominal pain upper	上腹部痛	1	N	TE	152	2	N	Not applicable	Recovered
			Dysphagia	嚥下障害	2	N	TE	152	4	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Asthenia	無力症	3	N	TE	152	4	N	Not applicable	Recovered
			Skin laceration	皮膚裂傷	1	N	TE	152	11	N	Not applicable	Recovered
			Dehydration	脱水	3	Y	TE	152	4	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	152		N	None	Not recovered, but no changes expected
			Cough	咳嗽	1	N	TE	152		N	Not applicable	Not recovered, but no changes expected
			Hypoxia	低酸素症	3	N	TE	152	11	N	Not applicable	Recovered
			Hypophosphataemia	低リン酸血症	3	N	TE	154		N	Not applicable	Not recovered, but no changes expected
			Pleural effusion	胸水	2	N	TE	154		N	Not applicable	Not recovered, but no changes expected
			Hypokalaemia	低カリウム血症	1	N	TE	155	50	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	155		N	Not applicable	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	162		N	Not applicable	Not recovered, but no changes expected
253001	USA	72/M/C	Constipation	便秘	1	N	Pre	1	29	N	None	Recovered
			Asthenia	無力症	1	N	Pre	1	13	N	None	Ongoing at time of death
			Micturition frequency decreased	排尿回数減少	1	N	Pre	1	13	N	None	Recovered
			Bone pain	骨痛	2	N	TE	3	11	N	None	Recovered
			Nausea	悪心	1	N	TE	13	29	N	None	Recovered
			Asthenia	無力症	2	N	TE	13	157	N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	13	17	Y	-	

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	2	N	TE	13	218	N	None	Recovered
			Hypocalcaemia	低カルシウム血症	1	N	TE	13	31	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	29	141	Y	-	
			Dehydration	脱水	2	N	TE	29	1	N	None	Recovered
			Neck pain	頚部痛	2	N	TE	29	13	N	None	Recovered
			Dizziness	浮動性めまい	2	N	TE	34		Y	None	Ongoing at time of death
			Ventricular extrasystoles	心室性期外収縮	2	N	TE	41	3	N	None	Recovered
			Skin laceration	皮膚裂傷	2	N	TE	41	17	N	None	Recovered
			Bone pain	骨痛	1	N	TE	41	3	N	None	Recovered
			Memory impairment	記憶障害	1	N	TE	41	3	N	None	Recovered
			Syncope	失神	3	Y	TE	41	3	N	None	Recovered
			Hypertension	高血圧	3	N	TE	41		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	42	44	Y	None	Recovered
			Hypocalcaemia	低カルシウム血症	2	N	TE	43	15	N	None	Recovered
			Constipation	便秘	1	N	TE	57	56	N	None	Recovered
			Hypocalcaemia	低カルシウム血症	1	N	TE	57	13	N	None	Recovered
			Ocular hyperaemia	眼充血	1	N	TE	140	7	N	None	Recovered
			Micturition frequency decreased	排尿回数減少	1	N	TE	140	30	N	None	Recovered
			Asthenia	無力症	3	N	TE	169		N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	169	61	Y	-	
			Depression	うつ病	2	N	TE	169		N	None	Ongoing at time of death
9006051	Norway	87/ /	Dizziness	浮動性めまい	1	N	TE	2	4	N	None	Recovered
			Weight increased	体重増加	1	N	TE	56	63	N	None	Recovered
			Bone pain	骨痛	2	N	TE	56	90	N	None	Recovered
			Urinary retention	尿閉	2	N	TE	57	1	N	None	Recovered
			Cystitis	膀胱炎	2	N	TE	124	12	N	None	Recovered
			Bone pain	骨痛	2	N	TE	141	33	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	173		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	Y	TE	173	9	N	None	Recovered
			Constipation	便秘	2	N	TE	176		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	181		N	None	Ongoing at study termination / withdrawal
9017026	Czech Republic	62/ /	Bone pain	骨痛	2	N	TE	113	44	N	None	Recovered
			General physical health deterioration	全身健康状態低下	5	Y	TE	201	1	N	None	Death
9020006	Sweden	71/ /	Anaemia	貧血	2	N	TE			N	None	Recovered
			Constipation	便秘	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE			Y	None	Recovered
			Vomiting	嘔吐	1	N	TE			N	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE			N	None	Recovered
			Sinusitis	副鼻腔炎	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			Y	None	Recovered
			Neuropathy peripheral	末梢性ニューロパチー	2	N	TE			N	None	Recovered with sequelae
			Bone pain	骨痛	1	N	TE	52	29	N	None	Recovered with sequelae
			Bone pain	骨痛	1	N	TE	80		Y	None	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Spinal cord compression	脊髄圧迫	4	Y	TE	119	6	N	Drug permanently withdrawn	Recovered with sequelae
			Urinary retention	尿閉	3	N	TE	119	52	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	120		N	None	Ongoing at study termination / withdrawal
			Hyperglycaemia	高血糖	1	N	TE	123	2	N	None	Recovered
			Hyponatraemia	低ナトリウム血症		N	TE	124	1	N	None	Recovered
			Abdominal distension	腹部膨満	1	N	TE	125		N	None	Recovered
			Herpes simplex	単純ヘルペス	1	N	TE	135	7	N	Not applicable	Recovered
			Wound infection	創傷感染	2	N	TE	135	20	N	None	Recovered
			Pneumonia	肺炎	2	Y	TE	154	6	N	Not applicable	Recovered
			Urinary tract infection	尿路感染	2	N	TE	155		N	None	Ongoing at study termination / withdrawal
			Pneumonia	肺炎	2	N	TE	159	8	N	Not applicable	Recovered
9025017	Sweden	72/ /	Headache	頭痛	1	N	TE			N	Not applicable	Recovered
			Atrial fibrillation	心房細動	1	Y	Pre	-29	2	N	Not applicable	Recovered
			Joint dislocation	関節脱臼	1	Y	Pre	-14	2	N	Not applicable	Recovered
			Concussion	脳振盪	2	Y	TE	15	2	N	None	Recovered
			Urinary tract infection	尿路感染	1	N	TE	29	52	N	None	Recovered
			Skin lesion	皮膚病変	1	N	TE	57	77	N	None	Recovered
			Bone pain	骨痛	1	N	TE	99	187	N	None	Recovered
			Urinary tract infection	尿路感染	1	N	TE	139	11	N	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	154	28	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary tract infection	尿路感染	1	N	TE	181	10	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	181	67	N	Not applicable	Recovered
			Upper respiratory tract infection	上気道感染	1	N	TE	197	3	N	Not applicable	Recovered
			Upper respiratory tract infection	上気道感染	2	Y	TE	199	4	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	223	63	N	Not applicable	Recovered
9026014	Sweden	82/ /	Diarrhoea	下痢	1	N	TE	11	89	N	None	Recovered
			Anaemia	貧血	1	N	TE	20	16	N	None	Recovered
			Nausea	悪心	2	N	TE	20	12	Y	None	Recovered
			Rectal haemorrhage	直腸出血	1	N	TE	20	12	N	None	Recovered
			Asthenia	無力症	2	N	TE	20	51	N	None	Recovered
			Malnutrition	栄養障害	2	Y	TE	20	12	Y	Drug administration postponed	Recovered
			Hyponatraemia	低ナトリウム血症	3	N	TE	26	10	N	None	Recovered
			Metastases to liver	肝転移	3	N	TE	29	223	N	None	Death
			Malnutrition	栄養障害	1	N	TE	31	9	N	Drug administration postponed	Recovered
			Incontinence	失禁	3	N	TE	31		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	35	23	N	None	Ongoing at time of death
			Hyponatraemia	低ナトリウム血症	1	N	TE	35	64	N	None	Recovered
			Anaemia	貧血	1	N	TE	57	126	N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	3	N	TE	98	30	N	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	127	28	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Muscular weakness	筋力低下	1	N	TE	155	29	N	None	Recovered
			Skin fragility	皮膚脆弱性	1	N	TE	155		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	175	9	N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	175	9	N	None	Recovered
			Anaemia	貧血	2	N	TE	182		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	183		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	203		N	Not applicable	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	205	2	N	Not applicable	Recovered
			Metastases to liver	肝転移	4	N	TE	251	40	N	None	Death
			Metastases to liver	肝転移	5	N	TE	290	1	N	None	Death
9033026	UK	70/ /	Neutropenia	好中球減少症	3	N	TE	85	15	Y	Drug administration postponed	Recovered
			Neutropenia	好中球減少症	1	N	TE	99	43	Y	Drug administration postponed	Recovered
			Leukopenia	白血球減少症	2	N	TE	183		Y	Drug permanently withdrawn	Not recovered, but no changes expected
			Urinary tract infection	尿路感染	2	N	TE	193	15	N	None	Recovered
			Fatigue	疲労	2	N	TE	223		Y	None	Not recovered, but no changes expected
			Lethargy	嗜眠	2	N	TE	223		Y	None	Not recovered, but no changes expected
			Neutropenic sepsis	好中球減少性敗血症	3	N	Post	247	12	Y	None	Recovered
			Neutropenia	好中球減少症	3	N	Post	295	23	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Femoral neck fracture	大腿骨頚部骨折	3	Y	Post	365		Y	Not applicable	Not recovered, but no changes expected
9033028	UK	71/ /	Diarrhoea	下痢	1	N	TE			Y	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	38	6	Y	None	Recovered with sequelae
			Medical device complication	医療機器合併症	3	Y	TE	95	26	N	Drug administration postponed	Recovered with sequelae
			Anorexia	食欲不振	1	N	TE	100		N	None	Not recovered, but no changes expected
			Anaemia	貧血	3	N	TE	151	12	Y	None	Not recovered, but no changes expected
			Anaemia	貧血	1	N	TE	162		Y	None	Not recovered, but no changes expected
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	2	N	TE	197		N	None	Not recovered, but no changes expected
9035026	UK	58/ /	Bone pain	骨痛	2	N	Pre			N	None	Recovered
			Nausea	悪心	2	N	TE	23	2	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	23	2	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	35	3	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	64	2	Y	None	Recovered
			Muscle spasms	筋痙縮	1	N	TE	78	2	N	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	86	3	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	156	18	Y	None	Recovered
			Cholecystitis	胆嚢炎	3	Y	TE	187	6	Y	None	Recovered
			Abdominal pain	腹痛	3	N	TE	207	1	N	Not applicable	Recovered
9035030	UK	64/ /	Fatigue	疲労	2	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Localised infection	限局性感染	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Not recovered, but no changes expected
			Muscular weakness	筋力低下	2	N	TE			N	None	Not recovered, but no changes expected
			Hypoaesthesia	感覚鈍麻	1	N	TE			N	None	Not recovered, but no changes expected
			Myoclonus	ミオクローヌス	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Confusional state	錯乱状態	1	N	TE			N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	2	N	TE			N	Not applicable	Recovered
			Dizziness	浮動性めまい	1	N	TE	18	5	N	None	Recovered
			Anaemia	貧血	2	N	TE	40	4	Y	None	Recovered
			Anaemia	貧血	1	N	TE	82		N	None	Ongoing at study termination / withdrawal
			Urinary tract infection	尿路感染	2	N	TE	115		N	None	Recovered
			Back pain	背部痛	2	Y	TE	133		N	None	Not recovered, but no changes expected
9042038	UK	75/ /	Joint swelling	関節腫脹	1	N	TE			N	None	Recovered
			Dysphonia	発声障害	1	N	TE			N	None	Ongoing at time of death
			Abdominal pain	腹痛	1	N	TE	2	3	Y	None	Recovered
			Nausea	悪心	1	N	TE	50	8	Y	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	80		N	None	Recovered
			Bone pain	骨痛	2	N	TE	129		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Musculoskeletal chest pain	筋骨格系胸痛	3	Y	TE	152	2	N	None	Recovered
9048014	UK	73/ /	Pitting oedema	圧痕浮腫	1	N	TE			N	Not applicable	Recovered
			Contusion	挫傷	1	N	TE			N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			N	Not applicable	Ongoing at time of death
			Chillblains	凍瘡	2	N	TE	42	15	N	None	Recovered
			Chillblains	凍瘡	3	N	TE	56	25	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	67	17	N	None	Recovered
			Chills	悪寒	1	N	TE	67	17	N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	67	17	N	None	Recovered
			Peripheral ischaemia	末梢性虚血	3	Y	TE	74	10	N	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	83	3	N	None	Recovered
			Fatigue	疲労	2	N	TE	91		N	None	Ongoing at time of death
9049001	UK	65/ /	Fatigue	疲労	1	N	TE			Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	3	N	TE	29	8	N	Drug administration postponed	Recovered
			Nausea	悪心	2	N	TE	29	43	Y	None	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	42	2	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	43	50	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	92		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	98	1	N	Drug permanently withdrawn	Death
9050018	UK	71/ /	Paraesthesia oral	口の錯感覚	1	N	TE			N	None	Ongoing at time of death
			Contusion	挫傷	1	N	TE			N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE			Y	None	Recovered
			Paraesthesia	錯感覚	1	N	TE			N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	30	18	N	None	Recovered
			Fatigue	疲労	2	N	TE	30	18	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	106		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	144	30	N	Not applicable	Death
			Bone pain	骨痛	2	N	TE	147	11	N	Not applicable	Recovered
			Anaemia	貧血	3	Y	TE	170		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	Y	TE	170		Y	Not applicable	Ongoing at time of death
			Rectal haemorrhage	直腸出血	3	Y	TE	170		Y	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	173	1	N	Not applicable	Death
9074001	Italy	79/ /	Anaemia	貧血	1	N	TE	28	14	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	28	14	N	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Blood potassium increased	血中カリウム増加	2	N	TE	42	14	N	None	Recovered
			Blood urea increased	血中尿素増加	1	N	TE	42		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	42	1	N	None	Recovered
			Asthenia	無力症	1	N	TE	74		N	None	Ongoing at time of death
			Somnolence	傾眠	1	N	TE	74	53	N	None	Recovered
			Hypercreatininaemia	高クレアチニン血症	1	N	TE	84	43	Y	None	Recovered
			Hyponatraemia	低ナトリウム血症	3	N	TE	84	14	N	-	
			Hyponatraemia	低ナトリウム血症	1	N	TE	98	14	N	-	
			Hyponatraemia	低ナトリウム血症	3	N	TE	112	15	N	-	
			Hyponatraemia	低ナトリウム血症	1	N	TE	127		N	None	Ongoing at time of death
			Syncope	失神	3	Y	TE	135	4	N	Not applicable	Death
			Syncope	失神	5	Y	TE	138	1	N	Not applicable	Death
9152001	Germany	79/ /	Lymphoedema	リンパ浮腫	1	N	TE			Y	None	Recovered with sequelae
			Renal pain	腎臓痛	2	N	TE	13	4	N	None	Recovered
			Pollakiuria	頻尿	1	N	TE	14	3	N	None	Recovered
			Renal pain	腎臓痛	3	Y	TE	16	6	N	None	Recovered
			Ureteric rupture	尿管破裂	3	N	TE	21	22	N	None	Recovered
			Nausea	悪心	1	N	TE	25	1	N	None	Recovered
			Anorexia	食欲不振	2	N	TE	25	33	Y	None	Ongoing at time of death
			Urinary tract infection enterococcal	腸球菌性尿路感染	2	N	TE	29	57	N	None	Recovered with sequelae
			Weight decreased	体重減少	2	N	TE	57	351	Y	None	Recovered with sequelae
			Anorexia	食欲不振	3	N	TE	57		Y	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

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			Pleural effusion	胸水	2	N	TE	183		N	Not applicable	Ongoing at time of death
9191003	Singapore	79/ /	Scrotal oedema	陰嚢浮腫	3	Y	Pre	-2	2	N	Drug administration postponed	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	26	4	N	None	Ongoing at study termination / withdrawal
			Scrotal oedema	陰嚢浮腫	3	Y	TE	27	3	N	None	Recovered
			Pulmonary hypertension	肺高血圧症	3	N	TE	27		N	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	1	N	TE	29		N	None	Ongoing at study termination / withdrawal
			Hyperkalaemia	高カリウム血症	3	N	TE	59	1	N	None	Recovered
9240003	USA	69/ /	Diarrhoea	下痢	1	N	TE	1	22	Y	None	Recovered
			Fatigue	疲労	1	N	TE	1	609	Y	None	Recovered with sequelae
			Injection site bruising	注射部位内出血	1	N	TE	1	22	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	84	1	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	117	1	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	118	492	Y	None	Recovered with sequelae
			Thrombocytopenia	血小板減少症	1	N	TE	173	283	Y	Not applicable	Ongoing at time of death
			Contusion	挫傷	1	N	TE	174	191	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	455	35	Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Haematochezia	血便排泄	1	N	Post	467	143	Y	Not applicable	Recovered with sequelae
			Thrombocytopenia	血小板減少症	3	N	TE	489	85	Y	Not applicable	Ongoing at time of death
			Pancytopenia	汎血球減少症	3	Y	Post	518	56	Y	Not applicable	Ongoing at time of death
			Pancytopenia	汎血球減少症	4	Y	Post	573	36	Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	573	36	Y	Not applicable	Ongoing at time of death
			Pancytopenia	汎血球減少症	3	Y	Post	608	106	Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	608	106	Y	Not applicable	Ongoing at time of death
			Pancytopenia	汎血球減少症	4	Y	Post	713		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	713		Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Placebo Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
9006051	Norway	87/ /	Dizziness	浮動性めまい	1	N	TE	2	4	N	None	Recovered
			Weight increased	体重増加	1	N	TE	56	63	N	None	Recovered
			Bone pain	骨痛	2	N	TE	56	90	N	None	Recovered
			Urinary retention	尿閉	2	N	TE	57	1	N	None	Recovered
			Cystitis	膀胱炎	2	N	TE	124	12	N	None	Recovered
			Bone pain	骨痛	2	N	TE	141	33	N	None	Recovered
			Anaemia	貧血	1	N	TE	173		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	Y	TE	173	9	N	None	Recovered
			Constipation	便秘	2	N	TE	176		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	181		N	None	Ongoing at study termination / withdrawal
9017026	Czech Republic	62/ /	Bone pain	骨痛	2	N	TE	113	44	N	None	Recovered
			General physical health deterioration	全身健康状態低下	5	Y	TE	201	1	N	None	Death
9020006	Sweden	71/ /	Anaemia	貧血	2	N	TE			N	None	Recovered
			Constipation	便秘	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE			Y	None	Recovered
			Vomiting	嘔吐	1	N	TE			N	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE			N	None	Recovered
			Sinusitis	副鼻腔炎	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Placebo Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neuropathy peripheral	末梢性ニューロパチー	2	N	TE			N	None	Recovered with sequelae
			Bone pain	骨痛	1	N	TE	52	29	N	None	Recovered with sequelae
			Bone pain	骨痛	1	N	TE	80		Y	None	Not recovered, but no changes expected
			Spinal cord compression	脊髄圧迫	4	Y	TE	119	6	N	Drug permanently withdrawn	Recovered with sequelae
			Urinary retention	尿閉	3	N	TE	119	52	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	120		N	None	Ongoing at study termination / withdrawal
			Hyperglycaemia	高血糖	1	N	TE	123	2	N	None	Recovered
			Hyponatraemia	低ナトリウム血症		N	TE	124	1	N	None	Recovered
			Abdominal distension	腹部膨満	1	N	TE	125		N	None	Recovered
			Herpes simplex	単純ヘルペス	1	N	TE	135	7	N	Not applicable	Recovered
			Wound infection	創傷感染	2	N	TE	135	20	N	None	Recovered
			Pneumonia	肺炎	2	Y	TE	154	6	N	Not applicable	Recovered
			Urinary tract infection	尿路感染	2	N	TE	155		N	None	Ongoing at study termination / withdrawal
			Pneumonia	肺炎	2	N	TE	159	8	N	Not applicable	Recovered
9025017	Sweden	72/ /	Headache	頭痛	1	N	TE			N	Not applicable	Recovered
			Atrial fibrillation	心房細動	1	Y	Pre	-29	2	N	Not applicable	Recovered
			Joint dislocation	関節脱臼	1	Y	Pre	-14	2	N	Not applicable	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Placebo Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Concussion	脳振盪	2	Y	TE	15	2	N	None	Recovered
			Urinary tract infection	尿路感染	1	N	TE	29	52	N	None	Recovered
			Skin lesion	皮膚病変	1	N	TE	57	77	N	None	Recovered
			Bone pain	骨痛	1	N	TE	99	187	N	None	Recovered
			Urinary tract infection	尿路感染	1	N	TE	139	11	N	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	154	28	N	None	Recovered
			Urinary tract infection	尿路感染	1	N	TE	181	10	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	181	67	N	Not applicable	Recovered
			Upper respiratory tract infection	上気道感染	1	N	TE	197	3	N	Not applicable	Recovered
			Upper respiratory tract infection	上気道感染	2	Y	TE	199	4	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	223	63	N	Not applicable	Recovered
9026014	Sweden	82/ /	Diarrhoea	下痢	1	N	TE	11	89	N	None	Recovered
			Anaemia	貧血	1	N	TE	20	16	N	None	Recovered
			Nausea	悪心	2	N	TE	20	12	Y	None	Recovered
			Rectal haemorrhage	直腸出血	1	N	TE	20	12	N	None	Recovered
			Asthenia	無力症	2	N	TE	20	51	N	None	Recovered
			Malnutrition	栄養障害	2	Y	TE	20	12	Y	Drug administration postponed	Recovered
			Hyponatraemia	低ナトリウム血症	3	N	TE	26	10	N	None	Recovered
			Metastases to liver	肝転移	3	N	TE	29	223	N	None	Death
			Malnutrition	栄養障害	1	N	TE	31	9	N	Drug administration postponed	Recovered
			Incontinence	失禁	3	N	TE	31		N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Placebo Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	35	23	N	None	Ongoing at time of death
			Hyponatraemia	低ナトリウム血症	1	N	TE	35	64	N	None	Recovered
			Anaemia	貧血	1	N	TE	57	126	N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	3	N	TE	98	30	N	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	127	28	N	None	Recovered
			Muscular weakness	筋力低下	1	N	TE	155	29	N	None	Recovered
			Skin fragility	皮膚脆弱性	1	N	TE	155		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	175	9	N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	175	9	N	None	Recovered
			Anaemia	貧血	2	N	TE	182		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	183		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	203		N	Not applicable	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	205	2	N	Not applicable	Recovered
			Metastases to liver	肝転移	4	N	TE	251	40	N	None	Death
			Metastases to liver	肝転移	5	N	TE	290	1	N	None	Death
9033026	UK	70/ /	Neutropenia	好中球減少症	3	N	TE	85	15	Y	Drug administration postponed	Recovered
			Neutropenia	好中球減少症	1	N	TE	99	43	Y	Drug administration postponed	Recovered
			Leukopenia	白血球減少症	2	N	TE	183		Y	Drug permanently withdrawn	Not recovered, but no changes expected

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Placebo Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary tract infection	尿路感染	2	N	TE	193	15	N	None	Recovered
			Fatigue	疲労	2	N	TE	223		Y	None	Not recovered, but no changes expected
			Lethargy	嗜眠	2	N	TE	223		Y	None	Not recovered, but no changes expected
			Neutropenic sepsis	好中球減少性敗血症	3	N	Post	247	12	Y	None	Recovered
			Neutropenia	好中球減少症	3	N	Post	295	23	Y	None	Recovered
			Femoral neck fracture	大腿骨頚部骨折	3	Y	Post	365		Y	Not applicable	Not recovered, but no changes expected
9033028	UK	71/ /	Diarrhoea	下痢	1	N	TE			Y	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	38	6	Y	None	Recovered with sequelae
			Medical device complication	医療機器合併症	3	Y	TE	95	26	N	Drug administration postponed	Recovered with sequelae
			Anorexia	食欲不振	1	N	TE	100		N	None	Not recovered, but no changes expected
			Anaemia	貧血	3	N	TE	151	12	Y	None	Not recovered, but no changes expected
			Anaemia	貧血	1	N	TE	162		Y	None	Not recovered, but no changes expected
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	2	N	TE	197		N	None	Not recovered, but no changes expected
9035026	UK	58/ /	Bone pain	骨痛	2	N	Pre			N	None	Recovered
			Nausea	悪心	2	N	TE	23	2	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	23	2	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	35	3	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	64	2	Y	None	Recovered
			Muscle spasms	筋痙縮	1	N	TE	78	2	N	None	Recovered
			Nasopharyngitis	鼻咽頭炎	1	N	TE	86	3	Y	None	Recovered

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Placebo Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Diarrhoea	下痢	1	N	TE	156	18	Y	None	Recovered
			Cholecystitis	胆嚢炎	3	Y	TE	187	6	Y	None	Recovered
			Abdominal pain	腹痛	3	N	TE	207	1	N	Not applicable	Recovered
9035030	UK	64/ /	Fatigue	疲労	2	N	TE			N	None	Ongoing at time of death
			Localised infection	限局性感染	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Not recovered, but no changes expected
			Muscular weakness	筋力低下	2	N	TE			N	None	Not recovered, but no changes expected
			Hypoaesthesia	感覚鈍麻	1	N	TE			N	None	Not recovered, but no changes expected
			Myoclonus	ミオクローヌス	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Confusional state	錯乱状態	1	N	TE			N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	2	N	TE			N	Not applicable	Recovered
			Dizziness	浮動性めまい	1	N	TE	18	5	N	None	Recovered
			Anaemia	貧血	2	N	TE	40	4	Y	None	Recovered
			Anaemia	貧血	1	N	TE	82		N	None	Ongoing at study termination / withdrawal
			Urinary tract infection	尿路感染	2	N	TE	115		N	None	Recovered
			Back pain	背部痛	2	Y	TE	133		N	None	Not recovered, but no changes expected
9042038	UK	75/ /	Joint swelling	関節腫脹	1	N	TE			N	None	Recovered
			Dysphonia	発声障害	1	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Placebo Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Abdominal pain	腹痛	1	N	TE	2	3	Y	None	Recovered
			Nausea	悪心	1	N	TE	50	8	Y	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	80		N	None	Recovered
			Bone pain	骨痛	2	N	TE	129		N	None	Ongoing at time of death
			Musculoskeletal chest pain	筋骨格系胸痛	3	Y	TE	152	2	N	None	Recovered
9048014	UK	73/ /	Pitting oedema	圧痕浮腫	1	N	TE			N	Not applicable	Recovered
			Contusion	挫傷	1	N	TE			N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			N	Not applicable	Ongoing at time of death
			Chillblains	凍瘡	2	N	TE	42	15	N	None	Recovered
			Chillblains	凍瘡	3	N	TE	56	25	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	67	17	N	None	Recovered
			Chills	悪寒	1	N	TE	67	17	N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	67	17	N	None	Recovered
			Peripheral ischaemia	末梢性虚血	3	Y	TE	74	10	N	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	83	3	N	None	Recovered
			Fatigue	疲労	2	N	TE	91		N	None	Ongoing at time of death
9049001	UK	65/ /	Fatigue	疲労	1	N	TE			Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	3	N	TE	29	8	N	Drug administration postponed	Recovered
			Nausea	悪心	2	N	TE	29	43	Y	None	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	42	2	N	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Placebo Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	2	N	TE	43	50	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	92		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	98	1	N	Drug permanently withdrawn	Death
9050018	UK	71/ /	Paraesthesia oral	口の錯感覚	1	N	TE			N	None	Ongoing at time of death
			Contusion	挫傷	1	N	TE			N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE			Y	None	Recovered
			Paraesthesia	錯感覚	1	N	TE			N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	30	18	N	None	Recovered
			Fatigue	疲労	2	N	TE	30	18	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	106		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	144	30	N	Not applicable	Death
			Bone pain	骨痛	2	N	TE	147	11	N	Not applicable	Recovered
			Anaemia	貧血	3	Y	TE	170		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	Y	TE	170		Y	Not applicable	Ongoing at time of death
			Rectal haemorrhage	直腸出血	3	Y	TE	170		Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Placebo Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	173	1	N	Not applicable	Death
9074001	Italy	79/ /	Anaemia	貧血	1	N	TE	28	14	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	28	14	N	None	Recovered
			Blood potassium increased	血中カリウム増加	2	N	TE	42	14	N	None	Recovered
			Blood urea increased	血中尿素増加	1	N	TE	42		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	42	1	N	None	Recovered
			Asthenia	無力症	1	N	TE	74		N	None	Ongoing at time of death
			Somnolence	傾眠	1	N	TE	74	53	N	None	Recovered
			Hypercreatininaemia	高クレアチニン血症	1	N	TE	84	43	Y	None	Recovered
			Hyponatraemia	低ナトリウム血症	3	N	TE	84	14	N	-	
			Hyponatraemia	低ナトリウム血症	1	N	TE	98	14	N	-	
			Hyponatraemia	低ナトリウム血症	3	N	TE	112	15	N	-	
			Hyponatraemia	低ナトリウム血症	1	N	TE	127		N	None	Ongoing at time of death
			Syncope	失神	3	Y	TE	135	4	N	Not applicable	Death
			Syncope	失神	5	Y	TE	138	1	N	Not applicable	Death
9152001	Germany	79/ /	Lymphoedema	リンパ浮腫	1	N	TE			Y	None	Recovered with sequelae
			Renal pain	腎臓痛	2	N	TE	13	4	N	None	Recovered
			Pollakiuria	頻尿	1	N	TE	14	3	N	None	Recovered
			Renal pain	腎臓痛	3	Y	TE	16	6	N	None	Recovered
			Ureteric rupture	尿管破裂	3	N	TE	21	22	N	None	Recovered
			Nausea	悪心	1	N	TE	25	1	N	None	Recovered
			Anorexia	食欲不振	2	N	TE	25	33	Y	None	Ongoing at time of death

表 2.7.4.7- 5 重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Placebo Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary tract infection enterococcal	腸球菌性尿路感染	2	N	TE	29	57	N	None	Recovered with sequelae
			Weight decreased	体重減少	2	N	TE	57	351	Y	None	Recovered with sequelae
			Anorexia	食欲不振	3	N	TE	57		Y	None	Ongoing at time of death
			Pleural effusion	胸水	2	N	TE	183		N	Not applicable	Ongoing at time of death
9191003	Singapore	79/ /	Scrotal oedema	陰嚢浮腫	3	Y	Pre	-2	2	N	Drug administration postponed	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	26	4	N	None	Ongoing at study termination / withdrawal
			Scrotal oedema	陰嚢浮腫	3	Y	TE	27	3	N	None	Recovered
			Pulmonary hypertension	肺高血圧症	3	N	TE	27		N	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	1	N	TE	29		N	None	Ongoing at study termination / withdrawal
			Hyperkalaemia	高カリウム血症	3	N	TE	59	1	N	None	Recovered
9240003	USA	69/ /	Diarrhoea	下痢	1	N	TE	1	22	Y	None	Recovered
			Fatigue	疲労	1	N	TE	1	609	Y	None	Recovered with sequelae
			Injection site bruising	注射部位内出血	1	N	TE	1	22	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	84	1	N	None	Recovered
			Diarrhoea	下痢	1	N	TE	117	1	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	118	492	Y	None	Recovered with sequelae

表 2.7.4.7- 5　重篤な TEAE が発現した被験者の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Placebo Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	1	N	TE	173	283	Y	Not applicable	Ongoing at time of death
			Contusion	挫傷	1	N	TE	174	191	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	455	35	Y	Not applicable	Ongoing at time of death
			Haematochezia	血便排泄	1	N	Post	467	143	Y	Not applicable	Recovered with sequelae
			Thrombocytopenia	血小板減少症	3	N	TE	489	85	Y	Not applicable	Ongoing at time of death
			Pancytopenia	汎血球減少症	3	Y	Post	518	56	Y	Not applicable	Ongoing at time of death
			Pancytopenia	汎血球減少症	4	Y	Post	573	36	Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	573	36	Y	Not applicable	Ongoing at time of death
			Pancytopenia	汎血球減少症	3	Y	Post	608	106	Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	608	106	Y	Not applicable	Ongoing at time of death
			Pancytopenia	汎血球減少症	4	Y	Post	713		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	713		Y	Not applicable	Ongoing at time of death

Sex is identified as: M = Male.

Race is identified as: A = Asian, B = Black, C = Caucasian, O = Other.

The unit for "Age" is years.

Phase is identified as: Pre = Pre-Treatment, TE = Treatment-Emergent, Post = Post-Treatment

Source: 5.3.5.1.11 BC1-06_J-table 3/Table 1.4/1

表 2.7.4.7- 6　重篤な有害事象が発現した被験者の一覧（試験 BC1-02、12 ヵ月報告）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events(AE) Preferred term (MedDRA version 7.0)	Adverse Events(AE) Preferred term (MedDRA version 7.0)	Intensity	CTCAE grade[a]	SAE	Relative week of AE	Duration of AE (day)	Related to study drug	Action taken with study treatment	Outcome of AE
BAY 88-8223 (55)	109	81/M/C	Confusional state	錯乱状態	Mild		Y	5.3	11	N	Drug permanently withdrawn	Recovered with sequelae
	202	71/M/C	Vomiting	嘔吐	Moderate	3	Y	0.0	1	Y	None	Recovered
	204	68/M/C	Chronic obstructive airways disease exacerbated	慢性閉塞性気道疾患増悪	Severe		Y	0.9	1	N	None	Recovered
			Chronic obstructive airways disease exacerbated	慢性閉塞性気道疾患増悪	Severe		Y	5.3	4	N	None	Recovered
			Pseudomonas infection	シュードモナス感染	Severe		Y	11.4	4	N	None	Recovered
	206	82/M/C	Dehydration	脱水	Severe		Y	7.9	4	N	Drug administration postponed	Not recovered
			Pneumonia	肺炎	Severe	3	Y	8.6	-	Uncertain	Drug permanently withdrawn	Lost to follow-up[b]
			Sepsis	敗血症	Severe	3	Y	8.9	6	Uncertain	Drug permanently withdrawn	Recovered

表 2.7.4.7- 6　重篤な有害事象が発現した被験者の一覧（試験 BC1-02、12 ヵ月報告）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events(AE) Preferred term (MedDRA version 7.0)	Adverse Events(AE) Preferred term (MedDRA version 7.0)	Intensity	CTCAE grade[a]	SAE	Relative week of AE	Duration of AE (day)	Related to study drug	Action taken with study treatment	Outcome of AE
	504	69/M/C	Spinal cord compression	脊髄圧迫	Moderate		Y	11.4	7	N	Drug administration postponed	Change in intensity[c]
			Spinal cord compression	脊髄圧迫	Moderate		Y	12.7	19	N	Drug administration postponed	Change in intensity[c]
	511	86/M/C	Pneumonia	肺炎	Moderate		Y	7.6	3	N	None	Recovered
	514	74/M/C	Chest pain	胸痛	Moderate		Y	8.1	28	N	None	Recovered
	552	71/M/C	Tumour flare	腫瘍フレア	Severe	3	Y	1.0	U	Uncertain	None	NA
			Myocardial infarction	心筋梗塞	Severe		Y	3.1	0	N	Drug permanently withdrawn	Death
Placebo	106	78/M/C	Ataxia	失調	Severe		Y	2.1	U	N	Drug administration postponed	Not recovered
	108	64/M/C	Subdural haematoma	硬膜下血腫	Severe		Y	14.1	U	N	None	Not recovered
	110	80/M/C	Deep vein thrombosis	深部静脈血栓症	Moderate		Y	4.1	U	N	None	Not recovered
	201	66/M/C	Perineal pain	会陰痛	Severe		Y	2.3	6	N	None	Change in intensity[c]
	203	61/M/C	Spinal cord compression	脊髄圧迫	Severe		Y	11.3	11	N	None	Recovered

表 2.7.4.7- 6　重篤な有害事象が発現した被験者の一覧（試験 BC1-02、12 ヵ月報告）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events(AE) Preferred term (MedDRA version 7.0)	Adverse Events(AE) Preferred term (MedDRA version 7.0)	Intensity	CTCAE grade[a]	SAE	Relative week of AE	Duration of AE (day)	Related to study drug	Action taken with study treatment	Outcome of AE
			Bone pain	骨痛	Severe		Y	17.1	47	N	None	Recovered
	205	68/M/C	Bone pain	骨痛	Moderate		Y	7.1	U	N	None	NA
			Atrial fibrillation	心房細動	Severe		Y	7.7	6	N	Drug permanently withdrawn	Death
			Sepsis	敗血症	Severe	4	Y	7.9	5	Uncertain	Drug administration postponed	Death
	304	75/M/C	Adrenal disorder	副腎障害	Moderate		Y	4.4	U	N	Drug permanently withdrawn	Not recovered
	404	67/M/C	Bone pain	骨痛	Severe		Y	4.7	8	N	None	Recovered
	505	84/M/C	Fall	転倒	Severe		Y	1.3	14	N	None	Recovered
			Cachexia	悪液質	Moderate		Y	6.9	65	N	Drug permanently withdrawn	Death
	513	74/M/C	Haemoglobin decreased	ヘモグロビン減少	Mild		Y	7.6	1	N	Drug administration postponed	Recovered
	551	68/M/C	Pyrexia	発熱	Moderate		Y	12.0	55	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	Severe		Y	13.1	U	N	None	Not recovered
	602	73/M/C	Tumour flare	腫瘍フレア	Severe		Y	0.3	2	N	None	Recovered

表 2.7.4.7- 6　重篤な有害事象が発現した被験者の一覧（試験 BC1-02、12 ヵ月報告）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events(AE) Preferred term (MedDRA version 7.0)	Adverse Events(AE) Preferred term (MedDRA version 7.0)	Intensity	CTCAE grade[a]	SAE	Relative week of AE	Duration of AE (day)	Related to study drug	Action taken with study treatment	Outcome of AE
	701	73/M/C	Hypocalcaemia	低カルシウム血症	Moderate		Y	14.0	14	N	None	Recovered
	951	84/M/C	Intestinal obstruction	腸管閉塞	Severe		Y	12.9	-	N	Drug administration postponed	Recovered

Y: Yes, N: No

Sex is identified as: M = Male.

Race is identified as: C = Caucasian

The unit for "Age" is years.

U = Unknown

a: CTCAE grade only indicated for adverse event related to investigational drug or of unknown relationship.

b: Died from other causes.

c: Change in intensity: severity changed and event not considered serious.

Source: 5.3.5.1.6 A58302/Listing 14.3.2.1, 14.3.2.3, 16.2.4

表 2.7.4.7- 7　重篤な有害事象が発現した被験者の一覧（試験 BC1-03、12 ヵ月報告書）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Intensity	CTCAE grade	SAE	Relative Week of AE[a]	Duration of AE (day)[b]	Related to study drug	Action taken to treat the event	Outcome of AE
BAY 88-8223 (6)	1008	74/M/C	Nausea	悪心		3	Y	13.4	10	Unlikely	Medication	Recovered
BAY 88-8223 (6)	1014	74/M/C	Rectal haemorrhage	直腸出血		3	Y	15.4	6	Unlikely	Medication	Recovered
BAY 88-8223 (6)	1015	61/M/C	Muscular weakness	筋力低下	Moderate		Y	0.6	8	Unlikely	Other: DECOMPRESSION TN 10	Recovered with sequelae
			Pneumonia	肺炎	Moderate		Y	3.3	3	Unlikely	Medication	Recovered with sequelae
			Respiratory failure	呼吸不全		3	Y	6.6		Unlikely	Other: OXYGEN	Not recovered
BAY 88-8223 (6)	1018	54/M/C	Pyelonephritis	腎盂腎炎		2	Y	4.3	4	Unlikely	Medication	Recovered
			Spinal cord compression	脊髄圧迫		3	Y	6.9		Possible	Medication	Not recovered
BAY 88-8223 (6)	1105	75/M/C	Bladder obstruction	膀胱閉塞		3	Y	6.3	15	Unlikely	Medication Therapy Other: BLADDER CATHETER AND ANTIBIOTICS (AND SURGERY IS PLANNED)	Recovered
			General physical health deterioration	全身健康状態低下	Moderate		Y	17.0		Unlikely	Medication	Unknown
			Dehydration	脱水	Moderate		Y	17.0		Unlikely	Medication	Unknown

表 2.7.4.7- 7 重篤な有害事象が発現した被験者の一覧（試験 BC1-03、12 ヵ月報告書）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Intensity	CTCAE grade	SAE	Relative Week of AE[a]	Duration of AE (day)[b]	Related to study drug	Action taken to treat the event	Outcome of AE
BAY 88-8223 (6)	1201	75/M/C	Hypotension	低血圧		3	Y	0.7	3	Unlikely	Other: STOP FUROSEMIDE + SYMPTOMATIC TREATEMENT	Recovered
			Constipation	便秘		3	Y	3.1	19	Unlikely	Medication	Recovered
			Spinal cord compression	脊髄圧迫		4	Y	6.9		Unlikely	Medication Other: BLADDER CATHETERISATION	Not recovered
			Disease progression	疾患進行	Severe		Y	11.9	0	Unlikely	None	Death
BAY 88-8223 (6)	1407	66/M/C	Asthenia	無力症		3	Y	3.0		Unlikely	Other: PARENTERAL NOURISHMENT	Not recovered
			Haemoglobin decreased	ヘモグロビン減少		2	Y	5.9		Unlikely	Therapy	Not recovered
			Blood glucose increased	血中ブドウ糖増加		3	Y	4.0		Unlikely	Medication	
BAY 88-8223 (6)	1601	75/M/C	Abdominal pain	腹痛		4	Y	2.7	9	Unlikely	Medication	Recovered
			Pyrexia	発熱		1	Y	0.1		Unlikely	Medication	Unknown
			Cardiopulmonary failure	心肺不全	Severe		Y	7.4	0	Unlikely	None	Death
BAY 88-8223 (6)	1606	76/M/C	Haemoglobin decreased	ヘモグロビン減少		3	Y	2.0		Unlikely	Other: 2 BLOOD TRANSFUSION S 27107106 AND 06109106	Not recovered

表 2.7.4.7- 7 重篤な有害事象が発現した被験者の一覧（試験 BC1-03、12 ヵ月報告書）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Intensity	CTCAE grade	SAE	Relative Week of AE[a]	Duration of AE (day)[b]	Related to study drug	Action taken to treat the event	Outcome of AE
			Fatigue	疲労		3	Y	15.4		Unlikely	None	Not recovered
			Disease progression	疾患進行		5	Y	15.9	0	Unlikely	None	Death
BAY 88-8223 (6)	1706	69/M/C	Fatigue	疲労		3	Y	3.0	7	Probable	Therapy	Recovered
			Fatigue	疲労		3	Y	6.4	37	Unlikely	Therapy	Death
BAY 88-8223 (6)	1707	63/M/C	Myocardial infarction	心筋梗塞		4	Y	5.3	6	Unlikely	Medication	Recovered
			Constipation	便秘		3	Y	9.3	4	Unlikely	Medication	Recovered
			Oedema peripheral	末梢性浮腫		3	Y	10.0		Unlikely	Medication	Not recovered
BAY 88-8223 (6)	2303	59/M/C	Chest pain	胸痛	Moderate		Y	0.4	13	Possible	Medication	Recovered
			Sepsis	敗血症	Severe		Y	10.7	33	Unlikely	Medication	Recovered
BAY 88-8223 (6)	4008	81/M/C	Gastrointestinal haemorrhage	胃腸出血		2	Y	13.3	1	Unlikely	None	Death
BAY 88-8223 (6)	5002	72/M/C	Lower limb fracture	下肢骨折		3	Y	2.9	91	Unlikely	Medication Other: SURGERY	Recovered
BAY 88-8223 (6)	9001	73/M/C	Pyrexia	発熱		1	Y	4.0	7	Unlikely	Medication	Recovered
BAY 88-8223 (28)	1007	76/M/C	Femur fracture	大腿骨骨折		3	Y	0.0	1	Unlikely	Other: SURGERY	Recovered
BAY 88-8223 (28)	1010	82/M/C	Bone pain	骨痛		4	Y	1.9	2	Unlikely	Medication	Recovered
BAY 88-8223 (28)	1016	49/M/C	Bone pain	骨痛		3	Y	8.0 D	4	Unlikely	Medication	Recovered
BAY 88-8223 (28)	1103	72/M/C	Platelet count decreased	血小板数減少		4	Y	1.1	55	Possible	Therapy	Recovered
			Metastases to skin	皮膚転移		2	Y	9.4	4	Unlikely	Therapy	Recovered

表 2.7.4.7- 7 重篤な有害事象が発現した被験者の一覧（試験 BC1-03、12 ヵ月報告書）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Intensity	CTCAE grade	SAE	Relative Week of AE[a]	Duration of AE (day)[b]	Related to study drug	Action taken to treat the event	Outcome of AE
BAY 88-8223 (28)	1313	74/M/C	Cardiac arrest	心停止		5	Y	7.3		Unlikely	Medication	Death
BAY 88-8223 (28)	1406	64/M/C	Nausea	悪心		3	Y	0.4	3	Unlikely	Medication	Recovered
			Vomiting	嘔吐		3	Y	0.4	3	Unlikely	Medication	Recovered
BAY 88-8223 (28)	2301	68/M/C	Urinary tract infection	尿路感染		2	Y	0.4	3	Unlikely	Medication	Recovered
			Blood creatinine increased	血中クレアチニン増加		2	Y	1.6	18	Unlikely	Therapy	Recovered
			General physical health deterioration	全身健康状態低下		4	Y	5.7	65	Unlikely	None	Death
BAY 88-8223 (28)	2302	69/M/C	Epistaxis	鼻出血	Severe		Y	14.7	1	Possible	Other: ELECTROCOAGULATION	Recovered
			General physical health deterioration	全身健康状態低下	Severe		Y	3.9	103	Unlikely	Medication Therapy	Death
			Anaemia	貧血		2	Y	8.0	74	Possible	Medication	Death
			Shoulder pain	肩部痛	Severe		Y	10.0	60	Unlikely	Medication	Death
			Disease progression	疾患進行		5	Y	12.9	40	Unlikely	None	Death
BAY 88-8223 (28)	4001	80/M/C	Diarrhoea	下痢		3	Y	4.4		Possible	Medication	Not recovered
BAY 88-8223 (28)	4011	67/M/C	Muscular weakness	筋力低下	Severe		Y	3.0	7	Unlikely	Medication	Recovered
			Bone pain	骨痛	Severe		Y	3.0	7	Unlikely	Medication	Recovered

表 2.7.4.7- 7 重篤な有害事象が発現した被験者の一覧（試験 BC1-03、12 ヵ月報告書）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Intensity	CTCAE grade	SAE	Relative Week of AE[a]	Duration of AE (day)[b]	Related to study drug	Action taken to treat the event	Outcome of AE
BAY 88-8223 (28)	6004	67/M/C	Muscular weakness	筋力低下		4	Y	8.0		Unlikely	Medication Therapy	Not recovered
			Urinary retention	尿閉		3	Y	8.0	1	Unlikely	Medication Therapy	Recovered
			Gait disturbance	歩行障害		4	Y	7.1		Unlikely	Medication Therapy	Not recovered
BAY 88-8223 (28)	6007	66/M/C	Disseminated intravascular coagulation	播種性血管内凝固		3	Y	1.3	5	Unlikely	Medication	Recovered
			Urinary tract infection	尿路感染		3	Y	1.3	5	Unlikely	Medication	Recovered
			Diarrhoea	下痢		3	Y	3.3	20	Unlikely	Medication	Recovered
			Diarrhoea	下痢		3	Y	7.7	18	Unlikely	Medication	Recovered
BAY 88-8223 (28)	7001	73/M/C	Disease progression	疾患進行		5	Y	3.7	0	Unlikely	None	Death
BAY 88-8223 (28)	7003	70/M/C	Paraesthesia	錯感覚		2	Y	0.0	34	Possible	None Other: OBSERVATION	Recovered
			Nausea	悪心		3	Y	0.1	33	Possible	Medication	Recovered with sequelae
			Vomiting	嘔吐		3	Y	4.6	2	Possible	Medication	Recovered
BAY 88-8223 (28)	9003	81/M/C	Urinary tract infection	尿路感染		2	Y	4.0	19	Unlikely	Medication	Recovered
			Dehydration	脱水		2	Y	5.6		Unlikely	Therapy	Not recovered
			Nausea	悪心		2	Y	4.3	20	Unlikely	None	Recovered
			Vomiting	嘔吐		2	Y	4.3	20	Unlikely	None	Recovered

表 2.7.4.7- 7 重篤な有害事象が発現した被験者の一覧（試験 BC1-03、12 ヵ月報告書）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Intensity	CTCAE grade	SAE	Relative Week of AE[a]	Duration of AE (day)[b]	Related to study drug	Action taken to treat the event	Outcome of AE
			Disease progression	疾患進行		5	Y	7.7	0	Unlikely	None	Death
BAY 88-8223 (28)	9005	68/M/C	Spinal cord compression	脊髄圧迫		3	Y	3.7		Unlikely	Medication Therapy	Not recovered
			Abdominal pain	腹痛		3	Y	4.4		Unlikely	Medication	Not recovered
			Intestinal perforation	腸管穿孔		4	Y	4.6	2	Unlikely	None	Death
BAY 88-8223 (55)	1002	66/M/C	Fatigue	疲労		3	Y	0.1	13	Probable	None	Recovered
BAY 88-8223 (55)	1012	66/M/C	Nausea	悪心		3	Y	12.0	25	Unlikely	Medication	Recovered
BAY 88-8223 (55)	1106	70/M/C	Hand fracture	手骨折		3	Y	14.6		Unlikely	Therapy	Not recovered
BAY 88-8223 (55)	1304	56/M/C	Bone pain	骨痛		3	Y	13.1		Unlikely	Medication	Not recovered
			General physical health deterioration	全身健康状態低下	Severe		Y	16.7		Unlikely	Other: REHYDRATION + BLOOD TRANSFUSION	Not recovered
BAY 88-8223 (55)	1402	70/M/C	Spinal column stenosis	脊柱管狭窄症	Moderate		Y	10.9	U	Unlikely	Therapy	Unknown
BAY 88-8223 (55)	1702	64/M/C	Haemoglobin decreased	ヘモグロビン減少		3	Y	11.1	2	Unlikely	Therapy	Recovered
			Back pain	背部痛		3	Y	14.7	8	Unlikely	Medication	Recovered
BAY 88-8223 (55)	1705	71/M/C	Upper gastrointestinal haemorrhage	上部消化管出血		3	Y	2.7	6	Possible	Medication	Recovered

表 2.7.4.7- 7　重篤な有害事象が発現した被験者の一覧（試験 BC1-03、12 ヵ月報告書）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Intensity	CTCAE grade	SAE	Relative Week of AE[a]	Duration of AE (day)[b]	Related to study drug	Action taken to treat the event	Outcome of AE
BAY 88-8223 (55)	4005	65/M/C	Spinal cord compression	脊髄圧迫		3	Y	5.1	20	Unlikely	Medication Therapy	Recovered MEDICATION: with CORTISON sequelae
BAY 88-8223 (55)	5001	57/M/C	Spinal cord compression	脊髄圧迫		3	Y	11.3	5	Unlikely	Therapy	Recovered with sequelae
			Muscular weakness	筋力低下		3	Y	10.9	28	Unlikely	None	Recovered
BAY 88-8223 (55)	6002	72/M/C	Infection	感染		4	Y	7.1	1	Unlikely	Medication	Death
			Renal failure acute	急性腎不全		4	Y	7.1	1	Unlikely	Medication	Death
BAY 88-8223 (110)	1301	69/M/C	Anaemia	貧血		2	Y	13.1		Possible	None	Not recovered
BAY 88-8223 (110)	1403	78/M/C	Urinary tract infection	尿路感染		1	Y	0.1	22	Unlikely	Medication	Unknown
			Cardiac arrest	心停止	Severe		Y	3.3	0	Unlikely	None	Death
BAY 88-8223 (110)	1603	58/M/C	Haemoglobin decreased	ヘモグロビン減少		4	Y	2.1		Possible	Therapy	Not recovered
			Red blood cell count decreased	赤血球数減少		2	Y	2.1		Possible	Therapy	Not recovered
			Diplopia	複視		2	Y	10.3		Unlikely	None	Not recovered
			Fatigue	疲労	Severe		Y	14.6	21	Unlikely	None	Death

表 2.7.4.7- 7　重篤な有害事象が発現した被験者の一覧（試験 BC1-03、12 ヵ月報告書）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Intensity	CTCAE grade	SAE	Relative Week of AE[a]	Duration of AE (day)[b]	Related to study drug	Action taken to treat the event	Outcome of AE
BAY 88-8223 (110)	1605	64/M/C	Fatigue	疲労		4		7.3	34	Unlikely	Therapy Other: BLOOD TRANSFUSION	Death
			Metastases to liver	肝転移	Severe		Y	11.6	4	Unlikely	None	Death
			Paraplegia	対麻痺		5	Y	11.6	4	Unlikely	None	Death
BAY 88-8223 (110)	1609	60/M/C	Bone pain	骨痛	Severe		Y	15.1	U	Unlikely	Other: ANALGESIC TREATMENT	Recovered with sequelae
BAY 88-8223 (110)	4009	74/M/C	Metastatic pain	転移部痛		3	Y	1.7		Unlikely	Medication	Not recovered
			Oedema peripheral	末梢性浮腫		3	Y	1.1		Unlikely	Medication	Not recovered
			General physical health deterioration	全身健康状態低下		2	Y	10.0		Unlikely	None	Not recovered
BAY 88-8223 (110)	6001	71/M/C	Haematuria	血尿		3	Y	14.0	12	Unlikely	Medication Therapy	Recovered
BAY 88-8223 (110)	7002	75/M/C	Muscular weakness	筋力低下		3	Y	11.1		Unlikely	Therapy	Not recovered

Sex is identified as: M = Male.

Race is identified as: C = Caucasian

The unit for "Age" is years.

a: In case of missing dates, shortcuts after dates refer to whether month and day or just day has been imputed.

b: U = Unknown

Source: 5.3.5.1.8 A58307/Listing 14.3.2.16W.3, 16.2.4.16W.1

表 2.7.4.7- 8　重篤な有害事象が発現した被験者の一覧（試験 BC1-04）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Intensity	CTCAE grade	SAE	Relative day of AE	Duration of AE (day)	Related to study drug	Specification of action	Outcome of AE
BAY 88-8223 (28)	102	70/M/C	Anaemia	貧血		3	Y	21	63	Unlikely	Other: BLOOD TRANSFUSION	Recovered with sequelae
			Anaemia	貧血		3	Y	78	6	Unlikely	Other: BLOOD TRANSFUSION	Recovered with sequelae
			Haemoglobin decreased	ヘモグロビン減少		2	Y	105	3	Unlikely	Other: BLOOD TRANSFUSION	Recovered
			Haemoglobin decreased	ヘモグロビン減少		3	Y	107	1	Unlikely	Other: BLOOD TRANSFUSION	Recovered
			Speech disorder	会話障害		2	Y	107	1	Unlikely	Therapy	Recovered
BAY 88-8223 (28)	202	79/M/C	Bone pain	骨痛		3	Y	4	-	Unlikely	Medication Therapy	Not recovered at study termination
			Bone pain	骨痛		2	Y	20	-	Unlikely	Medication Therapy	Not recovered at study termination
BAY 88-8223 (28)	801	73/M/C	Speech disorder	会話障害		2	Y	30	146	Unlikely	Medication Therapy	Recovered
			Speech disorder	会話障害	Severe		Y	35	141	Unlikely	Medication Therapy	Recovered
			Speech disorder	会話障害	Mild		Y	44	132	Unlikely	Medication Therapy	Recovered

表 2.7.4.7- 8　重篤な有害事象が発現した被験者の一覧（試験 BC1-04）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Intensity	CTCAE grade	SAE	Relative day of AE	Duration of AE (day)	Related to study drug	Specification of action	Outcome of AE
BAY 88-8223 (28)	804	68/M/C	Metastases to liver	肝転移	Severe		Y	73	6	Unlikely	None	Death
BAY 88-8223 (28)	901	76/M/C	Anaemia	貧血		2	Y	63	-	Unlikely	Therapy	Recovered with sequelae
			Anaemia	貧血		3	Y	77	-	Unlikely	Therapy	Recovered with sequelae
			Anaemia	貧血		3	Y	119	4	Unlikely	Therapy	Recovered with sequelae
			Fatigue	疲労		2	Y	73	-	Unlikely	Other: INTRAVENOUS FEEDING	Not known by DB lock
			Fatigue	疲労		3	Y	123	-	Unlikely	Other: INTRAVENOUS FEEDING	Not known by DB lock
			Fatigue	疲労		4	Y	133	-	Unlikely	Other: INTRAVENOUS FEEDING	Not known by DB lock
			Fatigue	疲労		5	Y	152	-	Unlikely	Other: INTRAVENOUS FEEDING	Not known by DB lock
BAY 88-8223 (28)	904	78/M/C	Cardiac failure	心不全	Moderate		Y	78	-	Unlikely	Medication Therapy	Death
			Cardiac failure	心不全	Severe		Y	114	-	Unlikely	Medication Therapy	Death

表 2.7.4.7- 8 重篤な有害事象が発現した被験者の一覧（試験 BC1-04）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Intensity	CTCAE grade	SAE	Relative day of AE	Duration of AE (day)	Related to study drug	Specification of action	Outcome of AE
BAY 88-8223 (28)	1402	71/M/C	Disease progression	疾患進行		5	Y	18	-	Unlikely	None	Death
BAY 88-8223 (28)	2302	59/M/C	Prostate cancer	前立腺癌	Severe		Y	101	-	Unlikely	Medication Other: HOSPITALIT.	Not known by DB lock
BAY 88-8223 (28)	2601	66/M/C	Bone pain	骨痛		3	Y	106	-	Unlikely	Medication	Not recovered at study termination
			Bone pain	骨痛		1	Y	115	-	Unlikely	Medication	Not recovered at study termination
			Bone pain	骨痛		2	Y	127	-	Unlikely	Medication	Not recovered at study termination
BAY 88-8223 (55)	103	51/M/C	Anaemia	貧血		4	Y	83	-	Unlikely	Medication	Recovered
			Neuropathy	ニューロパシー		3	Y	15	13	Unlikely	Medication	Recovered
BAY 88-8223 (55)	111	69/M/C	Bone pain	骨痛		3	Y	4	-	Unlikely	Medication	Recovered
			Dehydration	脱水		2	Y	126	-	Unlikely	Medication	U
			Disease progression	疾患進行		5	Y	173	-	Unlikely	None	Not known by DB lock
BAY 88-8223 (55)	208	64/M/C	Metastatic squamous cell carcinoma	転移性扁平上皮癌	Severe		Y	34	70	Unlikely	None	Death

表 2.7.4.7- 8　重篤な有害事象が発現した被験者の一覧（試験 BC1-04）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Intensity	CTCAE grade	SAE	Relative day of AE	Duration of AE (day)	Related to study drug	Specification of action	Outcome of AE
BAY 88-8223 (55)	403	73/M/C	Spinal cord compression	脊髄圧迫		3	Y	118	13	Unlikely	Medication Therapy	Not recovered at study termination
BAY 88-8223 (55)	404	70/M/C	Anaemia	貧血		1	Y	41	433	Unlikely	Therapy	Recovered
						2	Y	160	314	Unlikely	Therapy	Recovered
BAY 88-8223 (55)	603	54/M/C	Bone pain	骨痛		3	Y	0	9	Possible	Medication	Recovered
			Bone pain	骨痛		3	Y	55	-	Unlikely	Medication	Recovered with sequelae
			Prostate cancer	前立腺癌	Severe		Y	152	-	Unlikely	Medication	Not known by DB lock
BAY 88-8223 (55)	805	62/M/C	Blindness unilateral	片側盲		4	Y	6	35	Unlikely	Medication	Recovered with sequelae
			Blindness unilateral	片側盲		2	Y	6	35	Unlikely	Medication	Recovered with sequelae
			Blindness unilateral	片側盲		4	Y	12	29	Unlikely	Medication	Recovered with sequelae
			Disease progression	疾患進行	Severe		Y	23	-	Unlikely		Not known by DB lock
BAY 88-8223 (55)	903	73/M/C	Prostate cancer	前立腺癌	Severe		Y	153	-	Unlikely	Medication Therapy	Death

表 2.7.4.7- 8 重篤な有害事象が発現した被験者の一覧（試験 BC1-04）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Intensity	CTCAE grade	SAE	Relative day of AE	Duration of AE (day)	Related to study drug	Specification of action	Outcome of AE
BAY 88-8223 (88)	109	51/M/C	Bone pain	骨痛		3	Y	38	13	Unlikely	Medication Therapy	Recovered
			Bone pain	骨痛		4	Y	44	7	Unlikely	Medication Therapy	Recovered
			Bone pain	骨痛		2	Y	109	6	Unlikely	Medication	Recovered with sequelae
			Bone pain	骨痛		3	Y	111	4	Unlikely	Medication	Recovered with sequelae
BAY 88-8223 (88)	207	73/M/C	Bone pain	骨痛		3	Y	161	3	Possible	Medication Other: RADIOLOGICAL EXAMS	Recovered
BAY 88-8223 (88)	303	79/M/C	Pain	疼痛		2	Y	2	-	Unlikely	Medication	Not recovered at study termination
			Pain	疼痛		1	Y	10	-	Unlikely	Medication	Not recovered at study termination
			Pain	疼痛		3	Y	72	-	Unlikely	Medication	Not recovered at study termination

表 2.7.4.7- 8 重篤な有害事象が発現した被験者の一覧（試験 BC1-04）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Intensity	CTCAE grade	SAE	Relative day of AE	Duration of AE (day)	Related to study drug	Specification of action	Outcome of AE
			Pain	疼痛		4	Y	77	-	Unlikely	Medication	Not recovered at study termination
BAY 88-8223 (88)	305	73/M/C	Constipation	便秘		1	Y	105	227	Possible	Medication	Recovered
			Constipation	便秘		3	Y	132	200	Possible	Medication	Recovered
BAY 88-8223 (88)	311	66/M/C	Cough	咳嗽		4	Y	96	12	Unlikely	Medication	Recovered
			Spinal cord compression	脊髄圧迫		3	Y	10	-	Unlikely	Therapy	Recovered
			Upper respiratory tract infection	上気道感染		3	Y	97	8	Unlikely	Medication	Recovered
BAY 88-8223 (88)	316	75/M/C	Muscular weakness	筋力低下		2	Y	149	4	Possible	Medication	Recovered
BAY 88-8223 (88)	401	82/M/C	Chest pain	胸痛		3	Y	54	3	Unlikely	Medication	Death
BAY 88-8223 (88)	402	80/M/C	Urine flow decreased	尿流量減少		1	Y	85	-	Unlikely	Medication Therapy	Recovered
			Urine flow decreased	尿流量減少		2	Y	109	12	Unlikely	Medication Therapy	Recovered
			Urine flow decreased	尿流量減少		3	Y	119	2	Unlikely	Medication Therapy	Recovered
BAY 88-8223 (88)	1601	56/M/C	Urinary retention	尿閉		2	Y	24	12	Unlikely	Therapy	Recovered
			Urinary retention	尿閉		3	Y	33	3	Unlikely	Therapy	Recovered

表 2.7.4.7- 8 重篤な有害事象が発現した被験者の一覧（試験 BC1-04）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Intensity	CTCAE grade	SAE	Relative day of AE	Duration of AE (day)	Related to study drug	Specification of action	Outcome of AE
BAY 88-8223 (88)	1904	48/M/C	Confusional state	錯乱状態		4	Y	33	-	Unlikely	Medication	Not recovered at study termination
			Confusional state	錯乱状態		3	Y	38	-	Unlikely	Medication	Not recovered at study termination
BAY 88-8223 (88)	2306	55/M/C	Prostate cancer	前立腺癌	Severe		Y	158	-	Unlikely	Medication Therapy Other:HOSPITALIZATION	Not known by DB lock
BAY 88-8223 (88)	2313	64/M/C	Spinal cord compression	脊髄圧迫	Severe		Y	112	-	Unlikely	Medication Other:HOSPITALIZATION	Not known by DB lock
BAY 88-8223 (88)	2701	65/M/C	Anaemia	貧血	Moderate		Y	42	1	Unlikely	Other: BLOOD TRANSFUSION	Recovered with sequelae
			Anaemia	貧血	Moderate		Y	64	0	Unlikely	Other: BLOOD TRANSFUSION	Recovered with sequelae
			Anaemia	貧血	Severe		Y	86	-	Unlikely	Other: BLOOD TRANSFUSION	Not known by DB lock
			Disease progression	疾患進行	Moderate		Y	41	-	Unlikely	None	Recovered with sequelae

Sex is identified as: M = Male.

Race is identified as: C = Caucasian

The unit for "Age" is years.

Source: 5.3.4.2.1 A58308/Listing 16.2.4, 16.2.7.2

表 2.7.4.7- 9　重篤な TEAE が発現した被験者の一覧（試験 BC1-09）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 12.1)	Adverse Events (AE) Preferred term (MedDRA version 12.1)	CTCAE grade	SAE	Relative Day of AE	Duration of AE	Related to study drug	Action taken with study treatment	Outcome of AE
BAY 88-8223 (55)	2004	59/F/C	Depression	うつ病	3	Y	29	NA	Unrelated	None	Not recovered at study termination, but clinically stable
BAY 88-8223 (55)	2010	42/F/O (Egyptian)	Nasopharyngitis	鼻咽頭炎	2	Y	84	6	Unrelated	Drug adm. postponed	Recovered
BAY 88-8223 (55)	4004	73/F/C	Cardiac failure	心不全	5	Y	76	-	Unrelated	None	Death

NA = not applicable

Sex is identified as: F = Female.

Race is identified as: C = Caucasian, O = Other.

The unit for "Age" is years.

Source: 5.3.5.2.2 R-8779/Listing 16.2.4.1, 16.2.7.1, 16.2.7.2

表 2.7.4.7- 10 重篤な TEAE が発現した被験者の一覧（試験 16430）

Treatment：BAY 88-8223 55 kBq/kg

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 17.1)	Adverse Events (AE) Preferred term (MedDRA version 17.1)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
200010002	JPN	62/M/A	Anaemia	貧血	1	N	Pre	1		N	DOSE NOT CHANGED	
			Platelet count decreased	血小板数減少	1	N	TE	64		N	DOSE NOT CHANGED	
			Anaemia	貧血	2	N	TE	92		N	DOSE NOT CHANGED	
			Platelet count decreased	血小板数減少	2	N	TE	92		N	DOSE NOT CHANGED	
			Osteoporosis	骨粗鬆症	2	N	TE	111		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Cellulitis	蜂巣炎	2	Y	TE	113	7	N	NOT APPLICABLE	RECOVERED/RESOLVED
			Anaemia	貧血	3	N	TE	120		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Platelet count decreased	血小板数減少	1	N	TE	120		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Weight decreased	体重減少	1	N	TE	120		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
200010003	JPN	81/M/A	Lymphocyte count decreased	リンパ球数減少	3	N	Pre	1		N	DOSE NOT CHANGED	
			Spinal compression fracture	脊椎圧迫骨折	2	N	TE	7		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Back pain	背部痛	2	N	TE	7	8	N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Decreased appetite	食欲減退	2	N	TE	7	52	N	DOSE NOT CHANGED	RECOVERED/RESOLVED

表 2.7.4.7- 10 重篤な TEAE が発現した被験者の一覧（試験 16430）（続き）

Treatment: BAY 88-8223 55 kBq/kg

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 17.1)	Adverse Events (AE) Preferred term (MedDRA version 17.1)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Back pain	背部痛	2	Y	TE	15	42	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Dysphagia	嚥下障害	2	N	TE	33	14	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Dermatitis contact	接触性皮膚炎	2	N	TE	41	16	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Epidermolysis	表皮融解	1	N	TE	45	6	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Malaise	倦怠感	1	N	TE	47	2	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Lymphocyte count decreased	リンパ球数減少	2	N	TE	64		N	DOSE NOT CHANGED	
			Lymphocyte count decreased	リンパ球数減少	3	N	TE	92		N	DOSE NOT CHANGED	
			Bone pain	骨痛	2	N	TE	103		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Lymphocyte count decreased	リンパ球数減少	2	N	TE	118		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Oedema	浮腫	1	N	TE	148		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
200040001	JPN	83/M/A	Pneumonia	肺炎	2	N	Pre	1	29	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Dental caries	齲歯	3	N	TE	64	77	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Pneumonia	肺炎	2	N	TE	71	14	N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Nausea	悪心	2	N	TE	71	17	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Decreased appetite	食欲減退	3	N	TE	71	21	N	DOSE NOT CHANGED	RECOVERED/RESOLVED

表 2.7.4.7- 10 重篤な TEAE が発現した被験者の一覧（試験 16430）（続き）

Treatment: BAY 88-8223 55 kBq/kg

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 17.1)	Adverse Events (AE) Preferred term (MedDRA version 17.1)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pneumonia	肺炎	3	Y	TE	85	8	N	DOSE NOT CHANGED	RECOVERING/RESOLVING
			Pneumonia	肺炎	2	N	TE	93	21	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Tinea pedis	足部白癬	1	N	TE	127		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Pneumonia	肺炎	2	N	TE	140	29	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Weight decreased	体重減少	2	N	TE	140		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Chest discomfort	胸部不快感	2	N	TE	142		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Hypophosphataemia	低リン酸血症	3	N	TE	154		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			International normalised ratio increased	国際標準比増加	3	N	TE	154	15	N	NOT APPLICABLE	RECOVERED/RESOLVED
200090002	JPN	72/M/A	Decreased appetite	食欲減退	1	N	Pre	1		N	DOSE NOT CHANGED	
			Anaemia	貧血	2	N	TE	29		Y	DOSE NOT CHANGED	
			Sinusitis	副鼻腔炎	2	N	TE	65		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Anaemia	貧血	3	N	TE	85		Y	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Decreased appetite	食欲減退	2	N	TE	85		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Malaise	倦怠感	2	N	TE	85		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Peripheral vascular disorder	末梢血管障害	2	N	TE	85		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED

表 2.7.4.7- 10 重篤な TEAE が発現した被験者の一覧（試験 16430）（続き）

Treatment: BAY 88-8223 55 kBq/kg

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 17.1)	Adverse Events (AE) Preferred term (MedDRA version 17.1)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pancytopenia	汎血球減少症	3	Y	TE	106	35	Y	NOT APPLICABLE	RECOVERING/RESOLVING
			Pancytopenia	汎血球減少症	3	N	TE	141		Y	NOT APPLICABLE	RECOVERING/RESOLVING
200090004	JPN	65/M/A	Lymphocyte count decreased	リンパ球数減少	3	N	TE	29		Y	DOSE NOT CHANGED	
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	2	N	TE	43	23	N	NOT APPLICABLE	RECOVERED/RESOLVED
			Bone pain	骨痛	2	Y	TE	43	23	Y	NOT APPLICABLE	RECOVERED/RESOLVED
			Oedema peripheral	末梢性浮腫	1	N	TE	43	41	N	NOT APPLICABLE	RECOVERED/RESOLVED
			Malaise	倦怠感	2	N	TE	43	71	N	NOT APPLICABLE	RECOVERED/RESOLVED
			Lymphocyte count decreased	リンパ球数減少	2	N	Post	83	59	Y	NOT APPLICABLE	RECOVERED/RESOLVED
200090005	JPN	79/M/A	Lymphocyte count decreased	リンパ球数減少	2	N	TE	85		Y	DOSE NOT CHANGED	
			Lymphocyte count decreased	リンパ球数減少	3	N	TE	113		Y	DOSE NOT CHANGED	
			Periodontal disease	歯周病	1	N	TE	113		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Anaemia	貧血	2	N	TE	113		Y	DOSE NOT CHANGED	
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1	N	TE	113	88	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Decreased appetite	食欲減退	1	N	TE	141		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED

表 2.7.4.7- 10 重篤な TEAE が発現した被験者の一覧（試験 16430）（続き）

Treatment: BAY 88-8223 55 kBq/kg

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 17.1)	Adverse Events (AE) Preferred term (MedDRA version 17.1)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Platelet count decreased	血小板数減少	1	N	TE	141		Y	NOT APPLICABLE	
			Lymphocyte count decreased	リンパ球数減少	1	N	TE	141	8	Y	NOT APPLICABLE	RECOVERED/RESOLVED
			Anaemia	貧血	3	N	TE	141	28	Y	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Platelet count decreased	血小板数減少	2	N	Post	169		Y	NOT APPLICABLE	
			Anaemia	貧血	3	Y	TE	169		Y	NOT APPLICABLE	
			Platelet count decreased	血小板数減少	3	N	Post	180		Y	NOT APPLICABLE	
			Anaemia	貧血	2	Y	TE	181	4	Y	NOT APPLICABLE	RECOVERING/RESOLVING
			Anaemia	貧血	2	N	TE	185	13	Y	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Anaemia	貧血	3	Y	TE	198		Y	NOT APPLICABLE	
			Platelet count decreased	血小板数減少	2	N	Post	198		Y	NOT APPLICABLE	
			Platelet count decreased	血小板数減少	3	N	Post	200		Y	NOT APPLICABLE	
			Anaemia	貧血	2	Y	TE	202	4	Y	NOT APPLICABLE	RECOVERING/RESOLVING
			Platelet count decreased	血小板数減少	2	N	Post	204		Y	NOT APPLICABLE	
			Anaemia	貧血	2	N	TE	206		Y	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Platelet count decreased	血小板数減少	1	N	Post	211		Y	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED

表 2.7.4.7- 10 重篤な TEAE が発現した被験者の一覧（試験 16430）（続き）

Treatment: BAY 88-8223 55 kBq/kg

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 17.1)	Adverse Events (AE) Preferred term (MedDRA version 17.1)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
200120001	JPN	78/M/A	Decreased appetite	食欲減退	1	N	Pre	-2		N	DOSE NOT CHANGED	
			Malaise	倦怠感	1	N	TE			N	DOSE NOT CHANGED	
			Hypoaesthesia	感覚鈍麻	1	N	TE	7		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Alanine aminotransferase increased	アラニンアミノトランスフェラーゼ増加	1	N	TE	64		N	DOSE NOT CHANGED	
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1	N	TE	64		N	DOSE NOT CHANGED	
			Bone pain	骨痛	3	N	TE	84		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Nausea	悪心	2	N	TE	84	13	N	NOT APPLICABLE	RECOVERED/RESOLVED
			Vomiting	嘔吐	1	N	TE	84	13	N	NOT APPLICABLE	RECOVERED/RESOLVED
			Decreased appetite	食欲減退	2	N	TE	84	23	N	NOT APPLICABLE	RECOVERED/RESOLVED
			Malaise	倦怠感	2	N	TE	84	28	N	NOT APPLICABLE	RECOVERED/RESOLVED
			Alanine aminotransferase increased	アラニンアミノトランスフェラーゼ増加	3	N	TE	90		N	NOT APPLICABLE	
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	90		N	NOT APPLICABLE	
			Proteinuria	蛋白尿	2	N	TE	90	5	N	NOT APPLICABLE	RECOVERED/RESOLVED
			Prostate cancer	前立腺癌	3	Y	TE	90	22	N	DRUG WITHDRAWN	RECOVERING/RESOLVING
			Weight decreased	体重減少	2	N	TE	94	32	N	NOT APPLICABLE	RECOVERED/RESOLVED

表 2.7.4.7- 10 重篤な TEAE が発現した被験者の一覧（試験 16430）（続き）

Treatment: BAY 88-8223 55 kBq/kg

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 17.1)	Adverse Events (AE) Preferred term (MedDRA version 17.1)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Alanine aminotransferase increased	アラニンアミノトランスフェラーゼ増加	1	N	TE	94	62	N	NOT APPLICABLE	RECOVERED/RESOLVED
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1	N	TE	94	69	N	NOT APPLICABLE	RECOVERED/RESOLVED
200120005	JPN	65/M/A	Bone pain	骨痛	2	N	Pre	-14	9	N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Constipation	便秘	2	N	Pre	-9		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Hepatic function abnormal	肝機能異常	1	N	Pre	-7	5	N	NOT APPLICABLE	RECOVERED/RESOLVED
			Bone pain	骨痛	3	Y	Pre	-5	8	N	DOSE NOT CHANGED	RECOVERING/RESOLVING
			Bone pain	骨痛	2	N	TE	4		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Nausea	悪心	2	N	TE	5	11	N	NOT APPLICABLE	RECOVERED/RESOLVED
			Vomiting	嘔吐	1	N	TE	5	11	N	NOT APPLICABLE	RECOVERED/RESOLVED
			Hypocalcaemia	低カルシウム血症	1	N	TE	15		N	NOT APPLICABLE	
			Thrombocytopenia	血小板減少症	1	N	TE	15	14	N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Hepatic function abnormal	肝機能異常	1	N	TE	15	15	N	NOT APPLICABLE	RECOVERED/RESOLVED
			Dizziness	浮動性めまい	1	N	TE	29		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Malaise	倦怠感	1	N	TE	29		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Thrombocytopenia	血小板減少症	2	Y	TE	29		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED

表 2.7.4.7- 10 重篤な TEAE が発現した被験者の一覧（試験 16430）（続き）

Treatment: BAY 88-8223 55 kBq/kg

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 17.1)	Adverse Events (AE) Preferred term (MedDRA version 17.1)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hypocalcaemia	低カルシウム血症	2	N	TE	31		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
200160003	JPN	67/M/A	Bone pain	骨痛	2	N	TE	29	69	N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Lymphocyte count decreased	リンパ球数減少	2	N	TE	36	29	Y	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Spinal compression fracture	脊椎圧迫骨折	2	N	TE	48		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Upper respiratory tract infection	上気道感染	2	N	TE	52	19	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Weight decreased	体重減少	1	N	TE	64		N	DOSE NOT CHANGED	
			Constipation	便秘	2	N	TE	91		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Anaemia	貧血	2	N	TE	98		Y	DOSE NOT CHANGED	
			Lymphocyte count decreased	リンパ球数減少	2	N	TE	98		Y	DOSE NOT CHANGED	
			Platelet count decreased	血小板数減少	1	N	TE	98		Y	DOSE NOT CHANGED	
			Bone pain	骨痛	3	Y	TE	98	15	N	DOSE NOT CHANGED	RECOVERING/RESOLVING
			Weight decreased	体重減少	2	N	TE	99		N	DOSE NOT CHANGED	
			Delirium	譫妄	2	N	TE	100	9	N	NOT APPLICABLE	RECOVERED/RESOLVED
			Somnolence	傾眠	1	N	TE	100	10	N	NOT APPLICABLE	RECOVERED/RESOLVED
			Nausea	悪心	1	N	TE	100	72	N	NOT APPLICABLE	RECOVERED/RESOLVED

表 2.7.4.7- 10 重篤な TEAE が発現した被験者の一覧（試験 16430）（続き）

Treatment: BAY 88-8223 55 kBq/kg

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 17.1)	Adverse Events (AE) Preferred term (MedDRA version 17.1)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	1	N	TE	101		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Malaise	倦怠感	1	N	TE	101		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Decreased appetite	食欲減退	3	N	TE	103	41	N	NOT APPLICABLE	RECOVERED/RESOLVED
			Anaemia	貧血	3	N	TE	106		Y	NOT APPLICABLE	
			Lymphocyte count decreased	リンパ球数減少	4	N	TE	106		Y	NOT APPLICABLE	
			White blood cell count decreased	白血球数減少	2	N	TE	106	20	Y	NOT APPLICABLE	RECOVERED/RESOLVED
			Anaemia	貧血	2	N	TE	107		Y	NOT APPLICABLE	
			Lymphocyte count decreased	リンパ球数減少	3	N	TE	108		Y	NOT APPLICABLE	
			Anaemia	貧血	1	N	TE	111		Y	NOT APPLICABLE	
			Bone pain	骨痛	2	N	TE	113		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Anaemia	貧血	3	N	TE	125		Y	DRUG WITHDRAWN	
			Platelet count decreased	血小板数減少	2	N	TE	125		Y	NOT APPLICABLE	
			Lymphocyte count decreased	リンパ球数減少	2	N	Post	133		Y	NOT APPLICABLE	
			Platelet count decreased	血小板数減少	1	N	Post	133		Y	NOT APPLICABLE	
			Anaemia	貧血	2	N	Post	143		Y	NOT APPLICABLE	

表 2.7.4.7- 10 重篤な TEAE が発現した被験者の一覧（試験 16430）（続き）

Treatment: BAY 88-8223 55 kBq/kg

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 17.1)	Adverse Events (AE) Preferred term (MedDRA version 17.1)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Platelet count decreased	血小板数減少	2	N	Post	143		Y	NOT APPLICABLE	
			Anaemia	貧血	3	N	Post	157		Y	NOT APPLICABLE	
			Platelet count decreased	血小板数減少	3	N	Post	171		Y	NOT APPLICABLE	
			Anaemia	貧血	2	N	Post	178		Y	NOT APPLICABLE	
			Lymphocyte count decreased	リンパ球数減少	3	N	Post	178		Y	NOT APPLICABLE	
			Anaemia	貧血	3	N	Post	185		Y	NOT APPLICABLE	
			Lymphocyte count decreased	リンパ球数減少	2	N	Post	185		Y	NOT APPLICABLE	
			Platelet count decreased	血小板数減少	2	N	Post	185		Y	NOT APPLICABLE	
			Platelet count decreased	血小板数減少	3	N	Post	192		Y	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Anaemia	貧血	2	N	Post	199		Y	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Lymphocyte count decreased	リンパ球数減少	3	N	Post	199		Y	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
200180004	JPN	80/M/A	Constipation	便秘	2	N	TE	6		Y	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Tumour pain	腫瘍疼痛	2	N	TE	85	2	N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Tumour pain	腫瘍疼痛	2	Y	TE	87	15	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Contusion	挫傷	1	N	TE	88	3	N	DOSE NOT CHANGED	RECOVERED/RESOLVED

表 2.7.4.7- 10 重篤な TEAE が発現した被験者の一覧（試験 16430）（続き）

Treatment: BAY 88-8223 55 kBq/kg

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 17.1)	Adverse Events (AE) Preferred term (MedDRA version 17.1)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Abdominal discomfort	腹部不快感	2	N	TE	95	18	Y	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Vomiting	嘔吐	1	N	TE	96	1	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Pyrexia	発熱	1	N	TE	96	6	Y	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Lymphocyte count decreased	リンパ球数減少	3	N	TE	97	45	Y	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Anaemia	貧血	2	N	TE	98		Y	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Decreased appetite	食欲減退	3	N	TE	112		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Hypophosphataemia	低リン酸血症	2	N	TE	113	29	Y	DOSE NOT CHANGED	RECOVERED/RESOLVED
200180006	JPN	62/M/A	Diarrhoea	下痢	1	N	TE	33	130	Y	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Arthralgia	関節痛	1	N	TE	36	127	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Tumour pain	腫瘍疼痛	2	N	TE	138	24	N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Dyslipidaemia	脂質異常症	1	N	TE	141		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Dental caries	齲歯	1	N	TE	148	15	N	NOT APPLICABLE	RECOVERED/RESOLVED
			Urinary tract infection	尿路感染	2	N	TE	162	7	N	NOT APPLICABLE	RECOVERED/RESOLVED
			Tumour pain	腫瘍疼痛	3	Y	TE	162	10	N	NOT APPLICABLE	RECOVERING/RESOLVING

表 2.7.4.7- 10　重篤な TEAE が発現した被験者の一覧（試験 16430）（続き）

Treatment: BAY 88-8223 55 kBq/kg

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 17.1)	Adverse Events (AE) Preferred term (MedDRA version 17.1)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neuropathy peripheral	末梢性ニューロパチー	2	N	TE	164		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Insomnia	不眠症	2	N	TE	171	2	N	NOT APPLICABLE	RECOVERED/RESOLVED
			Tumour pain	腫瘍疼痛	2	N	Post	172		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
200190001	JPN	72/M/A	Skin exfoliation	皮膚剥脱	2	N	TE	8	22	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Bone pain	骨痛	3	Y	TE	135	17	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Weight decreased	体重減少	1	N	TE	141		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Decreased appetite	食欲減退	3	Y	TE	161		N	NOT APPLICABLE	RECOVERING/RESOLVING
200190003	JPN	79/M/A	Renal impairment	腎機能障害	1	N	TE	29	34	N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Decreased appetite	食欲減退	3	N	TE	52	19	N	NOT APPLICABLE	RECOVERED/RESOLVED
			Weight decreased	体重減少	1	N	Post	61	9	N	NOT APPLICABLE	RECOVERED/RESOLVED
			Renal impairment	腎機能障害	3	Y	Post	62	9	N	NOT APPLICABLE	RECOVERED/RESOLVED

Sex is identified as: M = Male.
Race is identified as: A = Asian.
The unit for "Age" is years.
Phase is identified as: Pre = Pre-Treatment, TE = Treatment-Emergent, Post = Post-Treatment
Source: 5.3.5.2.8 16430_add 5/Table 1.4/1

表 2.7.4.7- 11　重篤な TEAE が発現した被験者の一覧（試験 15354）

Treatment：Cohort 2

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 16.1)	Adverse Events (AE) Preferred term (MedDRA version 16.1)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
200020007	JPN	65/M/A	Bone pain	骨痛	1	N	Pre	-11	42	N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Diarrhoea	下痢	1	N	TE	2	9	Y	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Rash	発疹	1	N	TE	2	3	Y	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Nausea	悪心	1	N	TE	8	14	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Vomiting	嘔吐	1	N	TE	8	2	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Abdominal pain upper	上腹部痛	1	N	TE	9	13	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	1	N	TE	15		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Vomiting	嘔吐	1	N	TE	17	2	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1	N	TE	22	11	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Chest pain	胸痛	2	N	TE	26	3	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Vomiting	嘔吐	1	N	TE	27		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Bone pain	骨痛	2	Y	Post	32	3	N	NOT APPLICABLE	RECOVERED/RESOLVED

表 2.7.4.7- 11 重篤な TEAE が発現した被験者の一覧（試験 15354）（続き）

Treatment: Expansion Cohort

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 16.1)	Adverse Events (AE) Preferred term (MedDRA version 16.1)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
200010003	JPN	73/M/A	Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	1	N	Pre	-12		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Cancer pain	癌疼痛	2	N	TE	3	5	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Anaemia	貧血	2	N	TE	8		Y	DOSE NOT CHANGED	
			Platelet count decreased	血小板数減少	2	N	TE	21		Y	DRUG WITHDRAWN	
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	2	N	TE	29		N	DOSE NOT CHANGED	
			Vomiting	嘔吐	1	N	Post	35	2	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Anaemia	貧血	3	N	Post	36		Y	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	Post	36		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Nausea	悪心	2	N	Post	42		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Platelet count decreased	血小板数減少	4	N	Post	49		Y	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	Y	Post	49		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED

表 2.7.4.7- 11 重篤な TEAE が発現した被験者の一覧（試験 15354）（続き）

Treatment: Expansion Cohort

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 16.1)	Adverse Events (AE) Preferred term (MedDRA version 16.1)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Alanine aminotransferase increased	アラニンアミノトランスフェラーゼ増加	3	Y	Post	49		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	Post	49		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Blood bilirubin increased	血中ビリルビン増加	2	N	Post	49		N	NOT APPLICABLE	
			Constipation	便秘	2	N	Post	52		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Blood bilirubin increased	血中ビリルビン増加	3	N	Post	53		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Insomnia	不眠症	1	N	Post	59		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
200020009	JPN	81/M/A	Dizziness	浮動性めまい	1	N	TE	32	2	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Nausea	悪心	1	N	TE	32		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Decreased appetite	食欲減退	1	N	TE	46	23	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Bone pain	骨痛	2	N	TE	46	5	N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Lymphocyte count decreased	リンパ球数減少	3	N	TE	46		Y	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Malaise	倦怠感	1	N	TE	51	18	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Vomiting	嘔吐	1	N	TE	51	18	N	DOSE NOT CHANGED	RECOVERED/RESOLVED

表 2.7.4.7- 11 重篤な TEAE が発現した被験者の一覧（試験 15354）（続き）

Treatment: Expansion Cohort

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 16.1)	Adverse Events (AE) Preferred term (MedDRA version 16.1)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	51	18	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
200030004	JPN	68/M/A	Upper respiratory tract infection	上気道感染	1	N	Pre	-5		N	DOSE NOT CHANGED	
			Upper respiratory tract infection	上気道感染	2	N	TE	8	16	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Cancer pain	癌疼痛	2	N	TE	27		N	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
			Gastric haemorrhage	胃出血	3	Y	Post	48	15	N	DRUG WITHDRAWN	RECOVERING/RESOLVING
			Tumour associated fever	腫瘍熱	1	N	Post	58		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Erythema	紅斑	2	N	Post	59		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Gastric haemorrhage	胃出血	2	N	Post	63		N	NOT APPLICABLE	RECOVERING/RESOLVING
			Lung infection	肺感染	2	Y	Post	65		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Nausea	悪心	2	N	Post	65		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Prostate cancer	前立腺癌	3	Y	Post	77		N	NOT APPLICABLE	
			Prostate cancer	前立腺癌	5	Y	Long	111	1	N	NOT APPLICABLE	FATAL
200030005	JPN	72/M/A	Hypoglycaemia	低血糖症	1	N	TE	2	1	N	DOSE NOT CHANGED	RECOVERED/RESOLVED

表 2.7.4.7- 11 重篤な TEAE が発現した被験者の一覧（試験 15354）（続き）

Treatment: Expansion Cohort

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 16.1)	Adverse Events (AE) Preferred term (MedDRA version 16.1)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vitreous haemorrhage	硝子体出血	2	N	TE	58		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Infection	感染	3	Y	TE	68		N	DOSE NOT CHANGED	
			Diabetes mellitus inadequate control	コントロール不良の糖尿病	3	N	TE	68		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Hypoaesthesia	感覚鈍麻	2	N	TE	68		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Constipation	便秘	1	N	TE	68		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Anaemia	貧血	3	N	TE	72	20	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Infection	感染	1	Y	TE	75	21	N	DOSE NOT CHANGED	RECOVERING/RESOLVING
			Urinary retention	尿閉	2	N	TE	79		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Hypotension	低血圧	2	N	TE	92	1	N	DRUG INTERRUPTED	RECOVERED/RESOLVED
			Infection	感染	1	N	Post	96	11	N	DRUG INTERRUPTED	RECOVERED/RESOLVED
			Hepatic function abnormal	肝機能異常	3	N	Post	106		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Tumour associated fever	腫瘍熱	1	N	Post	106		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Prostate cancer	前立腺癌	4	Y	Post	109		N	NOT APPLICABLE	

表 2.7.4.7- 11 重篤な TEAE が発現した被験者の一覧（試験 15354）（続き）

Treatment: Expansion Cohort

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 16.1)	Adverse Events (AE) Preferred term (MedDRA version 16.1)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Prostate cancer	前立腺癌	5	Y	Post	118	1	N	NOT APPLICABLE	FATAL
200030007	JPN	79/M/A	Haematuria	血尿	2	N	Pre	1		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Cancer pain	癌疼痛	3	N	TE	2		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Rectal haemorrhage	直腸出血	2	Y	TE	40		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Renal impairment	腎機能障害	3	N	TE	40		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Anaemia	貧血	3	N	TE	41		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	42		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Vomiting	嘔吐	1	N	TE	44		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Nausea	悪心	3	N	TE	44		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Rectal stenosis	直腸狭窄	3	N	TE	45		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Malaise	倦怠感	2	N	TE	48		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Delirium	譫妄	1	N	TE	49		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Hypocalcaemia	低カルシウム血症	3	N	TE	49		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED

表 2.7.4.7- 11　重篤な TEAE が発現した被験者の一覧（試験 15354）（続き）

Treatment: Expansion Cohort

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 16.1)	Adverse Events (AE) Preferred term (MedDRA version 16.1)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pyrexia	発熱	1	N	TE	49		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Hypotension	低血圧	1	N	TE	49		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Prostate cancer	前立腺癌	3	Y	TE	49		N	NOT APPLICABLE	
			Lung infection	肺感染	3	Y	TE	58		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Prostate cancer	前立腺癌	5	Y	Post	59	1	N	NOT APPLICABLE	FATAL

Sex is identified as: M = Male.

Race is identified as: A = Asian.

The unit for "Age" is years.

Phase is identified as: Pre = Pre-Treatment, TE = Treatment-Emergent, Post = Post-Treatment, Long = Long-term Toxicities

Source: 5.3.3.2.6 15354_add 2/Table 1.4/1

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）

Treatment：BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
001023	Norway	62/M/C	Bone pain	骨痛	2	N	Pre	1		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	29		Y	None	Ongoing at study termination / withdrawal
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	57		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	TE	57		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	57		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	57	19	N	Drug permanently withdrawn	Death
			Metastases to liver	肝転移	3	Y	TE	57		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	75	1	N	Drug permanently withdrawn	Death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
002006	Norway	66/M/C	Bone pain	骨痛	2	N	Pre			N	None	Ongoing at study termination / withdrawal
			Urinary tract infection	尿路感染	3	N	TE	10	10	N	None	Recovered
			Anaemia	貧血	2	N	TE	29	34	N	None	Recovered
			Bone pain	骨痛	1	N	Pre	29	29	N	None	Ongoing at study termination / withdrawal
			Ascites	腹水	1	N	TE	57	6	N	None	Recovered
			Bone pain	骨痛	2	N	Pre	57		N	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	Y	TE	62	18	N	Drug permanently withdrawn	Recovered with sequelae
			Fungal infection	真菌感染	2	N	TE	76	5	N	None	Recovered
			Anxiety	不安	2	N	TE	77		N	None	Not recovered, but no changes expected
			Sepsis	敗血症	4	Y	TE	79	5	N	Not applicable	Death
			Anaemia	貧血	2	N	TE	81	2	N	None	Recovered
			Sepsis	敗血症	5	Y	TE	83	1	N	Not applicable	Death
002013	Norway	69/M/C	Vision blurred	霧視	1	N	TE			N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	2	N	TE	2	5	Y	None	Recovered
			Metastases to skin	皮膚転移	1	N	TE	57		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	85		N	None	Ongoing at study termination / withdrawal
			Metastases to soft tissue	軟部組織転移	1	N	TE	86		N	None	Ongoing at time of death
			Cerebral haemorrhage	脳出血	3	Y	TE	100	38	Y	Drug permanently withdrawn	Death
			Anaemia	貧血	2	N	TE	110		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	111		Y	Not applicable	Ongoing at time of death
			Cerebral haemorrhage	脳出血	5	Y	TE	137	1	Y	Drug permanently withdrawn	Death
004001	Norway	60/M/C	Dysgeusia	味覚異常	1	N	TE	2	28	Y	None	Recovered
			Anaemia	貧血	1	N	TE	92	24	Y	None	Recovered
			Anaemia	貧血	1	N	TE	92	24	Y	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	92	113	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	120		Y	None	Ongoing at time of death
			Respiratory tract infection viral	ウイルス性気道感染	2	N	TE	134	11	N	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	144		Y	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	2	N	TE	148	37	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	148	12	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	148	12	Y	None	Recovered with sequelae
			Pancytopenia	汎血球減少症	3	N	TE	155	5	Y	Not applicable	Recovered with sequelae
			Pancytopenia	汎血球減少症	3	Y	TE	159	11	Y	Not applicable	Recovered with sequelae
			Oedema	浮腫	2	Y	TE	159	11	Y	Not applicable	Recovered with sequelae
			Dyspnoea	呼吸困難	3	Y	TE	159	11	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	Y	TE	159	11	Y	Not applicable	Recovered with sequelae
			Pancytopenia	汎血球減少症	2	N	TE	169	16	Y	Not applicable	Recovered with sequelae
			Dyspnoea	呼吸困難	2	N	TE	169	16	Y	Not applicable	Recovered
			Pleural effusion	胸水	1	N	TE	170	15	Y	Not applicable	Recovered
			Pancytopenia	汎血球減少症	3	Y	TE	184	15	Y	Not applicable	Recovered with sequelae

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	3	Y	TE	184	15	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	Y	TE	184	15	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	Y	TE	184	15	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	198	7	Y	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	198	7	Y	Not applicable	Recovered with sequelae
			Pancytopenia	汎血球減少症	4	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	204		Y	Not applicable	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	3	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Pleural effusion	胸水	2	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Renal failure	腎不全	5	Y	TE	208	1	N	Not applicable	Death
005002	Norway	75/M/C	Bone pain	骨痛	1	N	TE			N	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	85		N	None	Not recovered, but no changes expected

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	162	36	N	Not applicable	Recovered
			Pneumonia	肺炎	3	Y	TE	169	15	N	Not applicable	Recovered
			Atrial fibrillation	心房細動	2	Y	TE	180	1	N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	197	7	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	198	6	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	1	N	TE	203		Y	Not applicable	Ongoing at time of death
			Pulmonary embolism	肺塞栓症	4	Y	TE	222	5	Y	Not applicable	Death
			Pulmonary embolism	肺塞栓症	5	Y	TE	226	1	Y	Not applicable	Death
006005	Norway	72/M/C	Diarrhoea	下痢	1	N	TE	3	1	Y	None	Recovered
			Pyrexia	発熱	2	Y	TE	22	7	N	None	Recovered
			Dehydration	脱水	2	Y	TE	22	7	N	None	Recovered
			Vomiting	嘔吐	1	Y	TE	38	1	N	None	Recovered
			Pyrexia	発熱	2	Y	TE	38	1	Y	None	Recovered
			Dehydration	脱水	2	Y	TE	38	6	Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	2	Y	TE	38	6	N	None	Recovered
			Vomiting	嘔吐	2	Y	TE	62	11	Y	None	Recovered
			Dehydration	脱水	2	Y	TE	62	11	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	62	11	N	None	Recovered with sequelae

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	85	15	N	None	Recovered with sequelae
			Dyspepsia	消化不良	2	N	TE	86		N	None	Ongoing at time of death
			Depression	うつ病	2	N	TE	99		N	None	Ongoing at time of death
			Pneumonia	肺炎	3	Y	TE	176	2	N	Not applicable	Death
			Bone pain	骨痛	3	Y	TE	176		N	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	5	Y	TE	177	1	N	Not applicable	Death
006008	Norway	70/M/C	Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	Pre	-1	29	N	None	Ongoing at time of death
			Hydronephrosis	水腎症	3	Y	Pre	-1	3	N	None	Recovered
			Constipation	便秘	2	N	TE	2	25	Y	None	Recovered
			Nausea	悪心	1	N	TE	2	6	Y	None	Recovered
			Fatigue	疲労	2	N	TE	2	6	N	None	Recovered
			Hyperhidrosis	多汗症	2	N	TE	2	6	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	17	11	N	None	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	Pre	28		N	None	Ongoing at time of death
			Small intestinal obstruction	小腸閉塞	3	Y	TE	55	3	N	Drug administration postponed	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Death	死亡	5	Y	TE	60	1	N	Drug permanently withdrawn	Death
008003	Norway	79/M/C	Nausea	悪心	2	N	Pre	1	25	N	None	Recovered
			Nausea	悪心	2	Y	TE	25	4	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	25		N	None	Ongoing at time of death
			Hypercalcaemia	高カルシウム血症	1	N	TE	25	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	27	2	Y	None	Recovered
			Nausea	悪心	2	N	TE	28		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	35	25	N	Drug permanently withdrawn	Recovered
			Dehydration	脱水	2	N	TE	51		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	59	1	N	Not applicable	Death
008011	Norway	69/M/C	Nausea	悪心	1	N	TE			N	None	Recovered
			Vomiting	嘔吐	1	N	TE			N	None	Recovered
			Fatigue	疲労	1	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE	2	2	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	2	2	N	None	Recovered
			Tendonitis	腱炎	2	N	TE	35		N	None	Recovered
			Constipation	便秘	1	N	TE	37		N	None	Recovered
			Nausea	悪心	1	N	TE	37	5	N	None	Recovered

表 2.7.4.7- 12　死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Musculoskeletal stiffness	筋骨格硬直	2	N	TE	99	15	N	None	Recovered
			Pharyngitis	咽頭炎	1	N	TE	138	3	N	None	Recovered
			Pathological fracture	病的骨折	2	N	TE	149		N	Not applicable	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	149	9	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	2	N	TE	157	10	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	166	6	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	167	22	N	None	Recovered
			Spinal cord compression	脊髄圧迫	3	N	TE	171	42	N	Not applicable	Ongoing at time of death
			Subileus	亜イレウス	2	Y	TE	181	4	N	Not applicable	Recovered
			Oesophageal pain	食道痛	1	N	TE	198	1	N	Not applicable	Recovered
			Cystitis	膀胱炎	1	N	TE	201	11	N	Not applicable	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	212	1	N	Not applicable	Death
011006	Czech Republic	68/M/C	Diarrhoea	下痢	1	N	TE	2	11	Y	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	150	256	Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	4	Y	TE	405		Y	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	4	Y	Post	405	2	Y	Not applicable	Death
			Pneumonia	肺炎	5	Y	Post	406	1	Y	Not applicable	Death
017003	Czech Republic	80/M/C	Cachexia	悪液質	4	Y	TE	115	10	N	None	Death
			Pneumonitis	肺臓炎	3	N	TE	115		N	None	Ongoing at time of death
			Cachexia	悪液質	5	Y	TE	124	1	N	None	Death
017004	Czech Republic	83/M/C	Angina pectoris	狭心症	3	Y	TE	105	15	N	None	Recovered with sequelae
			Depression	うつ病	2	N	TE	105	8	N	Drug administration postponed	Recovered
			Angina pectoris	狭心症	2	N	TE	119	184	N	None	Death
			Hypokalaemia	低カリウム血症	1	N	TE	119		N	None	Not recovered, but no changes expected
			Angina pectoris	狭心症	5	Y	TE	302	1	N	None	Death
017007	Czech Republic	80/M/C	Malignant neoplasm progression	悪性新生物進行	4	Y	TE	178	3	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	180	1	N	Not applicable	Death

表 2.7.4.7- 12　死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
017017	Czech Republic	77/M/C	General physical health deterioration	全身健康状態低下	4	Y	TE	151	2	N	Not applicable	Death
			General physical health deterioration	全身健康状態低下	5	Y	TE	152	1	N	Not applicable	Death
017018	Czech Republic	76/M/C	Bone pain	骨痛	1	Y	Pre	-61	10	N	None	Recovered
			Myocardial ischaemia	心筋虚血	4	Y	TE	146		N	Not applicable	Ongoing at time of death
			Myocardial infarction	心筋梗塞	5	Y	TE	154	1	N	Not applicable	Death
020005	Sweden	71/M/C	Anorexia	食欲不振	2	N	TE			N	None	Ongoing at time of death
			Micturition urgency	尿意切迫	2	N	Pre			N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	1	4	Y	None	Recovered
			Fatigue	疲労	2	N	TE	1		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	1		Y	None	Not recovered, but no changes expected
			Musculoskeletal pain	筋骨格痛	1	N	TE	1	4	Y	None	Recovered
			Haematuria	血尿	2	N	TE	11		N	None	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	17	3	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	33	5	Y	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	3	N	TE	39		N	None	Ongoing at study termination / withdrawal
			Chills	悪寒	1	N	TE	54		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	Y	TE	75	14	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	91	22	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	112	1	N	Drug permanently withdrawn	Death
024007	Sweden	63/M/C	Insomnia	不眠症	1	N	Pre	-2		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	Pre	-1		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	1	2	Y	None	Recovered
			Cystitis	膀胱炎	2	N	TE	30	41	N	None	Recovered
			Oedema	浮腫	2	N	TE	63	106	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	75		N	None	Not recovered, but no changes expected

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	114		N	None	Not recovered, but no changes expected
			Erysipelas	丹毒	2	N	TE	128		N	None	Recovered
			Thrombophlebitis	血栓性静脈炎	1	N	TE	128		N	None	Recovered
			Bone pain	骨痛	3	Y	TE	138		N	None	Ongoing at time of death
			Metastases to liver	肝転移	3	N	TE	141	28	N	Not applicable	Death
			Anaemia	貧血	2	N	TE	158	4	Y	Not applicable	Recovered
			Metastases to liver	肝転移	5	Y	TE	168	1	N	Not applicable	Death
024017	Sweden	73/M/C	Bone pain	骨痛	2	N	TE	34		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	64	27	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	64		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	117	30	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	204	1	N	Not applicable	Death
025004	Sweden	63/M/C	Fatigue	疲労	1	N	TE	31	-1	Y	None	Recovered
			Upper respiratory tract infection bacterial	細菌性上気道感染	1	N	TE	48	12	N	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Haematuria	血尿	3	Y	TE	82		N	Drug administration postponed	Ongoing at time of death
			Cardiac failure	心不全	4	Y	TE	90	2	N	Drug permanently withdrawn	Death
			Cardiac failure	心不全	5	Y	TE	91	1	N	Drug permanently withdrawn	Death
025014	Sweden	82/M/C	Haematuria	血尿	2	N	Pre			N	None	Recovered
			Fatigue	疲労	3	N	TE	29		N	Drug permanently withdrawn	Ongoing at time of death
			Hepatic failure	肝不全	3	Y	TE	29	9	N	Drug permanently withdrawn	Death
			Bone pain	骨痛	2	Y	TE	29		N	Drug permanently withdrawn	Ongoing at time of death
			Hepatic failure	肝不全	5	Y	TE	37	1	N	Drug permanently withdrawn	Death
025015	Sweden	72/M/C	Fatigue	疲労	2	N	TE	57		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Lymphadenopathy	リンパ節症	2	N	TE	62		N	None	Ongoing at time of death
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	TE	62		N	None	Ongoing at study termination / withdrawal
			Metastases to liver	肝転移	5	Y	TE	88	1	N	Not applicable	Death
025020	Sweden	61/M/C	Bone pain	骨痛	2	Y	TE	42	3	N	None	Recovered
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE	70	71	N	None	Recovered
			Bone pain	骨痛	1	N	TE	127		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	132	8	N	None	Recovered
			Sepsis	敗血症	4	Y	TE	160	11	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	4	Y	TE	160	14	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	166		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	220	1	N	Not applicable	Death
026001	Sweden	78/M/C	Bone pain	骨痛	3	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	3		N	None	Not recovered, but no changes expected

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Haematuria	血尿	1	N	TE	106	4	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	114		N	None	Ongoing at time of death
			Dehydration	脱水	2	Y	TE	117	12	N	None	Recovered
			Confusional state	錯乱状態	2	Y	TE	117	12	N	None	Recovered with sequelae
			Urinary retention	尿閉	2	N	TE	118		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	137	2	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	138	1	N	Drug permanently withdrawn	Death
026002	Sweden	66/M/C	Oesophageal spasm	食道痙攣	1	N	TE			N	None	Recovered
			Bone pain	骨痛	3	Y	Pre	-2	8	N	Not applicable	Recovered with sequelae
			Polyneuropathy	多発ニューロパチー	1	Y	TE	91	4	N	None	Recovered with sequelae
			Faecal incontinence	便失禁	3	Y	TE	108	8	N	None	Recovered with sequelae
			Hyperglycaemia	高血糖	3	Y	TE	108	8	N	None	Recovered with sequelae
			Urinary incontinence	尿失禁	3	Y	TE	108	8	N	None	Recovered with sequelae

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pancytopenia	汎血球減少症	2	N	TE	124	6	N	Drug permanently withdrawn	Ongoing at time of death
			Fall	転倒・転落	3	Y	TE	124		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	124	13	N	None	Death
			Urinary retention	尿閉	2	N	TE	124		N	Not applicable	Ongoing at time of death
			Mouth ulceration	口腔内潰瘍形成	2	N	TE	125		N	Not applicable	Ongoing at time of death
			Pancytopenia	汎血球減少症	3	Y	TE	129		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	136	1	N	None	Death
028002	Belgium	72/M/C	General physical health deterioration	全身健康状態低下	2	Y	Pre	-9	19	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	Y	Pre	-9	19	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	3	N	Pre	-1	2	N	None	Recovered
			Anal ulcer	肛門潰瘍	2	N	Pre	-1	88	N	None	Recovered
			General physical health deterioration	全身健康状態低下	1	N	Pre	10		N	None	Not recovered, but no changes expected

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	Pre	10		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	3	Y	TE	29	7	Y	Drug administration postponed	Recovered
			Weight decreased	体重減少	2	N	TE	29	28	N	None	Recovered
			Anorexia	食欲不振	3	N	TE	56	28	N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	56		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	Y	TE	83		Y	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	3	Y	TE	83	24	N	Drug permanently withdrawn	Death
			Anorexia	食欲不振	1	N	TE	83		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	87	20	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	91		N	Drug permanently withdrawn	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	105		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			General physical health deterioration	全身健康状態低下	5	Y	TE	106	1	N	Drug permanently withdrawn	Death
028003	Belgium	83/M/C	Nausea	悪心	1	N	TE	2	1	Y	None	Recovered
			Fatigue	疲労	1	N	TE	29		N	None	Ongoing at time of death
			Skin irritation	皮膚刺激	2	N	TE	50	15	N	None	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	55		Y	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	4	Y	TE	55		N	None	Ongoing at time of death
			Renal failure	腎不全	4	Y	TE	55		N	Drug permanently withdrawn	Ongoing at time of death
			Pulmonary oedema	肺水腫	4	Y	TE	55		N	None	Ongoing at time of death
			Multi-organ failure	多臓器不全	4	Y	TE	59	6	N	None	Death
			Multi-organ failure	多臓器不全	5	Y	TE	64	1	N	None	Death
028004	Belgium	84/M/C	Transient ischaemic attack	一過性脳虚血発作	2	Y	Pre	-13	55	N	Not applicable	Recovered
			Urinary retention	尿閉	2	N	Pre	-7	6	N	None	Recovered
			Pruritus	そう痒症	1	N	TE	8	7	N	None	Recovered with sequelae
			Pruritus	そう痒症	1	N	TE	8	27	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	14	48	N	None	Recovered
			Urinary tract infection	尿路感染	1	N	TE	28	29	N	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Confusional state	錯乱状態	1	N	TE	30		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	51		N	None	Ongoing at time of death
			Hypercholesterolaemia	高コレステロール血症	2	N	TE	51		N	None	Ongoing at time of death
			Inguinal hernia	鼠径ヘルニア	1	N	TE	55	14	N	None	Recovered
			Bone pain	骨痛	3	N	TE	57		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	93	1	N	Not applicable	Death
028007	Belgium	65/M/C	Fatigue	疲労	1	N	TE	28		Y	None	Ongoing at study termination / withdrawal
			Feeling cold	冷感	1	N	TE	28	36	Y	None	Recovered
			Pallor	蒼白	1	N	TE	28		Y	None	Ongoing at study termination / withdrawal
			Pyrexia	発熱	2	N	TE	50	6	N	None	Recovered
			Urinary retention	尿閉	3	Y	TE	50	2	N	None	Recovered with sequelae
			Anaemia	貧血	3	N	TE	55	9	Y	None	Recovered with sequelae
			Pleurisy	胸膜炎	2	N	TE	56	23	N	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	63		Y	None	Ongoing at study termination / withdrawal
			Tachycardia	頻脈	2	N	TE	91	15	N	None	Recovered
			Pleural effusion	胸水	2	N	TE	167	15	N	Not applicable	Recovered
			Paraesthesia	錯感覚	2	N	TE	168		N	None	Ongoing at study termination / withdrawal
			Lymphangiosis carcinomatosa	癌性リンパ管症	4	Y	TE	181	19	N	Not applicable	Recovered with sequelae
			Pleural effusion	胸水	4	Y	TE	181	2	N	Not applicable	Recovered
			Lymphangiosis carcinomatosa	癌性リンパ管症	4	N	TE	199	5	N	Not applicable	Recovered with sequelae
			Lymphangiosis carcinomatosa	癌性リンパ管症	5	Y	TE	203	1	N	Not applicable	Death
033005	UK	83/M/C	Bone pain	骨痛	1	N	TE	1	3	Y	None	Recovered
			Myocardial infarction	心筋梗塞	4	Y	TE	82	3	N	None	Death
			Myocardial infarction	心筋梗塞	5	Y	TE	84	1	N	None	Death
033023	UK	69/M/C	Post-traumatic pain	外傷後疼痛	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Muscular weakness	筋力低下	3	N	TE			N	None	Ongoing at time of death
			Pathological fracture	病的骨折	2	N	TE			N	None	Not recovered, but no changes expected
			Constipation	便秘	1	N	Pre	-673	882	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	28		N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	85	65	N	None	Recovered with sequelae
			Pathological fracture	病的骨折	3	Y	TE	149	20	Y	Drug administration postponed	Recovered
			Mobility decreased	運動性低下	2	N	TE	168	42	N	None	Ongoing at time of death
			Pathological fracture	病的骨折	2	N	TE	168		Y	None	Not recovered, but no changes expected
			Paraesthesia	錯感覚	1	Y	TE	175	5	N	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	178	7	N	None	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	178	32	N	None	Ongoing at time of death
			Upper limb fracture	上肢骨折	3	Y	TE	202		Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pneumonia	肺炎	5	Y	TE	209	1	N	Not applicable	Death
034004	UK	63/M/C	Nausea	悪心	1	N	TE	8		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	8		Y	None	Ongoing at time of death
			Oral candidiasis	口腔カンジダ症	1	N	TE	8		N	None	Ongoing at time of death
			Dizziness	浮動性めまい	1	N	TE	8		N	None	Ongoing at time of death
			Cerebral ischaemia	脳虚血	4	Y	TE	43	5	N	None	Recovered with sequelae
			Anorexia	食欲不振	3	N	TE	53		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	92	9	N	Not applicable	Recovered
			Diarrhoea	下痢	3	N	TE	95	6	Y	Not applicable	Recovered
			Vomiting	嘔吐	3	N	TE	95	6	N	Not applicable	Recovered
			Anaemia	貧血	4	N	TE	98	2	N	Not applicable	Recovered
			Bone marrow failure	骨髄機能不全	4	Y	TE	98	9	N	Not applicable	Death
			Sinus tachycardia	洞性頻脈	1	N	TE	98		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Confusional state	錯乱状態	3	N	TE	98	2	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	98	2	N	Not applicable	Recovered
			Rash	発疹	2	N	TE	98		N	None	Ongoing at time of death
			Haematemesis	吐血	3	N	TE	99	2	N	Not applicable	Recovered with sequelae
			Oesophagitis	食道炎	2	N	TE	99		N	Not applicable	Ongoing at time of death
			Bone marrow failure	骨髄機能不全	5	Y	TE	106	1	N	Not applicable	Death
035027	UK	68/M/C	Decreased appetite	食欲減退	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	1	3	Y	None	Recovered
			Constipation	便秘	2	N	TE	44		Y	None	Ongoing at time of death
			Intestinal obstruction	腸閉塞	4	Y	TE	54	2	Y	None	Death
			Intestinal obstruction	腸閉塞	5	Y	TE	55	1	Y	None	Death
035028	UK	70/M/C	Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Recovered
			Urine flow decreased	尿流量減少	1	N	TE	11	19	N	None	Recovered
			Bone pain	骨痛	2	N	TE	29		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	44	18	N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	44		N	None	Recovered
			Constipation	便秘	2	Y	TE	66	6	N	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Confusional state	錯乱状態	2	N	TE	71	79	N	Not applicable	Death
			Constipation	便秘	1	N	TE	72	42	N	None	Recovered
037012	UK	67/M/C	Abdominal pain	腹痛	1	N	TE			N	None	Not recovered, but no changes expected
			Hiatus hernia	裂孔ヘルニア	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			N	None	Recovered
			Pain in jaw	顎痛	1	N	TE			N	None	Ongoing at time of death
			Deep vein thrombosis	深部静脈血栓症	3	N	TE			Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	28	2	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	113		N	None	Ongoing at time of death
			Osteoarthritis	骨関節炎	1	N	TE	163		N	None	Not recovered, but no changes expected
			Dyspnoea exertional	労作性呼吸困難	1	N	TE	171		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	198		N	None	Ongoing at time of death
			Head injury	頭部損傷	3	N	TE	212	1	N	None	Recovered with sequelae

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Disseminated intravascular coagulation	播種性血管内凝固	3	N	TE	214		N	None	Not recovered, but no changes expected
			Thrombocytopenia	血小板減少症	3	Y	TE	214		N	Not applicable	Ongoing at time of death
			Extradural haematoma	硬膜外血腫	5	Y	TE	214	1	N	Not applicable	Death
039005	UK	72/M/C	Constipation	便秘	3	N	TE	4	38	N	None	Recovered
			Nausea	悪心	3	N	TE	13	29	N	None	Recovered
			Nausea	悪心	3	N	TE	35	7	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	35		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	N	TE	35	8	N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	42	1	N	None	Death
039007	UK	68/M/C	Bone pain	骨痛	1	N	Pre			N	None	Ongoing at time of death
			Anaemia	貧血	1	Y	Pre	-23	2	N	Drug administration postponed	Recovered
			Decreased appetite	食欲減退	1	N	Pre	-11		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	-11		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	-11	5	N	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	1	N	Pre	-4		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	Pre	-4		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	4	23	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	27		Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	29	36	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	60		Y	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	70	1	N	None	Recovered
			Anaemia	貧血	2	N	TE	92		Y	Drug administration postponed	Ongoing at time of death
			Joint injury	関節損傷	2	N	TE	94		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	95		Y	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	118	2	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	180	2	Y	Not applicable	Recovered
			Skin lesion	皮膚病変	3	N	TE	183		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	214	1	N	Not applicable	Death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
039012	UK	82/M/C	Anaemia	貧血	3	N	TE			N	None	Recovered
			Hyperchlorhydria	胃酸過多	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	2	N	Pre	-2	26	N	None	Recovered
			Hypoaesthesia	感覚鈍麻	2	N	Pre	-2		N	None	Ongoing at study termination / withdrawal
			Hypoaesthesia	感覚鈍麻	2	N	TE	8		N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	2	N	TE	8		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	24		N	None	Ongoing at time of death
			Pathological fracture	病的骨折	3	Y	TE	35	33	N	Drug administration postponed	Recovered
			Nausea	悪心	2	N	TE	71	86	Y	None	Ongoing at time of death
			Dry mouth	口内乾燥	3	N	TE	87	70	N	None	Ongoing at time of death
			Back injury	背部損傷	3	N	TE	91	66	N	None	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	125		N	None	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	156	1	N	None	Death
039027	UK	74/M/C	Nausea	悪心	2	N	TE	1		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	1		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	2	N	Pre	1		N	None	Ongoing at time of death
			Dizziness	浮動性めまい	2	N	TE	1		N	None	Ongoing at time of death
			Headache	頭痛	1	N	TE	1		N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	1	N	TE	1		N	None	Ongoing at time of death
			Dehydration	脱水	3	Y	TE	8	7	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	18	20	N	Drug administration postponed	Death
			Renal failure	腎不全	3	Y	TE	18	1	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	N	TE	19	4	N	Drug administration postponed	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	37	1	N	Drug administration postponed	Death
041008	UK	74/M/C	Anaemia	貧血	2	N	Pre	1	29	N	Drug administration postponed	Recovered
			Nausea	悪心	2	N	TE	1	3	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	1	3	N	None	Recovered
			Anaemia	貧血	2	Y	TE	29	4	N	Drug administration postponed	Recovered
			Acute myocardial infarction	急性心筋梗塞	4	Y	TE	29	4	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	32	19	N	Drug administration postponed	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE	35	13	N	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	50	4	N	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	50	3	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	52		N	None	Ongoing at time of death
			Anaemia	貧血		Y	TE	76		N	Drug administration postponed	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	5	Y	TE	79	1	N	None	Death
042015	UK	72/M/C	Increased appetite	食欲亢進	1	N	TE			N	None	Recovered
			Somnolence	傾眠	2	N	TE			N	None	Recovered
			Diplopia	複視	3	N	TE	14	10	Y	None	Recovered
			Balance disorder	平衡障害	1	N	TE	14	10	N	None	Recovered
			Confusional state	錯乱状態	3	N	TE	14	10	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	15	15	Y	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	53	6	N	None	Recovered
			Agitation	激越	2	N	TE	114	2	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	115	1	N	None	Death
			Increased bronchial secretion	気管支分泌増加	2	N	TE	115	1	N	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
044005	UK	76/M/C	Cardiac failure congestive	うっ血性心不全	4	N	TE			N	Drug administration postponed	Death
			Fatigue	疲労	2	N	TE			Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	7	1	Y	None	Recovered
			Left ventricular dysfunction	左室機能不全	3	N	TE	54	73	N	Drug administration postponed	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	54	73	N	Drug administration postponed	Ongoing at time of death
			Dyspnoea	呼吸困難	3	N	TE	54	17	N	Drug administration postponed	Ongoing at time of death
			Troponin T increased	トロポニンＴ増加	4	N	TE	57	70	N	Drug administration postponed	Ongoing at time of death
			Pleural effusion	胸水	2	N	TE	57	70	N	Drug administration postponed	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pulmonary embolism	肺塞栓症	3	Y	TE	57	3	N	Drug permanently withdrawn	Recovered with sequelae
			Pulmonary oedema	肺水腫	1	N	TE	58	69	N	Drug administration postponed	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	70	57	N	Drug administration postponed	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	5	Y	TE	126	1	N	Drug administration postponed	Death
047002	UK	81/M/C	Anaemia	貧血	3	N	TE	2	1	Y	None	Recovered
			Anaemia	貧血	3	N	TE	39	1	Y	None	Recovered
			Anaemia	貧血	3	N	TE	73	1	Y	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	3	N	TE	85		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	2	N	TE	136		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	154	1	N	Not applicable	Death

表 2.7.4.7- 12　死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment：BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
049002	UK	73/M/C	Lower respiratory tract infection	下気道感染	3	Y	TE	9	11	N	None	Recovered
			Oral candidiasis	口腔カンジダ症	2	N	TE	57	53	Y	None	Recovered
			Paraesthesia	錯感覚	1	N	TE	100	30	N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	Y	TE	109	3	N	Drug administration postponed	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	4	Y	TE	129		N	None	Ongoing at time of death
			Pneumonia	肺炎	4	Y	TE	135	7	N	Drug permanently withdrawn	Death
			Pneumonia	肺炎	5	Y	TE	141	1	N	Drug permanently withdrawn	Death
049007	UK	80/M/C	Nausea	悪心	2	N	TE	3		Y	None	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	3		Y	None	Ongoing at time of death
			Mucosal inflammation	粘膜の炎症	2	N	TE	29		Y	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	29		Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	120		N	None	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	128		N	None	Ongoing at time of death
			Headache	頭痛	2	N	TE	148	51	N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	176	3	N	Not applicable	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	198		N	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	3	Y	TE	198		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	198	12	N	Not applicable	Death
			Headache	頭痛	4	N	TE	198		N	None	Ongoing at time of death
			Urinary retention	尿閉	2	N	TE	204		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	209	1	N	Not applicable	Death
049008	UK	72/M/C	Decreased appetite	食欲減退	2	N	TE			N	None	Ongoing at time of death
			Lymphoedema	リンパ浮腫	1	N	Pre			N	None	Recovered
			Ear pain	耳痛	1	N	Pre	-7		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre	-3	5	N	None	Recovered
			Fatigue	疲労	2	N	TE	29		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	29	50	Y	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	2	N	TE	40		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	40	2	N	None	Recovered with sequelae
			Palpitations	動悸	1	N	TE	54	4	N	Not applicable	Recovered
			Depressed mood	抑うつ気分	1	N	TE	54		N	None	Ongoing at time of death
			Vomiting	嘔吐	2	Y	TE	57	6	N	Drug administration postponed	Recovered
			Pyrexia	発熱	1	Y	TE	61	2	N	Drug administration postponed	Recovered
			Nausea	悪心	2	Y	TE	65	6	N	Drug administration postponed	Recovered with sequelae
			Vomiting	嘔吐	2	Y	TE	65	6	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	N	TE	67	1	N	Not applicable	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	89	1	N	Not applicable	Recovered
			Abdominal pain	腹痛	3	Y	TE	111		N	Not applicable	Ongoing at time of death
			Nausea	悪心	3	Y	TE	111		N	Not applicable	Ongoing at time of death
			Vomiting	嘔吐	3	Y	TE	111		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	111	11	N	Not applicable	Death
			Anaemia	貧血	2	N	TE	113		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	121	1	N	Not applicable	Death
051012	UK	73/M/C	Decreased appetite	食欲減退	1	N	TE	30		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	108	1	N	None	Death
055002	Netherlands	66/M/C	Lung infection	肺感染	2	N	TE	18	27	N	None	Recovered
			Anorexia	食欲不振	2	N	TE	54		Y	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	54		Y	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	59		Y	None	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Drug intolerance	薬物不耐性	4	Y	TE	71	3	N	None	Recovered with sequelae
			Pulmonary embolism	肺塞栓症	4	Y	TE	71		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	74	1	N	None	Death
060002	Spain	84/M/C	Anorexia	食欲不振	2	N	TE	29		N	None	Ongoing at time of death
			Cardiac failure	心不全	3	N	TE	100		N	None	Ongoing at study termination / withdrawal
			Dyspnoea	呼吸困難	2	N	TE	100		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	101	31	N	Not applicable	Ongoing at time of death
			Bronchitis	気管支炎	2	N	TE	107	2	N	None	Recovered
			Renal failure	腎不全	2	N	TE	107	3	N	None	Recovered
			Bronchitis	気管支炎	3	Y	TE	108		N	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	N	TE	109	5	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	113	11	Y	None	Ongoing at time of death
			Hyperuricaemia	高尿酸血症	1	N	TE	113		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	123		Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	129	1	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	131		N	Not applicable	Ongoing at time of death
			Death	死亡	5	Y	TE	137	1	N	Not applicable	Death
060003	Spain	85/M/C	Bone pain	骨痛	3	N	TE	31	26	N	None	Ongoing at time of death
			Weight decreased	体重減少	2	N	TE	56	6	N	None	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	2	N	TE	56	11	N	None	Recovered
			Bone pain	骨痛	2	N	TE	56		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	57		N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	61		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	111	1	N	Not applicable	Death
060007	Spain	79/M/C	Nausea	悪心	1	N	Pre	-20	28	N	None	Recovered
			Anorexia	食欲不振	2	N	Pre	-20		N	None	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Haematuria	血尿	2	N	TE	5		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	6	4	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	6	12	N	Drug permanently withdrawn	Death
			Pyrexia	発熱	1	N	TE	7	2	N	None	Recovered
			Respiratory tract infection	気道感染	2	N	TE	7		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	3	N	TE	8		N	None	Ongoing at time of death
			Asthenia	無力症	1	N	TE	12	2	N	None	Ongoing at time of death
			Asthenia	無力症	3	N	TE	13		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	17	1	N	Drug permanently withdrawn	Death
063004	Spain	74/M/C	Abdominal pain upper	上腹部痛	1	N	TE	32	55	N	None	Recovered
			Somnolence	傾眠	2	N	TE	32	55	N	None	Recovered
			Anaemia	貧血	3	N	TE	58	29	N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	86		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	86	29	N	Not applicable	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Asthenia	無力症	1	N	TE	86		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	86		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	114		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	128	8	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	135	1	N	Drug permanently withdrawn	Death
075001	Italy	59/M/C	Strangury	有痛性排尿困難		N	TE	2	2	N	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	14	28	N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	33	10	Y	Drug administration postponed	Recovered
			Vomiting	嘔吐	1	N	TE	33	10	Y	Drug administration postponed	Recovered
			Anorexia	食欲不振	1	N	TE	33	10	Y	Drug administration postponed	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	1	N	TE	41		N	None	Ongoing at time of death
			Strangury	有痛性排尿困難	2	N	TE	78	1	N	None	Recovered
			Death	死亡	5	Y	TE	93	1	N	None	Death
078001	Italy	76/M/C	Constipation	便秘	1	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE			N	None	Recovered
			Pyrexia	発熱	1	N	TE			N	None	Recovered
			Confusional state	錯乱状態	1	N	TE			N	None	Recovered
			Hyperhidrosis	多汗症	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE	2	11	Y	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	38	21	N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	58	21	N	None	Ongoing at time of death
			Asthenia	無力症	2	N	TE	78	37	Y	None	Recovered
			Pyrexia	発熱	1	N	TE	78	29	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	78		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	78	37	N	None	Recovered
			Fatigue	疲労	2	N	TE	127	14	N	None	Ongoing at time of death
			Depression	うつ病	2	N	TE	127		N	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	141		N	None	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	147	2	Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	Y	TE	147	2	Y	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	149	14	Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	Y	TE	149	11	Y	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	1	Y	TE	163		Y	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	163	15	N	Not applicable	Death
093002	Slovakia	81/M/C	Anaemia	貧血	2	N	TE	29	48	N	-	
			Nausea	悪心	2	N	TE	29	85	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	29	6	Y	None	Recovered
			Constipation	便秘	1	N	TE	56	58	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	56	4	Y	None	Recovered
			Anaemia	貧血	3	N	TE	76	10	N	-	
			Bone pain	骨痛	3	Y	TE	76	8	N	None	Recovered with sequelae
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	76		N	None	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	85	29	N	-	
			Diarrhoea	下痢	2	N	TE	85	5	Y	None	Recovered
			Anaemia	貧血	2	N	TE	113	31	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	Y	TE	143	5	N	Drug administration postponed	Recovered
			Bronchopneumonia	気管支肺炎	3	N	TE	150		N	None	Ongoing at time of death
			Cardiopulmonary failure	心肺不全	5	Y	TE	160	1	N	Not applicable	Death
104005	Hong Kong	73/M/A	Constipation	便秘	1	N	TE	1	29	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	64	2	Y	None	Recovered
			Pneumonia	肺炎	2	N	TE	87		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	87	18	N	Drug permanently withdrawn	Death
			Spinal cord compression	脊髄圧迫	5	Y	TE	104	1	N	Drug permanently withdrawn	Death
106005	Hong Kong	79/M/A	Decreased appetite	食欲減退	1	N	TE	29	85	Y	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dysuria	排尿困難	1	N	TE	29		N	None	Ongoing at time of death
			Nocturia	夜間頻尿	2	N	TE	29	57	N	None	Recovered
			Anaemia	貧血	3	Y	TE	113	3	Y	Drug administration postponed	Recovered with sequelae
			Constipation	便秘	2	N	TE	113	29	N	None	Recovered
			Sleep disorder	睡眠障害	1	N	TE	113	3	N	None	Recovered
			Spinal compression fracture	脊椎圧迫骨折	3	N	TE	115		N	None	Ongoing at time of death
			Sepsis	敗血症	3	Y	TE	155		N	Not applicable	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	3	N	TE	156		N	Not applicable	Ongoing at time of death
			Haematuria	血尿	3	Y	TE	159		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	165	1	N	Not applicable	Death
106011	Hong Kong	79/M/A	Decreased appetite	食欲減退	1	N	TE	29	29	N	None	Recovered
			Abdominal pain upper	上腹部痛	1	N	TE	57	29	N	None	Recovered
			Liver function test abnormal	肝機能検査異常	3	Y	TE	57	13	N	Drug administration postponed	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	218	1	N	Not applicable	Death
133002	Poland	78/M/C	Pyrexia	発熱	1	N	TE	3	14	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	3	6	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	8	44	Y	None	Recovered
			Pathological fracture	病的骨折	2	Y	TE	43		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	51	53	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	72	34	N	None	Recovered
			Fatigue	疲労	3	N	TE	88	26	N	Drug permanently withdrawn	Ongoing at time of death
			Fatigue	疲労	4	N	TE	113		N	Drug permanently withdrawn	Ongoing at time of death
			Weight decreased	体重減少	2	N	TE	113		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	162	1	N	Not applicable	Death
133006	Poland	53/M/C	Bone pain	骨痛	2	N	TE	2	10	Y	None	Recovered
			Hypertension	高血圧	2	N	TE	29	29	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	50		N	None	Recovered
			Abdominal pain	腹痛	2	N	TE	71		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	140	29	N	None	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	N	TE	168		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	168		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	184	2	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	185	1	N	Not applicable	Death
133009	Poland	75/M/C	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2	N	TE	85	29	N	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1	N	TE	85	29	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	141	29	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	198	1	N	Not applicable	Death
133011	Poland	66/M/C	Anaemia	貧血	2	N	Pre	1		N	None	Ongoing at time of death
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	Pre	1		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre	1		N	None	Not recovered, but no changes expected
			Tremor	振戦	4	Y	TE	25	1	Y	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Confusional state	錯乱状態	4	Y	TE	25		Y	None	Ongoing at time of death
			Death	死亡	5	Y	TE	29	1	Y	None	Death
133012	Poland	67/M/C	Spinal cord compression	脊髄圧迫	3	Y	Pre	-35		N	Drug administration postponed	Ongoing at time of death
			Dyspnoea	呼吸困難	4	Y	TE	2	1	N	None	Death
			Dyspnoea	呼吸困難	5	Y	TE	2	1	N	None	Death
134001	Poland	57/M/C	Paralysis	麻痺	4	Y	Pre	-10		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	20	1	N	None	Death
137006	Poland	71/M/C	Anaemia	貧血	3	Y	TE	139	8	N	Not applicable	Recovered with sequelae
			Urinary tract infection	尿路感染	2	N	TE	157	8	N	Not applicable	Recovered
			Haematuria	血尿	3	Y	TE	197	7	N	Not applicable	Recovered
			Anaemia	貧血	4	Y	TE	203		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	213	1	N	Not applicable	Death
139001	Poland	76/M/C	Anaemia	貧血	1	N	TE	29		N	None	Ongoing at time of death
			Malaise	倦怠感	3	N	TE	29		N	None	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	46	1	N	None	Death
139005	Poland	71/M/C	Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre			N	None	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	57	5	Y	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	120	1	N	None	Death
148009	Germany	71/M/C	Nasopharyngitis	鼻咽頭炎	1	N	Pre	-14	15	N	None	Recovered
			Anaemia	貧血	2	N	Pre	1	57	Y	Drug administration postponed	Recovered
			Fatigue	疲労	2	N	TE	8		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	29	4	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	57	4	Y	Drug administration postponed	Recovered
			Anaemia	貧血	1	N	TE	60	31	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	60	1	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	60	2	Y	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Herpes zoster	帯状疱疹	3	Y	TE	96	12	Y	Drug administration postponed	Recovered
			Anaemia	貧血	2	Y	TE	98	1	Y	None	Recovered
			Anaemia	貧血	4	Y	TE	125	3	Y	Drug administration postponed	Recovered
			Syncope	失神	3	Y	TE	125	1	Y	Drug administration postponed	Recovered
			Pancytopenia	汎血球減少症		N	TE	140		Y	None	Ongoing at time of death
			Metastases to liver	肝転移	3	Y	TE	140	10	N	Drug permanently withdrawn	Death
			Epistaxis	鼻出血	2	N	TE	140	1	N	Not applicable	Recovered
			Metastases to liver	肝転移	5	Y	TE	149	1	N	Drug permanently withdrawn	Death
170004	Brazil	78/M/C	Pathological fracture	病的骨折	3	N	TE	127		N	Drug administration postponed	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary retention	尿閉	3	N	TE	156	1	N	None	Recovered
			Anaemia	貧血	2	N	TE	211		N	None	Ongoing at time of death
			Bone pain	骨痛	4	Y	TE	230		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	230	3	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	232	1	N	Drug permanently withdrawn	Death
173009	Brazil	66/M/O	Bone pain	骨痛	2	N	Pre	-9		N	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	4	Y	TE	29	20	N	Drug permanently withdrawn	Death
			General physical health deterioration	全身健康状態低下	5	Y	TE	48	1	N	Drug permanently withdrawn	Death
181005	Brazil	74/M/C	Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	Pre	1		N	None	Ongoing at time of death
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	Pre	1		N	None	Ongoing at time of death
			Hypoglycaemia	低血糖症	3	Y	TE	29	2	N	None	Recovered
			Pneumonia	肺炎	2	Y	TE	30	16	N	Not applicable	Death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Acute pulmonary oedema	急性肺水腫	2	Y	TE	30		N	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	5	Y	TE	45	1	N	Not applicable	Death
201002	Australia	72/M/C	Dysphagia	嚥下障害	2	N	Pre	-7	70	N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	48	46	N	None	Recovered
			Muscle strain	筋挫傷	2	N	TE	49	15	N	None	Recovered
			Dysphagia	嚥下障害	1	N	Pre	63	71	N	None	Ongoing at time of death
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	2	N	TE	93	4	N	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	99	8	N	None	Recovered
			Anaemia	貧血	3	Y	TE	132	9	N	Not applicable	Recovered
			Supraventricular tachycardia	上室性頻脈	2	Y	TE	132	1	N	Not applicable	Recovered
			Abdominal distension	腹部膨満	3	Y	TE	132	9	N	Not applicable	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	3	N	TE	132		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	132	39	N	Not applicable	Death
			Anxiety	不安	2	N	TE	132		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dysphagia	嚥下障害	2	N	Pre	133		N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	1	N	TE	137	3	N	Not applicable	Recovered
			Abdominal distension	腹部膨満	2	N	TE	140		N	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	147		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	161		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	170	1	N	Not applicable	Death
205004	Australia	82/M/C	Bone pain	骨痛	2	N	TE			Y	None	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	Pre	1		N	None	Ongoing at time of death
			Urinary incontinence	尿失禁	2	N	TE	6		Y	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	33		Y	None	Ongoing at time of death
			Hydrocephalus	水頭症	4	Y	TE	107	20	N	Drug permanently withdrawn	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	127	14	N	Drug permanently withdrawn	Death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	140	1	N	Drug permanently withdrawn	Death
209003	Australia	56/M/C	Bone pain	骨痛	1	N	Pre	-22		N	None	Ongoing at time of death
			Oesophagitis	食道炎	1	N	TE	29		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	29		N	None	Ongoing at time of death
			Muscle spasms	筋痙縮	1	N	TE	57		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	78		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	78		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	78		N	None	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	85		N	None	Ongoing at time of death
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	1	N	TE	85		N	None	Ongoing at time of death
			Breath sounds abnormal	呼吸音異常	1	N	TE	85		N	None	Ongoing at time of death
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1	N	TE	85		N	None	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neuropathy peripheral	末梢性ニューロパチー	1	N	TE	88		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	4	Y	TE	94	16	N	None	Recovered
			Burning sensation	灼熱感	1	N	TE	102	1	N	None	Recovered
			Rash	発疹	1	N	TE	103		N	None	Ongoing at time of death
			Pyrexia	発熱	1	N	TE	108	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	109		N	Not applicable	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	109		N	Not applicable	Ongoing at time of death
			Radiation skin injury	放射線皮膚損傷	1	N	TE	109		N	Not applicable	Ongoing at time of death
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	Y	TE	109	7	N	Drug permanently withdrawn	Recovered
			Anxiety	不安	1	N	TE	109		N	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	138		N	Not applicable	Ongoing at time of death
			Ascites	腹水	1	Y	TE	149		N	Not applicable	Ongoing at time of death
			Epistaxis	鼻出血	1	N	TE	149	18	N	Not applicable	Recovered
			Dry skin	皮膚乾燥	1	N	TE	149		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pruritus	そう痒症	1	N	TE	149		N	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE	153		N	None	Ongoing at time of death
			Rectal haemorrhage	直腸出血	1	N	TE	158		N	Not applicable	Ongoing at time of death
			Pitting oedema	圧痕浮腫	1	N	TE	158		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	158	9	N	Not applicable	Death
			Confusional state	錯乱状態	1	N	TE	158		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	166	1	N	Not applicable	Death
233005	UK	78/M/C	Nausea	悪心	1	N	TE	1	209	N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	29	181	Y	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	29	29	N	None	Recovered
			Anorexia	食欲不振	3	N	TE	29	113	Y	None	Ongoing at time of death
			Dehydration	脱水	3	N	TE	29	4	Y	Drug administration postponed	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malaise	倦怠感	2	Y	TE	32	6	Y	Drug administration postponed	Recovered
			Dehydration	脱水	3	Y	TE	32	6	Y	Drug administration postponed	Recovered
			Dehydration	脱水	2	Y	TE	45	5	Y	Drug administration postponed	Recovered
			Anaemia	貧血	3	Y	TE	53	3	Y	None	Recovered
			Hypertension	高血圧	3	N	TE	85	125	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	134	3	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	136	3	Y	None	Recovered
			Dehydration	脱水	2	N	TE	136	3	Y	None	Recovered
			Dyspnoea	呼吸困難	3	N	TE	136	2	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	141		Y	None	Ongoing at time of death
			Abdominal pain upper	上腹部痛	1	N	TE	167	3	Y	None	Recovered
			Anaemia	貧血	1	Y	TE	168	2	Y	None	Recovered
			Fatigue	疲労	2	N	TE	168		N	None	Ongoing at time of death
			Dehydration	脱水	2	Y	TE	168	2	Y	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	176	3	Y	Not applicable	Recovered
			Cough	咳嗽	2	N	TE	176	3	N	None	Recovered
			Cough	咳嗽	1	N	TE	176	3	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	N	TE	176	3	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	190		Y	Not applicable	Ongoing at time of death
			Neutropenia	好中球減少症	2	Y	TE	190		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	Y	TE	190		Y	Not applicable	Ongoing at time of death
			Abdominal pain	腹痛	1	N	TE	190	1	Y	Not applicable	Recovered
			Decreased appetite	食欲減退	3	N	TE	190		N	None	Ongoing at time of death
			Dehydration	脱水	3	Y	TE	190	4	Y	Not applicable	Recovered
			Hyperkalaemia	高カリウム血症	2	N	TE	190	20	Y	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	190		Y	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	190	4	Y	Not applicable	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dizziness	浮動性めまい	2	N	TE	190		N	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	3	Y	TE	209		N	Not applicable	Ongoing at time of death
			Bronchopneumonia	気管支肺炎	5	Y	TE	209	1	N	Not applicable	Death
			Dehydration	脱水	3	Y	TE	209		Y	Not applicable	Ongoing at time of death
			Agitation	激越	2	N	TE	209	1	N	None	Ongoing at time of death
240002	USA	68/M/C	Anaemia	貧血	3	N	TE	33	6	Y	Drug administration postponed	Recovered with sequelae
			Pneumonia	肺炎	3	Y	TE	33	6	N	Drug administration postponed	Recovered
			Sepsis	敗血症	4	Y	TE	33	6	N	Drug administration postponed	Recovered
			Pleural effusion	胸水	2	N	TE	33	4	N	None	Recovered
			Hypotension	低血圧	3	N	TE	33	1	N	None	Recovered
			Anaemia	貧血	1	N	TE	38	48	Y	None	Recovered with sequelae

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Diarrhoea	下痢	1	N	TE	62		Y	None	Ongoing at time of death
			Muscle spasms	筋痙縮	1	N	TE	72	43	N	None	Recovered
			Anaemia	貧血	2	N	TE	85	97	Y	None	Recovered with sequelae
			Nausea	悪心	1	N	TE	114	3	N	None	Recovered
			Fatigue	疲労	2	N	TE	114		Y	None	Ongoing at time of death
			Haematuria	血尿	1	N	TE	133	7	N	None	Recovered
			Leukopenia	白血球減少症	2	N	TE	139		Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	1	N	TE	139		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	139		Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	140		N	None	Ongoing at time of death
			Contusion	挫傷	1	N	TE	140		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	140		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	170		N	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	180	3	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	3	Y	TE	180	6	Y	Not applicable	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary tract infection	尿路感染	1	N	TE	180	11	N	Not applicable	Recovered
			Bone pain	骨痛	3	N	TE	180	6	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	180	62	N	Not applicable	Death
			Haematuria	血尿	2	Y	TE	180	6	Y	Not applicable	Recovered
			Urinary retention	尿閉	2	Y	TE	180	6	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	N	TE	180	24	N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	181	2	Y	None	Recovered with sequelae
			Dyspnoea	呼吸困難	1	N	TE	181	5	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	182	50	Y	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	194		N	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	199	5	Y	Not applicable	Ongoing at time of death
			Abdominal pain	腹痛	2	N	TE	199	11	N	Not applicable	Recovered
			Diarrhoea	下痢	1	N	TE	199	11	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	199	11	N	Not applicable	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	2	N	TE	199	11	N	Not applicable	Recovered
			Asthenia	無力症	2	N	TE	199		N	Not applicable	Ongoing at time of death
			Arthralgia	関節痛	1	N	TE	199	11	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	199	11	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	N	TE	199	5	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	203		Y	Not applicable	Ongoing at time of death
			Skin laceration	皮膚裂傷	2	N	TE	205		N	Not applicable	Ongoing at time of death
			Haemorrhoids	痔核	1	N	TE	210	6	N	Not applicable	Recovered
			Convulsion	痙攣	2	N	TE	223	1	N	Not applicable	Recovered
			Subcutaneous abscess	皮下組織膿瘍	2	N	TE	227		N	Not applicable	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	229		N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	231		Y	Not applicable	Ongoing at time of death
			Urinary retention	尿閉	2	N	TE	240	1	Y	Not applicable	Recovered

表 2.7.4.7- 12　死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment：BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Salivary hypersecretion	流涎過多	1	N	TE	241		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	241	1	N	Not applicable	Death
			Confusional state	錯乱状態	3	N	TE	241		N	Not applicable	Ongoing at time of death
240004	USA	56/M/C	Oedema peripheral	末梢性浮腫	1	N	TE	30	28	N	None	Recovered
			Supraventricular tachycardia	上室性頻脈	3	N	TE	55	1	N	None	Recovered
			Mental status changes	精神状態変化	1	N	TE	55	1	N	None	Recovered
			Fatigue	疲労	1	N	TE	57		N	None	Ongoing at study termination / withdrawal
			Arthralgia	関節痛	1	N	TE	57	1	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	117	79	N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	117	79	N	None	Ongoing at study termination / withdrawal
			Cardiac murmur	心雑音	1	N	TE	119	35	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	156	487	N	Not applicable	Death
			Nocturia	夜間頻尿	1	N	TE	156	112	N	Not applicable	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	195		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	195		N	None	Ongoing at study termination / withdrawal
			Depression	うつ病	1	N	TE	212	21	N	None	Recovered
			Anaemia	貧血	2	N	TE	216	9	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	N	TE	216	3	N	Not applicable	Recovered
			Pain	疼痛	3	N	TE	231		N	Not applicable	Ongoing at time of death
			Decreased appetite	食欲減退	2	N	TE	231		N	Not applicable	Ongoing at time of death
240006	USA	75/M/C	Constipation	便秘	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	Pre	-7	100	N	None	Recovered
			Cardiac murmur	心雑音	1	N	Pre	-2	35	N	None	Recovered
			Bone pain	骨痛	1	N	TE	31	63	N	None	Recovered
			Contusion	挫傷	1	N	TE	33		N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	3	N	TE	47	11	Y	None	Recovered
			Abdominal pain upper	上腹部痛	1	N	TE	64	25	N	None	Recovered
			Fatigue	疲労	1	N	TE	64		Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	64	60	N	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight increased	体重増加	1	N	TE	64		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	64	25	N	Drug administration postponed	Recovered
			Muscular weakness	筋力低下	1	N	TE	64		N	None	Ongoing at time of death
			Bone pain	骨痛	4	Y	TE	88	6	N	Drug administration postponed	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	88	115	N	Drug permanently withdrawn	Recovered
			Anaemia	貧血	2	N	TE	109	33	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	110	87	Y	Not applicable	Recovered
			Asthenia	無力症	2	N	TE	110		N	Not applicable	Ongoing at time of death
			Depression	うつ病	2	N	TE	110		N	Not applicable	Ongoing at time of death
			Fluid intake reduced	水分摂取量減少	2	N	TE	116	8	N	Not applicable	Recovered
			Cough	咳嗽	1	N	TE	118	17	N	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hypotension	低血圧	2	N	TE	120	55	N	Not applicable	Recovered
			Anorexia	食欲不振	2	N	TE	124		Y	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	145	203	N	Drug permanently withdrawn	Death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
002004	Norway	81/M/C	Anorexia	食欲不振	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	1	54	N	None	Ongoing at time of death
			Dizziness	浮動性めまい	2	N	Pre	1		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	54	9	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	57		Y	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	57		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	62		N	None	Ongoing at time of death
			Left ventricular dysfunction	左室機能不全	5	Y	TE	68	1	N	None	Death
002015	Norway	83/M/C	Oral candidiasis	口腔カンジダ症	2	N	TE			N	Not applicable	Ongoing at time of death
			Cough	咳嗽	2	N	TE			N	Not applicable	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	37	14	N	None	Recovered
			Conjunctivitis	結膜炎	2	N	TE	50	7	N	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	100	30	N	Drug permanently withdrawn	Death
			Cerebral haemorrhage	脳出血	2	Y	TE	100		Y	Drug permanently withdrawn	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	100	19	N	Not applicable	Recovered with sequelae
006014	Norway	81/M/C	Anorexia	食欲不振	2	N	TE	29		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	57	80	N	None	Recovered
			Cystitis	膀胱炎	2	N	TE	101	5	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	101	55	N	Drug administration postponed	Recovered
			Pneumonia	肺炎	3	N	TE	106	10	N	Drug administration postponed	Recovered
			Cystitis	膀胱炎	2	N	TE	159	8	N	None	Recovered
			Dyspnoea	呼吸困難	3	Y	TE	159	6	N	Drug administration postponed	Recovered with sequelae

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	175	10	N	Not applicable	Recovered with sequelae
			Cystitis	膀胱炎	2	N	TE	177	9	N	None	Recovered
			Bone pain	骨痛	1	Y	TE	184	2	N	Not applicable	Recovered with sequelae
			Death	死亡	5	Y	TE	205	1	N	Not applicable	Death
006029	Norway	77/M/C	Diarrhoea	下痢	1	N	TE	2	5	Y	None	Recovered
			Fatigue	疲労	1	N	TE	2	5	N	None	Recovered
			Anaemia	貧血	2	N	TE	35	39	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	56		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	68	12	N	None	Recovered with sequelae
			Dysphagia	嚥下障害	2	N	TE	69	5	N	None	Recovered
			Pyrexia	発熱	1	N	TE	69	2	Y	None	Recovered
			Infection	感染	3	N	TE	69	10	N	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	3	N	TE	69	9	N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	72	4	N	None	Recovered
			Anaemia	貧血	1	N	TE	73		N	None	Ongoing at time of death
			Psoriasis	乾癬	2	N	TE	75		N	None	Ongoing at time of death
			Urinary retention	尿閉	2	N	TE	76	1	N	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	1	N	TE	77		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	79		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	4	Y	TE	96	3	N	Not applicable	Death
			Dyspnoea	呼吸困難	5	Y	TE	98	1	N	Not applicable	Death
007003	Norway	65/M/C	Pleural effusion	胸水	2	Y	TE	1	11	N	None	Recovered
			Pneumonia	肺炎	2	N	TE	26	4	N	Drug administration postponed	Recovered
			Pneumonia	肺炎	3	Y	TE	29	9	N	Drug administration postponed	Recovered
			Bone pain	骨痛	3	N	TE	36		N	None	Ongoing at time of death
			Confusional state	錯乱状態	1	N	TE	53	3	Y	None	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	54		N	None	Ongoing at time of death
			Dizziness	浮動性めまい	1	N	TE	54	2	N	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pneumonia	肺炎	2	Y	TE	55	19	Y	Drug administration postponed	Recovered
			Confusional state	錯乱状態	2	Y	TE	55	19	Y	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	57	15	N	None	Recovered
			Metastases to meninges	髄膜転移	3	Y	TE	64	30	N	None	Death
			Thrombocytopenia	血小板減少症	4	Y	TE	86		Y	None	Ongoing at time of death
			Metastases to meninges	髄膜転移	5	Y	TE	93	1	N	None	Death
008014	Norway	77/M/C	Oedema peripheral	末梢性浮腫	1	N	TE			N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE			N	None	Ongoing at time of death
			Anaemia	貧血	1	N	Pre	1	3	N	-	
			Anaemia	貧血	2	N	TE	3	27	N	-	
			Cystitis	膀胱炎	2	N	TE	3	11	N	None	Recovered
			Myalgia	筋痛	2	Y	TE	3	4	N	None	Recovered
			Anaemia	貧血	1	N	TE	29	42	N	-	
			Respiratory tract infection	気道感染	2	N	TE	48		N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	69	12	N	None	Recovered
			Anaemia	貧血	2	N	TE	70	4	N	None	Ongoing at time of death
			Atrial fibrillation	心房細動	2	N	TE	70	2	N	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	73	37	N	None	Ongoing at time of death
			Weight decreased	体重減少	2	N	TE	85		N	None	Ongoing at time of death
			Gastroenteritis norovirus	ノロウイルス性胃腸炎	2	Y	TE	93	5	N	None	Recovered
			Post procedural infection	処置後感染	2	N	TE	93	17	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	109		N	None	Ongoing at time of death
			Post procedural infection	処置後感染	2	Y	TE	109	8	N	Drug administration postponed	Recovered
			Syncope	失神	2	N	TE	110	1	N	None	Recovered
			Syncope	失神	2	N	TE	111	1	N	None	Recovered
			Syncope	失神	2	N	TE	112	1	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	113	3	N	None	Recovered
			Pneumonia	肺炎	2	N	TE	114		N	Drug administration postponed	Recovered
			Dyspnoea	呼吸困難	3	Y	TE	152		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	155	16	N	Not applicable	Death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	170	1	N	Not applicable	Death
010005	Czech Republic	83/M/C	Cachexia	悪液質	5	Y	TE	147	1	N	Not applicable	Death
016001	Czech Republic	72/M/C	Malignant neoplasm progression	悪性新生物進行	3	Y	TE	78	10	N	None	Not recovered, but no changes expected
			Thrombocytopenia	血小板減少症	3	N	TE	84		Y	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	98	3	N	None	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	100	1	N	None	Death
017010	Czech Republic	69/M/C	Bursitis	滑液包炎	2	Y	TE	37	13	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	52	32	N	None	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	83	1	N	None	Death
017013	Czech Republic	78/M/C	Dyspepsia	消化不良	1	Y	Pre	-17	5	N	None	Recovered
			Constipation	便秘	1	N	Pre	-1		N	None	Ongoing at time of death
			Cerebral ischaemia	脳虚血	4	Y	TE	85	7	N	None	Death
			Cerebral ischaemia	脳虚血	5	Y	TE	91	1	N	None	Death
017014	Czech Republic	63/M/C	Bone pain	骨痛	2	N	TE	15		N	None	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	98	1	N	None	Death
017016	Czech Republic	79/M/C	Urinary tract infection	尿路感染	3	Y	TE	80	6	N	None	Death
			Urinary tract infection	尿路感染	5	Y	TE	85	1	N	None	Death
022005	Sweden	62/M/C	Dizziness	浮動性めまい	1	N	TE			N	None	Recovered
			Nausea	悪心	2	Y	TE	17	7	N	None	Recovered
			Vomiting	嘔吐	2	Y	TE	17	7	N	None	Recovered
			Dehydration	脱水	2	Y	TE	17	7	N	None	Recovered
			Bone pain	骨痛	2	N	TE	18	12	N	None	Recovered
			Fatigue	疲労	2	Y	TE	37	2	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	57		Y	None	Ongoing at time of death
			Sepsis	敗血症	4	Y	TE	57	5	N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	84	53	N	Not applicable	Death
			Anaemia	貧血	3	N	TE	85	14	N	None	Recovered with sequelae
			Anaemia	貧血	3	Y	TE	98	14	N	None	Recovered with sequelae
			Constipation	便秘	3	Y	TE	99	13	N	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	99	13	N	None	Recovered with sequelae

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	113	2	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	136	1	N	Not applicable	Death
024005	Sweden	69/M/C	Anaemia	貧血	2	N	TE	57	3	Y	None	Recovered
			Infection	感染	2	N	TE	103	11	N	None	Recovered
			Anaemia	貧血	1	N	TE	113	2	Y	None	Recovered
			General physical health deterioration	全身健康状態低下	3	N	TE	113		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	113	23	N	None	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	135	1	N	None	Death
024009	Sweden	73/M/C	Pathological fracture	病的骨折	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	11	50	N	None	Recovered
			Arrhythmia	不整脈	1	N	TE	29		N	None	Not recovered, but no changes expected
			Chills	悪寒	1	N	TE	29		Y	None	Recovered
			Oedema	浮腫	3	N	TE	29		N	Not applicable	Ongoing at time of death
			Magnesium deficiency	マグネシウム欠乏	1	N	TE	29	29	N	None	Recovered
			General physical health deterioration	全身健康状態低下	3	N	TE	57		N	None	Not recovered, but no changes expected

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pathological fracture	病的骨折	2	N	TE	61		N	None	Not recovered, but no changes expected
			Dyspepsia	消化不良	2	N	TE	65		N	None	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	Y	TE	65	15	N	None	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	3	N	TE	66		N	None	Not recovered, but no changes expected
			Metastases to liver	肝転移	2	N	TE	86		N	None	Not recovered, but no changes expected
			Metastases to liver	肝転移	2	N	TE	86		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	91	5	Y	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	92		N	Not applicable	Ongoing at time of death
			Anxiety	不安	2	N	TE	93		N	Not applicable	Ongoing at time of death
			Myocardial infarction	心筋梗塞	3	Y	TE	95		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	97	1	N	Drug permanently withdrawn	Death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
024014	Sweden	74/M/C	Dry eye	眼乾燥	1	N	TE	15		N	None	Ongoing at time of death
			Skin infection	皮膚感染	2	N	TE	53	9	N	None	Recovered
			Metastases to bone	骨転移	1	N	TE	53		N	None	Not recovered, but no changes expected
			Micturition urgency	尿意切迫	1	N	TE	53		N	None	Not recovered, but no changes expected
			Hypoaesthesia	感覚鈍麻	2	N	TE	61		N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	81		N	None	Not recovered, but no changes expected
			Dizziness	浮動性めまい	2	N	TE	81	27	N	None	Recovered
			Viral skin infection	皮膚ウイルス感染	2	N	TE	100		N	None	Ongoing at time of death
			Atrial fibrillation	心房細動	2	Y	TE	101	7	N	None	Recovered
			Oral fungal infection	口腔真菌感染	2	N	TE	103		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	126	1	N	Drug permanently withdrawn	Death
024022	Sweden	84/M/C	Constipation	便秘	2	N	TE			N	Not applicable	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pneumonia	肺炎	4	Y	TE			N	Drug permanently withdrawn	Ongoing at time of death
			Hip fracture	股関節部骨折	3	Y	Pre			N	Drug administration postponed	Recovered
			Pulmonary oedema	肺水腫	4	Y	TE			N	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	Y	Pre	-33	14	N	Drug administration postponed	Recovered with sequelae
			Urinary retention	尿閉	2	Y	Pre	-33	14	N	Drug administration postponed	Recovered with sequelae
			Vomiting	嘔吐	3	N	Pre	-18	10	N	Not applicable	Recovered
			Pyrexia	発熱	3	N	Pre	-18	10	N	Not applicable	Recovered
			Dislocation of joint prosthesis	人工骨頭関節脱臼	3	Y	Pre	-18	10	N	Not applicable	Recovered
			Bone pain	骨痛	3	N	Pre	-18	10	N	Not applicable	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pathological fracture	病的骨折	3	Y	TE	6		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	6	43	N	Drug permanently withdrawn	Death
			Sepsis	敗血症	3	Y	TE	15		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	48	1	N	Drug permanently withdrawn	Death
024024	Sweden	82/M/C	Fatigue	疲労	2	N	TE	59	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	112		N	None	Not recovered, but no changes expected
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	132	16	N	Drug permanently withdrawn	Not recovered, but no changes expected
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	148	14	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	161	1	N	Not applicable	Death
025002	Sweden	64/M/C	Nausea	悪心	1	N	TE	60	149	Y	None	Recovered
			Tremor	振戦	1	N	TE	88		N	None	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Listeriosis	リステリア症	2	Y	TE	92	26	N	Drug administration postponed	Recovered
			Fatigue	疲労	2	N	TE	155		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Haematuria	血尿	1	N	TE	185		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	204	5	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	208	1	N	Not applicable	Death
028005	Belgium	70/M/C	Radiculitis	神経根炎	2	N	Pre	-8		N	None	Ongoing at time of death
			Pathological fracture	病的骨折	3	Y	TE	21	3	N	None	Recovered
			Anaemia	貧血	3	N	TE	22	1	N	None	Recovered
			General physical health deterioration	全身健康状態低下	3	Y	TE	26	14	Y	None	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	82	12	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	93	1	N	Drug permanently withdrawn	Death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
029002	Belgium	81/M/C	Fatigue	疲労	1	N	TE	41	32	N	None	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	1	N	TE	41	30	N	None	Recovered
			Depression	うつ病	1	N	TE	59		N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	2	N	TE	72		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	105	2	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	106		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	Y	TE	106	12	N	None	Recovered
			Muscular weakness	筋力低下	1	N	TE	109		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	117		N	Not applicable	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	128	31	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	158	1	N	Not applicable	Death
033001	UK	84/M/C	Oedema peripheral	末梢性浮腫	1	N	Pre	1		N	None	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Lymphadenopathy	リンパ節症	1	N	TE	25		N	None	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	2	N	TE	25		N	None	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	25	14	N	None	Ongoing at time of death
			Muscular weakness	筋力低下	2	N	TE	29		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	29		N	None	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	N	TE	38		N	None	Ongoing at time of death
			Pulmonary embolism	肺塞栓症	5	Y	TE	59	1	N	None	Death
033014	UK	73/M/C	Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Pitting oedema	圧痕浮腫	2	N	TE			N	None	Ongoing at time of death
			Weight increased	体重増加	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			Y	None	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	1	N	TE			N	None	Not recovered, but no changes expected

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	112		Y	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	112	2	N	None	Recovered
			Nausea	悪心	1	N	TE	177	3	Y	None	Recovered
			Dysphasia	不全失語症	3	N	TE	177	3	N	None	Recovered
			Pleuritic pain	胸膜痛	3	Y	TE	177	3	N	Not applicable	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	184	1	N	Not applicable	Death
033017	UK	80/M/C	Abdominal pain lower	下腹部痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			Y	None	Recovered
			Dysuria	排尿困難	1	N	TE			N	None	Recovered
			Pollakiuria	頻尿	2	N	TE			N	None	Recovered with sequelae
			Pollakiuria	頻尿	2	N	TE			N	None	Recovered
			Urine flow decreased	尿流量減少	2	N	TE			N	None	Not recovered, but no changes expected
			Skin lesion	皮膚病変	1	N	TE			N	None	Not recovered, but no changes expected
			Pulmonary embolism	肺塞栓症	5	Y	TE	124	1	N	None	Death
039011	UK	65/M/C	Bone pain	骨痛	3	Y	Pre	-37	3	N	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	1	N	TE	3		N	None	Ongoing at time of death
			Nausea	悪心	3	Y	TE	4	4	Y	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dizziness	浮動性めまい	3	N	TE	5	17	Y	None	Ongoing at time of death
			Vomiting	嘔吐	3	N	TE	8		Y	None	Recovered
			Nausea	悪心	3	Y	TE	10		Y	Drug administration postponed	Ongoing at time of death
			Retching	レッチング	3	N	TE	10	12	Y	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	10	12	Y	None	Ongoing at time of death
			Paraesthesia	錯感覚	3	N	TE	10	12	N	None	Ongoing at time of death
			Somnolence	傾眠	1	N	TE	12		N	None	Ongoing at time of death
			Somnolence	傾眠	1	N	TE	12		N	None	Ongoing at time of death
			Tachycardia	頻脈	2	N	TE	13	9	N	None	Ongoing at time of death
			Abdominal pain	腹痛	2	N	TE	13	9	N	None	Ongoing at time of death
			Pleural effusion	胸水	2	N	TE	13	9	N	None	Ongoing at time of death
			Pleural effusion	胸水	3	N	TE	14	5	N	Drug administration postponed	Death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Sepsis	敗血症	2	N	TE	15	7	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	15	7	N	None	Ongoing at time of death
			Rash	発疹	2	N	TE	15	7	N	None	Ongoing at time of death
			Chest pain	胸痛	3	N	TE	17	5	N	None	Ongoing at time of death
			Depressed mood	抑うつ気分	2	N	TE	17	5	N	None	Ongoing at time of death
			Vomiting	嘔吐	3	N	TE	18		N	None	Ongoing at time of death
			Pleural effusion	胸水	4	Y	TE	18	4	N	Drug administration postponed	Death
			Constipation	便秘	3	N	TE	19	3	N	None	Ongoing at time of death
			Abdominal pain lower	下腹部痛	1	N	TE	20	2	N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	3	N	TE	20	2	N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	20	2	N	None	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pleural effusion	胸水	5	Y	TE	21	1	N	Drug administration postponed	Death
041007	UK	62/M/C	Lymphadenopathy	リンパ節症	1	N	Pre	1		N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	7		Y	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	7		N	None	Ongoing at time of death
			Eyelid function disorder	眼瞼機能障害	2	N	TE	12	19	N	None	Recovered
			Vision blurred	霧視	1	N	TE	12		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	29		Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	29		Y	None	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	29		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	60	6	N	None	Death
			Muscular weakness	筋力低下	2	N	TE	61		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	65	1	N	None	Death
042002	UK	64/M/C	Nausea	悪心	1	N	TE			Y	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	1	N	TE			Y	None	Recovered
			Peripheral coldness	末梢冷感	1	N	TE			N	None	Recovered
			Anorexia	食欲不振	1	N	TE			Y	None	Recovered
			Constipation	便秘	1	N	TE	3		Y	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	4	6	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	4	6	N	None	Recovered
			Bone pain	骨痛	2	N	TE	8	22	N	None	Recovered
			Tachycardia	頻脈	1	N	TE	28		N	None	Ongoing at time of death
			Hypotension	低血圧	1	N	TE	55	1	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	57	57	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	57	57	N	None	Recovered
			Spinal cord compression	脊髄圧迫	2	N	TE	58	56	N	None	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	164	12	N	Not applicable	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	192	1	N	Not applicable	Death
042003	UK	66/M/C	Anaemia	貧血	2	Y	TE	17	2	Y	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	17	7	N	None	Recovered
			Anaemia	貧血	3	N	TE	34	3	N	Not applicable	Recovered
			Cardiac failure congestive	うっ血性心不全	3	Y	TE	34	8	N	None	Death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	2	N	TE	34		N	Not applicable	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	34	4	N	Not applicable	Recovered
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	2	N	TE	34		N	Not applicable	Ongoing at time of death
			Hypokalaemia	低カリウム血症	3	N	TE	35	3	N	Not applicable	Recovered
			Rectal haemorrhage	直腸出血	1	N	TE	37	1	N	Not applicable	Recovered
			Neuropathy peripheral	末梢性ニューロパチー	2	N	TE	38		N	Not applicable	Ongoing at time of death
			Urinary tract obstruction	尿路閉塞	3	N	TE	38		N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	39		N	Not applicable	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	2	Y	TE	39		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	40	2	N	Not applicable	Recovered
			Pneumonia	肺炎	3	N	TE	40		N	Not applicable	Ongoing at time of death
			Confusional state	錯乱状態	1	N	TE	40		N	Not applicable	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	5	Y	TE	41	1	N	None	Death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
042004	UK	74/M/C	Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Cough	咳嗽	1	N	TE			N	None	Ongoing at time of death
			Dysphonia	発声障害	1	N	TE			N	None	Ongoing at time of death
			Small intestinal obstruction	小腸閉塞	2	Y	Pre	-35	9	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	3	27	N	None	Recovered
			Epistaxis	鼻出血	1	N	TE	5	1	N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	30	8	N	None	Recovered
			Lethargy	嗜眠	1	N	TE	30	140	Y	None	Ongoing at time of death
			Dysgeusia	味覚異常	2	N	TE	41	3	N	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	45	2	N	None	Recovered
			Pathological fracture	病的骨折	2	Y	TE	55	9	N	None	Recovered
			Nausea	悪心	1	N	TE	56		N	None	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	58	6	Y	None	Recovered
			Eye pain	眼痛	1	N	TE	80	3	N	None	Recovered
			Bone pain	骨痛	1	N	TE	106	1	N	None	Recovered
			Bone pain	骨痛	1	N	TE	112	1	N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	1	N	TE	113		N	None	Ongoing at time of death
			Oral pain	口腔内痛	1	N	TE	119	1	N	None	Recovered
			Palpitations	動悸	1	N	TE	121	1	N	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	1	N	TE	141		N	None	Ongoing at time of death
			Contusion	挫傷	1	N	TE	141		N	None	Ongoing at time of death
			Lethargy	嗜眠	2	N	TE	169		Y	None	Ongoing at time of death
			Pleural effusion	胸水	1	N	TE	169		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	198	1	N	Not applicable	Death
042024	UK	62/M/C	Fatigue	疲労	1	N	TE			N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE			N	None	Ongoing at time of death
			Confusional state	錯乱状態	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	1	29	Y	None	Recovered
			Anxiety	不安	1	N	TE	2	28	N	None	Recovered
			Hyperhidrosis	多汗症	2	N	TE	2		N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	8		N	None	Ongoing at time of death
			Pyrexia	発熱	1	N	TE	62	1	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	64		N	None	Ongoing at time of death
			Dysuria	排尿困難	2	N	TE	80	6	N	Not applicable	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	3	Y	TE	83	6	N	None	Recovered
			Pyrexia	発熱	3	Y	TE	83	6	N	None	Recovered
			Confusional state	錯乱状態	3	Y	TE	83	1	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	99	23	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	121	1	N	Not applicable	Death
050001	UK	80/M/C	Anaemia	貧血	3	N	TE			N	Not applicable	Recovered with sequelae
			Fatigue	疲労	2	N	TE			Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Ear infection	耳感染	2	N	TE			N	None	Recovered
			Anorexia	食欲不振	1	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at study termination / withdrawal
			Upper respiratory tract infection	上気道感染	2	N	Pre	-14	8	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	1	29	Y	-	
			Nausea	悪心	2	N	TE	2	2	Y	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	8	14	Y	None	Recovered
			Muscular weakness	筋力低下	2	N	TE	8	14	N	None	Recovered
			Myalgia	筋痛	2	N	TE	8	22	N	None	Recovered
			Fatigue	疲労	3	N	TE	21	4	Y	None	Recovered
			Muscular weakness	筋力低下	3	N	TE	21	9	N	None	Recovered
			Fatigue	疲労	1	N	TE	24	37	Y	None	Recovered
			Anaemia	貧血	1	N	TE	29	29	Y	-	
			Nausea	悪心	2	N	TE	30	1	Y	None	Recovered
			Hot flush	ほてり	2	N	TE	30		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	34	1	Y	None	Recovered
			Anaemia	貧血	3	N	TE	57	5	Y	-	
			Anaemia	貧血	1	N	TE	61	12	Y	-	
			Urinary tract infection	尿路感染	2	N	TE	61	6	N	None	Recovered
			Urinary retention	尿閉	3	Y	TE	61	2	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	72	70	Y	-	
			Haemorrhage urinary tract	尿路出血	2	N	TE	80	2	N	None	Recovered
			Urinary retention	尿閉	1	N	TE	84		N	None	Ongoing at study termination / withdrawal
			Urinary retention	尿閉	1	N	TE	84	3	N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	1	N	TE	85	57	N	None	Ongoing at study termination / withdrawal
			Urinary retention	尿閉	2	N	TE	86		N	None	Ongoing at study termination / withdrawal
			Insomnia	不眠症	2	N	TE	101	5	N	None	Recovered
			Fatigue	疲労	3	N	TE	113		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Muscular weakness	筋力低下	2	N	TE	113		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	N	TE	141	9	Y	-	
			Constipation	便秘	1	N	TE	141		Y	Not applicable	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	2	N	TE	141		N	None	Ongoing at study termination / withdrawal
			Muscular weakness	筋力低下	3	N	TE	141		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	4	N	TE	149	3	Y	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	151		Y	None	Ongoing at study termination / withdrawal
			Cranial neuropathy	脳ニューロパチー	2	N	TE	155		N	None	Ongoing at time of death
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	2	N	TE	155		N	None	Ongoing at time of death
			Oral candidiasis	口腔カンジダ症	2	N	TE	190		N	None	Ongoing at time of death
			Anaemia	貧血	4	Y	TE	192	5	N	Not applicable	Recovered with sequelae
			Gastric cancer	胃癌	4	Y	TE	192	28	N	Not applicable	Death
			Gastric cancer	胃癌	5	Y	TE	219	1	N	Not applicable	Death
050003	UK	60/M/C	Nausea	悪心	1	N	TE			N	None	Recovered
			Fatigue	疲労	2	N	TE			N	-	
			Fatigue	疲労	3	N	TE			N	-	
			Weight decreased	体重減少	1	N	TE			N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE			N	None	Ongoing at time of death
			Muscular weakness	筋力低下	3	N	TE			N	None	Ongoing at time of death
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE			N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	N	TE	6	10	N	-	

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema genital	性器浮腫		N	TE	10		N	None	Ongoing at time of death
			Pharyngolaryngeal pain	咽喉頭疼痛	1	N	TE	13		N	None	Recovered
			Contusion	挫傷	1	N	TE	14		Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	15	9	N	-	
			Constipation	便秘	2	N	TE	16		Y	None	Ongoing at time of death
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE	16		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	18		N	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	19	3	N	-	
			Pollakiuria	頻尿	1	N	TE	19	4	N	None	Recovered
			Fatigue	疲労	3	N	TE	21		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	4	N	TE	23	8	N	-	
			Dysphagia	嚥下障害	2	N	TE	26		N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	1	N	TE	26	3	N	None	Recovered
			Oedema peripheral	末梢性浮腫	3	N	TE	29	2	N	Not applicable	Ongoing at time of death
			Abdominal pain	腹痛	3	N	TE	30	1	N	None	Recovered
			Oedema peripheral	末梢性浮腫	4	N	TE	30		N	Not applicable	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	4	N	TE	30		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	31	1	N	Drug permanently withdrawn	Death
			Agitation	激越	2	N	TE	31	1	N	Not applicable	Recovered
055007	Netherlands	62/M/C	Confusional state	錯乱状態	2	Y	Pre	-13	2	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	8		N	Not applicable	Ongoing at time of death
			Nausea	悪心	2	N	TE	8		N	Not applicable	Ongoing at time of death
			Intertrigo	間擦疹	1	N	TE	8		Y	Not applicable	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	35	2	N	None	Recovered
			Anaemia	貧血	3	N	TE	36		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	85	1	N	Not applicable	Death
072001	Spain	78/M/C	Fatigue	疲労	1	N	Pre			N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	10		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	21	7	N	None	Recovered
			Cardiac failure	心不全	4	Y	TE	31	5	N	None	Death
			Cardiac failure	心不全	5	Y	TE	35	1	N	None	Death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
080001	Italy	73/M/C	Nausea	悪心	1	N	TE			Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE			Y	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	130	9	N	None	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	138	1	N	None	Death
085001	Israel	58/M/C	Pyrexia	発熱	1	N	TE	31	1	N	None	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	58	7	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	58	7	N	None	Recovered with sequelae
			Pneumonia	肺炎	1	Y	TE	79		N	None	Ongoing at time of death
			Respiratory failure	呼吸不全	4	Y	TE	83	2	N	None	Death
			Respiratory failure	呼吸不全	5	Y	TE	84	1	N	None	Death
085003	Israel	74/M/C	Deep vein thrombosis	深部静脈血栓症	2	Y	Pre	-16	3	N	Not applicable	Recovered with sequelae
			Dermatitis contact	接触性皮膚炎	1	N	TE	37	8	N	None	Recovered
			Asthenia	無力症	1	N	TE	49	1	N	None	Recovered
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	55		N	None	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	TE	62		N	None	Ongoing at time of death
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	3	N	TE	62		N	None	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	TE	63	11	N	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Rectal haemorrhage	直腸出血	2	Y	TE	82	4	N	None	Recovered
			Haematuria	血尿	2	Y	TE	82	4	N	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	90		N	None	Ongoing at time of death
			Tremor	振戦	2	N	TE	90		N	None	Ongoing at time of death
			Hypochromic anaemia	低色素性貧血	2	N	TE	96		N	None	Ongoing at time of death
			Localised oedema	限局性浮腫	1	N	TE	104		N	None	Ongoing at time of death
			Lobar pneumonia	大葉性肺炎	3	Y	TE	104	8	N	Drug permanently withdrawn	Death
			General physical health deterioration	全身健康状態低下	3	Y	TE	107		N	Drug permanently withdrawn	Ongoing at time of death
			Urosepsis	尿路性敗血症	3	Y	TE	107		N	Drug permanently withdrawn	Ongoing at time of death
			Lobar pneumonia	大葉性肺炎	5	Y	TE	111	1	N	Drug permanently withdrawn	Death
093001	Slovakia	72/M/C	Anaemia	貧血	2	N	Pre	-13	14	N	None	Recovered
			Constipation	便秘	1	N	Pre	-13	57	N	None	Recovered with sequelae
			Hyperbilirubinaemia	高ビリルビン血症	2	Y	Pre	-13	5	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	2	Y	Pre	-13	5	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	N	Pre	-13	5	N	Not applicable	Recovered with sequelae
			Hyperbilirubinaemia	高ビリルビン血症	2	N	Pre	-9	3	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	1	N	Pre	-9	10	N	None	Recovered with sequelae
			Hyperbilirubinaemia	高ビリルビン血症	2	Y	Pre	-7	7	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	Y	TE	1	40	N	None	Recovered with sequelae
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	TE	35		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	35		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	35		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	44		N	None	Ongoing at time of death
			Constipation	便秘	2	Y	TE	44	11	N	None	Recovered with sequelae
			Bone pain	骨痛	2	Y	TE	44	11	N	None	Recovered with sequelae
			Pneumonia	肺炎	4	Y	TE	75		N	None	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	90	1	N	None	Death
095001	Slovakia	75/M/C	Bone pain	骨痛	4	N	TE	3	8	Y	Drug administration postponed	Recovered
			Bone pain	骨痛	2	N	TE	10	26	Y	Drug administration postponed	Recovered
			Bone pain	骨痛	3	N	TE	14	61	Y	Drug administration postponed	Recovered
			Nausea	悪心	1	N	TE	20	64	N	None	Recovered
			Fatigue	疲労	2	N	TE	20	118	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	35	40	Y	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	83		Y	Not applicable	Ongoing at time of death
			Cardiopulmonary failure	心肺不全	4	Y	Post	235	13	Y	Not applicable	Death
			Cardiopulmonary failure	心肺不全	5	Y	Post	247	1	Y	Not applicable	Death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
097001	Slovakia	70/M/C	Anaemia	貧血	2	N	Pre	1		N	None	Ongoing at time of death
			Sudden death	突然死	5	Y	TE	9	1	N	None	Death
097004	Slovakia	80/M/C	Fatigue	疲労	3	N	TE	3		N	None	Ongoing at time of death
			Cerebral ischaemia	脳虚血	4	Y	TE	3	36	N	Drug administration postponed	Recovered with sequelae
			Micturition disorder	排尿異常	2	N	TE	112		N	None	Ongoing at time of death
			Constipation	便秘	3	N	TE	114		N	None	Ongoing at time of death
			Diarrhoea	下痢	3	Y	TE	143	29	Y	Drug permanently withdrawn	Recovered
			Vomiting	嘔吐	3	Y	TE	143	29	Y	Drug permanently withdrawn	Recovered
			Pyrexia	発熱	3	Y	TE	143	29	N	Drug permanently withdrawn	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	143	29	N	Drug permanently withdrawn	Recovered
			Disorientation	失見当識	3	N	TE	143	29	N	Not applicable	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cardiopulmonary failure	心肺不全	5	Y	TE	176	1	N	Not applicable	Death
097007	Slovakia	70/M/C	Bone pain	骨痛	2	N	Pre	-9	38	N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	2	56	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	29	84	N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	29	112	N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	57	56	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	112	9	Y	None	Recovered
			Anorexia	食欲不振	2	N	TE	112		N	None	Ongoing at time of death
			Sleep disorder	睡眠障害	1	N	TE	112	49	N	None	Recovered
			Mixed incontinence	混合性尿失禁	3	N	TE	112		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	120		Y	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	140		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	Pre	140		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	160	1	N	Not applicable	Death
097010	Slovakia	80/M/C	Nausea	悪心	1	N	TE	2	56	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	2		Y	None	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	1	N	TE	29	58	N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	64	6	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	64	6	N	None	Recovered
			Nausea	悪心	1	N	TE	86	91	Y	None	Recovered
			Fatigue	疲労	3	Y	TE	86	5	Y	Drug administration postponed	Recovered with sequelae
			Weight decreased	体重減少	2	N	TE	86		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	90	68	Y	None	Recovered with sequelae
			Vomiting	嘔吐	2	N	TE	152	6	Y	None	Recovered
			Anaemia	貧血	2	N	TE	157	5	Y	None	Recovered
			Fatigue	疲労	3	Y	TE	157	5	Y	None	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	206	1	N	Not applicable	Death
106012	Hong Kong	75/M/A	Cystitis	膀胱炎	2	N	TE	7	7	N	None	Recovered
			Anaemia	貧血	2	Y	TE	29	2	Y	None	Recovered
			Constipation	便秘	1	N	TE	29	29	Y	None	Recovered
			Faeces discoloured	変色便	1	N	TE	29	29	N	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	29	29	N	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	57	3	Y	Drug administration postponed	Recovered
			Hyperkalaemia	高カリウム血症	1	N	TE	57	23	N	None	Recovered
			Haematuria	血尿	1	N	TE	57	23	N	None	Recovered
			Gastroduodenal ulcer	胃十二指腸潰瘍	1	N	TE	73		N	None	Ongoing at time of death
			Haemorrhoids	痔核	1	N	TE	73	7	N	None	Recovered
			Muscular weakness	筋力低下	2	N	TE	77		N	None	Ongoing at time of death
			Sepsis	敗血症	2	N	TE	79	20	N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	79		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	79		N	Drug permanently withdrawn	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	2	N	TE	80		N	None	Ongoing at time of death
			Convulsion	痙攣	2	N	TE	85		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	4	Y	TE	90		N	Not applicable	Ongoing at time of death
			Pyrexia	発熱	2	N	TE	91	4	N	Not applicable	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Diabetes mellitus	糖尿病	2	N	TE	91	16	N	Not applicable	Recovered
			Anxiety	不安	2	N	TE	94	13	N	Not applicable	Recovered
			Metastases to bone	骨転移	5	Y	TE	106	1	N	Not applicable	Death
133022	Poland	84/M/C	General physical health deterioration	全身健康状態低下	4	N	TE	77		N	None	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	3	Y	TE	77	8	N	Drug permanently withdrawn	Death
			Dyspnoea	呼吸困難	5	Y	TE	84	1	N	Drug permanently withdrawn	Death
133029	Poland	56/M/C	Nausea	悪心	1	N	TE	2	2	Y	None	Recovered
			Asthenia	無力症	2	N	TE	2	3	Y	None	Recovered
			Urinary retention	尿閉	2	N	TE	53	4	N	None	Recovered
			Subileus	亜イレウス	3	Y	TE	63	5	Y	Drug administration postponed	Recovered
			Renal failure	腎不全	3	Y	TE	82	10	N	Drug permanently withdrawn	Death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Renal failure	腎不全	5	Y	TE	91	1	N	Drug permanently withdrawn	Death
141002	Poland	60/M/C	Haematuria	血尿	2	Y	TE	10	27	N	None	Recovered
			Haematuria	血尿	3	Y	TE	40	11	N	None	Recovered with sequelae
			Haematuria	血尿	2	N	TE	50		N	None	Not recovered, but no changes expected
			Hydronephrosis	水腎症	2	Y	TE	56	5	N	Drug administration postponed	Recovered with sequelae
			Anaemia	貧血	3	Y	TE	90	3	N	None	Recovered with sequelae
			Thrombocytopenia	血小板減少症	2	N	TE	92		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	2	N	TE	92		N	None	Ongoing at study termination / withdrawal
			Dyspnoea	呼吸困難	3	Y	TE	95	5	N	Not applicable	Death
			Dyspnoea	呼吸困難	5	Y	TE	99	1	N	Not applicable	Death
148005	Germany	63/M/C	Nausea	悪心	1	N	TE	27	1	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	57	38	Y	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	57	29	Y	None	Recovered
			Nausea	悪心	1	N	TE	59	5	Y	None	Recovered
			Fatigue	疲労	2	N	TE	64		Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	85	1	Y	None	Recovered
			Anaemia	貧血	1	Y	TE	94	2	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	112		N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	114	4	Y	None	Recovered
			Nausea	悪心	1	N	TE	114	4	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	114	4	Y	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	129	1	N	None	Death
149005	Germany	73/M/C	Bone pain	骨痛	1	N	TE	13	31	Y	None	Recovered
			Abdominal pain	腹痛	1	N	TE	31	13	Y	None	Recovered
			Nausea	悪心	1	N	TE	64	3	N	None	Recovered
			Fatigue	疲労	1	N	TE	64	5	N	Drug permanently withdrawn	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	64		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	1	N	TE	64	28	N	-	
			Insomnia	不眠症	1	N	TE	64	4	N	None	Recovered
			Fatigue	疲労	2	N	TE	68	13	N	Drug permanently withdrawn	Ongoing at time of death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	3	N	TE	80		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	91	24	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	114	2	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	115	1	N	Not applicable	Death
172001	Brazil	75/M/C	Fatigue	疲労	2	N	TE	31		N	None	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	1	N	TE	31	29	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	36	4	N	None	Recovered
			Nasal congestion	鼻閉	1	N	TE	38	22	N	None	Recovered
			Cachexia	悪液質	3	N	TE	59		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	86	2	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	86	28	N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	87		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	113		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	212	1	N	Not applicable	Death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
181006	Brazil	75/M/B	Sepsis	敗血症	4	Y	TE	146	11	N	None	Death
			Hypernatraemia	高ナトリウム血症	4	N	TE	146		N	Drug administration postponed	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	146		N	None	Ongoing at time of death
			Renal failure acute	急性腎不全	4	N	TE	146		N	Drug permanently withdrawn	Ongoing at time of death
			Respiratory failure	呼吸不全	4	N	TE	146		N	Drug permanently withdrawn	Ongoing at time of death
			Sepsis	敗血症	5	Y	TE	156	1	N	None	Death
207002	Australia	81/M/C	Anorexia	食欲不振	2	N	TE			N	None	Lost to follow-up
			Urinary incontinence	尿失禁	2	N	TE			N	None	Lost to follow-up
			Oedema peripheral	末梢性浮腫	1	N	TE	58		N	None	Lost to follow-up
			Swelling face	顔面腫脹	1	N	TE	58		N	None	Lost to follow-up
			Faecal incontinence	便失禁	1	N	TE	104		N	None	Ongoing at time of death
			Dementia	認知症	3	Y	TE	104	7	N	Drug permanently withdrawn	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	137	1	N	Not applicable	Death

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
233003	UK	61/M/C	Anorexia	食欲不振	1	N	Pre	-13	22	N	None	Recovered with sequelae
			Fatigue	疲労	2	N	Pre	1	163	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre	1	29	N	None	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	29	36	Y	None	Recovered
			Bone pain	骨痛	2	N	Pre	29	36	N	None	Ongoing at time of death
			Ageusia	味覚消失	2	N	TE	29	36	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	58	4	N	None	Recovered
			Constipation	便秘	2	N	TE	60		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	64	25	N	None	Recovered
			Bone pain	骨痛	3	N	Pre	64		N	None	Ongoing at time of death
			Muscular weakness	筋力低下	3	N	TE	64		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	92	17	N	None	Recovered
			Tachycardia	頻脈	1	N	TE	92		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	92		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	104	60	N	None	Recovered

表 2.7.4.7- 12 死亡例の一覧（試験 BC1-06、中間解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	135	3	N	Drug administration postponed	Recovered
			Asthenia	無力症	3	N	TE	135	3	Y	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	138		N	Drug administration postponed	Ongoing at study termination / withdrawal
			Dysarthria	構語障害	1	N	TE	145		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	3	N	TE	152	12	N	None	Death
			Cardiac failure	心不全	4	Y	TE	152		N	Drug permanently withdrawn	Ongoing at time of death
			Pleural effusion	胸水	2	N	TE	152		N	Not applicable	Ongoing at time of death
			Nausea	悪心	2	N	TE	159	5	N	Not applicable	Ongoing at time of death
			Anaemia	貧血	5	Y	TE	163	1	N	None	Death

Sex is identified as: M = Male.

Race is identified as: A = Asian, B = Black, C = Caucasian, O = Other.

The unit for "Age" is years.

Phase is identified as: Pre = Pre-Treatment, TE = Treatment-Emergent, Post = Post-Treatment

Source: 5.3.5.1.3 BC1-06_J-table 1/Table 1.4/2

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）

Treatment：BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
001023	Norway	62/M/C	Bone pain	骨痛	2	N	Pre	1		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	29		Y	None	Ongoing at study termination / withdrawal
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	57		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	TE	57		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	57		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	57	19	N	Drug permanently withdrawn	Death
			Metastases to liver	肝転移	3	Y	TE	57		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	75	1	N	Drug permanently withdrawn	Death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
002006	Norway	66/M/C	Bone pain	骨痛	2	N	Pre			N	None	Ongoing at study termination / withdrawal
			Urinary tract infection	尿路感染	3	N	TE	10	10	N	None	Recovered
			Anaemia	貧血	2	N	TE	29	34	N	None	Recovered
			Bone pain	骨痛	1	N	Pre	29	29	N	None	Ongoing at study termination / withdrawal
			Ascites	腹水	1	N	TE	57	6	N	None	Recovered
			Bone pain	骨痛	2	N	Pre	57		N	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	Y	TE	62	18	N	Drug permanently withdrawn	Recovered with sequelae
			Fungal infection	真菌感染	2	N	TE	76	5	N	None	Recovered
			Anxiety	不安	2	N	TE	77		N	None	Not recovered, but no changes expected
			Sepsis	敗血症	4	Y	TE	79	5	N	Not applicable	Death
			Anaemia	貧血	2	N	TE	81	2	N	None	Recovered
			Sepsis	敗血症	5	Y	TE	83	1	N	Not applicable	Death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
002013	Norway	69/M/C	Vision blurred	霧視	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	2	5	Y	None	Recovered
			Metastases to skin	皮膚転移	1	N	TE	57		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	85		N	None	Ongoing at study termination / withdrawal
			Metastases to soft tissue	軟部組織転移	1	N	TE	86		N	None	Ongoing at time of death
			Cerebral haemorrhage	脳出血	3	Y	TE	100	38	Y	Drug permanently withdrawn	Death
			Anaemia	貧血	2	N	TE	110		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	111		Y	Not applicable	Ongoing at time of death
			Cerebral haemorrhage	脳出血	5	Y	TE	137	1	Y	Drug permanently withdrawn	Death
003018	Norway	71/M/C	Constipation	便秘	2	N	TE			N	Not applicable	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Musculoskeletal pain	筋骨格痛	2	N	TE	2	134	N	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	1	N	TE	57	102	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	116	57	N	Not applicable	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	3	N	TE	135	24	N	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	2	N	TE	147	72	N	Not applicable	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	3	Y	TE	158	5	N	Not applicable	Recovered with sequelae
			Pelvic pain	骨盤痛	3	N	TE	162		Y	Not applicable	Ongoing at time of death
			Nausea	悪心	2	N	TE	172		N	Not applicable	Ongoing at time of death
			Weight decreased	体重減少	3	N	TE	172		N	Not applicable	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	3	Y	TE	172	38	N	Not applicable	Recovered with sequelae
			Gastric ulcer	胃潰瘍	3	N	TE	181		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	187	1	Y	Not applicable	Recovered
			Depression	うつ病	3	N	TE	208		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	218	1	N	Not applicable	Death
004001	Norway	60/M/C	Dysgeusia	味覚異常	1	N	TE	2	28	Y	None	Recovered
			Anaemia	貧血	1	N	TE	92	24	Y	None	Recovered
			Anaemia	貧血	1	N	TE	92	24	Y	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	92	113	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	120		Y	None	Ongoing at time of death
			Respiratory tract infection viral	ウイルス性気道感染	2	N	TE	134	11	N	None	Recovered
			Anaemia	貧血	2	N	TE	144		Y	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	2	N	TE	148	37	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	148	12	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	148	12	Y	None	Recovered with sequelae
			Pancytopenia	汎血球減少症	3	N	TE	155	5	Y	Not applicable	Recovered with sequelae
			Pancytopenia	汎血球減少症	3	Y	TE	159	11	Y	Not applicable	Recovered with sequelae
			Oedema	浮腫	2	Y	TE	159	11	Y	Not applicable	Recovered with sequelae

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	3	Y	TE	159	11	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	Y	TE	159	11	Y	Not applicable	Recovered with sequelae
			Pancytopenia	汎血球減少症	2	N	TE	169	16	Y	Not applicable	Recovered with sequelae
			Dyspnoea	呼吸困難	2	N	TE	169	16	Y	Not applicable	Recovered
			Pleural effusion	胸水	1	N	TE	170	15	Y	Not applicable	Recovered
			Pancytopenia	汎血球減少症	3	Y	TE	184	15	Y	Not applicable	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	3	Y	TE	184	15	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	Y	TE	184	15	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	Y	TE	184	15	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	198	7	Y	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	198	7	Y	Not applicable	Recovered with sequelae
			Pancytopenia	汎血球減少症	4	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	204		Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	3	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	3	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Pleural effusion	胸水	2	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Renal failure	腎不全	5	Y	TE	208	1	N	Not applicable	Death
005002	Norway	75/M/C	Bone pain	骨痛	1	N	TE			N	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	85		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	162	36	N	Not applicable	Recovered
			Pneumonia	肺炎	3	Y	TE	169	15	N	Not applicable	Recovered
			Atrial fibrillation	心房細動	2	Y	TE	180	1	N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	197	7	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	198	6	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	1	N	TE	203		Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pulmonary embolism	肺塞栓症	4	Y	TE	222	5	Y	Not applicable	Death
			Pulmonary embolism	肺塞栓症	5	Y	TE	226	1	Y	Not applicable	Death
006005	Norway	72/M/C	Diarrhoea	下痢	1	N	TE	3	1	Y	None	Recovered
			Pyrexia	発熱	2	Y	TE	22	7	N	None	Recovered
			Dehydration	脱水	2	Y	TE	22	7	N	None	Recovered
			Vomiting	嘔吐	1	Y	TE	38	1	N	None	Recovered
			Pyrexia	発熱	2	Y	TE	38	1	Y	None	Recovered
			Dehydration	脱水	2	Y	TE	38	6	Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	2	Y	TE	38	6	N	None	Recovered
			Vomiting	嘔吐	2	Y	TE	62	11	Y	None	Recovered
			Dehydration	脱水	2	Y	TE	62	11	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	62	11	N	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	85	15	N	None	Recovered with sequelae
			Dyspepsia	消化不良	2	N	TE	86		N	None	Ongoing at time of death
			Depression	うつ病	2	N	TE	99		N	None	Ongoing at time of death
			Pneumonia	肺炎	3	Y	TE	176	2	N	Not applicable	Death
			Bone pain	骨痛	3	Y	TE	176		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pneumonia	肺炎	5	Y	TE	177	1	N	Not applicable	Death
006008	Norway	70/M/C	Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	Pre	-1	29	N	None	Ongoing at time of death
			Hydronephrosis	水腎症	3	Y	Pre	-1	3	N	None	Recovered
			Constipation	便秘	2	N	TE	2	25	Y	None	Recovered
			Nausea	悪心	1	N	TE	2	6	Y	None	Recovered
			Fatigue	疲労	2	N	TE	2	6	N	None	Recovered
			Hyperhidrosis	多汗症	2	N	TE	2	6	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	17	11	N	None	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	Pre	28		N	None	Ongoing at time of death
			Small intestinal obstruction	小腸閉塞	3	Y	TE	55	3	N	Drug administration postponed	Recovered
			Death	死亡	5	Y	TE	60	1	N	Drug permanently withdrawn	Death
006055	Norway	63/M/C	Petechiae	点状出血	2	N	TE			N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nerve root compression	神経根圧迫	3	Y	Pre	-33	4	N	None	Recovered
			Groin pain	鼠径部痛	2	N	Pre	-2	3	N	None	Recovered
			Nerve root compression	神経根圧迫	3	Y	TE	1	4	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	1	4	N	None	Recovered
			Pyrexia	発熱	1	N	TE	23	3	N	None	Recovered
			Oedema peripheral	末梢性浮腫	3	Y	TE	24	4	N	None	Recovered with sequelae
			Hypoalbuminaemia	低アルブミン血症	2	N	TE	24	4	N	None	Ongoing at study termination / withdrawal
			Hypoaesthesia	感覚鈍麻	1	N	TE	24		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	27	8	N	None	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	2	N	TE	27	8	N	None	Ongoing at study termination / withdrawal
			Hypoalbuminaemia	低アルブミン血症	1	N	TE	27		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cardiac failure	心不全	2	N	TE	28		N	None	Ongoing at study termination / withdrawal
			Pyrexia	発熱	1	N	TE	28	2	N	None	Recovered
			Pneumonia	肺炎	3	Y	TE	28	6	N	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	28	7	N	None	Recovered
			Pleural effusion	胸水	2	N	TE	28	7	N	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	30	3	N	None	Recovered
			Pulmonary hypertension	肺高血圧症	2	N	TE	32		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	34	5	N	None	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	1	N	TE	34		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	38	31	N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	52	18	N	None	Ongoing at study termination / withdrawal
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	Y	TE	52	3	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	53	11	N	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	4	Y	TE	66	2	Y	Drug administration postponed	Recovered with sequelae
			Hypokalaemia	低カリウム血症	1	N	TE	66		N	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	Y	TE	66		N	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	3	N	TE	67	4	N	None	Ongoing at study termination / withdrawal
			Urinary tract infection	尿路感染	1	N	TE	67		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	N	TE	68		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	69		N	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	3	N	TE	70		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	4	N	TE	70	1	N	None	Ongoing at study termination / withdrawal
			General physical health deterioration	全身健康状態低下	3	N	TE	71		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	84	1	N	Not applicable	Death
008003	Norway	79/M/C	Nausea	悪心	2	N	Pre	1	25	N	None	Recovered
			Nausea	悪心	2	Y	TE	25	4	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	25		N	None	Ongoing at time of death
			Hypercalcaemia	高カルシウム血症	1	N	TE	25	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	27	2	Y	None	Recovered
			Nausea	悪心	2	N	TE	28		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	35	25	N	Drug permanently withdrawn	Recovered
			Dehydration	脱水	2	N	TE	51		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	59	1	N	Not applicable	Death
008011	Norway	69/M/C	Nausea	悪心	1	N	TE			N	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	1	N	TE			N	None	Recovered
			Fatigue	疲労	1	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE	2	2	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	2	2	N	None	Recovered
			Tendonitis	腱炎	2	N	TE	35		N	None	Recovered
			Constipation	便秘	1	N	TE	37		N	None	Recovered
			Nausea	悪心	1	N	TE	37	5	N	None	Recovered
			Musculoskeletal stiffness	筋骨格硬直	2	N	TE	99	15	N	None	Recovered
			Pharyngitis	咽頭炎	1	N	TE	138	3	N	None	Recovered
			Pathological fracture	病的骨折	2	N	TE	149		N	Not applicable	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	149	9	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	2	N	TE	157	10	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	166	6	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	167	22	N	None	Recovered
			Spinal cord compression	脊髄圧迫	3	N	TE	171	42	N	Not applicable	Ongoing at time of death
			Subileus	亜イレウス	2	Y	TE	181	4	N	Not applicable	Recovered
			Oesophageal pain	食道痛	1	N	TE	198	1	N	Not applicable	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cystitis	膀胱炎	1	N	TE	201	11	N	Not applicable	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	212	1	N	Not applicable	Death
011006	Czech Republic	68/M/C	Diarrhoea	下痢	1	N	TE	2	11	Y	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	150	256	Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	Y	TE	405		Y	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	4	Y	Post	405	2	Y	Not applicable	Death
			Pneumonia	肺炎	5	Y	Post	406	1	Y	Not applicable	Death
017003	Czech Republic	80/M/C	Cachexia	悪液質	4	Y	TE	115	10	N	None	Death
			Pneumonitis	肺臓炎	3	N	TE	115		N	None	Ongoing at time of death
			Cachexia	悪液質	5	Y	TE	124	1	N	None	Death
017004	Czech Republic	83/M/C	Angina pectoris	狭心症	3	Y	TE	105	15	N	None	Recovered with sequelae

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Depression	うつ病	2	N	TE	105	8	N	Drug administration postponed	Recovered
			Angina pectoris	狭心症	2	N	TE	119	184	N	None	Death
			Hypokalaemia	低カリウム血症	1	N	TE	119		N	None	Not recovered, but no changes expected
			Angina pectoris	狭心症	5	Y	TE	302	1	N	None	Death
017007	Czech Republic	80/M/C	Malignant neoplasm progression	悪性新生物進行	4	Y	TE	178	3	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	180	1	N	Not applicable	Death
017017	Czech Republic	77/M/C	General physical health deterioration	全身健康状態低下	4	Y	TE	151	2	N	Not applicable	Death
			General physical health deterioration	全身健康状態低下	5	Y	TE	152	1	N	Not applicable	Death
017018	Czech Republic	76/M/C	Bone pain	骨痛	1	Y	Pre	-61	10	N	None	Recovered
			Myocardial ischaemia	心筋虚血	4	Y	TE	146		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Myocardial infarction	心筋梗塞	5	Y	TE	154	1	N	Not applicable	Death
017027	Czech Republic	60/M/C	Anaemia	貧血	2	N	TE	79	43	N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	116	6	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	121	1	N	Drug permanently withdrawn	Death
017030	Czech Republic	86/M/C	Leukopenia	白血球減少症			TE			N	None	Recovered
			Anaemia	貧血	2	N	Pre	1		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	28		N	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	Y	TE	50	8	N	None	Recovered
			Thrombocytopenia	血小板減少症	3	Y	TE	50	8	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	Y	TE	57		N	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	5	Y	TE	59	1	N	None	Death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
017032	Czech Republic	57/M/C	Malignant neoplasm progression	悪性新生物進行	5	Y	TE	97	1	N	None	Death
020005	Sweden	71/M/C	Anorexia	食欲不振	2	N	TE			N	None	Ongoing at time of death
			Micturition urgency	尿意切迫	2	N	Pre			N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	1	4	Y	None	Recovered
			Fatigue	疲労	2	N	TE	1		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	1		Y	None	Not recovered, but no changes expected
			Musculoskeletal pain	筋骨格痛	1	N	TE	1	4	Y	None	Recovered
			Haematuria	血尿	2	N	TE	11		N	None	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	17	3	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	33	5	Y	None	Recovered
			Constipation	便秘	3	N	TE	39		N	None	Ongoing at study termination / withdrawal
			Chills	悪寒	1	N	TE	54		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	Y	TE	75	14	N	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	91	22	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	112	1	N	Drug permanently withdrawn	Death
020015	Sweden	74/M/C	Nausea	悪心	1	N	Pre			N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE			N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	N	TE			Y	None	Ongoing at time of death
			Myalgia	筋痛	1	N	Pre			N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE			Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	19		Y	None	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	3	Y	TE	28	15	Y	Drug administration postponed	Recovered with sequelae
			Constipation	便秘	2	N	TE	28		Y	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	2	N	TE	28	15	Y	None	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	1	N	TE	42		Y	None	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE	42		Y	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	106	5	N	Drug permanently withdrawn	Death
024007	Sweden	63/M/C	Insomnia	不眠症	1	N	Pre	-2		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	Pre	-1		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	1	2	Y	None	Recovered
			Cystitis	膀胱炎	2	N	TE	30	41	N	None	Recovered
			Oedema	浮腫	2	N	TE	63	106	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	75		N	None	Not recovered, but no changes expected
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	114		N	None	Not recovered, but no changes expected

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Erysipelas	丹毒	2	N	TE	128		N	None	Recovered
			Thrombophlebitis	血栓性静脈炎	1	N	TE	128		N	None	Recovered
			Bone pain	骨痛	3	Y	TE	138		N	None	Ongoing at time of death
			Metastases to liver	肝転移	3	N	TE	141	28	N	Not applicable	Death
			Anaemia	貧血	2	N	TE	158	4	Y	Not applicable	Recovered
			Metastases to liver	肝転移	5	Y	TE	168	1	N	Not applicable	Death
024017	Sweden	73/M/C	Bone pain	骨痛	2	N	TE	34		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	64	27	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	64		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	117	30	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	204	1	N	Not applicable	Death
025004	Sweden	63/M/C	Fatigue	疲労	1	N	TE	31	-1	Y	None	Recovered
			Upper respiratory tract infection bacterial	細菌性上気道感染	1	N	TE	48	12	N	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Haematuria	血尿	3	Y	TE	82		N	Drug administration postponed	Ongoing at time of death
			Cardiac failure	心不全	4	Y	TE	90	2	N	Drug permanently withdrawn	Death
			Cardiac failure	心不全	5	Y	TE	91	1	N	Drug permanently withdrawn	Death
025014	Sweden	82/M/C	Haematuria	血尿	2	N	Pre			N	None	Recovered
			Fatigue	疲労	3	N	TE	29		N	Drug permanently withdrawn	Ongoing at time of death
			Hepatic failure	肝不全	3	Y	TE	29	9	N	Drug permanently withdrawn	Death
			Bone pain	骨痛	2	Y	TE	29		N	Drug permanently withdrawn	Ongoing at time of death
			Hepatic failure	肝不全	5	Y	TE	37	1	N	Drug permanently withdrawn	Death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
025015	Sweden	72/M/C	Fatigue	疲労	2	N	TE	57		N	None	Ongoing at study termination / withdrawal
			Lymphadenopathy	リンパ節症	2	N	TE	62		N	None	Ongoing at time of death
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	TE	62		N	None	Ongoing at study termination / withdrawal
			Metastases to liver	肝転移	5	Y	TE	88	1	N	Not applicable	Death
025020	Sweden	61/M/C	Bone pain	骨痛	2	Y	TE	42	3	N	None	Recovered
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE	70	71	N	None	Recovered
			Bone pain	骨痛	1	N	TE	127		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	132	8	N	None	Recovered
			Sepsis	敗血症	4	Y	TE	160	11	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	4	Y	TE	160	14	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	166		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	220	1	N	Not applicable	Death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
026001	Sweden	78/M/C	Bone pain	骨痛	3	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	3		N	None	Not recovered, but no changes expected
			Haematuria	血尿	1	N	TE	106	4	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	114		N	None	Ongoing at time of death
			Dehydration	脱水	2	Y	TE	117	12	N	None	Recovered
			Confusional state	錯乱状態	2	Y	TE	117	12	N	None	Recovered with sequelae
			Urinary retention	尿閉	2	N	TE	118		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	137	2	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	138	1	N	Drug permanently withdrawn	Death
026002	Sweden	66/M/C	Oesophageal spasm	食道痙攣	1	N	TE			N	None	Recovered
			Bone pain	骨痛	3	Y	Pre	-2	8	N	Not applicable	Recovered with sequelae
			Polyneuropathy	多発ニューロパチー	1	Y	TE	91	4	N	None	Recovered with sequelae

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Faecal incontinence	便失禁	3	Y	TE	108	8	N	None	Recovered with sequelae
			Hyperglycaemia	高血糖	3	Y	TE	108	8	N	None	Recovered with sequelae
			Urinary incontinence	尿失禁	3	Y	TE	108	8	N	None	Recovered with sequelae
			Pancytopenia	汎血球減少症	2	N	TE	124	6	N	Drug permanently withdrawn	Ongoing at time of death
			Fall	転倒・転落	3	Y	TE	124		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	124	13	N	None	Death
			Urinary retention	尿閉	2	N	TE	124		N	Not applicable	Ongoing at time of death
			Mouth ulceration	口腔内潰瘍形成	2	N	TE	125		N	Not applicable	Ongoing at time of death
			Pancytopenia	汎血球減少症	3	Y	TE	129		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	136	1	N	None	Death
028002	Belgium	72/M/C	General physical health deterioration	全身健康状態低下	2	Y	Pre	-9	19	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	Y	Pre	-9	19	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	3	N	Pre	-1	2	N	None	Recovered
			Anal ulcer	肛門潰瘍	2	N	Pre	-1	88	N	None	Recovered
			General physical health deterioration	全身健康状態低下	1	N	Pre	10		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	Pre	10		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	3	Y	TE	29	7	Y	Drug administration postponed	Recovered
			Weight decreased	体重減少	2	N	TE	29	28	N	None	Recovered
			Anorexia	食欲不振	3	N	TE	56	28	N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	56		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	Y	TE	83		Y	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	3	Y	TE	83	24	N	Drug permanently withdrawn	Death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	1	N	TE	83		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	87	20	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	91		N	Drug permanently withdrawn	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	105		N	Not applicable	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	5	Y	TE	106	1	N	Drug permanently withdrawn	Death
028003	Belgium	83/M/C	Nausea	悪心	1	N	TE	2	1	Y	None	Recovered
			Fatigue	疲労	1	N	TE	29		N	None	Ongoing at time of death
			Skin irritation	皮膚刺激	2	N	TE	50	15	N	None	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	55		Y	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	4	Y	TE	55		N	None	Ongoing at time of death
			Renal failure	腎不全	4	Y	TE	55		N	Drug permanently withdrawn	Ongoing at time of death
			Pulmonary oedema	肺水腫	4	Y	TE	55		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Multi-organ failure	多臓器不全	4	Y	TE	59	6	N	None	Death
			Multi-organ failure	多臓器不全	5	Y	TE	64	1	N	None	Death
028004	Belgium	84/M/C	Transient ischaemic attack	一過性脳虚血発作	2	Y	Pre	-13	55	N	Not applicable	Recovered
			Urinary retention	尿閉	2	N	Pre	-7	6	N	None	Recovered
			Pruritus	そう痒症	1	N	TE	8	7	N	None	Recovered with sequelae
			Pruritus	そう痒症	1	N	TE	8	27	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	14	48	N	None	Recovered
			Urinary tract infection	尿路感染	1	N	TE	28	29	N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	30		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	51		N	None	Ongoing at time of death
			Hypercholesterolaemia	高コレステロール血症	2	N	TE	51		N	None	Ongoing at time of death
			Inguinal hernia	鼠径ヘルニア	1	N	TE	55	14	N	None	Recovered
			Bone pain	骨痛	3	N	TE	57		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	93	1	N	Not applicable	Death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
028007	Belgium	65/M/C	Fatigue	疲労	1	N	TE	28		Y	None	Ongoing at study termination / withdrawal
			Feeling cold	冷感	1	N	TE	28	36	Y	None	Recovered
			Pallor	蒼白	1	N	TE	28		Y	None	Ongoing at study termination / withdrawal
			Pyrexia	発熱	2	N	TE	50	6	N	None	Recovered
			Urinary retention	尿閉	3	Y	TE	50	2	N	None	Recovered with sequelae
			Anaemia	貧血	3	N	TE	55	9	Y	None	Recovered with sequelae
			Pleurisy	胸膜炎	2	N	TE	56	23	N	None	Recovered
			Anaemia	貧血	2	N	TE	63		Y	None	Ongoing at study termination / withdrawal
			Tachycardia	頻脈	2	N	TE	91	15	N	None	Recovered
			Pleural effusion	胸水	2	N	TE	167	15	N	Not applicable	Recovered
			Paraesthesia	錯感覚	2	N	TE	168		N	None	Ongoing at study termination / withdrawal
			Lymphangiosis carcinomatosa	癌性リンパ管症	4	Y	TE	181	19	N	Not applicable	Recovered with sequelae
			Pleural effusion	胸水	4	Y	TE	181	2	N	Not applicable	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Lymphangiosis carcinomatosa	癌性リンパ管症	4	N	TE	199	5	N	Not applicable	Recovered with sequelae
			Lymphangiosis carcinomatosa	癌性リンパ管症	5	Y	TE	203	1	N	Not applicable	Death
033005	UK	83/M/C	Bone pain	骨痛	1	N	TE	1	3	Y	None	Recovered
			Myocardial infarction	心筋梗塞	4	Y	TE	82	3	N	None	Death
			Myocardial infarction	心筋梗塞	5	Y	TE	84	1	N	None	Death
033023	UK	69/M/C	Post-traumatic pain	外傷後疼痛	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at time of death
			Muscular weakness	筋力低下	3	N	TE			N	None	Ongoing at time of death
			Pathological fracture	病的骨折	2	N	TE			N	None	Not recovered, but no changes expected
			Constipation	便秘	1	N	Pre	-673	882	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	28		N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	85	65	N	None	Recovered with sequelae

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pathological fracture	病的骨折	3	Y	TE	149	20	Y	Drug administration postponed	Recovered
			Mobility decreased	運動性低下	2	N	TE	168	42	N	None	Ongoing at time of death
			Pathological fracture	病的骨折	2	N	TE	168		Y	None	Not recovered, but no changes expected
			Paraesthesia	錯感覚	1	Y	TE	175	5	N	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	178	7	N	None	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	178	32	N	None	Ongoing at time of death
			Upper limb fracture	上肢骨折	3	Y	TE	202		Y	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	5	Y	TE	209	1	N	Not applicable	Death
034004	UK	63/M/C	Nausea	悪心	1	N	TE	8		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	8		Y	None	Ongoing at time of death
			Oral candidiasis	口腔カンジダ症	1	N	TE	8		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dizziness	浮動性めまい	1	N	TE	8		N	None	Ongoing at time of death
			Cerebral ischaemia	脳虚血	4	Y	TE	43	5	N	None	Recovered with sequelae
			Anorexia	食欲不振	3	N	TE	53		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	92	9	N	Not applicable	Recovered
			Diarrhoea	下痢	3	N	TE	95	6	Y	Not applicable	Recovered
			Vomiting	嘔吐	3	N	TE	95	6	N	Not applicable	Recovered
			Anaemia	貧血	4	N	TE	98	2	N	Not applicable	Recovered
			Bone marrow failure	骨髄機能不全	4	Y	TE	98	9	N	Not applicable	Death
			Sinus tachycardia	洞性頻脈	1	N	TE	98		N	Not applicable	Ongoing at time of death
			Confusional state	錯乱状態	3	N	TE	98	2	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	98	2	N	Not applicable	Recovered
			Rash	発疹	2	N	TE	98		N	None	Ongoing at time of death
			Haematemesis	吐血	3	N	TE	99	2	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oesophagitis	食道炎	2	N	TE	99		N	Not applicable	Ongoing at time of death
			Bone marrow failure	骨髄機能不全	5	Y	TE	106	1	N	Not applicable	Death
035027	UK	68/M/C	Decreased appetite	食欲減退	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	1	3	Y	None	Recovered
			Constipation	便秘	2	N	TE	44		Y	None	Ongoing at time of death
			Intestinal obstruction	腸閉塞	4	Y	TE	54	2	Y	None	Death
			Intestinal obstruction	腸閉塞	5	Y	TE	55	1	Y	None	Death
035028	UK	70/M/C	Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Recovered
			Urine flow decreased	尿流量減少	1	N	TE	11	19	N	None	Recovered
			Bone pain	骨痛	2	N	TE	29		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	44	18	N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	44		N	None	Recovered
			Constipation	便秘	2	Y	TE	66	6	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	71	79	N	Not applicable	Death
			Constipation	便秘	1	N	TE	72	42	N	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	141		Y	None	Ongoing at time of death
			Confusional state	錯乱状態	3	Y	TE	150	11	N	Not applicable	Death
			Confusional state	錯乱状態	5	Y	TE	160	1	N	Not applicable	Death
037012	UK	67/M/C	Abdominal pain	腹痛	1	N	TE			N	None	Not recovered, but no changes expected
			Hiatus hernia	裂孔ヘルニア	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			N	None	Recovered
			Pain in jaw	顎痛	1	N	TE			N	None	Ongoing at time of death
			Deep vein thrombosis	深部静脈血栓症	3	N	TE			Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	28	2	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	113		N	None	Ongoing at time of death
			Osteoarthritis	骨関節炎	1	N	TE	163		N	None	Not recovered, but no changes expected

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea exertional	労作性呼吸困難	1	N	TE	171		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	198		N	None	Ongoing at time of death
			Head injury	頭部損傷	3	N	TE	212	1	N	None	Recovered with sequelae
			Disseminated intravascular coagulation	播種性血管内凝固	3	N	TE	214		N	None	Not recovered, but no changes expected
			Thrombocytopenia	血小板減少症	3	Y	TE	214		N	Not applicable	Ongoing at time of death
			Extradural haematoma	硬膜外血腫	5	Y	TE	214	1	N	Not applicable	Death
039005	UK	72/M/C	Constipation	便秘	3	N	TE	4	38	N	None	Recovered
			Nausea	悪心	3	N	TE	13	29	N	None	Recovered
			Nausea	悪心	3	N	TE	35	7	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	35		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	N	TE	35	8	N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	42	1	N	None	Death
039007	UK	68/M/C	Bone pain	骨痛	1	N	Pre			N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	Y	Pre	-23	2	N	Drug administration postponed	Recovered
			Decreased appetite	食欲減退	1	N	Pre	-11		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	-11		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	-11	5	N	None	Recovered
			Nausea	悪心	1	N	Pre	-4		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	Pre	-4		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	4	23	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	27		Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	29	36	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	60		Y	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	70	1	N	None	Recovered
			Anaemia	貧血	2	N	TE	92		Y	Drug administration postponed	Ongoing at time of death
			Joint injury	関節損傷	2	N	TE	94		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	1	N	TE	95		Y	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	118	2	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	180	2	Y	Not applicable	Recovered
			Skin lesion	皮膚病変	3	N	TE	183		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	214	1	N	Not applicable	Death
039012	UK	82/M/C	Anaemia	貧血	3	N	TE			N	None	Recovered
			Hyperchlorhydria	胃酸過多	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	2	N	Pre	-2	26	N	None	Recovered
			Hypoaesthesia	感覚鈍麻	2	N	Pre	-2		N	None	Ongoing at study termination / withdrawal
			Hypoaesthesia	感覚鈍麻	2	N	TE	8		N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	2	N	TE	8		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	24		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pathological fracture	病的骨折	3	Y	TE	35	33	N	Drug administration postponed	Recovered
			Nausea	悪心	2	N	TE	71	86	Y	None	Ongoing at time of death
			Dry mouth	口内乾燥	3	N	TE	87	70	N	None	Ongoing at time of death
			Back injury	背部損傷	3	N	TE	91	66	N	None	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	125		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	156	1	N	None	Death
039027	UK	74/M/C	Nausea	悪心	2	N	TE	1		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	1		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	2	N	Pre	1		N	None	Ongoing at time of death
			Dizziness	浮動性めまい	2	N	TE	1		N	None	Ongoing at time of death
			Headache	頭痛	1	N	TE	1		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hypoaesthesia	感覚鈍麻	1	N	TE	1		N	None	Ongoing at time of death
			Dehydration	脱水	3	Y	TE	8	7	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	18	20	N	Drug administration postponed	Death
			Renal failure	腎不全	3	Y	TE	18	1	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	N	TE	19	4	N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	37	1	N	Drug administration postponed	Death
040005	UK	67/M/C	Bone pain	骨痛	3	N	TE			N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	2	3	Y	None	Recovered
			Malaise	倦怠感	2	N	TE	2	3	Y	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	2		N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	29	4	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	29	4	N	None	Recovered
			Lower respiratory tract infection	下気道感染	3	N	TE	49	13	N	None	Recovered
			Anaemia	貧血	2	N	TE	57	56	Y	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	68	60	N	Drug permanently withdrawn	Death
			Anaemia	貧血	3	Y	TE	112	3	Y	None	Recovered
			Fatigue	疲労	3	Y	TE	112	3	Y	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	N	TE	114		Y	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	2	N	TE	114		Y	Not applicable	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	127	1	N	Drug permanently withdrawn	Death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
041008	UK	74/M/C	Anaemia	貧血	2	N	Pre	1	29	N	Drug administration postponed	Recovered
			Nausea	悪心	2	N	TE	1	3	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	1	3	N	None	Recovered
			Anaemia	貧血	2	Y	TE	29	4	N	Drug administration postponed	Recovered
			Acute myocardial infarction	急性心筋梗塞	4	Y	TE	29	4	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	32	19	N	Drug administration postponed	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE	35	13	N	None	Recovered
			Anaemia	貧血	3	Y	TE	50	4	N	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	50	3	N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	2	N	TE	52		N	None	Ongoing at time of death
			Anaemia	貧血		Y	TE	76		N	Drug administration postponed	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	5	Y	TE	79	1	N	None	Death
041011	UK	58/M/C	Oral candidiasis	口腔カンジダ症	2	N	Pre	1		N	None	Recovered
			Metastases to bone	骨転移	2	N	TE	27	6	N	None	Recovered
			Anaemia	貧血	2	N	TE	29	84	Y	None	Ongoing at time of death
			Metastases to bone	骨転移	2	Y	TE	32	18	N	None	Recovered
			Metastases to bone	骨転移	2	N	TE	49		N	None	Not recovered, but no changes expected
			Oedema peripheral	末梢性浮腫	2	N	TE	57	57	N	None	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	3	Y	TE	63	6	N	Drug administration postponed	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	63	6	N	Drug administration postponed	Recovered
			Diabetes mellitus	糖尿病	2	N	TE	71	56	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	84	58	Y	Drug administration postponed	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	85	79	N	Drug permanently withdrawn	Death
			Anaemia	貧血	1	N	TE	112	30	Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	113	38	N	None	Ongoing at time of death
			Memory impairment	記憶障害	1	N	TE	113		N	None	Ongoing at time of death
			Rales	ラ音	1	N	TE	113		N	None	Ongoing at time of death
			Dizziness postural	体位性めまい	2	N	TE	116		N	None	Ongoing at time of death
			Diabetes mellitus	糖尿病	1	N	TE	126		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	141		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	141	5	Y	Drug administration postponed	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	145		Y	Drug administration postponed	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	Y	TE	150		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	163	1	N	Drug permanently withdrawn	Death
042015	UK	72/M/C	Increased appetite	食欲亢進	1	N	TE			N	None	Recovered
			Somnolence	傾眠	2	N	TE			N	None	Recovered
			Diplopia	複視	3	N	TE	14	10	Y	None	Recovered
			Balance disorder	平衡障害	1	N	TE	14	10	N	None	Recovered
			Confusional state	錯乱状態	3	N	TE	14	10	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	15	15	Y	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	53	6	N	None	Recovered
			Agitation	激越	2	N	TE	114	2	N	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	115	1	N	None	Death
			Increased bronchial secretion	気管支分泌増加	2	N	TE	115	1	N	None	Recovered
042034	UK	75/M/C	Oedema peripheral	末梢性浮腫	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	141		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	141		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	172	1	N	Not applicable	Death
044005	UK	76/M/C	Cardiac failure congestive	うっ血性心不全	4	N	TE			N	Drug administration postponed	Death
			Fatigue	疲労	2	N	TE			Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	7	1	Y	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Left ventricular dysfunction	左室機能不全	3	N	TE	54	73	N	Drug administration postponed	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	54	73	N	Drug administration postponed	Ongoing at time of death
			Dyspnoea	呼吸困難	3	N	TE	54	17	N	Drug administration postponed	Ongoing at time of death
			Troponin T increased	トロポニンＴ増加	4	N	TE	57	70	N	Drug administration postponed	Ongoing at time of death
			Pleural effusion	胸水	2	N	TE	57	70	N	Drug administration postponed	Ongoing at time of death
			Pulmonary embolism	肺塞栓症	3	Y	TE	57	3	N	Drug permanently withdrawn	Recovered with sequelae

表 2.7.4.7- 13　死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pulmonary oedema	肺水腫	1	N	TE	58	69	N	Drug administration postponed	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	70	57	N	Drug administration postponed	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	5	Y	TE	126	1	N	Drug administration postponed	Death
047002	UK	81/M/C	Anaemia	貧血	3	N	TE	2	1	Y	None	Recovered
			Anaemia	貧血	3	N	TE	39	1	Y	None	Recovered
			Anaemia	貧血	3	N	TE	73	1	Y	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	3	N	TE	85		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	2	N	TE	136		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	154	1	N	Not applicable	Death

表 2.7.4.7- 13　死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
049002	UK	73/M/C	Lower respiratory tract infection	下気道感染	3	Y	TE	9	11	N	None	Recovered
			Oral candidiasis	口腔カンジダ症	2	N	TE	57	53	Y	None	Recovered
			Paraesthesia	錯感覚	1	N	TE	100	30	N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	Y	TE	109	3	N	Drug administration postponed	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	4	Y	TE	129		N	None	Ongoing at time of death
			Pneumonia	肺炎	4	Y	TE	135	7	N	Drug permanently withdrawn	Death
			Pneumonia	肺炎	5	Y	TE	141	1	N	Drug permanently withdrawn	Death
049007	UK	80/M/C	Nausea	悪心	2	N	TE	3		Y	None	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	3		Y	None	Ongoing at time of death
			Mucosal inflammation	粘膜の炎症	2	N	TE	29		Y	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	29		Y	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	120		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	128		N	None	Ongoing at time of death
			Headache	頭痛	2	N	TE	148	51	N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	176	3	N	Not applicable	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	198		N	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	3	Y	TE	198		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	198	12	N	Not applicable	Death
			Headache	頭痛	4	N	TE	198		N	None	Ongoing at time of death
			Urinary retention	尿閉	2	N	TE	204		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	209	1	N	Not applicable	Death
049008	UK	72/M/C	Decreased appetite	食欲減退	2	N	TE			N	None	Ongoing at time of death
			Lymphoedema	リンパ浮腫	1	N	Pre			N	None	Recovered
			Ear pain	耳痛	1	N	Pre	-7		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	Pre	-3	5	N	None	Recovered
			Fatigue	疲労	2	N	TE	29		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	29	50	Y	None	Recovered
			Constipation	便秘	2	N	TE	40		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	40	2	N	None	Recovered with sequelae
			Palpitations	動悸	1	N	TE	54	4	N	Not applicable	Recovered
			Depressed mood	抑うつ気分	1	N	TE	54		N	None	Ongoing at time of death
			Vomiting	嘔吐	2	Y	TE	57	6	N	Drug administration postponed	Recovered
			Pyrexia	発熱	1	Y	TE	61	2	N	Drug administration postponed	Recovered
			Nausea	悪心	2	Y	TE	65	6	N	Drug administration postponed	Recovered with sequelae

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	2	Y	TE	65	6	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	N	TE	67	1	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	89	1	N	Not applicable	Recovered
			Abdominal pain	腹痛	3	Y	TE	111		N	Not applicable	Ongoing at time of death
			Nausea	悪心	3	Y	TE	111		N	Not applicable	Ongoing at time of death
			Vomiting	嘔吐	3	Y	TE	111		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	111	11	N	Not applicable	Death
			Anaemia	貧血	2	N	TE	113		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	121	1	N	Not applicable	Death
051012	UK	73/M/C	Decreased appetite	食欲減退	1	N	TE	30		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	108	1	N	None	Death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
055002	Netherlands	66/M/C	Lung infection	肺感染	2	N	TE	18	27	N	None	Recovered
			Anorexia	食欲不振	2	N	TE	54		Y	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	54		Y	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	59		Y	None	Ongoing at time of death
			Drug intolerance	薬物不耐性	4	Y	TE	71	3	N	None	Recovered with sequelae
			Pulmonary embolism	肺塞栓症	4	Y	TE	71		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	74	1	N	None	Death
060002	Spain	84/M/C	Anorexia	食欲不振	2	N	TE	29		N	None	Ongoing at time of death
			Cardiac failure	心不全	3	N	TE	100		N	None	Ongoing at study termination / withdrawal
			Dyspnoea	呼吸困難	2	N	TE	100		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	101	31	N	Not applicable	Ongoing at time of death
			Bronchitis	気管支炎	2	N	TE	107	2	N	None	Recovered
			Renal failure	腎不全	2	N	TE	107	3	N	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bronchitis	気管支炎	3	Y	TE	108		N	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	N	TE	109	5	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	113	11	Y	None	Ongoing at time of death
			Hyperuricaemia	高尿酸血症	1	N	TE	113		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	123		Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	129	1	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	131		N	Not applicable	Ongoing at time of death
			Death	死亡	5	Y	TE	137	1	N	Not applicable	Death
060003	Spain	85/M/C	Bone pain	骨痛	3	N	TE	31	26	N	None	Ongoing at time of death
			Weight decreased	体重減少	2	N	TE	56	6	N	None	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	2	N	TE	56	11	N	None	Recovered
			Bone pain	骨痛	2	N	TE	56		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	1	N	TE	57		N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	61		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	111	1	N	Not applicable	Death
060007	Spain	79/M/C	Nausea	悪心	1	N	Pre	-20	28	N	None	Recovered
			Anorexia	食欲不振	2	N	Pre	-20		N	None	Ongoing at time of death
			Haematuria	血尿	2	N	TE	5		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	6	4	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	6	12	N	Drug permanently withdrawn	Death
			Pyrexia	発熱	1	N	TE	7	2	N	None	Recovered
			Respiratory tract infection	気道感染	2	N	TE	7		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	3	N	TE	8		N	None	Ongoing at time of death
			Asthenia	無力症	1	N	TE	12	2	N	None	Ongoing at time of death
			Asthenia	無力症	3	N	TE	13		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	17	1	N	Drug permanently withdrawn	Death
063004	Spain	74/M/C	Abdominal pain upper	上腹部痛	1	N	TE	32	55	N	None	Recovered
			Somnolence	傾眠	2	N	TE	32	55	N	None	Recovered
			Anaemia	貧血	3	N	TE	58	29	N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	86		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	86	29	N	Not applicable	Ongoing at time of death
			Asthenia	無力症	1	N	TE	86		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	86		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	114		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	128	8	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	135	1	N	Drug permanently withdrawn	Death
074002	Italy	79/M/C	Muscle spasms	筋痙縮	1	N	Pre	-10	11	N	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Diarrhoea	下痢	2	N	TE	28	8	N	None	Recovered
			Asthenia	無力症	2	N	TE	33	3	N	None	Recovered
			Pyrexia	発熱	1	N	TE	33	15	N	Drug administration postponed	Recovered
			Urinary tract infection	尿路感染	2	N	TE	46	39	N	None	Recovered
			Dry skin	皮膚乾燥	1	N	TE	75	10	Y	None	Recovered
			Asthenia	無力症	1	N	TE	84	83	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	131	29	Y	None	Recovered
			Neutropenia	好中球減少症	2	N	TE	131	29	Y	Drug permanently withdrawn	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	131	29	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	159	18	Y	None	Recovered
			Leukopenia	白血球減少症	4	N	TE	159	4	Y	None	Recovered
			Neutropenia	好中球減少症	4	N	TE	159	4	Y	Drug permanently withdrawn	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	159	15	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	162	5	Y	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neutropenia	好中球減少症	1	N	TE	162	5	Y	Drug permanently withdrawn	Recovered
			Blood urea increased	血中尿素増加	1	N	TE	162	43	N	None	Recovered
			Asthenia	無力症	2	N	TE	166		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	173	8	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	180	8	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	183	5	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	187	32	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	187	8	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	194	11	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	204	15	Y	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	218	5	Y	None	Recovered
			Thrombocytopenia	血小板減少症	4	N	TE	218	5	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	222	2	Y	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	3	N	TE	222	2	Y	None	Ongoing at time of death
			Bone marrow tumour cell infiltration	腫瘍細胞の骨髄浸潤	3	Y	TE	222	37	N	Not applicable	Death
			Anaemia	貧血	3	N	TE	223	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	223	2	Y	None	
			Neutropenia	好中球減少症	1	N	TE	223	5	Y	Not applicable	
			Thrombocytopenia	血小板減少症	4	N	TE	223	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	1	N	TE	224	2	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	225	8	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	225	1	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	1	N	TE	225	3	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	225	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	227	3	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	2	N	TE	227	3	Y	Not applicable	

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	4	N	TE	227	4	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	229	2	Y	None	
			Neutropenia	好中球減少症	3	N	TE	229	2	Y	Not applicable	
			Leukopenia	白血球減少症	2	N	TE	230	4	Y	None	
			Neutropenia	好中球減少症	2	N	TE	230	2	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	230	3	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	1	N	TE	231	3	Y	Not applicable	Recovered
			Anaemia	貧血	1	N	TE	232	4	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	232	4	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	233	2	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	2	N	TE	233	2	Y	Not applicable	Recovered
			Leukopenia	白血球減少症	2	N	TE	234	4	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	235	7	Y	None	Recovered
			Neutropenia	好中球減少症	1	N	Post	235	3	Y	-	
			Thrombocytopenia	血小板減少症	3	N	TE	235	2	Y	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	4	N	TE	236	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	237	7	Y	None	
			Neutropenia	好中球減少症	2	N	Post	237	2	Y	-	
			Neutropenia	好中球減少症	3	N	Post	238	5	Y	-	
			Thrombocytopenia	血小板減少症	3	N	TE	238	4	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	241	2	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	241	3	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	242	8	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	2	N	Post	242	4	Y	Not applicable	Recovered
			Leukopenia	白血球減少症	2	N	TE	243	3	Y	None	
			Thrombocytopenia	血小板減少症	3	N	TE	243	2	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	244		Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	1	N	TE	245	9	Y	None	
			Anaemia	貧血	1	N	TE	249		Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	253	2	Y	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neutropenia	好中球減少症	1	N	Post	253	4	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	1	N	TE	254	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	256		Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	2	N	Post	256		Y	None	Ongoing at time of death
			Bone marrow tumour cell infiltration	腫瘍細胞の骨髄浸潤	5	Y	TE	258	1	N	Not applicable	Death
075001	Italy	59/M/C	Strangury	有痛性排尿困難		N	TE	2	2	N	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	14	28	N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	33	10	Y	Drug administration postponed	Recovered
			Vomiting	嘔吐	1	N	TE	33	10	Y	Drug administration postponed	Recovered
			Anorexia	食欲不振	1	N	TE	33	10	Y	Drug administration postponed	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	1	N	TE	41		N	None	Ongoing at time of death
			Strangury	有痛性排尿困難	2	N	TE	78	1	N	None	Recovered
			Death	死亡	5	Y	TE	93	1	N	None	Death
078001	Italy	76/M/C	Constipation	便秘	1	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE			N	None	Recovered
			Pyrexia	発熱	1	N	TE			N	None	Recovered
			Confusional state	錯乱状態	1	N	TE			N	None	Recovered
			Hyperhidrosis	多汗症	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE	2	11	Y	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	38	21	N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	58	21	N	None	Ongoing at time of death
			Asthenia	無力症	2	N	TE	78	37	Y	None	Recovered
			Pyrexia	発熱	1	N	TE	78	29	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	78		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	78	37	N	None	Recovered
			Fatigue	疲労	2	N	TE	127	14	N	None	Ongoing at time of death
			Depression	うつ病	2	N	TE	127		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	3	N	TE	141		N	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	147	2	Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	Y	TE	147	2	Y	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	149	14	Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	Y	TE	149	11	Y	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	1	Y	TE	163		Y	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	163	15	N	Not applicable	Death
078003	Italy	74/M/C	Somnolence	傾眠	2	N	Pre	1		N	None	Ongoing at time of death
			Confusional state	錯乱状態	2	N	Pre	1		N	None	Ongoing at time of death
			Upper limb fracture	上肢骨折	2	N	TE	20	25	N	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Asthenia	無力症	2	N	TE	49		Y	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	187		N	Not applicable	Ongoing at time of death
			Amnesia	健忘	2	N	TE	198		N	Not applicable	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	3	Y	TE	213	8	N	Not applicable	Death
			General physical health deterioration	全身健康状態低下	5	Y	TE	220	1	N	Not applicable	Death
078006	Italy	77/M/C	Pyrexia	発熱	1	N	TE	39	34	N	None	Recovered
			Pyrexia	発熱	1	N	TE	91	14	N	None	Recovered
			Anaemia	貧血	2	N	TE	104		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	104		Y	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	104	28	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	131	1	N	Drug permanently withdrawn	Death
080004	Italy	72/M/C	Weight decreased	体重減少	1	N	Pre	-13	13	N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	2	N	Pre	-1		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	Pre	-1	50	N	None	Recovered
			Bone pain	骨痛	3	N	TE	49	85	N	None	Recovered
			Fatigue	疲労	3	N	TE	133		N	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	133		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	161	1	N	Not applicable	Death
093002	Slovakia	81/M/C	Anaemia	貧血	2	N	TE	29	48	N	-	
			Nausea	悪心	2	N	TE	29	85	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	29	6	Y	None	Recovered
			Constipation	便秘	1	N	TE	56	58	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	56	4	Y	None	Recovered
			Anaemia	貧血	3	N	TE	76	10	N	-	
			Bone pain	骨痛	3	Y	TE	76	8	N	None	Recovered with sequelae
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	76		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	85	29	N	-	
			Diarrhoea	下痢	2	N	TE	85	5	Y	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	113	31	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	Y	TE	143	5	N	Drug administration postponed	Recovered
			Bronchopneumonia	気管支肺炎	3	N	TE	150		N	None	Ongoing at time of death
			Cardiopulmonary failure	心肺不全	5	Y	TE	160	1	N	Not applicable	Death
104005	Hong Kong	73/M/A	Constipation	便秘	1	N	TE	1	29	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	64	2	Y	None	Recovered
			Pneumonia	肺炎	2	N	TE	87		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	87	18	N	Drug permanently withdrawn	Death
			Spinal cord compression	脊髄圧迫	5	Y	TE	104	1	N	Drug permanently withdrawn	Death

表 2.7.4.7- 13　死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
106005	Hong Kong	79/M/A	Decreased appetite	食欲減退	1	N	TE	29	85	Y	None	Recovered
			Dysuria	排尿困難	1	N	TE	29		N	None	Ongoing at time of death
			Nocturia	夜間頻尿	2	N	TE	29	57	N	None	Recovered
			Anaemia	貧血	3	Y	TE	113	3	Y	Drug administration postponed	Recovered with sequelae
			Constipation	便秘	2	N	TE	113	29	N	None	Recovered
			Sleep disorder	睡眠障害	1	N	TE	113	3	N	None	Recovered
			Spinal compression fracture	脊椎圧迫骨折	3	N	TE	115		N	None	Ongoing at time of death
			Sepsis	敗血症	3	Y	TE	155		N	Not applicable	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	3	N	TE	156		N	Not applicable	Ongoing at time of death
			Haematuria	血尿	3	Y	TE	159		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	165	1	N	Not applicable	Death
106011	Hong Kong	79/M/A	Decreased appetite	食欲減退	1	N	TE	29	29	N	None	Recovered
			Abdominal pain upper	上腹部痛	1	N	TE	57	29	N	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Liver function test abnormal	肝機能検査異常	3	Y	TE	57	13	N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	218	1	N	Not applicable	Death
133002	Poland	78/M/C	Pyrexia	発熱	1	N	TE	3	14	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	3	6	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	8	44	Y	None	Recovered
			Pathological fracture	病的骨折	2	Y	TE	43		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	51	53	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	72	34	N	None	Recovered
			Fatigue	疲労	3	N	TE	88	26	N	Drug permanently withdrawn	Ongoing at time of death
			Fatigue	疲労	4	N	TE	113		N	Drug permanently withdrawn	Ongoing at time of death
			Weight decreased	体重減少	2	N	TE	113		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	162	1	N	Not applicable	Death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
133006	Poland	53/M/C	Bone pain	骨痛	2	N	TE	2	10	Y	None	Recovered
			Hypertension	高血圧	2	N	TE	29	29	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	50		N	None	Recovered
			Abdominal pain	腹痛	2	N	TE	71		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	140	29	N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	168		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	168		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	184	2	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	185	1	N	Not applicable	Death
133009	Poland	75/M/C	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2	N	TE	85	29	N	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1	N	TE	85	29	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	141	29	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	198	1	N	Not applicable	Death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
133011	Poland	66/M/C	Anaemia	貧血	2	N	Pre	1		N	None	Ongoing at time of death
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	Pre	1		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre	1		N	None	Not recovered, but no changes expected
			Tremor	振戦	4	Y	TE	25	1	Y	None	Recovered
			Confusional state	錯乱状態	4	Y	TE	25		Y	None	Ongoing at time of death
			Death	死亡	5	Y	TE	29	1	Y	None	Death
133012	Poland	67/M/C	Spinal cord compression	脊髄圧迫	3	Y	Pre	-35		N	Drug administration postponed	Ongoing at time of death
			Dyspnoea	呼吸困難	4	Y	TE	2	1	N	None	Death
			Dyspnoea	呼吸困難	5	Y	TE	2	1	N	None	Death
134001	Poland	57/M/C	Paralysis	麻痺	4	Y	Pre	-10		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	20	1	N	None	Death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
137006	Poland	71/M/C	Anaemia	貧血	3	Y	TE	139	8	N	Not applicable	Recovered with sequelae
			Urinary tract infection	尿路感染	2	N	TE	157	8	N	Not applicable	Recovered
			Haematuria	血尿	3	Y	TE	197	7	N	Not applicable	Recovered
			Anaemia	貧血	4	Y	TE	203		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	213	1	N	Not applicable	Death
139001	Poland	76/M/C	Anaemia	貧血	1	N	TE	29		N	None	Ongoing at time of death
			Malaise	倦怠感	3	N	TE	29		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	46	1	N	None	Death
139005	Poland	71/M/C	Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre			N	None	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	57	5	Y	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	120	1	N	None	Death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
146004	Germany	77/M/C	Anaemia	貧血	2	N	TE	17	5	N	Drug administration postponed	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	17		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Multi-organ failure	多臓器不全	4	Y	TE	17	12	N	None	Death
			Anaemia	貧血	4	N	TE	21		N	Drug administration postponed	Ongoing at time of death
			Multi-organ failure	多臓器不全	5	Y	TE	28	1	N	None	Death
148009	Germany	71/M/C	Nasopharyngitis	鼻咽頭炎	1	N	Pre	-14	15	N	None	Recovered
			Anaemia	貧血	2	N	Pre	1	57	Y	Drug administration postponed	Recovered
			Fatigue	疲労	2	N	TE	8		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	29	4	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	57	4	Y	Drug administration postponed	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	60	31	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	60	1	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	60	2	Y	None	Recovered
			Herpes zoster	帯状疱疹	3	Y	TE	96	12	Y	Drug administration postponed	Recovered
			Anaemia	貧血	2	Y	TE	98	1	Y	None	Recovered
			Anaemia	貧血	4	Y	TE	125	3	Y	Drug administration postponed	Recovered
			Syncope	失神	3	Y	TE	125	1	Y	Drug administration postponed	Recovered
			Pancytopenia	汎血球減少症		N	TE	140		Y	None	Ongoing at time of death
			Metastases to liver	肝転移	3	Y	TE	140	10	N	Drug permanently withdrawn	Death
			Epistaxis	鼻出血	2	N	TE	140	1	N	Not applicable	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Metastases to liver	肝転移	5	Y	TE	149	1	N	Drug permanently withdrawn	Death
148019	Germany	65/M/C	Conjunctivitis	結膜炎	2	N	TE	2	8	N	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	29	1	Y	None	Recovered
			Nausea	悪心	1	N	TE	31	4	Y	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	32	1	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	32	1	Y	None	Recovered
			Pleural effusion	胸水	1	N	TE	93		N	None	Ongoing at time of death
			Blood urea increased	血中尿素増加	2	N	TE	109	11	N	None	Recovered
			Blood creatinine increased	血中クレアチニン増加	2	N	TE	113	7	N	None	Recovered
			Hydronephrosis	水腎症	3	Y	TE	113	2	N	None	Recovered
			Dyspnoea	呼吸困難	2	N	TE	113		N	None	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	119	4	N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	119		N	None	Ongoing at time of death
			Blood creatinine increased	血中クレアチニン増加	3	N	TE	119	4	N	None	Recovered
			Blood urea increased	血中尿素増加	3	N	TE	119	4	N	None	Recovered
			Hydronephrosis	水腎症	3	Y	TE	119	4	N	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	143	1	N	Drug permanently withdrawn	Death
170004	Brazil	78/M/C	Pathological fracture	病的骨折	3	N	TE	127		N	Drug administration postponed	Ongoing at time of death
			Urinary retention	尿閉	3	N	TE	156	1	N	None	Recovered
			Anaemia	貧血	2	N	TE	211		N	None	Ongoing at time of death
			Bone pain	骨痛	4	Y	TE	230		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	230	3	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	232	1	N	Drug permanently withdrawn	Death
173008	Brazil	67/M/C	Anaemia	貧血	2	N	Pre	1	33	N	Drug administration postponed	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	Pre	1	63	N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	N	TE	33	2	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	34	30	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	N	TE	63	3	N	Drug administration postponed	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	Pre	63		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	65	83	N	Drug administration postponed	Recovered
			Anorexia	食欲不振	2	N	TE	87	70	N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	147	5	N	Drug administration postponed	Recovered
			Anorexia	食欲不振	3	N	TE	156		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	156		N	None	Ongoing at time of death
			Weight decreased	体重減少	3	N	TE	183		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	3	N	TE	184	11	N	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	184	11	N	None	Ongoing at time of death
			Anaemia	貧血	4	N	TE	194	5	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	194	5	N	None	Ongoing at time of death
			Neutropenia	好中球減少症	4	N	TE	198		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	198		N	None	Ongoing at time of death
			Cerebrovascular accident	脳血管発作	4	Y	TE	198	4	Y	Not applicable	Death
			Cerebrovascular accident	脳血管発作	5	Y	TE	201	1	Y	Not applicable	Death
173009	Brazil	66/M/O	Bone pain	骨痛	2	N	Pre	-9		N	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	4	Y	TE	29	20	N	Drug permanently withdrawn	Death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			General physical health deterioration	全身健康状態低下	5	Y	TE	48	1	N	Drug permanently withdrawn	Death
179006	Brazil	79/M/C	Nausea	悪心	1	N	Pre	-17	3	N	Not applicable	Recovered
			Cough	咳嗽	1	N	Pre	-6	5	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	34	99	N	None	Recovered
			Arthralgia	関節痛	1	N	TE	132		N	None	Recovered
			Bone pain	骨痛	1	N	TE	159	2	N	None	Recovered
			Myocardial infarction	心筋梗塞	5	Y	TE	244	1	N	Not applicable	Death
181005	Brazil	74/M/C	Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	Pre	1		N	None	Ongoing at time of death
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	Pre	1		N	None	Ongoing at time of death
			Hypoglycaemia	低血糖症	3	Y	TE	29	2	N	None	Recovered
			Pneumonia	肺炎	2	Y	TE	30	16	N	Not applicable	Death
			Acute pulmonary oedema	急性肺水腫	2	Y	TE	30		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pneumonia	肺炎	5	Y	TE	45	1	N	Not applicable	Death
201002	Australia	72/M/C	Dysphagia	嚥下障害	2	N	Pre	-7	70	N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	48	46	N	None	Recovered
			Muscle strain	筋挫傷	2	N	TE	49	15	N	None	Recovered
			Dysphagia	嚥下障害	1	N	Pre	63	71	N	None	Ongoing at time of death
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	2	N	TE	93	4	N	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	99	8	N	None	Recovered
			Anaemia	貧血	3	Y	TE	132	9	N	Not applicable	Recovered
			Supraventricular tachycardia	上室性頻脈	2	Y	TE	132	1	N	Not applicable	Recovered
			Abdominal distension	腹部膨満	3	Y	TE	132	9	N	Not applicable	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	3	N	TE	132		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	132	39	N	Not applicable	Death
			Anxiety	不安	2	N	TE	132		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dysphagia	嚥下障害	2	N	Pre	133		N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	1	N	TE	137	3	N	Not applicable	Recovered
			Abdominal distension	腹部膨満	2	N	TE	140		N	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	147		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	161		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	170	1	N	Not applicable	Death
203007	Australia	70/M/C	Bone pain	骨痛	2	N	Pre	-7	63	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	Pre	-7	63	N	None	Recovered
			Constipation	便秘	2	Y	Pre	-1	3	N	None	Recovered
			Anorexia	食欲不振	2	N	TE	3		N	None	Ongoing at time of death
			Dysgeusia	味覚異常	1	N	TE	3		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	4	2	Y	None	Recovered
			Anaemia	貧血	2	N	TE	28	49	Y	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	28	29	N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	28	83	N	Not applicable	Death
			Fatigue	疲労	2	N	TE	35		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	53	5	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	56	3	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	56	3	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	56	3	N	None	Recovered
			Bone pain	骨痛	1	N	TE	58		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	58		N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	66	8	N	Not applicable	Recovered
			Constipation	便秘	3	Y	TE	73	6	N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	76	3	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	78		Y	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	110	1	N	Not applicable	Death

表 2.7.4.7- 13　死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
204001	Australia	76/M/C	Dyspnoea	呼吸困難	1	N	Pre	-392	366	N	None	Recovered
			Nausea	悪心	1	N	TE	1		Y	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	2		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	2		Y	None	Ongoing at study termination / withdrawal
			Chills	悪寒	1	N	TE	6	1	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	8	1	Y	None	Recovered
			Constipation	便秘	1	N	TE	9		Y	None	Ongoing at study termination / withdrawal
			Contusion	挫傷	1	N	TE	10		N	None	Ongoing at study termination / withdrawal
			Gastroenteritis	胃腸炎	4	Y	TE	18	6	Y	None	Recovered with sequelae
			Renal failure acute	急性腎不全	2	Y	TE	18	6	Y	None	Recovered
			Gastroenteritis	胃腸炎	3	N	TE	21	3	Y	None	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	22	2	Y	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Gastroenteritis	胃腸炎	2	N	TE	23	1	Y	None	Recovered with sequelae
			Bone pain	骨痛	1	N	TE	34		Y	None	Ongoing at time of death
			Mobility decreased	運動性低下	1	N	TE	34		Y	None	Ongoing at time of death
			Tremor	振戦	1	N	TE	34		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	43	26	N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	63	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	68	9	N	Not applicable	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	76		N	Not applicable	Ongoing at study termination / withdrawal
			Anxiety	不安	1	N	TE	79	1	Y	None	Recovered
			Anxiety	不安	1	N	TE	83	3	Y	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	116	1	N	Drug permanently withdrawn	Death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
205004	Australia	82/M/C	Bone pain	骨痛	2	N	TE			Y	None	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	Pre	1		N	None	Ongoing at time of death
			Urinary incontinence	尿失禁	2	N	TE	6		Y	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	33		Y	None	Ongoing at time of death
			Hydrocephalus	水頭症	4	Y	TE	107	20	N	Drug permanently withdrawn	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	127	14	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	140	1	N	Drug permanently withdrawn	Death
206001	Australia	83/M/C	Meniere's disease	メニエール病	2	N	TE	78	18	Y	Drug administration postponed	Recovered with sequelae
			Deep vein thrombosis	深部静脈血栓症	3	Y	TE	90	6	Y	None	Recovered with sequelae

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	1	N	TE	91	4	N	Drug administration postponed	Recovered
			Pollakiuria	頻尿	3	N	TE	189		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	201		N	Not applicable	Ongoing at time of death
			Nausea	悪心	3	N	TE	201		N	Not applicable	Ongoing at time of death
			Pain	疼痛	3	N	TE	201		N	Not applicable	Ongoing at time of death
			Urinary tract infection	尿路感染	3	N	TE	201		N	Not applicable	Ongoing at time of death
			Hydronephrosis	水腎症	3	Y	TE	201		N	Not applicable	Ongoing at time of death
			Fluid overload	水分過負荷	3	N	TE	202		N	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	4	N	TE	202		N	Not applicable	Ongoing at time of death
			Lung consolidation	肺硬化	3	N	TE	202		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	212	1	N	Not applicable	Death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
209003	Australia	56/M/C	Bone pain	骨痛	1	N	Pre	-22		N	None	Ongoing at time of death
			Oesophagitis	食道炎	1	N	TE	29		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	29		N	None	Ongoing at time of death
			Muscle spasms	筋痙縮	1	N	TE	57		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	78		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	78		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	78		N	None	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	85		N	None	Ongoing at time of death
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	1	N	TE	85		N	None	Ongoing at time of death
			Breath sounds abnormal	呼吸音異常	1	N	TE	85		N	None	Ongoing at time of death
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1	N	TE	85		N	None	Ongoing at time of death
			Neuropathy peripheral	末梢性ニューロパチー	1	N	TE	88		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Spinal cord compression	脊髄圧迫	4	Y	TE	94	16	N	None	Recovered
			Burning sensation	灼熱感	1	N	TE	102	1	N	None	Recovered
			Rash	発疹	1	N	TE	103		N	None	Ongoing at time of death
			Pyrexia	発熱	1	N	TE	108	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	109		N	Not applicable	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	109		N	Not applicable	Ongoing at time of death
			Radiation skin injury	放射線皮膚損傷	1	N	TE	109		N	Not applicable	Ongoing at time of death
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	Y	TE	109	7	N	Drug permanently withdrawn	Recovered
			Anxiety	不安	1	N	TE	109		N	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	138		N	Not applicable	Ongoing at time of death
			Ascites	腹水	1	Y	TE	149		N	Not applicable	Ongoing at time of death
			Epistaxis	鼻出血	1	N	TE	149	18	N	Not applicable	Recovered
			Dry skin	皮膚乾燥	1	N	TE	149		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pruritus	そう痒症	1	N	TE	149		N	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE	153		N	None	Ongoing at time of death
			Rectal haemorrhage	直腸出血	1	N	TE	158		N	Not applicable	Ongoing at time of death
			Pitting oedema	圧痕浮腫	1	N	TE	158		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	158	9	N	Not applicable	Death
			Confusional state	錯乱状態	1	N	TE	158		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	166	1	N	Not applicable	Death
233005	UK	78/M/C	Nausea	悪心	1	N	TE	1	209	N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	29	181	Y	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	29	29	N	None	Recovered
			Anorexia	食欲不振	3	N	TE	29	113	Y	None	Ongoing at time of death
			Dehydration	脱水	3	N	TE	29	4	Y	Drug administration postponed	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malaise	倦怠感	2	Y	TE	32	6	Y	Drug administration postponed	Recovered
			Dehydration	脱水	3	Y	TE	32	6	Y	Drug administration postponed	Recovered
			Dehydration	脱水	2	Y	TE	45	5	Y	Drug administration postponed	Recovered
			Anaemia	貧血	3	Y	TE	53	3	Y	None	Recovered
			Hypertension	高血圧	3	N	TE	85	125	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	134	3	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	136	3	Y	None	Recovered
			Dehydration	脱水	2	N	TE	136	3	Y	None	Recovered
			Dyspnoea	呼吸困難	3	N	TE	136	2	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	141		Y	None	Ongoing at time of death
			Abdominal pain upper	上腹部痛	1	N	TE	167	3	Y	None	Recovered
			Anaemia	貧血	1	Y	TE	168	2	Y	None	Recovered
			Fatigue	疲労	2	N	TE	168		N	None	Ongoing at time of death
			Dehydration	脱水	2	Y	TE	168	2	Y	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	176	3	Y	Not applicable	Recovered
			Cough	咳嗽	2	N	TE	176	3	N	None	Recovered
			Cough	咳嗽	1	N	TE	176	3	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	N	TE	176	3	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	190		Y	Not applicable	Ongoing at time of death
			Neutropenia	好中球減少症	2	Y	TE	190		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	Y	TE	190		Y	Not applicable	Ongoing at time of death
			Abdominal pain	腹痛	1	N	TE	190	1	Y	Not applicable	Recovered
			Decreased appetite	食欲減退	3	N	TE	190		N	None	Ongoing at time of death
			Dehydration	脱水	3	Y	TE	190	4	Y	Not applicable	Recovered
			Hyperkalaemia	高カリウム血症	2	N	TE	190	20	Y	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	190		Y	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	190	4	Y	Not applicable	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dizziness	浮動性めまい	2	N	TE	190		N	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	3	Y	TE	209		N	Not applicable	Ongoing at time of death
			Bronchopneumonia	気管支肺炎	5	Y	TE	209	1	N	Not applicable	Death
			Dehydration	脱水	3	Y	TE	209		Y	Not applicable	Ongoing at time of death
			Agitation	激越	2	N	TE	209	1	N	None	Ongoing at time of death
240002	USA	68/M/C	Anaemia	貧血	3	N	TE	33	6	Y	Drug administration postponed	Recovered with sequelae
			Pneumonia	肺炎	3	Y	TE	33	6	N	Drug administration postponed	Recovered
			Sepsis	敗血症	4	Y	TE	33	6	N	Drug administration postponed	Recovered
			Pleural effusion	胸水	2	N	TE	33	4	N	None	Recovered
			Hypotension	低血圧	3	N	TE	33	1	N	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	38	48	Y	None	Recovered with sequelae
			Diarrhoea	下痢	1	N	TE	62		Y	None	Ongoing at time of death
			Muscle spasms	筋痙縮	1	N	TE	72	43	N	None	Recovered
			Anaemia	貧血	2	N	TE	85	97	Y	None	Recovered with sequelae
			Nausea	悪心	1	N	TE	114	3	N	None	Recovered
			Fatigue	疲労	2	N	TE	114		Y	None	Ongoing at time of death
			Haematuria	血尿	1	N	TE	133	7	N	None	Recovered
			Leukopenia	白血球減少症	2	N	TE	139		Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	1	N	TE	139		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	139		Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	140		N	None	Ongoing at time of death
			Contusion	挫傷	1	N	TE	140		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	140		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	170		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Leukopenia	白血球減少症	3	N	TE	180	3	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	3	Y	TE	180	6	Y	Not applicable	Recovered
			Urinary tract infection	尿路感染	1	N	TE	180	11	N	Not applicable	Recovered
			Bone pain	骨痛	3	N	TE	180	6	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	180	62	N	Not applicable	Death
			Haematuria	血尿	2	Y	TE	180	6	Y	Not applicable	Recovered
			Urinary retention	尿閉	2	Y	TE	180	6	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	N	TE	180	24	N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	181	2	Y	None	Recovered with sequelae
			Dyspnoea	呼吸困難	1	N	TE	181	5	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	182	50	Y	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	194		N	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	199	5	Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Abdominal pain	腹痛	2	N	TE	199	11	N	Not applicable	Recovered
			Diarrhoea	下痢	1	N	TE	199	11	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	199	11	N	Not applicable	Recovered
			Vomiting	嘔吐	2	N	TE	199	11	N	Not applicable	Recovered
			Asthenia	無力症	2	N	TE	199		N	Not applicable	Ongoing at time of death
			Arthralgia	関節痛	1	N	TE	199	11	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	199	11	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	N	TE	199	5	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	203		Y	Not applicable	Ongoing at time of death
			Skin laceration	皮膚裂傷	2	N	TE	205		N	Not applicable	Ongoing at time of death
			Haemorrhoids	痔核	1	N	TE	210	6	N	Not applicable	Recovered
			Convulsion	痙攣	2	N	TE	223	1	N	Not applicable	Recovered
			Subcutaneous abscess	皮下組織膿瘍	2	N	TE	227		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Insomnia	不眠症	1	N	TE	229		N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	231		Y	Not applicable	Ongoing at time of death
			Urinary retention	尿閉	2	N	TE	240	1	Y	Not applicable	Recovered
			Salivary hypersecretion	流涎過多	1	N	TE	241		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	241	1	N	Not applicable	Death
			Confusional state	錯乱状態	3	N	TE	241		N	Not applicable	Ongoing at time of death
240004	USA	56/M/C	Oedema peripheral	末梢性浮腫	1	N	TE	30	28	N	None	Recovered
			Supraventricular tachycardia	上室性頻脈	3	N	TE	55	1	N	None	Recovered
			Mental status changes	精神状態変化	1	N	TE	55	1	N	None	Recovered
			Fatigue	疲労	1	N	TE	57		N	None	Ongoing at study termination / withdrawal
			Arthralgia	関節痛	1	N	TE	57	1	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	117	79	N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	117	79	N	None	Ongoing at study termination / withdrawal
			Cardiac murmur	心雑音	1	N	TE	119	35	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	156	487	N	Not applicable	Death
			Nocturia	夜間頻尿	1	N	TE	156	112	N	Not applicable	Recovered
			Bone pain	骨痛	3	N	TE	195		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	195		N	None	Ongoing at study termination / withdrawal
			Depression	うつ病	1	N	TE	212	21	N	None	Recovered
			Anaemia	貧血	2	N	TE	216	9	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	N	TE	216	3	N	Not applicable	Recovered
			Pain	疼痛	3	N	TE	231		N	Not applicable	Ongoing at time of death
			Decreased appetite	食欲減退	2	N	TE	231		N	Not applicable	Ongoing at time of death
240006	USA	75/M/C	Constipation	便秘	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	Pre	-7	100	N	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cardiac murmur	心雑音	1	N	Pre	-2	35	N	None	Recovered
			Bone pain	骨痛	1	N	TE	31	63	N	None	Recovered
			Contusion	挫傷	1	N	TE	33		N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	3	N	TE	47	11	Y	None	Recovered
			Abdominal pain upper	上腹部痛	1	N	TE	64	25	N	None	Recovered
			Fatigue	疲労	1	N	TE	64		Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	64	60	N	None	Recovered
			Weight increased	体重増加	1	N	TE	64		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	64	25	N	Drug administration postponed	Recovered
			Muscular weakness	筋力低下	1	N	TE	64		N	None	Ongoing at time of death
			Bone pain	骨痛	4	Y	TE	88	6	N	Drug administration postponed	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	88	115	N	Drug permanently withdrawn	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	109	33	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	110	87	Y	Not applicable	Recovered
			Asthenia	無力症	2	N	TE	110		N	Not applicable	Ongoing at time of death
			Depression	うつ病	2	N	TE	110		N	Not applicable	Ongoing at time of death
			Fluid intake reduced	水分摂取量減少	2	N	TE	116	8	N	Not applicable	Recovered
			Cough	咳嗽	1	N	TE	118	17	N	None	Recovered
			Hypotension	低血圧	2	N	TE	120	55	N	Not applicable	Recovered
			Anorexia	食欲不振	2	N	TE	124		Y	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	145	203	N	Drug permanently withdrawn	Death
			Spinal cord compression	脊髄圧迫	3	N		202		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	347	1	N	Drug permanently withdrawn	Death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
002004	Norway	81/M/C	Anorexia	食欲不振	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	1	54	N	None	Ongoing at time of death
			Dizziness	浮動性めまい	2	N	Pre	1		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	54	9	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	57		Y	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	57		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	62		N	None	Ongoing at time of death
			Left ventricular dysfunction	左室機能不全	5	Y	TE	68	1	N	None	Death
002015	Norway	83/M/C	Oral candidiasis	口腔カンジダ症	2	N	TE			N	Not applicable	Ongoing at time of death
			Cough	咳嗽	2	N	TE			N	Not applicable	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	37	14	N	None	Recovered
			Conjunctivitis	結膜炎	2	N	TE	50	7	N	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	100	30	N	Drug permanently withdrawn	Death
			Cerebral haemorrhage	脳出血	2	Y	TE	100		Y	Drug permanently withdrawn	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	100	19	N	Not applicable	Recovered with sequelae
			Confusional state	錯乱状態	2	N	TE	127		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	129	1	N	Drug permanently withdrawn	Death
002018	Norway	70/M/C	Bone pain	骨痛	2	N	TE	2	21	Y	None	Recovered
			Stomatitis	口内炎	2	N	TE	22	9	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	22	14	Y	None	Recovered
			Insomnia	不眠症	1	N	TE	22		N	None	Ongoing at study termination / withdrawal
			Constipation	便秘	2	N	TE	29	5	N	None	Recovered
			Bone pain	骨痛	2	N	TE	35		Y	None	Not recovered, but no changes expected
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	44	63	N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pneumonia	肺炎	2	N	TE	75		N	Not applicable	Ongoing at study termination / withdrawal
			Metastases to central nervous system	中枢神経系転移	4	Y	TE	79		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	106	1	N	None	Death
006014	Norway	81/M/C	Anorexia	食欲不振	2	N	TE	29		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	57	80	N	None	Recovered
			Cystitis	膀胱炎	2	N	TE	101	5	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	101	55	N	Drug administration postponed	Recovered
			Pneumonia	肺炎	3	N	TE	106	10	N	Drug administration postponed	Recovered
			Cystitis	膀胱炎	2	N	TE	159	8	N	None	Recovered
			Dyspnoea	呼吸困難	3	Y	TE	159	6	N	Drug administration postponed	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	175	10	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cystitis	膀胱炎	2	N	TE	177	9	N	None	Recovered
			Bone pain	骨痛	1	Y	TE	184	2	N	Not applicable	Recovered with sequelae
			Death	死亡	5	Y	TE	205	1	N	Not applicable	Death
006029	Norway	77/M/C	Diarrhoea	下痢	1	N	TE	2	5	Y	None	Recovered
			Fatigue	疲労	1	N	TE	2	5	N	None	Recovered
			Anaemia	貧血	2	N	TE	35	39	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	56		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	68	12	N	None	Recovered with sequelae
			Dysphagia	嚥下障害	2	N	TE	69	5	N	None	Recovered
			Pyrexia	発熱	1	N	TE	69	2	Y	None	Recovered
			Infection	感染	3	N	TE	69	10	N	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	3	N	TE	69	9	N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	72	4	N	None	Recovered
			Anaemia	貧血	1	N	TE	73		N	None	Ongoing at time of death
			Psoriasis	乾癬	2	N	TE	75		N	None	Ongoing at time of death
			Urinary retention	尿閉	2	N	TE	76	1	N	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	1	N	TE	77		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	79		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	4	Y	TE	96	3	N	Not applicable	Death
			Dyspnoea	呼吸困難	5	Y	TE	98	1	N	Not applicable	Death
007003	Norway	65/M/C	Pleural effusion	胸水	2	Y	TE	1	11	N	None	Recovered
			Pneumonia	肺炎	2	N	TE	26	4	N	Drug administration postponed	Recovered
			Pneumonia	肺炎	3	Y	TE	29	9	N	Drug administration postponed	Recovered
			Bone pain	骨痛	3	N	TE	36		N	None	Ongoing at time of death
			Confusional state	錯乱状態	1	N	TE	53	3	Y	None	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	54		N	None	Ongoing at time of death
			Dizziness	浮動性めまい	1	N	TE	54	2	N	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pneumonia	肺炎	2	Y	TE	55	19	Y	Drug administration postponed	Recovered
			Confusional state	錯乱状態	2	Y	TE	55	19	Y	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	57	15	N	None	Recovered
			Metastases to meninges	髄膜転移	3	Y	TE	64	30	N	None	Death
			Thrombocytopenia	血小板減少症	4	Y	TE	86		Y	None	Ongoing at time of death
			Metastases to meninges	髄膜転移	5	Y	TE	93	1	N	None	Death
007009	Norway	67/M/C	Thrombocytopenia	血小板減少症	1	N	Pre	1	2	N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	4	Y	Pre	1		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	2	4	N	None	Ongoing at time of death
			Myocardial infarction	心筋梗塞	2	Y	TE	3	14	N	None	Death
			Hyperglycaemia	高血糖	4	Y	TE	4		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	5	8	N	None	Ongoing at time of death
			Localised oedema	限局性浮腫	1	N	TE	11		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	2	N	TE	12		N	None	Ongoing at time of death
			Myocardial infarction	心筋梗塞	5	Y	TE	16	1	N	None	Death
008014	Norway	77/M/C	Oedema peripheral	末梢性浮腫	1	N	TE			N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE			N	None	Ongoing at time of death
			Anaemia	貧血	1	N	Pre	1	3	N	-	
			Anaemia	貧血	2	N	TE	3	27	N	-	
			Cystitis	膀胱炎	2	N	TE	3	11	N	None	Recovered
			Myalgia	筋痛	2	Y	TE	3	4	N	None	Recovered
			Anaemia	貧血	1	N	TE	29	42	N	-	
			Respiratory tract infection	気道感染	2	N	TE	48		N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	69	12	N	None	Recovered
			Anaemia	貧血	2	N	TE	70	4	N	None	Ongoing at time of death
			Atrial fibrillation	心房細動	2	N	TE	70	2	N	None	Recovered
			Anaemia	貧血	1	N	TE	73	37	N	None	Ongoing at time of death
			Weight decreased	体重減少	2	N	TE	85		N	None	Ongoing at time of death
			Gastroenteritis norovirus	ノロウイルス性胃腸炎	2	Y	TE	93	5	N	None	Recovered
			Post procedural infection	処置後感染	2	N	TE	93	17	N	None	Recovered with sequelae

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	109		N	None	Ongoing at time of death
			Post procedural infection	処置後感染	2	Y	TE	109	8	N	Drug administration postponed	Recovered
			Syncope	失神	2	N	TE	110	1	N	None	Recovered
			Syncope	失神	2	N	TE	111	1	N	None	Recovered
			Syncope	失神	2	N	TE	112	1	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	113	3	N	None	Recovered
			Pneumonia	肺炎	2	N	TE	114		N	Drug administration postponed	Recovered
			Dyspnoea	呼吸困難	3	Y	TE	152		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	155	16	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	170	1	N	Not applicable	Death
010005	Czech Republic	83/M/C	Cachexia	悪液質	5	Y	TE	147	1	N	Not applicable	Death
016001	Czech Republic	72/M/C	Malignant neoplasm progression	悪性新生物進行	3	Y	TE	78	10	N	None	Not recovered, but no changes expected
			Thrombocytopenia	血小板減少症	3	N	TE	84		Y	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	98	3	N	None	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	100	1	N	None	Death
017010	Czech Republic	69/M/C	Bursitis	滑液包炎	2	Y	TE	37	13	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	52	32	N	None	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	83	1	N	None	Death
017013	Czech Republic	78/M/C	Dyspepsia	消化不良	1	Y	Pre	-17	5	N	None	Recovered
			Constipation	便秘	1	N	Pre	-1		N	None	Ongoing at time of death
			Cerebral ischaemia	脳虚血	4	Y	TE	85	7	N	None	Death
			Cerebral ischaemia	脳虚血	5	Y	TE	91	1	N	None	Death
017014	Czech Republic	63/M/C	Bone pain	骨痛	2	N	TE	15		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	98	1	N	None	Death
017016	Czech Republic	79/M/C	Urinary tract infection	尿路感染	3	Y	TE	80	6	N	None	Death
			Urinary tract infection	尿路感染	5	Y	TE	85	1	N	None	Death
017028	Czech Republic	63/M/C	Insomnia	不眠症	1	N	TE	113	29	N	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	141	29	N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	169	64	N	Not applicable	Ongoing at time of death
			Venous thrombosis	静脈血栓症	3	Y	TE	184	8	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	191	42	N	Not applicable	Ongoing at time of death
			Renal failure	腎不全	3	Y	TE	191	42	N	Not applicable	Death
			Staphylococcal infection	ブドウ球菌感染	3	Y	TE	200		N	Not applicable	Ongoing at time of death
			Renal failure	腎不全	5	Y	TE	232	1	N	Not applicable	Death
022005	Sweden	62/M/C	Dizziness	浮動性めまい	1	N	TE			N	None	Recovered
			Nausea	悪心	2	Y	TE	17	7	N	None	Recovered
			Vomiting	嘔吐	2	Y	TE	17	7	N	None	Recovered
			Dehydration	脱水	2	Y	TE	17	7	N	None	Recovered
			Bone pain	骨痛	2	N	TE	18	12	N	None	Recovered
			Fatigue	疲労	2	Y	TE	37	2	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	57		Y	None	Ongoing at time of death
			Sepsis	敗血症	4	Y	TE	57	5	N	Drug administration postponed	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	84	53	N	Not applicable	Death
			Anaemia	貧血	3	N	TE	85	14	N	None	Recovered with sequelae
			Anaemia	貧血	3	Y	TE	98	14	N	None	Recovered with sequelae
			Constipation	便秘	3	Y	TE	99	13	N	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	99	13	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	113	2	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	136	1	N	Not applicable	Death
024005	Sweden	69/M/C	Anaemia	貧血	2	N	TE	57	3	Y	None	Recovered
			Infection	感染	2	N	TE	103	11	N	None	Recovered
			Anaemia	貧血	1	N	TE	113	2	Y	None	Recovered
			General physical health deterioration	全身健康状態低下	3	N	TE	113		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	113	23	N	None	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	135	1	N	None	Death
024009	Sweden	73/M/C	Pathological fracture	病的骨折	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	11	50	N	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Arrhythmia	不整脈	1	N	TE	29		N	None	Not recovered, but no changes expected
			Chills	悪寒	1	N	TE	29		Y	None	Recovered
			Oedema	浮腫	3	N	TE	29		N	Not applicable	Ongoing at time of death
			Magnesium deficiency	マグネシウム欠乏	1	N	TE	29	29	N	None	Recovered
			General physical health deterioration	全身健康状態低下	3	N	TE	57		N	None	Not recovered, but no changes expected
			Pathological fracture	病的骨折	2	N	TE	61		N	None	Not recovered, but no changes expected
			Dyspepsia	消化不良	2	N	TE	65		N	None	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	Y	TE	65	15	N	None	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	3	N	TE	66		N	None	Not recovered, but no changes expected
			Metastases to liver	肝転移	2	N	TE	86		N	None	Not recovered, but no changes expected
			Metastases to liver	肝転移	2	N	TE	86		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	91	5	Y	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary tract infection	尿路感染	2	N	TE	92		N	Not applicable	Ongoing at time of death
			Anxiety	不安	2	N	TE	93		N	Not applicable	Ongoing at time of death
			Myocardial infarction	心筋梗塞	3	Y	TE	95		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	97	1	N	Drug permanently withdrawn	Death
024014	Sweden	74/M/C	Dry eye	眼乾燥	1	N	TE	15		N	None	Ongoing at time of death
			Skin infection	皮膚感染	2	N	TE	53	9	N	None	Recovered
			Metastases to bone	骨転移	1	N	TE	53		N	None	Not recovered, but no changes expected
			Micturition urgency	尿意切迫	1	N	TE	53		N	None	Not recovered, but no changes expected
			Hypoaesthesia	感覚鈍麻	2	N	TE	61		N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	81		N	None	Not recovered, but no changes expected
			Dizziness	浮動性めまい	2	N	TE	81	27	N	None	Recovered
			Viral skin infection	皮膚ウイルス感染	2	N	TE	100		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Atrial fibrillation	心房細動	2	Y	TE	101	7	N	None	Recovered
			Oral fungal infection	口腔真菌感染	2	N	TE	103		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	126	1	N	Drug permanently withdrawn	Death
024022	Sweden	84/M/C	Constipation	便秘	2	N	TE			N	Not applicable	Recovered
			Pneumonia	肺炎	4	Y	TE			N	Drug permanently withdrawn	Ongoing at time of death
			Hip fracture	股関節部骨折	3	Y	Pre			N	Drug administration postponed	Recovered
			Pulmonary oedema	肺水腫	4	Y	TE			N	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	Y	Pre	-33	14	N	Drug administration postponed	Recovered with sequelae
			Urinary retention	尿閉	2	Y	Pre	-33	14	N	Drug administration postponed	Recovered with sequelae

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	3	N	Pre	-18	10	N	Not applicable	Recovered
			Pyrexia	発熱	3	N	Pre	-18	10	N	Not applicable	Recovered
			Dislocation of joint prosthesis	人工骨頭関節脱臼	3	Y	Pre	-18	10	N	Not applicable	Recovered
			Bone pain	骨痛	3	N	Pre	-18	10	N	Not applicable	Recovered
			Pathological fracture	病的骨折	3	Y	TE	6		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	6	43	N	Drug permanently withdrawn	Death
			Sepsis	敗血症	3	Y	TE	15		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	48	1	N	Drug permanently withdrawn	Death
024024	Sweden	82/M/C	Fatigue	疲労	2	N	TE	59	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	112		N	None	Not recovered, but no changes expected
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	132	16	N	Drug permanently withdrawn	Not recovered, but no changes expected

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	148	14	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	161	1	N	Not applicable	Death
024026	Sweden	68/M/C	Nausea	悪心	2	N	TE			Y	None	Recovered
			Infection	感染	3	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE			N	Drug administration postponed	Death
			Restless legs syndrome	下肢静止不能症候群	1	N	TE	31	27	N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	57	30	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	57		N	None	Lost to follow-up
			Restless legs syndrome	下肢静止不能症候群	2	N	TE	57		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	79	8	N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	86		N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	86		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	3	Y	TE	102	12	N	Drug administration postponed	Recovered
			Pyrexia	発熱	3	Y	TE	102	12	N	Drug administration postponed	Recovered
			Bone pain	骨痛	3	Y	TE	102	12	N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	126	1	N	Drug administration postponed	Death
025002	Sweden	64/M/C	Nausea	悪心	1	N	TE	60	149	Y	None	Recovered
			Tremor	振戦	1	N	TE	88		N	None	Ongoing at time of death
			Listeriosis	リステリア症	2	Y	TE	92	26	N	Drug administration postponed	Recovered
			Fatigue	疲労	2	N	TE	155		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Haematuria	血尿	1	N	TE	185		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	204	5	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	208	1	N	Not applicable	Death
028005	Belgium	70/M/C	Radiculitis	神経根炎	2	N	Pre	-8		N	None	Ongoing at time of death
			Pathological fracture	病的骨折	3	Y	TE	21	3	N	None	Recovered
			Anaemia	貧血	3	N	TE	22	1	N	None	Recovered
			General physical health deterioration	全身健康状態低下	3	Y	TE	26	14	Y	None	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	82	12	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	93	1	N	Drug permanently withdrawn	Death
029002	Belgium	81/M/C	Fatigue	疲労	1	N	TE	41	32	N	None	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	1	N	TE	41	30	N	None	Recovered
			Depression	うつ病	1	N	TE	59		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	72		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	105	2	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	106		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	Y	TE	106	12	N	None	Recovered
			Muscular weakness	筋力低下	1	N	TE	109		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	117		N	Not applicable	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	128	31	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	158	1	N	Not applicable	Death
033001	UK	84/M/C	Oedema peripheral	末梢性浮腫	1	N	Pre	1		N	None	Ongoing at time of death
			Lymphadenopathy	リンパ節症	1	N	TE	25		N	None	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	2	N	TE	25		N	None	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	25	14	N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Muscular weakness	筋力低下	2	N	TE	29		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	29		N	None	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	N	TE	38		N	None	Ongoing at time of death
			Pulmonary embolism	肺塞栓症	5	Y	TE	59	1	N	None	Death
033014	UK	73/M/C	Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Pitting oedema	圧痕浮腫	2	N	TE			N	None	Ongoing at time of death
			Weight increased	体重増加	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			Y	None	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	1	N	TE			N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	112		Y	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	112	2	N	None	Recovered
			Nausea	悪心	1	N	TE	177	3	Y	None	Recovered
			Dysphasia	不全失語症	3	N	TE	177	3	N	None	Recovered
			Pleuritic pain	胸膜痛	3	Y	TE	177	3	N	Not applicable	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	184	1	N	Not applicable	Death
033017	UK	80/M/C	Abdominal pain lower	下腹部痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			Y	None	Recovered
			Dysuria	排尿困難	1	N	TE			N	None	Recovered
			Pollakiuria	頻尿	2	N	TE			N	None	Recovered with sequelae
			Pollakiuria	頻尿	2	N	TE			N	None	Recovered
			Urine flow decreased	尿流量減少	2	N	TE			N	None	Not recovered, but no changes expected
			Skin lesion	皮膚病変	1	N	TE			N	None	Not recovered, but no changes expected
			Pulmonary embolism	肺塞栓症	5	Y	TE	124	1	N	None	Death
033025	UK	66/M/C	Fatigue	疲労	2	N	TE			N	None	Not recovered, but no changes expected
			Tooth fracture	歯牙破折	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			Y	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	Pre	-35		Y	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE	4	14	Y	None	Recovered
			Anaemia	貧血	2	N	TE	29	64	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	85	2	Y	None	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE	88		N	None	Recovered
			Anaemia	貧血	3	N	TE	116	19	Y	None	Recovered
			Anaemia	貧血	2	N	TE	134	29	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	162	5	Y	None	Recovered
			Disseminated intravascular coagulation	播種性血管内凝固	4	Y	TE	165		N	Not applicable	Ongoing at time of death
			Respiratory failure	呼吸不全	4	Y	TE	168		N	Not applicable	Ongoing at time of death
			Haemorrhage intracranial	頭蓋内出血	5	Y	TE	169	1	N	Not applicable	Death
037018	UK	68/M/C	Somnolence	傾眠	1	N	TE			N	None	Recovered
			Tachycardia	頻脈	1	N	Pre	1	29	N	None	Recovered
			Muscle atrophy	筋萎縮	1	N	Pre	1		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	28	49	N	Drug administration postponed	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	63		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	76	4	N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	3	Y	TE	76		N	Drug administration postponed	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	76	30	N	None	Death
			Herpes zoster	帯状疱疹	2	Y	TE	78	8	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	79		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	79	9	N	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	79		N	None	Ongoing at time of death
			Fall	転倒・転落	1	N	TE	80	1	N	None	Recovered
			Bone pain	骨痛	2	N	TE	81		N	None	Ongoing at time of death
			Hypotension	低血圧	1	N	TE	85	2	N	None	Recovered
			Muscular weakness	筋力低下	1	N	TE	88	2	N	None	Recovered
			Cough	咳嗽	1	N	TE	90	4	N	None	Recovered
			Dyspnoea	呼吸困難	3	N	TE	92		N	None	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	3	Y	TE	93	6	N	None	Recovered
			Somnolence	傾眠	1	N	TE	96		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dry mouth	口内乾燥	1	N	TE	103		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	105	1	N	None	Death
039011	UK	65/M/C	Bone pain	骨痛	3	Y	Pre	-37	3	N	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	1	N	TE	3		N	None	Ongoing at time of death
			Nausea	悪心	3	Y	TE	4	4	Y	None	Recovered
			Dizziness	浮動性めまい	3	N	TE	5	17	Y	None	Ongoing at time of death
			Vomiting	嘔吐	3	N	TE	8		Y	None	Recovered
			Nausea	悪心	3	Y	TE	10		Y	Drug administration postponed	Ongoing at time of death
			Retching	レッチング	3	N	TE	10	12	Y	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	10	12	Y	None	Ongoing at time of death
			Paraesthesia	錯感覚	3	N	TE	10	12	N	None	Ongoing at time of death
			Somnolence	傾眠	1	N	TE	12		N	None	Ongoing at time of death
			Somnolence	傾眠	1	N	TE	12		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Tachycardia	頻脈	2	N	TE	13	9	N	None	Ongoing at time of death
			Abdominal pain	腹痛	2	N	TE	13	9	N	None	Ongoing at time of death
			Pleural effusion	胸水	2	N	TE	13	9	N	None	Ongoing at time of death
			Pleural effusion	胸水	3	N	TE	14	5	N	Drug administration postponed	Death
			Sepsis	敗血症	2	N	TE	15	7	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	15	7	N	None	Ongoing at time of death
			Rash	発疹	2	N	TE	15	7	N	None	Ongoing at time of death
			Chest pain	胸痛	3	N	TE	17	5	N	None	Ongoing at time of death
			Depressed mood	抑うつ気分	2	N	TE	17	5	N	None	Ongoing at time of death
			Vomiting	嘔吐	3	N	TE	18		N	None	Ongoing at time of death
			Pleural effusion	胸水	4	Y	TE	18	4	N	Drug administration postponed	Death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	3	N	TE	19	3	N	None	Ongoing at time of death
			Abdominal pain lower	下腹部痛	1	N	TE	20	2	N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	3	N	TE	20	2	N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	20	2	N	None	Ongoing at time of death
			Pleural effusion	胸水	5	Y	TE	21	1	N	Drug administration postponed	Death
041007	UK	62/M/C	Lymphadenopathy	リンパ節症	1	N	Pre	1		N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	7		Y	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	7		N	None	Ongoing at time of death
			Eyelid function disorder	眼瞼機能障害	2	N	TE	12	19	N	None	Recovered
			Vision blurred	霧視	1	N	TE	12		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	29		Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	29		Y	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Insomnia	不眠症	1	N	TE	29		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	60	6	N	None	Death
			Muscular weakness	筋力低下	2	N	TE	61		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	65	1	N	None	Death
042002	UK	64/M/C	Nausea	悪心	1	N	TE			Y	None	Recovered
			Vomiting	嘔吐	1	N	TE			Y	None	Recovered
			Peripheral coldness	末梢冷感	1	N	TE			N	None	Recovered
			Anorexia	食欲不振	1	N	TE			Y	None	Recovered
			Constipation	便秘	1	N	TE	3		Y	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	4	6	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	4	6	N	None	Recovered
			Bone pain	骨痛	2	N	TE	8	22	N	None	Recovered
			Tachycardia	頻脈	1	N	TE	28		N	None	Ongoing at time of death
			Hypotension	低血圧	1	N	TE	55	1	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	57	57	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	57	57	N	None	Recovered
			Spinal cord compression	脊髄圧迫	2	N	TE	58	56	N	None	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	164	12	N	Not applicable	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	192	1	N	Not applicable	Death
042003	UK	66/M/C	Anaemia	貧血	2	Y	TE	17	2	Y	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	17	7	N	None	Recovered
			Anaemia	貧血	3	N	TE	34	3	N	Not applicable	Recovered
			Cardiac failure congestive	うっ血性心不全	3	Y	TE	34	8	N	None	Death
			Constipation	便秘	2	N	TE	34		N	Not applicable	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	34	4	N	Not applicable	Recovered
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	2	N	TE	34		N	Not applicable	Ongoing at time of death
			Hypokalaemia	低カリウム血症	3	N	TE	35	3	N	Not applicable	Recovered
			Rectal haemorrhage	直腸出血	1	N	TE	37	1	N	Not applicable	Recovered
			Neuropathy peripheral	末梢性ニューロパチー	2	N	TE	38		N	Not applicable	Ongoing at time of death
			Urinary tract obstruction	尿路閉塞	3	N	TE	38		N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	39		N	Not applicable	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	2	Y	TE	39		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	1	N	TE	40	2	N	Not applicable	Recovered
			Pneumonia	肺炎	3	N	TE	40		N	Not applicable	Ongoing at time of death
			Confusional state	錯乱状態	1	N	TE	40		N	Not applicable	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	5	Y	TE	41	1	N	None	Death
042004	UK	74/M/C	Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Cough	咳嗽	1	N	TE			N	None	Ongoing at time of death
			Dysphonia	発声障害	1	N	TE			N	None	Ongoing at time of death
			Small intestinal obstruction	小腸閉塞	2	Y	Pre	-35	9	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	3	27	N	None	Recovered
			Epistaxis	鼻出血	1	N	TE	5	1	N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	30	8	N	None	Recovered
			Lethargy	嗜眠	1	N	TE	30	140	Y	None	Ongoing at time of death
			Dysgeusia	味覚異常	2	N	TE	41	3	N	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	45	2	N	None	Recovered
			Pathological fracture	病的骨折	2	Y	TE	55	9	N	None	Recovered
			Nausea	悪心	1	N	TE	56		N	None	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	58	6	Y	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Eye pain	眼痛	1	N	TE	80	3	N	None	Recovered
			Bone pain	骨痛	1	N	TE	106	1	N	None	Recovered
			Bone pain	骨痛	1	N	TE	112	1	N	None	Recovered
			Dyspnoea exertional	労作性呼吸困難	1	N	TE	113		N	None	Ongoing at time of death
			Oral pain	口腔内痛	1	N	TE	119	1	N	None	Recovered
			Palpitations	動悸	1	N	TE	121	1	N	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	141		N	None	Ongoing at time of death
			Contusion	挫傷	1	N	TE	141		N	None	Ongoing at time of death
			Lethargy	嗜眠	2	N	TE	169		Y	None	Ongoing at time of death
			Pleural effusion	胸水	1	N	TE	169		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	198	1	N	Not applicable	Death
042024	UK	62/M/C	Fatigue	疲労	1	N	TE			N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE			N	None	Ongoing at time of death
			Confusional state	錯乱状態	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	1	29	Y	None	Recovered
			Anxiety	不安	1	N	TE	2	28	N	None	Recovered
			Hyperhidrosis	多汗症	2	N	TE	2		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	2	N	TE	8		N	None	Ongoing at time of death
			Pyrexia	発熱	1	N	TE	62	1	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	64		N	None	Ongoing at time of death
			Dysuria	排尿困難	2	N	TE	80	6	N	Not applicable	Recovered
			Vomiting	嘔吐	3	Y	TE	83	6	N	None	Recovered
			Pyrexia	発熱	3	Y	TE	83	6	N	None	Recovered
			Confusional state	錯乱状態	3	Y	TE	83	1	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	99	23	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	121	1	N	Not applicable	Death
042031	UK	73/M/C	Depression	うつ病	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	-10	115	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	18	40	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	29	85	N	None	Recovered
			Decreased appetite	食欲減退	2	N	TE	29	85	N	None	Recovered
			Constipation	便秘	1	N	TE	53		N	None	Ongoing at time of death
			Cough	咳嗽	2	N	TE	53	8	N	None	Recovered
			Bone pain	骨痛	2	N	TE	105	22	N	None	Recovered
			Bone pain	骨痛	3	N	TE	126	16	N	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	142		N	Drug administration postponed	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	142	24	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	165	1	N	Drug permanently withdrawn	Death
043018	UK	63/M/C	Neuropathy peripheral	末梢性ニューロパチー	3	N	Pre	-3		N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	4	4	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	23	9	N	None	Recovered
			Contusion	挫傷	2	N	TE	50		N	None	Ongoing at time of death
			Skin disorder	皮膚障害	2	N	TE	50	8	N	None	Recovered
			Hypoaesthesia	感覚鈍麻	2	N	TE	76		N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	90	25	Y	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	90	25	Y	None	Ongoing at time of death
			Metastases to central nervous system	中枢神経系転移	4	Y	TE	106	9	N	Drug permanently withdrawn	Death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Metastases to central nervous system	中枢神経系転移	5	Y	TE	114	1	N	Drug permanently withdrawn	Death
047006	UK	73/M/C	Cardiac arrest	心停止	5	Y	TE	25	1	N	Drug permanently withdrawn	Death
048012	UK	68/M/C	Anorexia	食欲不振	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	8	76	N	None	Ongoing at time of death
			Asthenia	無力症	1	N	TE	41		Y	None	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE	51		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	57	2	N	None	Recovered
			Vision blurred	霧視	1	N	TE	69		N	None	Ongoing at time of death
			Headache	頭痛	2	N	TE	73	10	N	None	Recovered
			Bone pain	骨痛	1	N	TE	83		N	None	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	103	5	N	None	Recovered
			Anaemia	貧血	2	N	TE	112	3	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	189	1	N	Not applicable	Death
050001	UK	80/M/C	Anaemia	貧血	3	N	TE			N	Not applicable	Recovered with sequelae

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE			Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Ear infection	耳感染	2	N	TE			N	None	Recovered
			Anorexia	食欲不振	1	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at study termination / withdrawal
			Upper respiratory tract infection	上気道感染	2	N	Pre	-14	8	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	1	29	Y	-	
			Nausea	悪心	2	N	TE	2	2	Y	None	Recovered
			Fatigue	疲労	2	N	TE	8	14	Y	None	Recovered
			Muscular weakness	筋力低下	2	N	TE	8	14	N	None	Recovered
			Myalgia	筋痛	2	N	TE	8	22	N	None	Recovered
			Fatigue	疲労	3	N	TE	21	4	Y	None	Recovered
			Muscular weakness	筋力低下	3	N	TE	21	9	N	None	Recovered
			Fatigue	疲労	1	N	TE	24	37	Y	None	Recovered
			Anaemia	貧血	1	N	TE	29	29	Y	-	
			Nausea	悪心	2	N	TE	30	1	Y	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hot flush	ほてり	2	N	TE	30		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	34	1	Y	None	Recovered
			Anaemia	貧血	3	N	TE	57	5	Y	-	
			Anaemia	貧血	1	N	TE	61	12	Y	-	
			Urinary tract infection	尿路感染	2	N	TE	61	6	N	None	Recovered
			Urinary retention	尿閉	3	Y	TE	61	2	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	72	70	Y	-	
			Haemorrhage urinary tract	尿路出血	2	N	TE	80	2	N	None	Recovered
			Urinary retention	尿閉	1	N	TE	84		N	None	Ongoing at study termination / withdrawal
			Urinary retention	尿閉	1	N	TE	84	3	N	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	85	57	N	None	Ongoing at study termination / withdrawal
			Urinary retention	尿閉	2	N	TE	86		N	None	Ongoing at study termination / withdrawal
			Insomnia	不眠症	2	N	TE	101	5	N	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	3	N	TE	113		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Muscular weakness	筋力低下	2	N	TE	113		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	3	N	TE	141	9	Y	-	
			Constipation	便秘	1	N	TE	141		Y	Not applicable	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	2	N	TE	141		N	None	Ongoing at study termination / withdrawal
			Muscular weakness	筋力低下	3	N	TE	141		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	4	N	TE	149	3	Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	151		Y	None	Ongoing at study termination / withdrawal
			Cranial neuropathy	脳ニューロパチー	2	N	TE	155		N	None	Ongoing at time of death
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	2	N	TE	155		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oral candidiasis	口腔カンジダ症	2	N	TE	190		N	None	Ongoing at time of death
			Anaemia	貧血	4	Y	TE	192	5	N	Not applicable	Recovered with sequelae
			Gastric cancer	胃癌	4	Y	TE	192	28	N	Not applicable	Death
			Gastric cancer	胃癌	5	Y	TE	219	1	N	Not applicable	Death
050003	UK	60/M/C	Nausea	悪心	1	N	TE			N	None	Recovered
			Fatigue	疲労	2	N	TE			N	-	
			Fatigue	疲労	3	N	TE			N	-	
			Weight decreased	体重減少	1	N	TE			N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE			N	None	Ongoing at time of death
			Muscular weakness	筋力低下	3	N	TE			N	None	Ongoing at time of death
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE			N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	N	TE	6	10	N	-	
			Oedema genital	性器浮腫		N	TE	10		N	None	Ongoing at time of death
			Pharyngolaryngeal pain	咽喉頭疼痛	1	N	TE	13		N	None	Recovered
			Contusion	挫傷	1	N	TE	14		Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	15	9	N	-	

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	2	N	TE	16		Y	None	Ongoing at time of death
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE	16		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	18		N	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	19	3	N	-	
			Pollakiuria	頻尿	1	N	TE	19	4	N	None	Recovered
			Fatigue	疲労	3	N	TE	21		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	4	N	TE	23	8	N	-	
			Dysphagia	嚥下障害	2	N	TE	26		N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	1	N	TE	26	3	N	None	Recovered
			Oedema peripheral	末梢性浮腫	3	N	TE	29	2	N	Not applicable	Ongoing at time of death
			Abdominal pain	腹痛	3	N	TE	30	1	N	None	Recovered
			Oedema peripheral	末梢性浮腫	4	N	TE	30		N	Not applicable	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	4	N	TE	30		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	31	1	N	Drug permanently withdrawn	Death
			Agitation	激越	2	N	TE	31	1	N	Not applicable	Recovered
050016	UK	63/M/C	Constipation	便秘	1	N	TE			Y	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE			N	Not applicable	Ongoing at time of death
			Herpes zoster	帯状疱疹	2	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at time of death
			Memory impairment	記憶障害	1	N	TE			N	Not applicable	Ongoing at time of death
			Agitation	激越	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	Pre	-41	3	N	Not applicable	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	3	27	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	43	8	N	None	Recovered with sequelae
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	Y	TE	43	8	N	None	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	3	N	TE	43	16	N	None	Recovered
			Lung infection	肺感染	2	Y	TE	80	11	N	Drug administration postponed	Recovered with sequelae
			Fatigue	疲労	2	N	TE	99		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	1	N	TE	99		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	100		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	134	4	Y	None	Recovered
			Nausea	悪心	2	N	TE	138		Y	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	148		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	165	4	Y	Not applicable	Recovered
			General physical health deterioration	全身健康状態低下	2	Y	TE	168	17	N	Not applicable	Death
			Oral candidiasis	口腔カンジダ症	2	N	TE	171	6	N	Not applicable	Recovered
			Epilepsy	てんかん	3	Y	TE	175	1	N	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	5	Y	TE	184	1	N	Not applicable	Death
055007	Netherlands	62/M/C	Confusional state	錯乱状態	2	Y	Pre	-13	2	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	8		N	Not applicable	Ongoing at time of death
			Nausea	悪心	2	N	TE	8		N	Not applicable	Ongoing at time of death
			Intertrigo	間擦疹	1	N	TE	8		Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	35	2	N	None	Recovered
			Anaemia	貧血	3	N	TE	36		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	85	1	N	Not applicable	Death
072001	Spain	78/M/C	Fatigue	疲労	1	N	Pre			N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	10		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	21	7	N	None	Recovered
			Cardiac failure	心不全	4	Y	TE	31	5	N	None	Death
			Cardiac failure	心不全	5	Y	TE	35	1	N	None	Death
080001	Italy	73/M/C	Nausea	悪心	1	N	TE			Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE			Y	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	130	9	N	None	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	138	1	N	None	Death
085001	Israel	58/M/C	Pyrexia	発熱	1	N	TE	31	1	N	None	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	58	7	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	58	7	N	None	Recovered with sequelae

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pneumonia	肺炎	1	Y	TE	79		N	None	Ongoing at time of death
			Respiratory failure	呼吸不全	4	Y	TE	83	2	N	None	Death
			Respiratory failure	呼吸不全	5	Y	TE	84	1	N	None	Death
085003	Israel	74/M/C	Deep vein thrombosis	深部静脈血栓症	2	Y	Pre	-16	3	N	Not applicable	Recovered with sequelae
			Dermatitis contact	接触性皮膚炎	1	N	TE	37	8	N	None	Recovered
			Asthenia	無力症	1	N	TE	49	1	N	None	Recovered
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	55		N	None	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	TE	62		N	None	Ongoing at time of death
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	3	N	TE	62		N	None	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	TE	63	11	N	None	Recovered
			Rectal haemorrhage	直腸出血	2	Y	TE	82	4	N	None	Recovered
			Haematuria	血尿	2	Y	TE	82	4	N	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	90		N	None	Ongoing at time of death
			Tremor	振戦	2	N	TE	90		N	None	Ongoing at time of death
			Hypochromic anaemia	低色素性貧血	2	N	TE	96		N	None	Ongoing at time of death
			Localised oedema	限局性浮腫	1	N	TE	104		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Lobar pneumonia	大葉性肺炎	3	Y	TE	104	8	N	Drug permanently withdrawn	Death
			General physical health deterioration	全身健康状態低下	3	Y	TE	107		N	Drug permanently withdrawn	Ongoing at time of death
			Urosepsis	尿路性敗血症	3	Y	TE	107		N	Drug permanently withdrawn	Ongoing at time of death
			Lobar pneumonia	大葉性肺炎	5	Y	TE	111	1	N	Drug permanently withdrawn	Death
093001	Slovakia	72/M/C	Anaemia	貧血	2	N	Pre	-13	14	N	None	Recovered
			Constipation	便秘	1	N	Pre	-13	57	N	None	Recovered with sequelae
			Hyperbilirubinaemia	高ビリルビン血症	2	Y	Pre	-13	5	N	Not applicable	Recovered with sequelae
			Weight decreased	体重減少	2	Y	Pre	-13	5	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	N	Pre	-13	5	N	Not applicable	Recovered with sequelae
			Hyperbilirubinaemia	高ビリルビン血症	2	N	Pre	-9	3	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	1	N	Pre	-9	10	N	None	Recovered with sequelae
			Hyperbilirubinaemia	高ビリルビン血症	2	Y	Pre	-7	7	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	Y	TE	1	40	N	None	Recovered with sequelae
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	TE	35		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	35		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	35		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	44		N	None	Ongoing at time of death
			Constipation	便秘	2	Y	TE	44	11	N	None	Recovered with sequelae
			Bone pain	骨痛	2	Y	TE	44	11	N	None	Recovered with sequelae
			Pneumonia	肺炎	4	Y	TE	75		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	90	1	N	None	Death
095001	Slovakia	75/M/C	Bone pain	骨痛	4	N	TE	3	8	Y	Drug administration postponed	Recovered
			Bone pain	骨痛	2	N	TE	10	26	Y	Drug administration postponed	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	14	61	Y	Drug administration postponed	Recovered
			Nausea	悪心	1	N	TE	20	64	N	None	Recovered
			Fatigue	疲労	2	N	TE	20	118	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	35	40	Y	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	83		Y	Not applicable	Ongoing at time of death
			Cardiopulmonary failure	心肺不全	4	Y	Post	235	13	Y	Not applicable	Death
			Cardiopulmonary failure	心肺不全	5	Y	Post	247	1	Y	Not applicable	Death
097001	Slovakia	70/M/C	Anaemia	貧血	2	N	Pre	1		N	None	Ongoing at time of death
			Sudden death	突然死	5	Y	TE	9	1	N	None	Death
097004	Slovakia	80/M/C	Fatigue	疲労	3	N	TE	3		N	None	Ongoing at time of death
			Cerebral ischaemia	脳虚血	4	Y	TE	3	36	N	Drug administration postponed	Recovered with sequelae
			Micturition disorder	排尿異常	2	N	TE	112		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	3	N	TE	114		N	None	Ongoing at time of death
			Diarrhoea	下痢	3	Y	TE	143	29	Y	Drug permanently withdrawn	Recovered
			Vomiting	嘔吐	3	Y	TE	143	29	Y	Drug permanently withdrawn	Recovered
			Pyrexia	発熱	3	Y	TE	143	29	N	Drug permanently withdrawn	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	143	29	N	Drug permanently withdrawn	Recovered
			Disorientation	失見当識	3	N	TE	143	29	N	Not applicable	Recovered
			Cardiopulmonary failure	心肺不全	5	Y	TE	176	1	N	Not applicable	Death
097007	Slovakia	70/M/C	Bone pain	骨痛	2	N	Pre	-9	38	N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	2	56	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	29	84	N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	29	112	N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	57	56	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	112	9	Y	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	2	N	TE	112		N	None	Ongoing at time of death
			Sleep disorder	睡眠障害	1	N	TE	112	49	N	None	Recovered
			Mixed incontinence	混合性尿失禁	3	N	TE	112		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	120		Y	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	140		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	Pre	140		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	160	1	N	Not applicable	Death
097010	Slovakia	80/M/C	Nausea	悪心	1	N	TE	2	56	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	2		Y	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	29	58	N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	64	6	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	64	6	N	None	Recovered
			Nausea	悪心	1	N	TE	86	91	Y	None	Recovered
			Fatigue	疲労	3	Y	TE	86	5	Y	Drug administration postponed	Recovered with sequelae
			Weight decreased	体重減少	2	N	TE	86		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	90	68	Y	None	Recovered with sequelae
			Vomiting	嘔吐	2	N	TE	152	6	Y	None	Recovered
			Anaemia	貧血	2	N	TE	157	5	Y	None	Recovered
			Fatigue	疲労	3	Y	TE	157	5	Y	None	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	206	1	N	Not applicable	Death
106012	Hong Kong	75/M/A	Cystitis	膀胱炎	2	N	TE	7	7	N	None	Recovered
			Anaemia	貧血	2	Y	TE	29	2	Y	None	Recovered
			Constipation	便秘	1	N	TE	29	29	Y	None	Recovered
			Faeces discoloured	変色便	1	N	TE	29	29	N	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	29	29	N	None	Recovered
			Anaemia	貧血	3	Y	TE	57	3	Y	Drug administration postponed	Recovered
			Hyperkalaemia	高カリウム血症	1	N	TE	57	23	N	None	Recovered
			Haematuria	血尿	1	N	TE	57	23	N	None	Recovered
			Gastroduodenal ulcer	胃十二指腸潰瘍	1	N	TE	73		N	None	Ongoing at time of death
			Haemorrhoids	痔核	1	N	TE	73	7	N	None	Recovered
			Muscular weakness	筋力低下	2	N	TE	77		N	None	Ongoing at time of death
			Sepsis	敗血症	2	N	TE	79	20	N	Not applicable	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	79		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	79		N	Drug permanently withdrawn	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	2	N	TE	80		N	None	Ongoing at time of death
			Convulsion	痙攣	2	N	TE	85		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	4	Y	TE	90		N	Not applicable	Ongoing at time of death
			Pyrexia	発熱	2	N	TE	91	4	N	Not applicable	Recovered
			Diabetes mellitus	糖尿病	2	N	TE	91	16	N	Not applicable	Recovered
			Anxiety	不安	2	N	TE	94	13	N	Not applicable	Recovered
			Metastases to bone	骨転移	5	Y	TE	106	1	N	Not applicable	Death
133022	Poland	84/M/C	General physical health deterioration	全身健康状態低下	4	N	TE	77		N	None	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	3	Y	TE	77	8	N	Drug permanently withdrawn	Death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	5	Y	TE	84	1	N	Drug permanently withdrawn	Death
133029	Poland	56/M/C	Nausea	悪心	1	N	TE	2	2	Y	None	Recovered
			Asthenia	無力症	2	N	TE	2	3	Y	None	Recovered
			Urinary retention	尿閉	2	N	TE	53	4	N	None	Recovered
			Subileus	亜イレウス	3	Y	TE	63	5	Y	Drug administration postponed	Recovered
			Renal failure	腎不全	3	Y	TE	82	10	N	Drug permanently withdrawn	Death
			Renal failure	腎不全	5	Y	TE	91	1	N	Drug permanently withdrawn	Death
141002	Poland	60/M/C	Haematuria	血尿	2	Y	TE	10	27	N	None	Recovered
			Haematuria	血尿	3	Y	TE	40	11	N	None	Recovered with sequelae
			Haematuria	血尿	2	N	TE	50		N	None	Not recovered, but no changes expected
			Hydronephrosis	水腎症	2	Y	TE	56	5	N	Drug administration postponed	Recovered with sequelae

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	90	3	N	None	Recovered with sequelae
			Thrombocytopenia	血小板減少症	2	N	TE	92		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	2	N	TE	92		N	None	Ongoing at study termination / withdrawal
			Dyspnoea	呼吸困難	3	Y	TE	95	5	N	Not applicable	Death
			Dyspnoea	呼吸困難	5	Y	TE	99	1	N	Not applicable	Death
148005	Germany	63/M/C	Nausea	悪心	1	N	TE	27	1	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	57	38	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	57	29	Y	None	Recovered
			Nausea	悪心	1	N	TE	59	5	Y	None	Recovered
			Fatigue	疲労	2	N	TE	64		Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	85	1	Y	None	Recovered
			Anaemia	貧血	1	Y	TE	94	2	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	112		N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	114	4	Y	None	Recovered
			Nausea	悪心	1	N	TE	114	4	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	114	4	Y	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	129	1	N	None	Death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
149005	Germany	73/M/C	Bone pain	骨痛	1	N	TE	13	31	Y	None	Recovered
			Abdominal pain	腹痛	1	N	TE	31	13	Y	None	Recovered
			Nausea	悪心	1	N	TE	64	3	N	None	Recovered
			Fatigue	疲労	1	N	TE	64	5	N	Drug permanently withdrawn	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	64		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	1	N	TE	64	28	N	-	
			Insomnia	不眠症	1	N	TE	64	4	N	None	Recovered
			Fatigue	疲労	2	N	TE	68	13	N	Drug permanently withdrawn	Ongoing at time of death
			Fatigue	疲労	3	N	TE	80		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	91	24	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	114	2	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	115	1	N	Not applicable	Death
155010	Germany	80/M/C	Gastritis	胃炎	1	N	TE			N	None	Recovered
			General physical health deterioration	全身健康状態低下	1	N	TE	1	86	N	None	Recovered
			Gastritis	胃炎	2	N	TE	54		N	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	120		N	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	1	N	TE	120		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	135		N	Not applicable	Ongoing at time of death
			Atrial fibrillation	心房細動	4	N	TE	203		N	Not applicable	Ongoing at time of death
			Sinusitis	副鼻腔炎	1	N	TE	203		N	Not applicable	Ongoing at time of death
			Cerebral haemorrhage	脳出血	4	Y	TE	203		N	Not applicable	Ongoing at time of death
			Epilepsy	てんかん	2	N	TE	203	2	N	Not applicable	Ongoing at time of death
			Pneumonia aspiration	嚥下性肺炎	4	Y	TE	203	2	N	Not applicable	Death
			Pneumonia aspiration	嚥下性肺炎	5	Y	TE	204	1	N	Not applicable	Death
172001	Brazil	75/M/C	Fatigue	疲労	2	N	TE	31		N	None	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	1	N	TE	31	29	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	36	4	N	None	Recovered
			Nasal congestion	鼻閉	1	N	TE	38	22	N	None	Recovered
			Cachexia	悪液質	3	N	TE	59		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	N	TE	86	2	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	86	28	N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	87		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	113		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	212	1	N	Not applicable	Death
174003	Brazil	71/M/A	Weight decreased	体重減少	1	N	Pre	1	76	N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	4	15	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	41	17	N	None	Recovered
			Bone pain	骨痛	3	N	TE	41	4	N	None	Recovered
			Bone pain	骨痛	3	N	TE	41	17	N	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	2	N	TE	44		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	44	14	N	None	Recovered
			Constipation	便秘	2	N	TE	48	10	N	None	Recovered
			Nausea	悪心	2	N	TE	51	7	N	None	Recovered
			Bone pain	骨痛	2	N	TE	57		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	57		N	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	57		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	63	28	N	None	Recovered
			Nausea	悪心	1	N	TE	63	156	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	76	116	N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	99	43	N	None	Recovered
			Bone pain	骨痛	1	N	TE	105	1	N	None	Recovered
			Anaemia	貧血	3	N	TE	106	29	Y	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	106	29	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	134		Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	162	30	Y	None	Recovered
			Weight decreased	体重減少	3	N	TE	191		N	None	Ongoing at time of death
			Pneumonia	肺炎		N	TE	225		N	Not applicable	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	4	Y	TE	240	8	N	Not applicable	Death
			General physical health deterioration	全身健康状態低下	5	Y	TE	247	1	N	Not applicable	Death
181006	Brazil	75/M/B	Sepsis	敗血症	4	Y	TE	146	11	N	None	Death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hypernatraemia	高ナトリウム血症	4	N	TE	146		N	Drug administration postponed	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	146		N	None	Ongoing at time of death
			Renal failure acute	急性腎不全	4	N	TE	146		N	Drug permanently withdrawn	Ongoing at time of death
			Respiratory failure	呼吸不全	4	N	TE	146		N	Drug permanently withdrawn	Ongoing at time of death
			Sepsis	敗血症	5	Y	TE	156	1	N	None	Death
191006	Singapore	71/M/A	Hypoaesthesia	感覚鈍麻	1	N	Pre	-5		N	None	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	1	N	Pre	-4		N	None	Ongoing at time of death
			Myopathy	ミオパチー	1	N	Pre	-4		N	None	Ongoing at time of death
			Insomnia	不眠症	1	N	Pre	-4		N	None	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	Pre	1	7	N	None	Recovered
			Hyperkalaemia	高カリウム血症	2	N	Pre	1	28	N	None	Recovered
			Constipation	便秘	1	N	TE	16		Y	None	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	1	N	TE	16		Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	24	46	N	None	Recovered
			Headache	頭痛	1	N	TE	24		Y	None	Ongoing at time of death
			Urinary incontinence	尿失禁	2	N	TE	69		N	None	Ongoing at time of death
			Anal sphincter atony	肛門括約筋無緊張症	3	N	TE	118	59	N	Not applicable	Ongoing at time of death
			Somnolence	傾眠	3	N	TE	169		N	Not applicable	Ongoing at time of death
			Intestinal perforation	腸管穿孔	4	Y	TE	174		N	Not applicable	Ongoing at time of death
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	3	Y	TE	174		N	Not applicable	Ongoing at time of death
			Myocardial infarction	心筋梗塞	5	Y	TE	176	1	N	Not applicable	Death
207002	Australia	81/M/C	Anorexia	食欲不振	2	N	TE			N	None	Lost to follow-up
			Urinary incontinence	尿失禁	2	N	TE			N	None	Lost to follow-up
			Oedema peripheral	末梢性浮腫	1	N	TE	58		N	None	Lost to follow-up
			Swelling face	顔面腫脹	1	N	TE	58		N	None	Lost to follow-up
			Faecal incontinence	便失禁	1	N	TE	104		N	None	Ongoing at time of death
			Dementia	認知症	3	Y	TE	104	7	N	Drug permanently withdrawn	Recovered with sequelae

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	137	1	N	Not applicable	Death
213006	Australia	72/M/C	Constipation	便秘	1	N	TE			N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			N	None	Recovered
			Fatigue	疲労	1	N	TE	1	2	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	3	55	N	None	Recovered
			Ingrowing nail	嵌入爪	1	N	TE	18		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	29	3	Y	None	Recovered
			Fatigue	疲労	1	N	TE	57	3	Y	None	Recovered
			Constipation	便秘	1	N	TE	59	7	N	None	Recovered
			Fatigue	疲労	1	N	TE	85		Y	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	142		N	None	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	4	Y	TE	185	30	N	Not applicable	Recovered with sequelae
			Pneumonia	肺炎	3	Y	TE	188	5	N	Not applicable	Recovered
			Gastrointestinal haemorrhage	胃腸出血	3	Y	TE	196	2	N	Not applicable	Recovered
			Oral candidiasis	口腔カンジダ症	2	N	TE	200		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Postoperative wound infection	術後創感染	3	Y	TE	201	14	N	Not applicable	Recovered with sequelae
			Postoperative wound infection	術後創感染	2	N	TE	214		N	Not applicable	Ongoing at time of death
			Pulmonary embolism	肺塞栓症	4	Y	TE	220	5	N	Not applicable	Death
			Pulmonary embolism	肺塞栓症	5	Y	TE	224	1	N	Not applicable	Death
233003	UK	61/M/C	Anorexia	食欲不振	1	N	Pre	-13	22	N	None	Recovered with sequelae
			Fatigue	疲労	2	N	Pre	1	163	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre	1	29	N	None	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	29	36	Y	None	Recovered
			Bone pain	骨痛	2	N	Pre	29	36	N	None	Ongoing at time of death
			Ageusia	味覚消失	2	N	TE	29	36	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	58	4	N	None	Recovered
			Constipation	便秘	2	N	TE	60		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	64	25	N	None	Recovered
			Bone pain	骨痛	3	N	Pre	64		N	None	Ongoing at time of death
			Muscular weakness	筋力低下	3	N	TE	64		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	92	17	N	None	Recovered

表 2.7.4.7- 13 死亡例の一覧（試験 BC1-06、2 回目の解析）（続き）

Treatment：Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Tachycardia	頻脈	1	N	TE	92		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	92		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	104	60	N	None	Recovered
			Anaemia	貧血	3	Y	TE	135	3	N	Drug administration postponed	Recovered
			Asthenia	無力症	3	N	TE	135	3	Y	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	138		N	Drug administration postponed	Ongoing at study termination / withdrawal
			Dysarthria	構語障害	1	N	TE	145		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	3	N	TE	152	12	N	None	Death
			Cardiac failure	心不全	4	Y	TE	152		N	Drug permanently withdrawn	Ongoing at time of death
			Pleural effusion	胸水	2	N	TE	152		N	Not applicable	Ongoing at time of death
			Nausea	悪心	2	N	TE	159	5	N	Not applicable	Ongoing at time of death

Sex is identified as: M = Male.

Race is identified as: A = Asian, B = Black, C = Caucasian, O = Other.

The unit for "Age" is years.

Phase is identified as: Pre = Pre-Treatment, TE = Treatment-Emergent, Post = Post-Treatment

Source: 5.3.5.1.4 BC1-06_J-table 2/Table 1.4/2

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
001023	Norway	62/M/C	Bone pain	骨痛	2	N	Pre	1		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	29		Y	None	Ongoing at study termination / withdrawal
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	57		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	TE	57		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	57		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	57	19	N	Drug permanently withdrawn	Death
			Metastases to liver	肝転移	3	Y	TE	57		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	75	1	N	Drug permanently withdrawn	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
002006	Norway	66/M/C	Bone pain	骨痛	2	N	Pre			N	None	Ongoing at study termination / withdrawal
			Urinary tract infection	尿路感染	3	N	TE	10	10	N	None	Recovered
			Anaemia	貧血	2	N	TE	29	34	N	None	Recovered
			Bone pain	骨痛	1	N	Pre	29	29	N	None	Ongoing at study termination / withdrawal
			Ascites	腹水	1	N	TE	57	6	N	None	Recovered
			Bone pain	骨痛	2	N	Pre	57		N	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	Y	TE	62	18	N	Drug permanently withdrawn	Recovered with sequelae
			Fungal infection	真菌感染	2	N	TE	76	5	N	None	Recovered
			Anxiety	不安	2	N	TE	77		N	None	Not recovered, but no changes expected
			Sepsis	敗血症	4	Y	TE	79	5	N	Not applicable	Death
			Anaemia	貧血	2	N	TE	81	2	N	None	Recovered
			Sepsis	敗血症	5	Y	TE	83	1	N	Not applicable	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
02013	Norway	69/M/C	Vision blurred	霧視	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	2	5	Y	None	Recovered
			Metastases to skin	皮膚転移	1	N	TE	57		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	85		N	None	Ongoing at study termination / withdrawal
			Metastases to soft tissue	軟部組織転移	1	N	TE	86		N	None	Ongoing at time of death
			Cerebral haemorrhage	脳出血	3	Y	TE	100	38	Y	Drug permanently withdrawn	Death
			Anaemia	貧血	2	N	TE	110		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	111		Y	Not applicable	Ongoing at time of death
			Cerebral haemorrhage	脳出血	5	Y	TE	137	1	Y	Drug permanently withdrawn	Death
003018	Norway	71/M/C	Constipation	便秘	2	N	TE			N	Not applicable	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	2	N	TE	2	134	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	1	N	TE	57	102	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	116	57	N	Not applicable	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	3	N	TE	135	24	N	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	2	N	TE	147	72	N	Not applicable	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	3	Y	TE	158	5	N	Not applicable	Recovered with sequelae
			Pelvic pain	骨盤痛	3	N	TE	162		Y	Not applicable	Ongoing at time of death
			Nausea	悪心	2	N	TE	172		N	Not applicable	Ongoing at time of death
			Weight decreased	体重減少	3	N	TE	172		N	Not applicable	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	3	Y	TE	172	38	N	Not applicable	Recovered with sequelae
			Gastric ulcer	胃潰瘍	3	N	TE	181		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	187	1	Y	Not applicable	Recovered
			Depression	うつ病	3	N	TE	208		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	218	1	N	Not applicable	Death
004001	Norway	60/M/C	Dysgeusia	味覚異常	1	N	TE	2	28	Y	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	92	24	Y	None	Recovered
			Anaemia	貧血	1	N	TE	92	24	Y	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	92	113	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	120		Y	None	Ongoing at time of death
			Respiratory tract infection viral	ウイルス性気道感染	2	N	TE	134	11	N	None	Recovered
			Anaemia	貧血	2	N	TE	144		Y	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	2	N	TE	148	37	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	148	12	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	148	12	Y	None	Recovered with sequelae
			Pancytopenia	汎血球減少症	3	N	TE	155	5	Y	Not applicable	Recovered with sequelae
			Pancytopenia	汎血球減少症	3	Y	TE	159	11	Y	Not applicable	Recovered with sequelae
			Oedema	浮腫	2	Y	TE	159	11	Y	Not applicable	Recovered with sequelae
			Dyspnoea	呼吸困難	3	Y	TE	159	11	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	Y	TE	159	11	Y	Not applicable	Recovered with sequelae

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pancytopenia	汎血球減少症	2	N	TE	169	16	Y	Not applicable	Recovered with sequelae
			Dyspnoea	呼吸困難	2	N	TE	169	16	Y	Not applicable	Recovered
			Pleural effusion	胸水	1	N	TE	170	15	Y	Not applicable	Recovered
			Pancytopenia	汎血球減少症	3	Y	TE	184	15	Y	Not applicable	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	3	Y	TE	184	15	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	Y	TE	184	15	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	Y	TE	184	15	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	198	7	Y	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	198	7	Y	Not applicable	Recovered with sequelae
			Pancytopenia	汎血球減少症	4	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	204		Y	Not applicable	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	3	Y	TE	204		Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pleural effusion	胸水	2	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Renal failure	腎不全	5	Y	TE	208	1	N	Not applicable	Death
005002	Norway	75/M/C	Bone pain	骨痛	1	N	TE			N	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	85		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	162	36	N	Not applicable	Recovered
			Pneumonia	肺炎	3	Y	TE	169	15	N	Not applicable	Recovered
			Atrial fibrillation	心房細動	2	Y	TE	180	1	N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	197	7	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	198	6	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	1	N	TE	203		Y	Not applicable	Ongoing at time of death
			Pulmonary embolism	肺塞栓症	4	Y	TE	222	5	Y	Not applicable	Death
			Pulmonary embolism	肺塞栓症	5	Y	TE	226	1	Y	Not applicable	Death
006005	Norway	72/M/C	Diarrhoea	下痢	1	N	TE	3	1	Y	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pyrexia	発熱	2	Y	TE	22	7	N	None	Recovered
			Dehydration	脱水	2	Y	TE	22	7	N	None	Recovered
			Vomiting	嘔吐	1	Y	TE	38	1	N	None	Recovered
			Pyrexia	発熱	2	Y	TE	38	1	Y	None	Recovered
			Dehydration	脱水	2	Y	TE	38	6	Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	2	Y	TE	38	6	N	None	Recovered
			Vomiting	嘔吐	2	Y	TE	62	11	Y	None	Recovered
			Dehydration	脱水	2	Y	TE	62	11	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	62	11	N	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	85	15	N	None	Recovered with sequelae
			Dyspepsia	消化不良	2	N	TE	86		N	None	Ongoing at time of death
			Depression	うつ病	2	N	TE	99		N	None	Ongoing at time of death
			Pneumonia	肺炎	3	Y	TE	176	2	N	Not applicable	Death
			Bone pain	骨痛	3	Y	TE	176		N	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	5	Y	TE	177	1	N	Not applicable	Death
006008	Norway	70/M/C	Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	Pre	-1	29	N	None	Ongoing at time of death
			Hydronephrosis	水腎症	3	Y	Pre	-1	3	N	None	Recovered
			Constipation	便秘	2	N	TE	2	25	Y	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	1	N	TE	2	6	Y	None	Recovered
			Fatigue	疲労	2	N	TE	2	6	N	None	Recovered
			Hyperhidrosis	多汗症	2	N	TE	2	6	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	17	11	N	None	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	Pre	28		N	None	Ongoing at time of death
			Small intestinal obstruction	小腸閉塞	3	Y	TE	55	3	N	Drug administration postponed	Recovered
			Death	死亡	5	Y	TE	60	1	N	Drug permanently withdrawn	Death
006055	Norway	63/M/C	Petechiae	点状出血	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Nerve root compression	神経根圧迫	3	Y	Pre	-33	4	N	None	Recovered
			Groin pain	鼠径部痛	2	N	Pre	-2	3	N	None	Recovered
			Nerve root compression	神経根圧迫	3	Y	TE	1	4	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	1	4	N	None	Recovered
			Pyrexia	発熱	1	N	TE	23	3	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	3	Y	TE	24	4	N	None	Recovered with sequelae
			Hypoalbuminaemia	低アルブミン血症	2	N	TE	24	4	N	None	Ongoing at study termination / withdrawal
			Hypoaesthesia	感覚鈍麻	1	N	TE	24		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	27	8	N	None	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	2	N	TE	27	8	N	None	Ongoing at study termination / withdrawal
			Hypoalbuminaemia	低アルブミン血症	1	N	TE	27		N	None	Ongoing at study termination / withdrawal
			Cardiac failure	心不全	2	N	TE	28		N	None	Ongoing at study termination / withdrawal
			Pyrexia	発熱	1	N	TE	28	2	N	None	Recovered
			Pneumonia	肺炎	3	Y	TE	28	6	N	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	28	7	N	None	Recovered
			Pleural effusion	胸水	2	N	TE	28	7	N	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	30	3	N	None	Recovered
			Pulmonary hypertension	肺高血圧症	2	N	TE	32		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	34	5	N	None	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	1	N	TE	34		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	38	31	N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	52	18	N	None	Ongoing at study termination / withdrawal
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	Y	TE	52	3	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	53	11	N	None	Recovered
			Thrombocytopenia	血小板減少症	4	Y	TE	66	2	Y	Drug administration postponed	Recovered with sequelae
			Hypokalaemia	低カリウム血症	1	N	TE	66		N	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	Y	TE	66		N	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	3	N	TE	67	4	N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary tract infection	尿路感染	1	N	TE	67		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	N	TE	68		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	69		N	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	3	N	TE	70		N	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	4	N	TE	70	1	N	None	Ongoing at study termination / withdrawal
			General physical health deterioration	全身健康状態低下	3	N	TE	71		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	84	1	N	Not applicable	Death
008003	Norway	79/M/C	Nausea	悪心	2	N	Pre	1	25	N	None	Recovered
			Nausea	悪心	2	Y	TE	25	4	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	25		N	None	Ongoing at time of death
			Hypercalcaemia	高カルシウム血症	1	N	TE	25	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	27	2	Y	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	2	N	TE	28		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	35	25	N	Drug permanently withdrawn	Recovered
			Dehydration	脱水	2	N	TE	51		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	59	1	N	Not applicable	Death
008011	Norway	69/M/C	Nausea	悪心	1	N	TE			N	None	Recovered
			Vomiting	嘔吐	1	N	TE			N	None	Recovered
			Fatigue	疲労	1	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE	2	2	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	2	2	N	None	Recovered
			Tendonitis	腱炎	2	N	TE	35		N	None	Recovered
			Constipation	便秘	1	N	TE	37		N	None	Recovered
			Nausea	悪心	1	N	TE	37	5	N	None	Recovered
			Musculoskeletal stiffness	筋骨格硬直	2	N	TE	99	15	N	None	Recovered
			Pharyngitis	咽頭炎	1	N	TE	138	3	N	None	Recovered
			Pathological fracture	病的骨折	2	N	TE	149		N	Not applicable	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	149	9	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	2	N	TE	157	10	N	Not applicable	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Spinal cord compression	脊髄圧迫	3	Y	TE	166	6	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	167	22	N	None	Recovered
			Spinal cord compression	脊髄圧迫	3	N	TE	171	42	N	Not applicable	Ongoing at time of death
			Subileus	亜イレウス	2	Y	TE	181	4	N	Not applicable	Recovered
			Oesophageal pain	食道痛	1	N	TE	198	1	N	Not applicable	Recovered
			Cystitis	膀胱炎	1	N	TE	201	11	N	Not applicable	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	212	1	N	Not applicable	Death
011006	Czech Republic	68/M/C	Diarrhoea	下痢	1	N	TE	2	11	Y	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	150	256	Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	Y	TE	405		Y	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	4	Y	Post	405	2	Y	Not applicable	Death
			Pneumonia	肺炎	5	Y	Post	406	1	Y	Not applicable	Death
017003	Czech Republic	80/M/C	Cachexia	悪液質	4	Y	TE	115	10	N	None	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pneumonitis	肺臓炎	3	N	TE	115		N	None	Ongoing at time of death
			Cachexia	悪液質	5	Y	TE	124	1	N	None	Death
017004	Czech Republic	83/M/C	Angina pectoris	狭心症	3	Y	TE	105	15	N	None	Recovered with sequelae
			Depression	うつ病	2	N	TE	105	8	N	Drug administration postponed	Recovered
			Angina pectoris	狭心症	2	N	TE	119	184	N	None	Death
			Hypokalaemia	低カリウム血症	1	N	TE	119		N	None	Not recovered, but no changes expected
			Angina pectoris	狭心症	5	Y	TE	302	1	N	None	Death
017007	Czech Republic	80/M/C	Malignant neoplasm progression	悪性新生物進行	4	Y	TE	178	3	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	180	1	N	Not applicable	Death
017017	Czech Republic	77/M/C	General physical health deterioration	全身健康状態低下	4	Y	TE	151	2	N	Not applicable	Death
			General physical health deterioration	全身健康状態低下	5	Y	TE	152	1	N	Not applicable	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
017018	Czech Republic	76/M/C	Bone pain	骨痛	1	Y	Pre	-61	10	N	None	Recovered
			Myocardial ischaemia	心筋虚血	4	Y	TE	146		N	Not applicable	Ongoing at time of death
			Myocardial infarction	心筋梗塞	5	Y	TE	154	1	N	Not applicable	Death
017027	Czech Republic	60/M/C	Anaemia	貧血	2	N	TE	79	43	N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	116	6	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	121	1	N	Drug permanently withdrawn	Death
017030	Czech Republic	86/M/C	Leukopenia	白血球減少症			TE			N	None	Recovered
			Anaemia	貧血	2	N	Pre	1		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	28		N	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	Y	TE	50	8	N	None	Recovered
			Thrombocytopenia	血小板減少症	3	Y	TE	50	8	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	Y	TE	57		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			General physical health deterioration	全身健康状態低下	5	Y	TE	59	1	N	None	Death
017032	Czech Republic	57/M/C	Malignant neoplasm progression	悪性新生物進行	5	Y	TE	97	1	N	None	Death
020005	Sweden	71/M/C	Anorexia	食欲不振	2	N	TE			N	None	Ongoing at time of death
			Micturition urgency	尿意切迫	2	N	Pre			N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	1	4	Y	None	Recovered
			Fatigue	疲労	2	N	TE	1		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	1		Y	None	Not recovered, but no changes expected
			Musculoskeletal pain	筋骨格痛	1	N	TE	1	4	Y	None	Recovered
			Haematuria	血尿	2	N	TE	11		N	None	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	17	3	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	33	5	Y	None	Recovered
			Constipation	便秘	3	N	TE	39		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Chills	悪寒	1	N	TE	54		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	Y	TE	75	14	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	91	22	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	112	1	N	Drug permanently withdrawn	Death
020015	Sweden	74/M/C	Nausea	悪心	1	N	Pre			N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE			N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	N	TE			Y	None	Ongoing at time of death
			Myalgia	筋痛	1	N	Pre			N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE			Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	19		Y	None	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	3	Y	TE	28	15	Y	Drug administration postponed	Recovered with sequelae

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	2	N	TE	28		Y	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	28	15	Y	None	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	1	N	TE	42		Y	None	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE	42		Y	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	106	5	N	Drug permanently withdrawn	Death
024007	Sweden	63/M/C	Insomnia	不眠症	1	N	Pre	-2		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	Pre	-1		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	1	2	Y	None	Recovered
			Cystitis	膀胱炎	2	N	TE	30	41	N	None	Recovered
			Oedema	浮腫	2	N	TE	63	106	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	75		N	None	Not recovered, but no changes expected

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	114		N	None	Not recovered, but no changes expected
			Erysipelas	丹毒	2	N	TE	128		N	None	Recovered
			Thrombophlebitis	血栓性静脈炎	1	N	TE	128		N	None	Recovered
			Bone pain	骨痛	3	Y	TE	138		N	None	Ongoing at time of death
			Metastases to liver	肝転移	3	N	TE	141	28	N	Not applicable	Death
			Anaemia	貧血	2	N	TE	158	4	Y	Not applicable	Recovered
			Metastases to liver	肝転移	5	Y	TE	168	1	N	Not applicable	Death
024017	Sweden	73/M/C	Bone pain	骨痛	2	N	TE	34		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	64	27	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	64		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	117	30	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	204	1	N	Not applicable	Death
025004	Sweden	63/M/C	Fatigue	疲労	1	N	TE	31	-1	Y	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Upper respiratory tract infection bacterial	細菌性上気道感染	1	N	TE	48	12	N	None	Recovered
			Haematuria	血尿	3	Y	TE	82		N	Drug administration postponed	Ongoing at time of death
			Cardiac failure	心不全	4	Y	TE	90	2	N	Drug permanently withdrawn	Death
			Cardiac failure	心不全	5	Y	TE	91	1	N	Drug permanently withdrawn	Death
025014	Sweden	82/M/C	Haematuria	血尿	2	N	Pre			N	None	Recovered
			Fatigue	疲労	3	N	TE	29		N	Drug permanently withdrawn	Ongoing at time of death
			Hepatic failure	肝不全	3	Y	TE	29	9	N	Drug permanently withdrawn	Death
			Bone pain	骨痛	2	Y	TE	29		N	Drug permanently withdrawn	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hepatic failure	肝不全	5	Y	TE	37	1	N	Drug permanently withdrawn	Death
025015	Sweden	72/M/C	Fatigue	疲労	2	N	TE	57		N	None	Ongoing at study termination / withdrawal
			Lymphadenopathy	リンパ節症	2	N	TE	62		N	None	Ongoing at time of death
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	TE	62		N	None	Ongoing at study termination / withdrawal
			Metastases to liver	肝転移	5	Y	TE	88	1	N	Not applicable	Death
025020	Sweden	61/M/C	Bone pain	骨痛	2	Y	TE	42	3	N	None	Recovered
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE	70	71	N	None	Recovered
			Bone pain	骨痛	1	N	TE	127		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	132	8	N	None	Recovered
			Sepsis	敗血症	4	Y	TE	160	11	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	4	Y	TE	160	14	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	166		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	220	1	N	Not applicable	Death
026001	Sweden	78/M/C	Bone pain	骨痛	3	N	TE			N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	3		N	None	Not recovered, but no changes expected
			Haematuria	血尿	1	N	TE	106	4	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	114		N	None	Ongoing at time of death
			Dehydration	脱水	2	Y	TE	117	12	N	None	Recovered
			Confusional state	錯乱状態	2	Y	TE	117	12	N	None	Recovered with sequelae
			Urinary retention	尿閉	2	N	TE	118		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	137	2	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	138	1	N	Drug permanently withdrawn	Death
026002	Sweden	66/M/C	Oesophageal spasm	食道痙攣	1	N	TE			N	None	Recovered
			Bone pain	骨痛	3	Y	Pre	-2	8	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Polyneuropathy	多発ニューロパチー	1	Y	TE	91	4	N	None	Recovered with sequelae
			Faecal incontinence	便失禁	3	Y	TE	108	8	N	None	Recovered with sequelae
			Hyperglycaemia	高血糖	3	Y	TE	108	8	N	None	Recovered with sequelae
			Urinary incontinence	尿失禁	3	Y	TE	108	8	N	None	Recovered with sequelae
			Pancytopenia	汎血球減少症	2	N	TE	124	6	N	Drug permanently withdrawn	Ongoing at time of death
			Fall	転倒・転落	3	Y	TE	124		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	124	13	N	None	Death
			Urinary retention	尿閉	2	N	TE	124		N	Not applicable	Ongoing at time of death
			Mouth ulceration	口腔内潰瘍形成	2	N	TE	125		N	Not applicable	Ongoing at time of death
			Pancytopenia	汎血球減少症	3	Y	TE	129		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	136	1	N	None	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
027002	Sweden	67/M/C	Hypertension	高血圧	2	N	TE	29		N	None	Not recovered, but no changes expected
			Onycholysis	爪甲離床症	2	N	TE	78	64	N	None	Recovered with sequelae
			Constipation	便秘	4	Y	Post	684	9	Y	Not applicable	Death
			Constipation	便秘	5	Y	Post	692	1	Y	Not applicable	Death
			Multi-organ failure	多臓器不全	5	Y	Post	692	1	Y	Not applicable	Death
028002	Belgium	72/M/C	General physical health deterioration	全身健康状態低下	2	Y	Pre	-9	19	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	Y	Pre	-9	19	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	3	N	Pre	-1	2	N	None	Recovered
			Anal ulcer	肛門潰瘍	2	N	Pre	-1	88	N	None	Recovered
			General physical health deterioration	全身健康状態低下	1	N	Pre	10		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	Pre	10		Y	None	Not recovered, but no changes expected

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	29	7	Y	Drug administration postponed	Recovered
			Weight decreased	体重減少	2	N	TE	29	28	N	None	Recovered
			Anorexia	食欲不振	3	N	TE	56	28	N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	56		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	Y	TE	83		Y	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	3	Y	TE	83	24	N	Drug permanently withdrawn	Death
			Anorexia	食欲不振	1	N	TE	83		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	87	20	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	91		N	Drug permanently withdrawn	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	105		N	Not applicable	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	5	Y	TE	106	1	N	Drug permanently withdrawn	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
028003	Belgium	83/M/C	Nausea	悪心	1	N	TE	2	1	Y	None	Recovered
			Fatigue	疲労	1	N	TE	29		N	None	Ongoing at time of death
			Skin irritation	皮膚刺激	2	N	TE	50	15	N	None	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	55		Y	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	4	Y	TE	55		N	None	Ongoing at time of death
			Renal failure	腎不全	4	Y	TE	55		N	Drug permanently withdrawn	Ongoing at time of death
			Pulmonary oedema	肺水腫	4	Y	TE	55		N	None	Ongoing at time of death
			Multi-organ failure	多臓器不全	4	Y	TE	59	6	N	None	Death
			Multi-organ failure	多臓器不全	5	Y	TE	64	1	N	None	Death
028004	Belgium	84/M/C	Transient ischaemic attack	一過性脳虚血発作	2	Y	Pre	-13	55	N	Not applicable	Recovered
			Urinary retention	尿閉	2	N	Pre	-7	6	N	None	Recovered
			Pruritus	そう痒症	1	N	TE	8	7	N	None	Recovered with sequelae
			Pruritus	そう痒症	1	N	TE	8	27	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	14	48	N	None	Recovered
			Urinary tract infection	尿路感染	1	N	TE	28	29	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Confusional state	錯乱状態	1	N	TE	30		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	51		N	None	Ongoing at time of death
			Hypercholesterolaemia	高コレステロール血症	2	N	TE	51		N	None	Ongoing at time of death
			Inguinal hernia	鼠径ヘルニア	1	N	TE	55	14	N	None	Recovered
			Bone pain	骨痛	3	N	TE	57		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	93	1	N	Not applicable	Death
028007	Belgium	65/M/C	Fatigue	疲労	1	N	TE	28		Y	None	Ongoing at study termination / withdrawal
			Feeling cold	冷感	1	N	TE	28	36	Y	None	Recovered
			Pallor	蒼白	1	N	TE	28		Y	None	Ongoing at study termination / withdrawal
			Pyrexia	発熱	2	N	TE	50	6	N	None	Recovered
			Urinary retention	尿閉	3	Y	TE	50	2	N	None	Recovered with sequelae
			Anaemia	貧血	3	N	TE	55	9	Y	None	Recovered with sequelae
			Pleurisy	胸膜炎	2	N	TE	56	23	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	63		Y	None	Ongoing at study termination / withdrawal
			Tachycardia	頻脈	2	N	TE	91	15	N	None	Recovered
			Pleural effusion	胸水	2	N	TE	167	15	N	Not applicable	Recovered
			Paraesthesia	錯感覚	2	N	TE	168		N	None	Ongoing at study termination / withdrawal
			Lymphangiosis carcinomatosa	癌性リンパ管症	4	Y	TE	181	19	N	Not applicable	Recovered with sequelae
			Pleural effusion	胸水	4	Y	TE	181	2	N	Not applicable	Recovered
			Lymphangiosis carcinomatosa	癌性リンパ管症	4	N	TE	199	5	N	Not applicable	Recovered with sequelae
			Lymphangiosis carcinomatosa	癌性リンパ管症	5	Y	TE	203	1	N	Not applicable	Death
033005	UK	83/M/C	Bone pain	骨痛	1	N	TE	1	3	Y	None	Recovered
			Myocardial infarction	心筋梗塞	4	Y	TE	82	3	N	None	Death
			Myocardial infarction	心筋梗塞	5	Y	TE	84	1	N	None	Death
033023	UK	69/M/C	Post-traumatic pain	外傷後疼痛	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre			N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at time of death
			Muscular weakness	筋力低下	3	N	TE			N	None	Ongoing at time of death
			Pathological fracture	病的骨折	2	N	TE			N	None	Not recovered, but no changes expected
			Constipation	便秘	1	N	Pre	-673	882	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	28		N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	85	65	N	None	Recovered with sequelae
			Pathological fracture	病的骨折	3	Y	TE	149	20	Y	Drug administration postponed	Recovered
			Mobility decreased	運動性低下	2	N	TE	168	42	N	None	Ongoing at time of death
			Pathological fracture	病的骨折	2	N	TE	168		Y	None	Not recovered, but no changes expected
			Paraesthesia	錯感覚	1	Y	TE	175	5	N	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	178	7	N	None	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	178	32	N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Upper limb fracture	上肢骨折	3	Y	TE	202		Y	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	5	Y	TE	209	1	N	Not applicable	Death
034004	UK	63/M/C	Nausea	悪心	1	N	TE	8		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	8		Y	None	Ongoing at time of death
			Oral candidiasis	口腔カンジダ症	1	N	TE	8		N	None	Ongoing at time of death
			Dizziness	浮動性めまい	1	N	TE	8		N	None	Ongoing at time of death
			Cerebral ischaemia	脳虚血	4	Y	TE	43	5	N	None	Recovered with sequelae
			Anorexia	食欲不振	3	N	TE	53		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	92	9	N	Not applicable	Recovered
			Diarrhoea	下痢	3	N	TE	95	6	Y	Not applicable	Recovered
			Vomiting	嘔吐	3	N	TE	95	6	N	Not applicable	Recovered
			Anaemia	貧血	4	N	TE	98	2	N	Not applicable	Recovered
			Bone marrow failure	骨髄機能不全	4	Y	TE	98	9	N	Not applicable	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Sinus tachycardia	洞性頻脈	1	N	TE	98		N	Not applicable	Ongoing at time of death
			Confusional state	錯乱状態	3	N	TE	98	2	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	98	2	N	Not applicable	Recovered
			Rash	発疹	2	N	TE	98		N	None	Ongoing at time of death
			Haematemesis	吐血	3	N	TE	99	2	N	Not applicable	Recovered with sequelae
			Oesophagitis	食道炎	2	N	TE	99		N	Not applicable	Ongoing at time of death
			Bone marrow failure	骨髄機能不全	5	Y	TE	106	1	N	Not applicable	Death
035027	UK	68/M/C	Decreased appetite	食欲減退	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	1	3	Y	None	Recovered
			Constipation	便秘	2	N	TE	44		Y	None	Ongoing at time of death
			Intestinal obstruction	腸閉塞	4	Y	TE	54	2	Y	None	Death
			Intestinal obstruction	腸閉塞	5	Y	TE	55	1	Y	None	Death
035028	UK	70/M/C	Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urine flow decreased	尿流量減少	1	N	TE	11	19	N	None	Recovered
			Bone pain	骨痛	2	N	TE	29		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	44	18	N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	44		N	None	Recovered
			Constipation	便秘	2	Y	TE	66	6	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	71	79	N	Not applicable	Death
			Constipation	便秘	1	N	TE	72	42	N	None	Recovered
			Anaemia	貧血	2	N	TE	141		Y	None	Ongoing at time of death
			Confusional state	錯乱状態	3	Y	TE	150	11	N	Not applicable	Death
			Confusional state	錯乱状態	5	Y	TE	160	1	N	Not applicable	Death
037012	UK	67/M/C	Abdominal pain	腹痛	1	N	TE			N	None	Not recovered, but no changes expected
			Hiatus hernia	裂孔ヘルニア	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			N	None	Recovered
			Pain in jaw	顎痛	1	N	TE			N	None	Ongoing at time of death
			Deep vein thrombosis	深部静脈血栓症	3	N	TE			Y	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Diarrhoea	下痢	1	N	TE	28	2	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	113		N	None	Ongoing at time of death
			Osteoarthritis	骨関節炎	1	N	TE	163		N	None	Not recovered, but no changes expected
			Dyspnoea exertional	労作性呼吸困難	1	N	TE	171		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	198		N	None	Ongoing at time of death
			Head injury	頭部損傷	3	N	TE	212	1	N	None	Recovered with sequelae
			Disseminated intravascular coagulation	播種性血管内凝固	3	N	TE	214		N	None	Not recovered, but no changes expected
			Thrombocytopenia	血小板減少症	3	Y	TE	214		N	Not applicable	Ongoing at time of death
			Extradural haematoma	硬膜外血腫	5	Y	TE	214	1	N	Not applicable	Death
039005	UK	72/M/C	Constipation	便秘	3	N	TE	4	38	N	None	Recovered
			Nausea	悪心	3	N	TE	13	29	N	None	Recovered
			Nausea	悪心	3	N	TE	35	7	Y	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	35		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	N	TE	35	8	N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	42	1	N	None	Death
039007	UK	68/M/C	Bone pain	骨痛	1	N	Pre			N	None	Ongoing at time of death
			Anaemia	貧血	1	Y	Pre	-23	2	N	Drug administration postponed	Recovered
			Decreased appetite	食欲減退	1	N	Pre	-11		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	-11		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	-11	5	N	None	Recovered
			Nausea	悪心	1	N	Pre	-4		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	Pre	-4		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	4	23	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	27		Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	29	36	Y	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	60		Y	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	70	1	N	None	Recovered
			Anaemia	貧血	2	N	TE	92		Y	Drug administration postponed	Ongoing at time of death
			Joint injury	関節損傷	2	N	TE	94		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	95		Y	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	118	2	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	180	2	Y	Not applicable	Recovered
			Skin lesion	皮膚病変	3	N	TE	183		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	214	1	N	Not applicable	Death
039012	UK	82/M/C	Anaemia	貧血	3	N	TE			N	None	Recovered
			Hyperchlorhydria	胃酸過多	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	2	N	Pre	-2	26	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hypoaesthesia	感覚鈍麻	2	N	Pre	-2		N	None	Ongoing at study termination / withdrawal
			Hypoaesthesia	感覚鈍麻	2	N	TE	8		N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	2	N	TE	8		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	24		N	None	Ongoing at time of death
			Pathological fracture	病的骨折	3	Y	TE	35	33	N	Drug administration postponed	Recovered
			Nausea	悪心	2	N	TE	71	86	Y	None	Ongoing at time of death
			Dry mouth	口内乾燥	3	N	TE	87	70	N	None	Ongoing at time of death
			Back injury	背部損傷	3	N	TE	91	66	N	None	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	125		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	156	1	N	None	Death
039027	UK	74/M/C	Nausea	悪心	2	N	TE	1		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	1		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	2	N	Pre	1		N	None	Ongoing at time of death
			Dizziness	浮動性めまい	2	N	TE	1		N	None	Ongoing at time of death
			Headache	頭痛	1	N	TE	1		N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	1	N	TE	1		N	None	Ongoing at time of death
			Dehydration	脱水	3	Y	TE	8	7	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	18	20	N	Drug administration postponed	Death
			Renal failure	腎不全	3	Y	TE	18	1	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	N	TE	19	4	N	Drug administration postponed	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	37	1	N	Drug administration postponed	Death
040005	UK	67/M/C	Bone pain	骨痛	3	N	TE			N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	2	3	Y	None	Recovered
			Malaise	倦怠感	2	N	TE	2	3	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	2		N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	29	4	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	29	4	N	None	Recovered
			Lower respiratory tract infection	下気道感染	3	N	TE	49	13	N	None	Recovered
			Anaemia	貧血	2	N	TE	57	56	Y	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	68	60	N	Drug permanently withdrawn	Death
			Anaemia	貧血	3	Y	TE	112	3	Y	None	Recovered
			Fatigue	疲労	3	Y	TE	112	3	Y	Not applicable	Ongoing at study termination / withdrawal

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	114		Y	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	2	N	TE	114		Y	Not applicable	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	127	1	N	Drug permanently withdrawn	Death
041008	UK	74/M/C	Anaemia	貧血	2	N	Pre	1	29	N	Drug administration postponed	Recovered
			Nausea	悪心	2	N	TE	1	3	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	1	3	N	None	Recovered
			Anaemia	貧血	2	Y	TE	29	4	N	Drug administration postponed	Recovered
			Acute myocardial infarction	急性心筋梗塞	4	Y	TE	29	4	N	Drug administration postponed	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	32	19	N	Drug administration postponed	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE	35	13	N	None	Recovered
			Anaemia	貧血	3	Y	TE	50	4	N	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	50	3	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	52		N	None	Ongoing at time of death
			Anaemia	貧血		Y	TE	76		N	Drug administration postponed	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	5	Y	TE	79	1	N	None	Death
041011	UK	58/M/C	Oral candidiasis	口腔カンジダ症	2	N	Pre	1		N	None	Recovered
			Metastases to bone	骨転移	2	N	TE	27	6	N	None	Recovered
			Anaemia	貧血	2	N	TE	29	84	Y	None	Ongoing at time of death
			Metastases to bone	骨転移	2	Y	TE	32	18	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Metastases to bone	骨転移	2	N	TE	49		N	None	Not recovered, but no changes expected
			Oedema peripheral	末梢性浮腫	2	N	TE	57	57	N	None	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	3	Y	TE	63	6	N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	63	6	N	Drug administration postponed	Recovered
			Diabetes mellitus	糖尿病	2	N	TE	71	56	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	84	58	Y	Drug administration postponed	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	85	79	N	Drug permanently withdrawn	Death
			Anaemia	貧血	1	N	TE	112	30	Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	113	38	N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Memory impairment	記憶障害	1	N	TE	113		N	None	Ongoing at time of death
			Rales	ラ音	1	N	TE	113		N	None	Ongoing at time of death
			Dizziness postural	体位性めまい	2	N	TE	116		N	None	Ongoing at time of death
			Diabetes mellitus	糖尿病	1	N	TE	126		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	141		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	141	5	Y	Drug administration postponed	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	145		Y	Drug administration postponed	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	Y	TE	150		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	163	1	N	Drug permanently withdrawn	Death
042015	UK	72/M/C	Increased appetite	食欲亢進	1	N	TE			N	None	Recovered
			Somnolence	傾眠	2	N	TE			N	None	Recovered
			Diplopia	複視	3	N	TE	14	10	Y	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Balance disorder	平衡障害	1	N	TE	14	10	N	None	Recovered
			Confusional state	錯乱状態	3	N	TE	14	10	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	15	15	Y	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	53	6	N	None	Recovered
			Agitation	激越	2	N	TE	114	2	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	115	1	N	None	Death
			Increased bronchial secretion	気管支分泌増加	2	N	TE	115	1	N	None	Recovered
042034	UK	75/M/C	Oedema peripheral	末梢性浮腫	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	141		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	141		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	172	1	N	Not applicable	Death
044005	UK	76/M/C	Cardiac failure congestive	うっ血性心不全	4	N	TE			N	Drug administration postponed	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE			Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	7	1	Y	None	Recovered
			Left ventricular dysfunction	左室機能不全	3	N	TE	54	73	N	Drug administration postponed	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	54	73	N	Drug administration postponed	Ongoing at time of death
			Dyspnoea	呼吸困難	3	N	TE	54	17	N	Drug administration postponed	Ongoing at time of death
			Troponin T increased	トロポニンＴ増加	4	N	TE	57	70	N	Drug administration postponed	Ongoing at time of death
			Pleural effusion	胸水	2	N	TE	57	70	N	Drug administration postponed	Ongoing at time of death
			Pulmonary embolism	肺塞栓症	3	Y	TE	57	3	N	Drug permanently withdrawn	Recovered with sequelae

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pulmonary oedema	肺水腫	1	N	TE	58	69	N	Drug administration postponed	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	70	57	N	Drug administration postponed	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	5	Y	TE	126	1	N	Drug administration postponed	Death
047002	UK	81/M/C	Anaemia	貧血	3	N	TE	2	1	Y	None	Recovered
			Anaemia	貧血	3	N	TE	39	1	Y	None	Recovered
			Anaemia	貧血	3	N	TE	73	1	Y	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	3	N	TE	85		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	2	N	TE	136		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	154	1	N	Not applicable	Death
049002	UK	73/M/C	Lower respiratory tract infection	下気道感染	3	Y	TE	9	11	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oral candidiasis	口腔カンジダ症	2	N	TE	57	53	Y	None	Recovered
			Paraesthesia	錯感覚	1	N	TE	100	30	N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	Y	TE	109	3	N	Drug administration postponed	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	4	Y	TE	129		N	None	Ongoing at time of death
			Pneumonia	肺炎	4	Y	TE	135	7	N	Drug permanently withdrawn	Death
			Pneumonia	肺炎	5	Y	TE	141	1	N	Drug permanently withdrawn	Death
049007	UK	80/M/C	Nausea	悪心	2	N	TE	3		Y	None	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	3		Y	None	Ongoing at time of death
			Mucosal inflammation	粘膜の炎症	2	N	TE	29		Y	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	29		Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	120		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	128		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Headache	頭痛	2	N	TE	148	51	N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	176	3	N	Not applicable	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	198		N	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	3	Y	TE	198		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	198	12	N	Not applicable	Death
			Headache	頭痛	4	N	TE	198		N	None	Ongoing at time of death
			Urinary retention	尿閉	2	N	TE	204		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	209	1	N	Not applicable	Death
049008	UK	72/M/C	Decreased appetite	食欲減退	2	N	TE			N	None	Ongoing at time of death
			Lymphoedema	リンパ浮腫	1	N	Pre			N	None	Recovered
			Ear pain	耳痛	1	N	Pre	-7		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre	-3	5	N	None	Recovered
			Fatigue	疲労	2	N	TE	29		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	29	50	Y	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	2	N	TE	40		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	40	2	N	None	Recovered with sequelae
			Palpitations	動悸	1	N	TE	54	4	N	Not applicable	Recovered
			Depressed mood	抑うつ気分	1	N	TE	54		N	None	Ongoing at time of death
			Vomiting	嘔吐	2	Y	TE	57	6	N	Drug administration postponed	Recovered
			Pyrexia	発熱	1	Y	TE	61	2	N	Drug administration postponed	Recovered
			Nausea	悪心	2	Y	TE	65	6	N	Drug administration postponed	Recovered with sequelae
			Vomiting	嘔吐	2	Y	TE	65	6	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	N	TE	67	1	N	Not applicable	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	89	1	N	Not applicable	Recovered
			Abdominal pain	腹痛	3	Y	TE	111		N	Not applicable	Ongoing at time of death
			Nausea	悪心	3	Y	TE	111		N	Not applicable	Ongoing at time of death
			Vomiting	嘔吐	3	Y	TE	111		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	111	11	N	Not applicable	Death
			Anaemia	貧血	2	N	TE	113		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	121	1	N	Not applicable	Death
051012	UK	73/M/C	Decreased appetite	食欲減退	1	N	TE	30		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	108	1	N	None	Death
055002	Netherlands	66/M/C	Lung infection	肺感染	2	N	TE	18	27	N	None	Recovered
			Anorexia	食欲不振	2	N	TE	54		Y	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	54		Y	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	3	N	TE	59		Y	None	Ongoing at time of death
			Drug intolerance	薬物不耐性	4	Y	TE	71	3	N	None	Recovered with sequelae
			Pulmonary embolism	肺塞栓症	4	Y	TE	71		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	74	1	N	None	Death
060002	Spain	84/M/C	Anorexia	食欲不振	2	N	TE	29		N	None	Ongoing at time of death
			Cardiac failure	心不全	3	N	TE	100		N	None	Ongoing at study termination / withdrawal
			Dyspnoea	呼吸困難	2	N	TE	100		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	101	31	N	Not applicable	Ongoing at time of death
			Bronchitis	気管支炎	2	N	TE	107	2	N	None	Recovered
			Renal failure	腎不全	2	N	TE	107	3	N	None	Recovered
			Bronchitis	気管支炎	3	Y	TE	108		N	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	N	TE	109	5	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	113	11	Y	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hyperuricaemia	高尿酸血症	1	N	TE	113		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	123		Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	129	1	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	131		N	Not applicable	Ongoing at time of death
			Death	死亡	5	Y	TE	137	1	N	Not applicable	Death
060003	Spain	85/M/C	Bone pain	骨痛	3	N	TE	31	26	N	None	Ongoing at time of death
			Weight decreased	体重減少	2	N	TE	56	6	N	None	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	2	N	TE	56	11	N	None	Recovered
			Bone pain	骨痛	2	N	TE	56		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	57		N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	61		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	111	1	N	Not applicable	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
060007	Spain	79/M/C	Nausea	悪心	1	N	Pre	-20	28	N	None	Recovered
			Anorexia	食欲不振	2	N	Pre	-20		N	None	Ongoing at time of death
			Haematuria	血尿	2	N	TE	5		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	6	4	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	6	12	N	Drug permanently withdrawn	Death
			Pyrexia	発熱	1	N	TE	7	2	N	None	Recovered
			Respiratory tract infection	気道感染	2	N	TE	7		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	3	N	TE	8		N	None	Ongoing at time of death
			Asthenia	無力症	1	N	TE	12	2	N	None	Ongoing at time of death
			Asthenia	無力症	3	N	TE	13		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	17	1	N	Drug permanently withdrawn	Death
063004	Spain	74/M/C	Abdominal pain upper	上腹部痛	1	N	TE	32	55	N	None	Recovered
			Somnolence	傾眠	2	N	TE	32	55	N	None	Recovered
			Anaemia	貧血	3	N	TE	58	29	N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	86		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	86	29	N	Not applicable	Ongoing at time of death
			Asthenia	無力症	1	N	TE	86		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	86		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	114		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	128	8	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	135	1	N	Drug permanently withdrawn	Death
074002	Italy	79/M/C	Muscle spasms	筋痙縮	1	N	Pre	-10	11	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	28	8	N	None	Recovered
			Asthenia	無力症	2	N	TE	33	3	N	None	Recovered
			Pyrexia	発熱	1	N	TE	33	15	N	Drug administration postponed	Recovered
			Urinary tract infection	尿路感染	2	N	TE	46	39	N	None	Recovered
			Dry skin	皮膚乾燥	1	N	TE	75	10	Y	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Asthenia	無力症	1	N	TE	84	83	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	131	29	Y	None	Recovered
			Neutropenia	好中球減少症	2	N	TE	131	29	Y	Drug permanently withdrawn	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	131	29	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	159	18	Y	None	Recovered
			Leukopenia	白血球減少症	4	N	TE	159	4	Y	None	Recovered
			Neutropenia	好中球減少症	4	N	TE	159	4	Y	Drug permanently withdrawn	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	159	15	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	162	5	Y	None	Recovered
			Neutropenia	好中球減少症	1	N	TE	162	5	Y	Drug permanently withdrawn	Recovered
			Blood urea increased	血中尿素増加	1	N	TE	162	43	N	None	Recovered
			Asthenia	無力症	2	N	TE	166		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	173	8	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	180	8	Y	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	183	5	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	187	32	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	187	8	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	194	11	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	204	15	Y	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	218	5	Y	None	Recovered
			Thrombocytopenia	血小板減少症	4	N	TE	218	5	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	222	2	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	222	2	Y	None	Ongoing at time of death
			Bone marrow tumour cell infiltration	腫瘍細胞の骨髄浸潤	3	Y	TE	222	37	N	Not applicable	Death
			Anaemia	貧血	3	N	TE	223	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	223	2	Y	None	
			Neutropenia	好中球減少症	1	N	TE	223	5	Y	Not applicable	
			Thrombocytopenia	血小板減少症	4	N	TE	223	3	Y	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Leukopenia	白血球減少症	1	N	TE	224	2	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	225	8	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	225	1	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	1	N	TE	225	3	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	225	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	227	3	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	2	N	TE	227	3	Y	Not applicable	
			Thrombocytopenia	血小板減少症	4	N	TE	227	4	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	229	2	Y	None	
			Neutropenia	好中球減少症	3	N	TE	229	2	Y	Not applicable	
			Leukopenia	白血球減少症	2	N	TE	230	4	Y	None	
			Neutropenia	好中球減少症	2	N	TE	230	2	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	230	3	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	1	N	TE	231	3	Y	Not applicable	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	232	4	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	232	4	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	233	2	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	2	N	TE	233	2	Y	Not applicable	Recovered
			Leukopenia	白血球減少症	2	N	TE	234	4	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	235	7	Y	None	Recovered
			Neutropenia	好中球減少症	1	N	Post	235	3	Y	-	
			Thrombocytopenia	血小板減少症	3	N	TE	235	2	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	236	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	237	7	Y	None	
			Neutropenia	好中球減少症	2	N	Post	237	2	Y	-	
			Neutropenia	好中球減少症	3	N	Post	238	5	Y	-	
			Thrombocytopenia	血小板減少症	3	N	TE	238	4	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	241	2	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	241	3	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	242	8	Y	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neutropenia	好中球減少症	2	N	Post	242	4	Y	Not applicable	Recovered
			Leukopenia	白血球減少症	2	N	TE	243	3	Y	None	
			Thrombocytopenia	血小板減少症	3	N	TE	243	2	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	244		Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	1	N	TE	245	9	Y	None	
			Anaemia	貧血	1	N	TE	249		Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	253	2	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	1	N	Post	253	4	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	1	N	TE	254	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	256		Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	2	N	Post	256		Y	None	Ongoing at time of death
			Bone marrow tumour cell infiltration	腫瘍細胞の骨髄浸潤	5	Y	TE	258	1	N	Not applicable	Death
075001	Italy	59/M/C	Strangury	有痛性排尿困難		N	TE	2	2	N	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	14	28	N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Diarrhoea	下痢	1	N	TE	33	10	Y	Drug administration postponed	Recovered
			Vomiting	嘔吐	1	N	TE	33	10	Y	Drug administration postponed	Recovered
			Anorexia	食欲不振	1	N	TE	33	10	Y	Drug administration postponed	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	41		N	None	Ongoing at time of death
			Strangury	有痛性排尿困難	2	N	TE	78	1	N	None	Recovered
			Death	死亡	5	Y	TE	93	1	N	None	Death
078001	Italy	76/M/C	Constipation	便秘	1	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE			N	None	Recovered
			Pyrexia	発熱	1	N	TE			N	None	Recovered
			Confusional state	錯乱状態	1	N	TE			N	None	Recovered
			Hyperhidrosis	多汗症	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE	2	11	Y	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	38	21	N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE	58	21	N	None	Ongoing at time of death
			Asthenia	無力症	2	N	TE	78	37	Y	None	Recovered
			Pyrexia	発熱	1	N	TE	78	29	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	78		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	78	37	N	None	Recovered
			Fatigue	疲労	2	N	TE	127	14	N	None	Ongoing at time of death
			Depression	うつ病	2	N	TE	127		N	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	141		N	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	147	2	Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	Y	TE	147	2	Y	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	149	14	Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	Y	TE	149	11	Y	Drug permanently withdrawn	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	Y	TE	163		Y	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	163	15	N	Not applicable	Death
078003	Italy	74/M/C	Somnolence	傾眠	2	N	Pre	1		N	None	Ongoing at time of death
			Confusional state	錯乱状態	2	N	Pre	1		N	None	Ongoing at time of death
			Upper limb fracture	上肢骨折	2	N	TE	20	25	N	None	Recovered
			Asthenia	無力症	2	N	TE	49		Y	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	187		N	Not applicable	Ongoing at time of death
			Amnesia	健忘	2	N	TE	198		N	Not applicable	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	3	Y	TE	213	8	N	Not applicable	Death
			General physical health deterioration	全身健康状態低下	5	Y	TE	220	1	N	Not applicable	Death
078006	Italy	77/M/C	Pyrexia	発熱	1	N	TE	39	34	N	None	Recovered
			Pyrexia	発熱	1	N	TE	91	14	N	None	Recovered
			Anaemia	貧血	2	N	TE	104		Y	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	4	N	TE	104		Y	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	104	28	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	131	1	N	Drug permanently withdrawn	Death
080004	Italy	72/M/C	Weight decreased	体重減少	1	N	Pre	-13	13	N	None	Ongoing at time of death
			Weight decreased	体重減少	2	N	Pre	-1		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	Pre	-1	50	N	None	Recovered
			Bone pain	骨痛	3	N	TE	49	85	N	None	Recovered
			Fatigue	疲労	3	N	TE	133		N	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	133		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	161	1	N	Not applicable	Death
093002	Slovakia	81/M/C	Anaemia	貧血	2	N	TE	29	48	N	-	
			Nausea	悪心	2	N	TE	29	85	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	29	6	Y	None	Recovered
			Constipation	便秘	1	N	TE	56	58	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	56	4	Y	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	N	TE	76	10	N	-	
			Bone pain	骨痛	3	Y	TE	76	8	N	None	Recovered with sequelae
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	76		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	85	29	N	-	
			Diarrhoea	下痢	2	N	TE	85	5	Y	None	Recovered
			Anaemia	貧血	2	N	TE	113	31	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	Y	TE	143	5	N	Drug administration postponed	Recovered
			Bronchopneumonia	気管支肺炎	3	N	TE	150		N	None	Ongoing at time of death
			Cardiopulmonary failure	心肺不全	5	Y	TE	160	1	N	Not applicable	Death
104005	Hong Kong	73/M/A	Constipation	便秘	1	N	TE	1	29	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	64	2	Y	None	Recovered
			Pneumonia	肺炎	2	N	TE	87		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Spinal cord compression	脊髄圧迫	3	Y	TE	87	18	N	Drug permanently withdrawn	Death
			Spinal cord compression	脊髄圧迫	5	Y	TE	104	1	N	Drug permanently withdrawn	Death
106005	Hong Kong	79/M/A	Decreased appetite	食欲減退	1	N	TE	29	85	Y	None	Recovered
			Dysuria	排尿困難	1	N	TE	29		N	None	Ongoing at time of death
			Nocturia	夜間頻尿	2	N	TE	29	57	N	None	Recovered
			Anaemia	貧血	3	Y	TE	113	3	Y	Drug administration postponed	Recovered with sequelae
			Constipation	便秘	2	N	TE	113	29	N	None	Recovered
			Sleep disorder	睡眠障害	1	N	TE	113	3	N	None	Recovered
			Spinal compression fracture	脊椎圧迫骨折	3	N	TE	115		N	None	Ongoing at time of death
			Sepsis	敗血症	3	Y	TE	155		N	Not applicable	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	3	N	TE	156		N	Not applicable	Ongoing at time of death
			Haematuria	血尿	3	Y	TE	159		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	165	1	N	Not applicable	Death
106011	Hong Kong	79/M/A	Decreased appetite	食欲減退	1	N	TE	29	29	N	None	Recovered
			Abdominal pain upper	上腹部痛	1	N	TE	57	29	N	None	Recovered
			Liver function test abnormal	肝機能検査異常	3	Y	TE	57	13	N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	218	1	N	Not applicable	Death
133002	Poland	78/M/C	Pyrexia	発熱	1	N	TE	3	14	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	3	6	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	8	44	Y	None	Recovered
			Pathological fracture	病的骨折	2	Y	TE	43		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	51	53	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	72	34	N	None	Recovered
			Fatigue	疲労	3	N	TE	88	26	N	Drug permanently withdrawn	Ongoing at time of death
			Fatigue	疲労	4	N	TE	113		N	Drug permanently withdrawn	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	2	N	TE	113		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	162	1	N	Not applicable	Death
133006	Poland	53/M/C	Bone pain	骨痛	2	N	TE	2	10	Y	None	Recovered
			Hypertension	高血圧	2	N	TE	29	29	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	50		N	None	Recovered
			Abdominal pain	腹痛	2	N	TE	71		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	140	29	N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	168		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	168		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	184	2	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	185	1	N	Not applicable	Death
133009	Poland	75/M/C	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2	N	TE	85	29	N	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1	N	TE	85	29	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	1	N	TE	141	29	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	198	1	N	Not applicable	Death
133011	Poland	66/M/C	Anaemia	貧血	2	N	Pre	1		N	None	Ongoing at time of death
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	Pre	1		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre	1		N	None	Not recovered, but no changes expected
			Tremor	振戦	4	Y	TE	25	1	Y	None	Recovered
			Confusional state	錯乱状態	4	Y	TE	25		Y	None	Ongoing at time of death
			Death	死亡	5	Y	TE	29	1	Y	None	Death
133012	Poland	67/M/C	Spinal cord compression	脊髄圧迫	3	Y	Pre	-35		N	Drug administration postponed	Ongoing at time of death
			Dyspnoea	呼吸困難	4	Y	TE	2	1	N	None	Death
			Dyspnoea	呼吸困難	5	Y	TE	2	1	N	None	Death
134001	Poland	57/M/C	Paralysis	麻痺	4	Y	Pre	-10		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	20	1	N	None	Death
137006	Poland	71/M/C	Anaemia	貧血	3	Y	TE	139	8	N	Not applicable	Recovered with sequelae
			Urinary tract infection	尿路感染	2	N	TE	157	8	N	Not applicable	Recovered
			Haematuria	血尿	3	Y	TE	197	7	N	Not applicable	Recovered
			Anaemia	貧血	4	Y	TE	203		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	213	1	N	Not applicable	Death
139001	Poland	76/M/C	Anaemia	貧血	1	N	TE	29		N	None	Ongoing at time of death
			Malaise	倦怠感	3	N	TE	29		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	46	1	N	None	Death
139005	Poland	71/M/C	Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre			N	None	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	57	5	Y	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	120	1	N	None	Death
146004	Germany	77/M/C	Anaemia	貧血	2	N	TE	17	5	N	Drug administration postponed	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	17		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Multi-organ failure	多臓器不全	4	Y	TE	17	12	N	None	Death
			Anaemia	貧血	4	N	TE	21		N	Drug administration postponed	Ongoing at time of death
			Multi-organ failure	多臓器不全	5	Y	TE	28	1	N	None	Death
148009	Germany	71/M/C	Nasopharyngitis	鼻咽頭炎	1	N	Pre	-14	15	N	None	Recovered
			Anaemia	貧血	2	N	Pre	1	57	Y	Drug administration postponed	Recovered
			Fatigue	疲労	2	N	TE	8		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	29	4	Y	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	57	4	Y	Drug administration postponed	Recovered
			Anaemia	貧血	1	N	TE	60	31	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	60	1	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	60	2	Y	None	Recovered
			Herpes zoster	帯状疱疹	3	Y	TE	96	12	Y	Drug administration postponed	Recovered
			Anaemia	貧血	2	Y	TE	98	1	Y	None	Recovered
			Anaemia	貧血	4	Y	TE	125	3	Y	Drug administration postponed	Recovered
			Syncope	失神	3	Y	TE	125	1	Y	Drug administration postponed	Recovered
			Pancytopenia	汎血球減少症		N	TE	140		Y	None	Ongoing at time of death
			Metastases to liver	肝転移	3	Y	TE	140	10	N	Drug permanently withdrawn	Death
			Epistaxis	鼻出血	2	N	TE	140	1	N	Not applicable	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Metastases to liver	肝転移	5	Y	TE	149	1	N	Drug permanently withdrawn	Death
148019	Germany	65/M/C	Conjunctivitis	結膜炎	2	N	TE	2	8	N	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	29	1	Y	None	Recovered
			Nausea	悪心	1	N	TE	31	4	Y	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	32	1	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	32	1	Y	None	Recovered
			Pleural effusion	胸水	1	N	TE	93		N	None	Ongoing at time of death
			Blood urea increased	血中尿素増加	2	N	TE	109	11	N	None	Recovered
			Blood creatinine increased	血中クレアチニン増加	2	N	TE	113	7	N	None	Recovered
			Hydronephrosis	水腎症	3	Y	TE	113	2	N	None	Recovered
			Dyspnoea	呼吸困難	2	N	TE	113		N	None	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	119	4	N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	119		N	None	Ongoing at time of death
			Blood creatinine increased	血中クレアチニン増加	3	N	TE	119	4	N	None	Recovered
			Blood urea increased	血中尿素増加	3	N	TE	119	4	N	None	Recovered
			Hydronephrosis	水腎症	3	Y	TE	119	4	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	143	1	N	Drug permanently withdrawn	Death
152004	Germany	75/M/C	Bone pain	骨痛	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	1	N	TE	1		N	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	1	N	TE	79		N	None	Recovered
			Bone pain	骨痛	3	Y	TE	79	14	N	Drug administration postponed	Recovered with sequelae
			Disturbance in attention	注意力障害	1	N	TE	79		N	None	Ongoing at study termination / withdrawal
			Insomnia	不眠症	1	N	TE	79		N	None	Recovered
			Pleural effusion	胸水	1	N	TE	79		N	None	Recovered
			Bone pain	骨痛	2	N	TE	92	37	N	None	Recovered with sequelae
			Pancytopenia	汎血球減少症	2	N	TE	128		N	None	Recovered with sequelae
			Nausea	悪心	1	N	TE	128	8	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	128	8	N	None	Recovered
			Infection	感染	2	N	TE	128	8	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hypokalaemia	低カリウム血症	1	N	TE	128	8	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	128	8	N	None	Recovered with sequelae
			Pneumonia primary atypical	原発性異型肺炎	3	Y	TE	147	22	N	Drug administration postponed	Recovered with sequelae
			Asthenia	無力症	2	N	TE	161		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			General physical health deterioration	全身健康状態低下	5	Y	TE	195	1	N	None	Death
170004	Brazil	78/M/C	Pathological fracture	病的骨折	3	N	TE	127		N	Drug administration postponed	Ongoing at time of death
			Urinary retention	尿閉	3	N	TE	156	1	N	None	Recovered
			Anaemia	貧血	2	N	TE	211		N	None	Ongoing at time of death
			Bone pain	骨痛	4	Y	TE	230		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	230	3	N	Drug permanently withdrawn	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	232	1	N	Drug permanently withdrawn	Death
173008	Brazil	67/M/C	Anaemia	貧血	2	N	Pre	1	33	N	Drug administration postponed	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	Pre	1	63	N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	33	2	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	34	30	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	N	TE	63	3	N	Drug administration postponed	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	Pre	63		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	65	83	N	Drug administration postponed	Recovered
			Anorexia	食欲不振	2	N	TE	87	70	N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	147	5	N	Drug administration postponed	Recovered
			Anorexia	食欲不振	3	N	TE	156		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	156		N	None	Ongoing at time of death
			Weight decreased	体重減少	3	N	TE	183		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	3	N	TE	184	11	N	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	184	11	N	None	Ongoing at time of death
			Anaemia	貧血	4	N	TE	194	5	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	194	5	N	None	Ongoing at time of death
			Neutropenia	好中球減少症	4	N	TE	198		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	198		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cerebrovascular accident	脳血管発作	4	Y	TE	198	4	Y	Not applicable	Death
			Cerebrovascular accident	脳血管発作	5	Y	TE	201	1	Y	Not applicable	Death
173009	Brazil	66/M/0	Bone pain	骨痛	2	N	Pre	-9		N	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	4	Y	TE	29	20	N	Drug permanently withdrawn	Death
			General physical health deterioration	全身健康状態低下	5	Y	TE	48	1	N	Drug permanently withdrawn	Death
178007	Brazil	71/M/0	Hypercalcaemia	高カルシウム血症	3	N	Pre	1	88	Y	None	Recovered
			Neutropenia	好中球減少症	2	N	TE	29	29	Y	Drug administration postponed	Recovered
			Bone pain	骨痛	2	N	TE	48	77	N	None	Ongoing at time of death
			Neutropenia	好中球減少症	3	N	TE	57	4	Y	Drug administration postponed	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neutropenia	好中球減少症	2	N	TE	60	65	Y	Drug administration postponed	Recovered
			Insomnia	不眠症	2	N	TE	78		N	None	Ongoing at time of death
			Pathological fracture	病的骨折	3	Y	TE	121	28	N	Drug administration postponed	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	124		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	124	15	N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	138	25	N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	139	7	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	141	1	N	Not applicable	Recovered
			Anaemia	貧血	3	Y	TE	147	2	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	148		N	Not applicable	Lost to follow-up
			Device dislocation	医療機器位置異常	3	Y	TE	162	3	N	Not applicable	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Procedural pain	処置による疼痛	3	Y	TE	162	3	N	Not applicable	Recovered
			Pneumonia	肺炎	3	Y	TE	165	3	N	Not applicable	Recovered
			Pulmonary embolism	肺塞栓症	3	Y	TE	165	3	N	Not applicable	Death
			Pneumonia	肺炎	4	Y	TE	167	28	N	Not applicable	Recovered
			Pulmonary embolism	肺塞栓症	4	Y	TE	167	63	N	Not applicable	Death
			Pulmonary embolism	肺塞栓症	5	Y	TE	229	1	N	Not applicable	Death
179006	Brazil	79/M/C	Nausea	悪心	1	N	Pre	-17	3	N	Not applicable	Recovered
			Cough	咳嗽	1	N	Pre	-6	5	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	34	99	N	None	Recovered
			Arthralgia	関節痛	1	N	TE	132		N	None	Recovered
			Bone pain	骨痛	1	N	TE	159	2	N	None	Recovered
			Myocardial infarction	心筋梗塞	5	Y	TE	244	1	N	Not applicable	Death
181005	Brazil	74/M/C	Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	Pre	1		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	Pre	1		N	None	Ongoing at time of death
			Hypoglycaemia	低血糖症	3	Y	TE	29	2	N	None	Recovered
			Pneumonia	肺炎	2	Y	TE	30	16	N	Not applicable	Death
			Acute pulmonary oedema	急性肺水腫	2	Y	TE	30		N	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	5	Y	TE	45	1	N	Not applicable	Death
201002	Australia	72/M/C	Dysphagia	嚥下障害	2	N	Pre	-7	70	N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	48	46	N	None	Recovered
			Muscle strain	筋挫傷	2	N	TE	49	15	N	None	Recovered
			Dysphagia	嚥下障害	1	N	Pre	63	71	N	None	Ongoing at time of death
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	2	N	TE	93	4	N	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	99	8	N	None	Recovered
			Anaemia	貧血	3	Y	TE	132	9	N	Not applicable	Recovered
			Supraventricular tachycardia	上室性頻脈	2	Y	TE	132	1	N	Not applicable	Recovered
			Abdominal distension	腹部膨満	3	Y	TE	132	9	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	3	N	TE	132		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	132	39	N	Not applicable	Death
			Anxiety	不安	2	N	TE	132		N	Not applicable	Ongoing at time of death
			Dysphagia	嚥下障害	2	N	Pre	133		N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	1	N	TE	137	3	N	Not applicable	Recovered
			Abdominal distension	腹部膨満	2	N	TE	140		N	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	147		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	161		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	170	1	N	Not applicable	Death
203007	Australia	70/M/C	Bone pain	骨痛	2	N	Pre	-7	63	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	Pre	-7	63	N	None	Recovered
			Constipation	便秘	2	Y	Pre	-1	3	N	None	Recovered
			Anorexia	食欲不振	2	N	TE	3		N	None	Ongoing at time of death
			Dysgeusia	味覚異常	1	N	TE	3		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	1	N	TE	4	2	Y	None	Recovered
			Anaemia	貧血	2	N	TE	28	49	Y	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	28	29	N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	28	83	N	Not applicable	Death
			Fatigue	疲労	2	N	TE	35		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	53	5	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	56	3	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	56	3	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	56	3	N	None	Recovered
			Bone pain	骨痛	1	N	TE	58		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	58		N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	66	8	N	Not applicable	Recovered
			Constipation	便秘	3	Y	TE	73	6	N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	76	3	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	78		Y	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	110	1	N	Not applicable	Death
204001	Australia	76/M/C	Dyspnoea	呼吸困難	1	N	Pre	-392	366	N	None	Recovered
			Nausea	悪心	1	N	TE	1		Y	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	2		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	2		Y	None	Ongoing at study termination / withdrawal
			Chills	悪寒	1	N	TE	6	1	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	8	1	Y	None	Recovered
			Constipation	便秘	1	N	TE	9		Y	None	Ongoing at study termination / withdrawal
			Contusion	挫傷	1	N	TE	10		N	None	Ongoing at study termination / withdrawal
			Gastroenteritis	胃腸炎	4	Y	TE	18	6	Y	None	Recovered with sequelae
			Renal failure acute	急性腎不全	2	Y	TE	18	6	Y	None	Recovered
			Gastroenteritis	胃腸炎	3	N	TE	21	3	Y	None	Recovered with sequelae

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	Y	TE	22	2	Y	None	Recovered
			Gastroenteritis	胃腸炎	2	N	TE	23	1	Y	None	Recovered with sequelae
			Bone pain	骨痛	1	N	TE	34		Y	None	Ongoing at time of death
			Mobility decreased	運動性低下	1	N	TE	34		Y	None	Ongoing at time of death
			Tremor	振戦	1	N	TE	34		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	43	26	N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	63	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	68	9	N	Not applicable	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	76		N	Not applicable	Ongoing at study termination / withdrawal
			Anxiety	不安	1	N	TE	79	1	Y	None	Recovered
			Anxiety	不安	1	N	TE	83	3	Y	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	116	1	N	Drug permanently withdrawn	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
205004	Australia	82/M/C	Bone pain	骨痛	2	N	TE			Y	None	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	Pre	1		N	None	Ongoing at time of death
			Urinary incontinence	尿失禁	2	N	TE	6		Y	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	33		Y	None	Ongoing at time of death
			Hydrocephalus	水頭症	4	Y	TE	107	20	N	Drug permanently withdrawn	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	127	14	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	140	1	N	Drug permanently withdrawn	Death
206001	Australia	83/M/C	Meniere's disease	メニエール病	2	N	TE	78	18	Y	Drug administration postponed	Recovered with sequelae
			Deep vein thrombosis	深部静脈血栓症	3	Y	TE	90	6	Y	None	Recovered with sequelae

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	1	N	TE	91	4	N	Drug administration postponed	Recovered
			Pollakiuria	頻尿	3	N	TE	189		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	201		N	Not applicable	Ongoing at time of death
			Nausea	悪心	3	N	TE	201		N	Not applicable	Ongoing at time of death
			Pain	疼痛	3	N	TE	201		N	Not applicable	Ongoing at time of death
			Urinary tract infection	尿路感染	3	N	TE	201		N	Not applicable	Ongoing at time of death
			Hydronephrosis	水腎症	3	Y	TE	201		N	Not applicable	Ongoing at time of death
			Fluid overload	水分過負荷	3	N	TE	202		N	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	4	N	TE	202		N	Not applicable	Ongoing at time of death
			Lung consolidation	肺硬化	3	N	TE	202		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	212	1	N	Not applicable	Death
209003	Australia	56/M/C	Bone pain	骨痛	1	N	Pre	-22		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oesophagitis	食道炎	1	N	TE	29		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	29		N	None	Ongoing at time of death
			Muscle spasms	筋痙縮	1	N	TE	57		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	78		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	78		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	78		N	None	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	85		N	None	Ongoing at time of death
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	1	N	TE	85		N	None	Ongoing at time of death
			Breath sounds abnormal	呼吸音異常	1	N	TE	85		N	None	Ongoing at time of death
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1	N	TE	85		N	None	Ongoing at time of death
			Neuropathy peripheral	末梢性ニューロパチー	1	N	TE	88		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	4	Y	TE	94	16	N	None	Recovered
			Burning sensation	灼熱感	1	N	TE	102	1	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Rash	発疹	1	N	TE	103		N	None	Ongoing at time of death
			Pyrexia	発熱	1	N	TE	108	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	109		N	Not applicable	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	109		N	Not applicable	Ongoing at time of death
			Radiation skin injury	放射線皮膚損傷	1	N	TE	109		N	Not applicable	Ongoing at time of death
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	Y	TE	109	7	N	Drug permanently withdrawn	Recovered
			Anxiety	不安	1	N	TE	109		N	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	138		N	Not applicable	Ongoing at time of death
			Ascites	腹水	1	Y	TE	149		N	Not applicable	Ongoing at time of death
			Epistaxis	鼻出血	1	N	TE	149	18	N	Not applicable	Recovered
			Dry skin	皮膚乾燥	1	N	TE	149		N	Not applicable	Ongoing at time of death
			Pruritus	そう痒症	1	N	TE	149		N	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE	153		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Rectal haemorrhage	直腸出血	1	N	TE	158		N	Not applicable	Ongoing at time of death
			Pitting oedema	圧痕浮腫	1	N	TE	158		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	158	9	N	Not applicable	Death
			Confusional state	錯乱状態	1	N	TE	158		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	166	1	N	Not applicable	Death
233005	UK	78/M/C	Nausea	悪心	1	N	TE	1	209	N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	29	181	Y	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	29	29	N	None	Recovered
			Anorexia	食欲不振	3	N	TE	29	113	Y	None	Ongoing at time of death
			Dehydration	脱水	3	N	TE	29	4	Y	Drug administration postponed	Recovered
			Malaise	倦怠感	2	Y	TE	32	6	Y	Drug administration postponed	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dehydration	脱水	3	Y	TE	32	6	Y	Drug administration postponed	Recovered
			Dehydration	脱水	2	Y	TE	45	5	Y	Drug administration postponed	Recovered
			Anaemia	貧血	3	Y	TE	53	3	Y	None	Recovered
			Hypertension	高血圧	3	N	TE	85	125	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	134	3	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	136	3	Y	None	Recovered
			Dehydration	脱水	2	N	TE	136	3	Y	None	Recovered
			Dyspnoea	呼吸困難	3	N	TE	136	2	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	141		Y	None	Ongoing at time of death
			Abdominal pain upper	上腹部痛	1	N	TE	167	3	Y	None	Recovered
			Anaemia	貧血	1	Y	TE	168	2	Y	None	Recovered
			Fatigue	疲労	2	N	TE	168		N	None	Ongoing at time of death
			Dehydration	脱水	2	Y	TE	168	2	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	176	3	Y	Not applicable	Recovered
			Cough	咳嗽	2	N	TE	176	3	N	None	Recovered
			Cough	咳嗽	1	N	TE	176	3	N	Not applicable	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

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Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	3	N	TE	176	3	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	190		Y	Not applicable	Ongoing at time of death
			Neutropenia	好中球減少症	2	Y	TE	190		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	Y	TE	190		Y	Not applicable	Ongoing at time of death
			Abdominal pain	腹痛	1	N	TE	190	1	Y	Not applicable	Recovered
			Decreased appetite	食欲減退	3	N	TE	190		N	None	Ongoing at time of death
			Dehydration	脱水	3	Y	TE	190	4	Y	Not applicable	Recovered
			Hyperkalaemia	高カリウム血症	2	N	TE	190	20	Y	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	190		Y	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	190	4	Y	Not applicable	Recovered
			Dizziness	浮動性めまい	2	N	TE	190		N	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	3	Y	TE	209		N	Not applicable	Ongoing at time of death
			Bronchopneumonia	気管支肺炎	5	Y	TE	209	1	N	Not applicable	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dehydration	脱水	3	Y	TE	209		Y	Not applicable	Ongoing at time of death
			Agitation	激越	2	N	TE	209	1	N	None	Ongoing at time of death
240002	USA	68/M/C	Anaemia	貧血	3	N	TE	33	6	Y	Drug administration postponed	Recovered with sequelae
			Pneumonia	肺炎	3	Y	TE	33	6	N	Drug administration postponed	Recovered
			Sepsis	敗血症	4	Y	TE	33	6	N	Drug administration postponed	Recovered
			Pleural effusion	胸水	2	N	TE	33	4	N	None	Recovered
			Hypotension	低血圧	3	N	TE	33	1	N	None	Recovered
			Anaemia	貧血	1	N	TE	38	48	Y	None	Recovered with sequelae
			Diarrhoea	下痢	1	N	TE	62		Y	None	Ongoing at time of death
			Muscle spasms	筋痙縮	1	N	TE	72	43	N	None	Recovered
			Anaemia	貧血	2	N	TE	85	97	Y	None	Recovered with sequelae
			Nausea	悪心	1	N	TE	114	3	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	114		Y	None	Ongoing at time of death
			Haematuria	血尿	1	N	TE	133	7	N	None	Recovered
			Leukopenia	白血球減少症	2	N	TE	139		Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	1	N	TE	139		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	139		Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	140		N	None	Ongoing at time of death
			Contusion	挫傷	1	N	TE	140		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	140		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	170		N	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	180	3	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	3	Y	TE	180	6	Y	Not applicable	Recovered
			Urinary tract infection	尿路感染	1	N	TE	180	11	N	Not applicable	Recovered
			Bone pain	骨痛	3	N	TE	180	6	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	180	62	N	Not applicable	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Haematuria	血尿	2	Y	TE	180	6	Y	Not applicable	Recovered
			Urinary retention	尿閉	2	Y	TE	180	6	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	N	TE	180	24	N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	181	2	Y	None	Recovered with sequelae
			Dyspnoea	呼吸困難	1	N	TE	181	5	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	182	50	Y	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	194		N	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	199	5	Y	Not applicable	Ongoing at time of death
			Abdominal pain	腹痛	2	N	TE	199	11	N	Not applicable	Recovered
			Diarrhoea	下痢	1	N	TE	199	11	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	199	11	N	Not applicable	Recovered
			Vomiting	嘔吐	2	N	TE	199	11	N	Not applicable	Recovered
			Asthenia	無力症	2	N	TE	199		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Arthralgia	関節痛	1	N	TE	199	11	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	199	11	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	N	TE	199	5	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	203		Y	Not applicable	Ongoing at time of death
			Skin laceration	皮膚裂傷	2	N	TE	205		N	Not applicable	Ongoing at time of death
			Haemorrhoids	痔核	1	N	TE	210	6	N	Not applicable	Recovered
			Convulsion	痙攣	2	N	TE	223	1	N	Not applicable	Recovered
			Subcutaneous abscess	皮下組織膿瘍	2	N	TE	227		N	Not applicable	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	229		N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	231		Y	Not applicable	Ongoing at time of death
			Urinary retention	尿閉	2	N	TE	240	1	Y	Not applicable	Recovered
			Salivary hypersecretion	流涎過多	1	N	TE	241		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	241	1	N	Not applicable	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Confusional state	錯乱状態	3	N	TE	241		N	Not applicable	Ongoing at time of death
240004	USA	56/M/C	Oedema peripheral	末梢性浮腫	1	N	TE	30	28	N	None	Recovered
			Supraventricular tachycardia	上室性頻脈	3	N	TE	55	1	N	None	Recovered
			Mental status changes	精神状態変化	1	N	TE	55	1	N	None	Recovered
			Fatigue	疲労	1	N	TE	57		N	None	Ongoing at study termination / withdrawal
			Arthralgia	関節痛	1	N	TE	57	1	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	117	79	N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	117	79	N	None	Ongoing at study termination / withdrawal
			Cardiac murmur	心雑音	1	N	TE	119	35	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	156	487	N	Not applicable	Death
			Nocturia	夜間頻尿	1	N	TE	156	112	N	Not applicable	Recovered
			Bone pain	骨痛	3	N	TE	195		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	195		N	None	Ongoing at study termination / withdrawal
			Depression	うつ病	1	N	TE	212	21	N	None	Recovered
			Anaemia	貧血	2	N	TE	216	9	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	N	TE	216	3	N	Not applicable	Recovered
			Pain	疼痛	3	N	TE	231		N	Not applicable	Ongoing at time of death
			Decreased appetite	食欲減退	2	N	TE	231		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	N	TE	642	1	N	Not applicable	Death
240006	USA	75/M/C	Constipation	便秘	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	Pre	-7	100	N	None	Recovered
			Cardiac murmur	心雑音	1	N	Pre	-2	35	N	None	Recovered
			Bone pain	骨痛	1	N	TE	31	63	N	None	Recovered
			Contusion	挫傷	1	N	TE	33		N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	3	N	TE	47	11	Y	None	Recovered
			Abdominal pain upper	上腹部痛	1	N	TE	64	25	N	None	Recovered
			Fatigue	疲労	1	N	TE	64		Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	64	60	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight increased	体重増加	1	N	TE	64		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	64	25	N	Drug administration postponed	Recovered
			Muscular weakness	筋力低下	1	N	TE	64		N	None	Ongoing at time of death
			Bone pain	骨痛	4	Y	TE	88	6	N	Drug administration postponed	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	88	115	N	Drug permanently withdrawn	Recovered
			Anaemia	貧血	2	N	TE	109	33	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	110	87	Y	Not applicable	Recovered
			Asthenia	無力症	2	N	TE	110		N	Not applicable	Ongoing at time of death
			Depression	うつ病	2	N	TE	110		N	Not applicable	Ongoing at time of death
			Fluid intake reduced	水分摂取量減少	2	N	TE	116	8	N	Not applicable	Recovered
			Cough	咳嗽	1	N	TE	118	17	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main study: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hypotension	低血圧	2	N	TE	120	55	N	Not applicable	Recovered
			Anorexia	食欲不振	2	N	TE	124		Y	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	145	203	N	Drug permanently withdrawn	Death
			Spinal cord compression	脊髄圧迫	3	N		202		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	347	1	N	Drug permanently withdrawn	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
002004	Norway	81/M/C	Anorexia	食欲不振	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	1	54	N	None	Ongoing at time of death
			Dizziness	浮動性めまい	2	N	Pre	1		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	54	9	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	57		Y	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	57		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	62		N	None	Ongoing at time of death
			Left ventricular dysfunction	左室機能不全	5	Y	TE	68	1	N	None	Death
002015	Norway	83/M/C	Oral candidiasis	口腔カンジダ症	2	N	TE			N	Not applicable	Ongoing at time of death
			Cough	咳嗽	2	N	TE			N	Not applicable	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	37	14	N	None	Recovered
			Conjunctivitis	結膜炎	2	N	TE	50	7	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	100	30	N	Drug permanently withdrawn	Death
			Cerebral haemorrhage	脳出血	2	Y	TE	100		Y	Drug permanently withdrawn	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	100	19	N	Not applicable	Recovered with sequelae
			Confusional state	錯乱状態	2	N	TE	127		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	129	1	N	Drug permanently withdrawn	Death
002018	Norway	70/M/C	Bone pain	骨痛	2	N	TE	2	21	Y	None	Recovered
			Stomatitis	口内炎	2	N	TE	22	9	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	22	14	Y	None	Recovered
			Insomnia	不眠症	1	N	TE	22		N	None	Ongoing at study termination / withdrawal
			Constipation	便秘	2	N	TE	29	5	N	None	Recovered
			Bone pain	骨痛	2	N	TE	35		Y	None	Not recovered, but no changes expected
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	44	63	N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pneumonia	肺炎	2	N	TE	75		N	Not applicable	Ongoing at study termination / withdrawal
			Metastases to central nervous system	中枢神経系転移	4	Y	TE	79		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	106	1	N	None	Death
006014	Norway	81/M/C	Anorexia	食欲不振	2	N	TE	29		Y	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	57	80	N	None	Recovered
			Cystitis	膀胱炎	2	N	TE	101	5	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	101	55	N	Drug administration postponed	Recovered
			Pneumonia	肺炎	3	N	TE	106	10	N	Drug administration postponed	Recovered
			Cystitis	膀胱炎	2	N	TE	159	8	N	None	Recovered
			Dyspnoea	呼吸困難	3	Y	TE	159	6	N	Drug administration postponed	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	175	10	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cystitis	膀胱炎	2	N	TE	177	9	N	None	Recovered
			Bone pain	骨痛	1	Y	TE	184	2	N	Not applicable	Recovered with sequelae
			Death	死亡	5	Y	TE	205	1	N	Not applicable	Death
006029	Norway	77/M/C	Diarrhoea	下痢	1	N	TE	2	5	Y	None	Recovered
			Fatigue	疲労	1	N	TE	2	5	N	None	Recovered
			Anaemia	貧血	2	N	TE	35	39	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	56		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	68	12	N	None	Recovered with sequelae
			Dysphagia	嚥下障害	2	N	TE	69	5	N	None	Recovered
			Pyrexia	発熱	1	N	TE	69	2	Y	None	Recovered
			Infection	感染	3	N	TE	69	10	N	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	3	N	TE	69	9	N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	72	4	N	None	Recovered
			Anaemia	貧血	1	N	TE	73		N	None	Ongoing at time of death
			Psoriasis	乾癬	2	N	TE	75		N	None	Ongoing at time of death
			Urinary retention	尿閉	2	N	TE	76	1	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	1	N	TE	77		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	79		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	4	Y	TE	96	3	N	Not applicable	Death
			Dyspnoea	呼吸困難	5	Y	TE	98	1	N	Not applicable	Death
007003	Norway	65/M/C	Pleural effusion	胸水	2	Y	TE	1	11	N	None	Recovered
			Pneumonia	肺炎	2	N	TE	26	4	N	Drug administration postponed	Recovered
			Pneumonia	肺炎	3	Y	TE	29	9	N	Drug administration postponed	Recovered
			Bone pain	骨痛	3	N	TE	36		N	None	Ongoing at time of death
			Confusional state	錯乱状態	1	N	TE	53	3	Y	None	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	54		N	None	Ongoing at time of death
			Dizziness	浮動性めまい	1	N	TE	54	2	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pneumonia	肺炎	2	Y	TE	55	19	Y	Drug administration postponed	Recovered
			Confusional state	錯乱状態	2	Y	TE	55	19	Y	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	57	15	N	None	Recovered
			Metastases to meninges	髄膜転移	3	Y	TE	64	30	N	None	Death
			Thrombocytopenia	血小板減少症	4	Y	TE	86		Y	None	Ongoing at time of death
			Metastases to meninges	髄膜転移	5	Y	TE	93	1	N	None	Death
007009	Norway	67/M/C	Thrombocytopenia	血小板減少症	1	N	Pre	1	2	N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	4	Y	Pre	1		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	2	4	N	None	Ongoing at time of death
			Myocardial infarction	心筋梗塞	2	Y	TE	3	14	N	None	Death
			Hyperglycaemia	高血糖	4	Y	TE	4		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	5	8	N	None	Ongoing at time of death
			Localised oedema	限局性浮腫	1	N	TE	11		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	12		N	None	Ongoing at time of death
			Myocardial infarction	心筋梗塞	5	Y	TE	16	1	N	None	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
008014	Norway	77/M/C	Oedema peripheral	末梢性浮腫	1	N	TE			N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE			N	None	Ongoing at time of death
			Anaemia	貧血	1	N	Pre	1	3	N	-	
			Anaemia	貧血	2	N	TE	3	27	N	-	
			Cystitis	膀胱炎	2	N	TE	3	11	N	None	Recovered
			Myalgia	筋痛	2	Y	TE	3	4	N	None	Recovered
			Anaemia	貧血	1	N	TE	29	42	N	-	
			Respiratory tract infection	気道感染	2	N	TE	48		N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	69	12	N	None	Recovered
			Anaemia	貧血	2	N	TE	70	4	N	None	Ongoing at time of death
			Atrial fibrillation	心房細動	2	N	TE	70	2	N	None	Recovered
			Anaemia	貧血	1	N	TE	73	37	N	None	Ongoing at time of death
			Weight decreased	体重減少	2	N	TE	85		N	None	Ongoing at time of death
			Gastroenteritis norovirus	ノロウイルス性胃腸炎	2	Y	TE	93	5	N	None	Recovered
			Post procedural infection	処置後感染	2	N	TE	93	17	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	109		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Post procedural infection	処置後感染	2	Y	TE	109	8	N	Drug administration postponed	Recovered
			Syncope	失神	2	N	TE	110	1	N	None	Recovered
			Syncope	失神	2	N	TE	111	1	N	None	Recovered
			Syncope	失神	2	N	TE	112	1	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	113	3	N	None	Recovered
			Pneumonia	肺炎	2	N	TE	114		N	Drug administration postponed	Recovered
			Dyspnoea	呼吸困難	3	Y	TE	152		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	155	16	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	170	1	N	Not applicable	Death
010005	Czech Republic	83/M/C	Cachexia	悪液質	5	Y	TE	147	1	N	Not applicable	Death
016001	Czech Republic	72/M/C	Malignant neoplasm progression	悪性新生物進行	3	Y	TE	78	10	N	None	Not recovered, but no changes expected
			Thrombocytopenia	血小板減少症	3	N	TE	84		Y	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	98	3	N	None	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	100	1	N	None	Death
017010	Czech Republic	69/M/C	Bursitis	滑液包炎	2	Y	TE	37	13	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	52	32	N	None	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	83	1	N	None	Death
017013	Czech Republic	78/M/C	Dyspepsia	消化不良	1	Y	Pre	-17	5	N	None	Recovered
			Constipation	便秘	1	N	Pre	-1		N	None	Ongoing at time of death
			Cerebral ischaemia	脳虚血	4	Y	TE	85	7	N	None	Death
			Cerebral ischaemia	脳虚血	5	Y	TE	91	1	N	None	Death
017014	Czech Republic	63/M/C	Bone pain	骨痛	2	N	TE	15		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	98	1	N	None	Death
017016	Czech Republic	79/M/C	Urinary tract infection	尿路感染	3	Y	TE	80	6	N	None	Death
			Urinary tract infection	尿路感染	5	Y	TE	85	1	N	None	Death
017028	Czech Republic	63/M/C	Insomnia	不眠症	1	N	TE	113	29	N	None	Recovered
			Bone pain	骨痛	2	N	TE	141	29	N	Not applicable	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	169	64	N	Not applicable	Ongoing at time of death
			Venous thrombosis	静脈血栓症	3	Y	TE	184	8	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	191	42	N	Not applicable	Ongoing at time of death
			Renal failure	腎不全	3	Y	TE	191	42	N	Not applicable	Death
			Staphylococcal infection	ブドウ球菌感染	3	Y	TE	200		N	Not applicable	Ongoing at time of death
			Renal failure	腎不全	5	Y	TE	232	1	N	Not applicable	Death
022005	Sweden	62/M/C	Dizziness	浮動性めまい	1	N	TE			N	None	Recovered
			Nausea	悪心	2	Y	TE	17	7	N	None	Recovered
			Vomiting	嘔吐	2	Y	TE	17	7	N	None	Recovered
			Dehydration	脱水	2	Y	TE	17	7	N	None	Recovered
			Bone pain	骨痛	2	N	TE	18	12	N	None	Recovered
			Fatigue	疲労	2	Y	TE	37	2	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	57		Y	None	Ongoing at time of death
			Sepsis	敗血症	4	Y	TE	57	5	N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	84	53	N	Not applicable	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	N	TE	85	14	N	None	Recovered with sequelae
			Anaemia	貧血	3	Y	TE	98	14	N	None	Recovered with sequelae
			Constipation	便秘	3	Y	TE	99	13	N	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	99	13	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	113	2	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	136	1	N	Not applicable	Death
024005	Sweden	69/M/C	Anaemia	貧血	2	N	TE	57	3	Y	None	Recovered
			Infection	感染	2	N	TE	103	11	N	None	Recovered
			Anaemia	貧血	1	N	TE	113	2	Y	None	Recovered
			General physical health deterioration	全身健康状態低下	3	N	TE	113		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	113	23	N	None	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	135	1	N	None	Death
024009	Sweden	73/M/C	Pathological fracture	病的骨折	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	11	50	N	None	Recovered
			Arrhythmia	不整脈	1	N	TE	29		N	None	Not recovered, but no changes expected

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Chills	悪寒	1	N	TE	29		Y	None	Recovered
			Oedema	浮腫	3	N	TE	29		N	Not applicable	Ongoing at time of death
			Magnesium deficiency	マグネシウム欠乏	1	N	TE	29	29	N	None	Recovered
			General physical health deterioration	全身健康状態低下	3	N	TE	57		N	None	Not recovered, but no changes expected
			Pathological fracture	病的骨折	2	N	TE	61		N	None	Not recovered, but no changes expected
			Dyspepsia	消化不良	2	N	TE	65		N	None	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	Y	TE	65	15	N	None	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	3	N	TE	66		N	None	Not recovered, but no changes expected
			Metastases to liver	肝転移	2	N	TE	86		N	None	Not recovered, but no changes expected
			Metastases to liver	肝転移	2	N	TE	86		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	91	5	Y	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	92		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anxiety	不安	2	N	TE	93		N	Not applicable	Ongoing at time of death
			Myocardial infarction	心筋梗塞	3	Y	TE	95		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	97	1	N	Drug permanently withdrawn	Death
024014	Sweden	74/M/C	Dry eye	眼乾燥	1	N	TE	15		N	None	Ongoing at time of death
			Skin infection	皮膚感染	2	N	TE	53	9	N	None	Recovered
			Metastases to bone	骨転移	1	N	TE	53		N	None	Not recovered, but no changes expected
			Micturition urgency	尿意切迫	1	N	TE	53		N	None	Not recovered, but no changes expected
			Hypoaesthesia	感覚鈍麻	2	N	TE	61		N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	81		N	None	Not recovered, but no changes expected
			Dizziness	浮動性めまい	2	N	TE	81	27	N	None	Recovered
			Viral skin infection	皮膚ウイルス感染	2	N	TE	100		N	None	Ongoing at time of death
			Atrial fibrillation	心房細動	2	Y	TE	101	7	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oral fungal infection	口腔真菌感染	2	N	TE	103		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	126	1	N	Drug permanently withdrawn	Death
024022	Sweden	84/M/C	Constipation	便秘	2	N	TE			N	Not applicable	Recovered
			Pneumonia	肺炎	4	Y	TE			N	Drug permanently withdrawn	Ongoing at time of death
			Hip fracture	股関節部骨折	3	Y	Pre			N	Drug administration postponed	Recovered
			Pulmonary oedema	肺水腫	4	Y	TE			N	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	Y	Pre	-33	14	N	Drug administration postponed	Recovered with sequelae
			Urinary retention	尿閉	2	Y	Pre	-33	14	N	Drug administration postponed	Recovered with sequelae
			Vomiting	嘔吐	3	N	Pre	-18	10	N	Not applicable	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pyrexia	発熱	3	N	Pre	-18	10	N	Not applicable	Recovered
			Dislocation of joint prosthesis	人工骨頭関節脱臼	3	Y	Pre	-18	10	N	Not applicable	Recovered
			Bone pain	骨痛	3	N	Pre	-18	10	N	Not applicable	Recovered
			Pathological fracture	病的骨折	3	Y	TE	6		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	6	43	N	Drug permanently withdrawn	Death
			Sepsis	敗血症	3	Y	TE	15		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	48	1	N	Drug permanently withdrawn	Death
024024	Sweden	82/M/C	Fatigue	疲労	2	N	TE	59	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	112		N	None	Not recovered, but no changes expected
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	132	16	N	Drug permanently withdrawn	Not recovered, but no changes expected
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	148	14	N	Not applicable	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	161	1	N	Not applicable	Death
024026	Sweden	68/M/C	Nausea	悪心	2	N	TE			Y	None	Recovered
			Infection	感染	3	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE			N	Drug administration postponed	Death
			Restless legs syndrome	下肢静止不能症候群	1	N	TE	31	27	N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	57	30	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	57		N	None	Lost to follow-up
			Restless legs syndrome	下肢静止不能症候群	2	N	TE	57		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	79	8	N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	86		N	None	Not recovered, but no changes expected
			Weight decreased	体重減少	1	N	TE	86		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	3	Y	TE	102	12	N	Drug administration postponed	Recovered
			Pyrexia	発熱	3	Y	TE	102	12	N	Drug administration postponed	Recovered
			Bone pain	骨痛	3	Y	TE	102	12	N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	126	1	N	Drug administration postponed	Death
025002	Sweden	64/M/C	Nausea	悪心	1	N	TE	60	149	Y	None	Recovered
			Tremor	振戦	1	N	TE	88		N	None	Ongoing at time of death
			Listeriosis	リステリア症	2	Y	TE	92	26	N	Drug administration postponed	Recovered
			Fatigue	疲労	2	N	TE	155		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Haematuria	血尿	1	N	TE	185		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	204	5	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	208	1	N	Not applicable	Death
028005	Belgium	70/M/C	Radiculitis	神経根炎	2	N	Pre	-8		N	None	Ongoing at time of death
			Pathological fracture	病的骨折	3	Y	TE	21	3	N	None	Recovered
			Anaemia	貧血	3	N	TE	22	1	N	None	Recovered
			General physical health deterioration	全身健康状態低下	3	Y	TE	26	14	Y	None	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	82	12	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	93	1	N	Drug permanently withdrawn	Death
029002	Belgium	81/M/C	Fatigue	疲労	1	N	TE	41	32	N	None	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	1	N	TE	41	30	N	None	Recovered
			Depression	うつ病	1	N	TE	59		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	72		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	105	2	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	106		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	Y	TE	106	12	N	None	Recovered
			Muscular weakness	筋力低下	1	N	TE	109		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	117		N	Not applicable	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	128	31	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	158	1	N	Not applicable	Death
033001	UK	84/M/C	Oedema peripheral	末梢性浮腫	1	N	Pre	1		N	None	Ongoing at time of death
			Lymphadenopathy	リンパ節症	1	N	TE	25		N	None	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	2	N	TE	25		N	None	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	25	14	N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Muscular weakness	筋力低下	2	N	TE	29		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	29		N	None	Ongoing at time of death
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	N	TE	38		N	None	Ongoing at time of death
			Pulmonary embolism	肺塞栓症	5	Y	TE	59	1	N	None	Death
033014	UK	73/M/C	Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Pitting oedema	圧痕浮腫	2	N	TE			N	None	Ongoing at time of death
			Weight increased	体重増加	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			Y	None	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	1	N	TE			N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	112		Y	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	112	2	N	None	Recovered
			Nausea	悪心	1	N	TE	177	3	Y	None	Recovered
			Dysphasia	不全失語症	3	N	TE	177	3	N	None	Recovered
			Pleuritic pain	胸膜痛	3	Y	TE	177	3	N	Not applicable	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	184	1	N	Not applicable	Death
033017	UK	80/M/C	Abdominal pain lower	下腹部痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			Y	None	Recovered
			Dysuria	排尿困難	1	N	TE			N	None	Recovered
			Pollakiuria	頻尿	2	N	TE			N	None	Recovered with sequelae
			Pollakiuria	頻尿	2	N	TE			N	None	Recovered
			Urine flow decreased	尿流量減少	2	N	TE			N	None	Not recovered, but no changes expected
			Skin lesion	皮膚病変	1	N	TE			N	None	Not recovered, but no changes expected
			Pulmonary embolism	肺塞栓症	5	Y	TE	124	1	N	None	Death
033025	UK	66/M/C	Fatigue	疲労	2	N	TE			N	None	Not recovered, but no changes expected
			Tooth fracture	歯牙破折	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			Y	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	TE			N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	Pre	-35		Y	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	1	N	TE	4	14	Y	None	Recovered
			Anaemia	貧血	2	N	TE	29	64	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	85	2	Y	None	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE	88		N	None	Recovered
			Anaemia	貧血	3	N	TE	116	19	Y	None	Recovered
			Anaemia	貧血	2	N	TE	134	29	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	162	5	Y	None	Recovered
			Disseminated intravascular coagulation	播種性血管内凝固	4	Y	TE	165		N	Not applicable	Ongoing at time of death
			Respiratory failure	呼吸不全	4	Y	TE	168		N	Not applicable	Ongoing at time of death
			Haemorrhage intracranial	頭蓋内出血	5	Y	TE	169	1	N	Not applicable	Death
035037	UK	70/M/C	Bone pain	骨痛	2	N	Pre			N	None	Recovered
			Anaemia	貧血	3	N	TE	28	43	Y	Drug administration postponed	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	39	116	N	None	Not recovered, but no changes expected
			Oedema peripheral	末梢性浮腫	1	N	TE	39		N	None	Not recovered, but no changes expected

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	154	3	Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	154		N	None	Not recovered, but no changes expected
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	185	9	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	193	1	N	Not applicable	Death
037018	UK	68/M/C	Somnolence	傾眠	1	N	TE			N	None	Recovered
			Tachycardia	頻脈	1	N	Pre	1	29	N	None	Recovered
			Muscle atrophy	筋萎縮	1	N	Pre	1		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	28	49	N	Drug administration postponed	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	63		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	76	4	N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	Y	TE	76		N	Drug administration postponed	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	76	30	N	None	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Herpes zoster	帯状疱疹	2	Y	TE	78	8	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	79		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	79	9	N	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	79		N	None	Ongoing at time of death
			Fall	転倒・転落	1	N	TE	80	1	N	None	Recovered
			Bone pain	骨痛	2	N	TE	81		N	None	Ongoing at time of death
			Hypotension	低血圧	1	N	TE	85	2	N	None	Recovered
			Muscular weakness	筋力低下	1	N	TE	88	2	N	None	Recovered
			Cough	咳嗽	1	N	TE	90	4	N	None	Recovered
			Dyspnoea	呼吸困難	3	N	TE	92		N	None	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	3	Y	TE	93	6	N	None	Recovered
			Somnolence	傾眠	1	N	TE	96		N	None	Ongoing at time of death
			Dry mouth	口内乾燥	1	N	TE	103		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	105	1	N	None	Death
039011	UK	65/M/C	Bone pain	骨痛	3	Y	Pre	-37	3	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	1	N	TE	3		N	None	Ongoing at time of death
			Nausea	悪心	3	Y	TE	4	4	Y	None	Recovered
			Dizziness	浮動性めまい	3	N	TE	5	17	Y	None	Ongoing at time of death
			Vomiting	嘔吐	3	N	TE	8		Y	None	Recovered
			Nausea	悪心	3	Y	TE	10		Y	Drug administration postponed	Ongoing at time of death
			Retching	レッチング	3	N	TE	10	12	Y	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	10	12	Y	None	Ongoing at time of death
			Paraesthesia	錯感覚	3	N	TE	10	12	N	None	Ongoing at time of death
			Somnolence	傾眠	1	N	TE	12		N	None	Ongoing at time of death
			Somnolence	傾眠	1	N	TE	12		N	None	Ongoing at time of death
			Tachycardia	頻脈	2	N	TE	13	9	N	None	Ongoing at time of death
			Abdominal pain	腹痛	2	N	TE	13	9	N	None	Ongoing at time of death
			Pleural effusion	胸水	2	N	TE	13	9	N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pleural effusion	胸水	3	N	TE	14	5	N	Drug administration postponed	Death
			Sepsis	敗血症	2	N	TE	15	7	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	15	7	N	None	Ongoing at time of death
			Rash	発疹	2	N	TE	15	7	N	None	Ongoing at time of death
			Chest pain	胸痛	3	N	TE	17	5	N	None	Ongoing at time of death
			Depressed mood	抑うつ気分	2	N	TE	17	5	N	None	Ongoing at time of death
			Vomiting	嘔吐	3	N	TE	18		N	None	Ongoing at time of death
			Pleural effusion	胸水	4	Y	TE	18	4	N	Drug administration postponed	Death
			Constipation	便秘	3	N	TE	19	3	N	None	Ongoing at time of death
			Abdominal pain lower	下腹部痛	1	N	TE	20	2	N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	3	N	TE	20	2	N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	2	N	TE	20	2	N	None	Ongoing at time of death
			Pleural effusion	胸水	5	Y	TE	21	1	N	Drug administration postponed	Death
041007	UK	62/M/C	Lymphadenopathy	リンパ節症	1	N	Pre	1		N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	7		Y	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	7		N	None	Ongoing at time of death
			Eyelid function disorder	眼瞼機能障害	2	N	TE	12	19	N	None	Recovered
			Vision blurred	霧視	1	N	TE	12		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	29		Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	29		Y	None	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	29		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	60	6	N	None	Death
			Muscular weakness	筋力低下	2	N	TE	61		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	65	1	N	None	Death
042002	UK	64/M/C	Nausea	悪心	1	N	TE			Y	None	Recovered
			Vomiting	嘔吐	1	N	TE			Y	None	Recovered
			Peripheral coldness	末梢冷感	1	N	TE			N	None	Recovered
			Anorexia	食欲不振	1	N	TE			Y	None	Recovered
			Constipation	便秘	1	N	TE	3		Y	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	4	6	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	4	6	N	None	Recovered
			Bone pain	骨痛	2	N	TE	8	22	N	None	Recovered
			Tachycardia	頻脈	1	N	TE	28		N	None	Ongoing at time of death
			Hypotension	低血圧	1	N	TE	55	1	Y	None	Recovered
			Weight decreased	体重減少	2	N	TE	57	57	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	57	57	N	None	Recovered
			Spinal cord compression	脊髄圧迫	2	N	TE	58	56	N	None	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	164	12	N	Not applicable	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	192	1	N	Not applicable	Death
042003	UK	66/M/C	Anaemia	貧血	2	Y	TE	17	2	Y	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	17	7	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	N	TE	34	3	N	Not applicable	Recovered
			Cardiac failure congestive	うっ血性心不全	3	Y	TE	34	8	N	None	Death
			Constipation	便秘	2	N	TE	34		N	Not applicable	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	34	4	N	Not applicable	Recovered
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	2	N	TE	34		N	Not applicable	Ongoing at time of death
			Hypokalaemia	低カリウム血症	3	N	TE	35	3	N	Not applicable	Recovered
			Rectal haemorrhage	直腸出血	1	N	TE	37	1	N	Not applicable	Recovered
			Neuropathy peripheral	末梢性ニューロパチー	2	N	TE	38		N	Not applicable	Ongoing at time of death
			Urinary tract obstruction	尿路閉塞	3	N	TE	38		N	Not applicable	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	39		N	Not applicable	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	2	Y	TE	39		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	40	2	N	Not applicable	Recovered
			Pneumonia	肺炎	3	N	TE	40		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Confusional state	錯乱状態	1	N	TE	40		N	Not applicable	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	5	Y	TE	41	1	N	None	Death
042004	UK	74/M/C	Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Cough	咳嗽	1	N	TE			N	None	Ongoing at time of death
			Dysphonia	発声障害	1	N	TE			N	None	Ongoing at time of death
			Small intestinal obstruction	小腸閉塞	2	Y	Pre	-35	9	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	3	27	N	None	Recovered
			Epistaxis	鼻出血	1	N	TE	5	1	N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	30	8	N	None	Recovered
			Lethargy	嗜眠	1	N	TE	30	140	Y	None	Ongoing at time of death
			Dysgeusia	味覚異常	2	N	TE	41	3	N	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	45	2	N	None	Recovered
			Pathological fracture	病的骨折	2	Y	TE	55	9	N	None	Recovered
			Nausea	悪心	1	N	TE	56		N	None	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	58	6	Y	None	Recovered
			Eye pain	眼痛	1	N	TE	80	3	N	None	Recovered
			Bone pain	骨痛	1	N	TE	106	1	N	None	Recovered
			Bone pain	骨痛	1	N	TE	112	1	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea exertional	労作性呼吸困難	1	N	TE	113		N	None	Ongoing at time of death
			Oral pain	口腔内痛	1	N	TE	119	1	N	None	Recovered
			Palpitations	動悸	1	N	TE	121	1	N	None	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	141		N	None	Ongoing at time of death
			Contusion	挫傷	1	N	TE	141		N	None	Ongoing at time of death
			Lethargy	嗜眠	2	N	TE	169		Y	None	Ongoing at time of death
			Pleural effusion	胸水	1	N	TE	169		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	198	1	N	Not applicable	Death
042024	UK	62/M/C	Fatigue	疲労	1	N	TE			N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE			N	None	Ongoing at time of death
			Confusional state	錯乱状態	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	1	29	Y	None	Recovered
			Anxiety	不安	1	N	TE	2	28	N	None	Recovered
			Hyperhidrosis	多汗症	2	N	TE	2		N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	8		N	None	Ongoing at time of death
			Pyrexia	発熱	1	N	TE	62	1	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Weight decreased	体重減少	1	N	TE	64		N	None	Ongoing at time of death
			Dysuria	排尿困難	2	N	TE	80	6	N	Not applicable	Recovered
			Vomiting	嘔吐	3	Y	TE	83	6	N	None	Recovered
			Pyrexia	発熱	3	Y	TE	83	6	N	None	Recovered
			Confusional state	錯乱状態	3	Y	TE	83	1	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	99	23	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	121	1	N	Not applicable	Death
042031	UK	73/M/C	Depression	うつ病	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	-10	115	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	18	40	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	29	85	N	None	Recovered
			Decreased appetite	食欲減退	2	N	TE	29	85	N	None	Recovered
			Constipation	便秘	1	N	TE	53		N	None	Ongoing at time of death
			Cough	咳嗽	2	N	TE	53	8	N	None	Recovered
			Bone pain	骨痛	2	N	TE	105	22	N	None	Recovered
			Bone pain	骨痛	3	N	TE	126	16	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	142		N	Drug administration postponed	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	142	24	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	165	1	N	Drug permanently withdrawn	Death
043018	UK	63/M/C	Neuropathy peripheral	末梢性ニューロパチー	3	N	Pre	-3		N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	4	4	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	23	9	N	None	Recovered
			Contusion	挫傷	2	N	TE	50		N	None	Ongoing at time of death
			Skin disorder	皮膚障害	2	N	TE	50	8	N	None	Recovered
			Hypoaesthesia	感覚鈍麻	2	N	TE	76		N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	90	25	Y	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	90	25	Y	None	Ongoing at time of death
			Metastases to central nervous system	中枢神経系転移	4	Y	TE	106	9	N	Drug permanently withdrawn	Death
			Metastases to central nervous system	中枢神経系転移	5	Y	TE	114	1	N	Drug permanently withdrawn	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
047006	UK	73/M/C	Cardiac arrest	心停止	5	Y	TE	25	1	N	Drug permanently withdrawn	Death
048012	UK	68/M/C	Anorexia	食欲不振	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	8	76	N	None	Ongoing at time of death
			Asthenia	無力症	1	N	TE	41		Y	None	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE	51		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	57	2	N	None	Recovered
			Vision blurred	霧視	1	N	TE	69		N	None	Ongoing at time of death
			Headache	頭痛	2	N	TE	73	10	N	None	Recovered
			Bone pain	骨痛	1	N	TE	83		N	None	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	103	5	N	None	Recovered
			Anaemia	貧血	2	N	TE	112	3	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	189	1	N	Not applicable	Death
050001	UK	80/M/C	Anaemia	貧血	3	N	TE			N	Not applicable	Recovered with sequelae
			Fatigue	疲労	2	N	TE			Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Ear infection	耳感染	2	N	TE			N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	1	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at study termination / withdrawal
			Upper respiratory tract infection	上気道感染	2	N	Pre	-14	8	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	1	29	Y	-	
			Nausea	悪心	2	N	TE	2	2	Y	None	Recovered
			Fatigue	疲労	2	N	TE	8	14	Y	None	Recovered
			Muscular weakness	筋力低下	2	N	TE	8	14	N	None	Recovered
			Myalgia	筋痛	2	N	TE	8	22	N	None	Recovered
			Fatigue	疲労	3	N	TE	21	4	Y	None	Recovered
			Muscular weakness	筋力低下	3	N	TE	21	9	N	None	Recovered
			Fatigue	疲労	1	N	TE	24	37	Y	None	Recovered
			Anaemia	貧血	1	N	TE	29	29	Y	-	
			Nausea	悪心	2	N	TE	30	1	Y	None	Recovered
			Hot flush	ほてり	2	N	TE	30		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	1	N	TE	34	1	Y	None	Recovered
			Anaemia	貧血	3	N	TE	57	5	Y	-	

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	61	12	Y	-	
			Urinary tract infection	尿路感染	2	N	TE	61	6	N	None	Recovered
			Urinary retention	尿閉	3	Y	TE	61	2	N	None	Recovered with sequelae
			Anaemia	貧血	2	N	TE	72	70	Y	-	
			Haemorrhage urinary tract	尿路出血	2	N	TE	80	2	N	None	Recovered
			Urinary retention	尿閉	1	N	TE	84		N	None	Ongoing at study termination / withdrawal
			Urinary retention	尿閉	1	N	TE	84	3	N	None	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	85	57	N	None	Ongoing at study termination / withdrawal
			Urinary retention	尿閉	2	N	TE	86		N	None	Ongoing at study termination / withdrawal
			Insomnia	不眠症	2	N	TE	101	5	N	None	Recovered
			Fatigue	疲労	3	N	TE	113		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Muscular weakness	筋力低下	2	N	TE	113		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	N	TE	141	9	Y	-	
			Constipation	便秘	1	N	TE	141		Y	Not applicable	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	2	N	TE	141		N	None	Ongoing at study termination / withdrawal
			Muscular weakness	筋力低下	3	N	TE	141		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	4	N	TE	149	3	Y	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	151		Y	None	Ongoing at study termination / withdrawal
			Cranial neuropathy	脳ニューロパチー	2	N	TE	155		N	None	Ongoing at time of death
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	2	N	TE	155		N	None	Ongoing at time of death
			Oral candidiasis	口腔カンジダ症	2	N	TE	190		N	None	Ongoing at time of death
			Anaemia	貧血	4	Y	TE	192	5	N	Not applicable	Recovered with sequelae
			Gastric cancer	胃癌	4	Y	TE	192	28	N	Not applicable	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Gastric cancer	胃癌	5	Y	TE	219	1	N	Not applicable	Death
050003	UK	60/M/C	Nausea	悪心	1	N	TE			N	None	Recovered
			Fatigue	疲労	2	N	TE			N	-	
			Fatigue	疲労	3	N	TE			N	-	
			Weight decreased	体重減少	1	N	TE			N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE			N	None	Ongoing at time of death
			Muscular weakness	筋力低下	3	N	TE			N	None	Ongoing at time of death
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE			N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	N	TE	6	10	N	-	
			Oedema genital	性器浮腫		N	TE	10		N	None	Ongoing at time of death
			Pharyngolaryngeal pain	咽喉頭疼痛	1	N	TE	13		N	None	Recovered
			Contusion	挫傷	1	N	TE	14		Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	15	9	N	-	
			Constipation	便秘	2	N	TE	16		Y	None	Ongoing at time of death
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE	16		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	18		N	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	19	3	N	-	

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pollakiuria	頻尿	1	N	TE	19	4	N	None	Recovered
			Fatigue	疲労	3	N	TE	21		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	4	N	TE	23	8	N	-	
			Dysphagia	嚥下障害	2	N	TE	26		N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	1	N	TE	26	3	N	None	Recovered
			Oedema peripheral	末梢性浮腫	3	N	TE	29	2	N	Not applicable	Ongoing at time of death
			Abdominal pain	腹痛	3	N	TE	30	1	N	None	Recovered
			Oedema peripheral	末梢性浮腫	4	N	TE	30		N	Not applicable	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	4	N	TE	30		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	31	1	N	Drug permanently withdrawn	Death
			Agitation	激越	2	N	TE	31	1	N	Not applicable	Recovered
050016	UK	63/M/C	Constipation	便秘	1	N	TE			Y	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE			N	Not applicable	Ongoing at time of death
			Herpes zoster	帯状疱疹	2	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at time of death
			Memory impairment	記憶障害	1	N	TE			N	Not applicable	Ongoing at time of death
			Agitation	激越	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	Pre	-41	3	N	Not applicable	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	3	27	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	43	8	N	None	Recovered with sequelae
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	Y	TE	43	8	N	None	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	3	N	TE	43	16	N	None	Recovered
			Lung infection	肺感染	2	Y	TE	80	11	N	Drug administration postponed	Recovered with sequelae
			Fatigue	疲労	2	N	TE	99		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	99		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	100		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	134	4	Y	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	2	N	TE	138		Y	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	148		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	165	4	Y	Not applicable	Recovered
			General physical health deterioration	全身健康状態低下	2	Y	TE	168	17	N	Not applicable	Death
			Oral candidiasis	口腔カンジダ症	2	N	TE	171	6	N	Not applicable	Recovered
			Epilepsy	てんかん	3	Y	TE	175	1	N	Not applicable	Recovered with sequelae
			General physical health deterioration	全身健康状態低下	5	Y	TE	184	1	N	Not applicable	Death
055007	Netherlands	62/M/C	Confusional state	錯乱状態	2	Y	Pre	-13	2	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	8		N	Not applicable	Ongoing at time of death
			Nausea	悪心	2	N	TE	8		N	Not applicable	Ongoing at time of death
			Intertrigo	間擦疹	1	N	TE	8		Y	Not applicable	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	35	2	N	None	Recovered
			Anaemia	貧血	3	N	TE	36		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	85	1	N	Not applicable	Death
072001	Spain	78/M/C	Fatigue	疲労	1	N	Pre			N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	10		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	21	7	N	None	Recovered
			Cardiac failure	心不全	4	Y	TE	31	5	N	None	Death
			Cardiac failure	心不全	5	Y	TE	35	1	N	None	Death
080001	Italy	73/M/C	Nausea	悪心	1	N	TE			Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE			Y	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	130	9	N	None	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	138	1	N	None	Death
085001	Israel	58/M/C	Pyrexia	発熱	1	N	TE	31	1	N	None	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	58	7	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	58	7	N	None	Recovered with sequelae
			Pneumonia	肺炎	1	Y	TE	79		N	None	Ongoing at time of death
			Respiratory failure	呼吸不全	4	Y	TE	83	2	N	None	Death
			Respiratory failure	呼吸不全	5	Y	TE	84	1	N	None	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
085003	Israel	74/M/C	Deep vein thrombosis	深部静脈血栓症	2	Y	Pre	-16	3	N	Not applicable	Recovered with sequelae
			Dermatitis contact	接触性皮膚炎	1	N	TE	37	8	N	None	Recovered
			Asthenia	無力症	1	N	TE	49	1	N	None	Recovered
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	55		N	None	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	TE	62		N	None	Ongoing at time of death
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	3	N	TE	62		N	None	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	TE	63	11	N	None	Recovered
			Rectal haemorrhage	直腸出血	2	Y	TE	82	4	N	None	Recovered
			Haematuria	血尿	2	Y	TE	82	4	N	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	90		N	None	Ongoing at time of death
			Tremor	振戦	2	N	TE	90		N	None	Ongoing at time of death
			Hypochromic anaemia	低色素性貧血	2	N	TE	96		N	None	Ongoing at time of death
			Localised oedema	限局性浮腫	1	N	TE	104		N	None	Ongoing at time of death
			Lobar pneumonia	大葉性肺炎	3	Y	TE	104	8	N	Drug permanently withdrawn	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			General physical health deterioration	全身健康状態低下	3	Y	TE	107		N	Drug permanently withdrawn	Ongoing at time of death
			Urosepsis	尿路性敗血症	3	Y	TE	107		N	Drug permanently withdrawn	Ongoing at time of death
			Lobar pneumonia	大葉性肺炎	5	Y	TE	111	1	N	Drug permanently withdrawn	Death
093001	Slovakia	72/M/C	Anaemia	貧血	2	N	Pre	-13	14	N	None	Recovered
			Constipation	便秘	1	N	Pre	-13	57	N	None	Recovered with sequelae
			Hyperbilirubinaemia	高ビリルビン血症	2	Y	Pre	-13	5	N	Not applicable	Recovered with sequelae
			Weight decreased	体重減少	2	Y	Pre	-13	5	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	N	Pre	-13	5	N	Not applicable	Recovered with sequelae
			Hyperbilirubinaemia	高ビリルビン血症	2	N	Pre	-9	3	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	1	N	Pre	-9	10	N	None	Recovered with sequelae
			Hyperbilirubinaemia	高ビリルビン血症	2	Y	Pre	-7	7	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	Y	TE	1	40	N	None	Recovered with sequelae

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	TE	35		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	35		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	35		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	44		N	None	Ongoing at time of death
			Constipation	便秘	2	Y	TE	44	11	N	None	Recovered with sequelae
			Bone pain	骨痛	2	Y	TE	44	11	N	None	Recovered with sequelae
			Pneumonia	肺炎	4	Y	TE	75		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	90	1	N	None	Death
095001	Slovakia	75/M/C	Bone pain	骨痛	4	N	TE	3	8	Y	Drug administration postponed	Recovered
			Bone pain	骨痛	2	N	TE	10	26	Y	Drug administration postponed	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	N	TE	14	61	Y	Drug administration postponed	Recovered
			Nausea	悪心	1	N	TE	20	64	N	None	Recovered
			Fatigue	疲労	2	N	TE	20	118	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	35	40	Y	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	83		Y	Not applicable	Ongoing at time of death
			Cardiopulmonary failure	心肺不全	4	Y	Post	235	13	Y	Not applicable	Death
			Cardiopulmonary failure	心肺不全	5	Y	Post	247	1	Y	Not applicable	Death
097001	Slovakia	70/M/C	Anaemia	貧血	2	N	Pre	1		N	None	Ongoing at time of death
			Sudden death	突然死	5	Y	TE	9	1	N	None	Death
097004	Slovakia	80/M/C	Fatigue	疲労	3	N	TE	3		N	None	Ongoing at time of death
			Cerebral ischaemia	脳虚血	4	Y	TE	3	36	N	Drug administration postponed	Recovered with sequelae
			Micturition disorder	排尿異常	2	N	TE	112		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	3	N	TE	114		N	None	Ongoing at time of death
			Diarrhoea	下痢	3	Y	TE	143	29	Y	Drug permanently withdrawn	Recovered
			Vomiting	嘔吐	3	Y	TE	143	29	Y	Drug permanently withdrawn	Recovered
			Pyrexia	発熱	3	Y	TE	143	29	N	Drug permanently withdrawn	Recovered
			Urinary tract infection	尿路感染	3	Y	TE	143	29	N	Drug permanently withdrawn	Recovered
			Disorientation	失見当識	3	N	TE	143	29	N	Not applicable	Recovered
			Cardiopulmonary failure	心肺不全	5	Y	TE	176	1	N	Not applicable	Death
097007	Slovakia	70/M/C	Bone pain	骨痛	2	N	Pre	-9	38	N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	2	56	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	29	84	N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	29	112	N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	57	56	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	112	9	Y	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	2	N	TE	112		N	None	Ongoing at time of death
			Sleep disorder	睡眠障害	1	N	TE	112	49	N	None	Recovered
			Mixed incontinence	混合性尿失禁	3	N	TE	112		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	120		Y	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	140		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	Pre	140		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	160	1	N	Not applicable	Death
097010	Slovakia	80/M/C	Nausea	悪心	1	N	TE	2	56	Y	None	Recovered
			Anorexia	食欲不振	1	N	TE	2		Y	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	29	58	N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	64	6	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	64	6	N	None	Recovered
			Nausea	悪心	1	N	TE	86	91	Y	None	Recovered
			Fatigue	疲労	3	Y	TE	86	5	Y	Drug administration postponed	Recovered with sequelae
			Weight decreased	体重減少	2	N	TE	86		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	90	68	Y	None	Recovered with sequelae
			Vomiting	嘔吐	2	N	TE	152	6	Y	None	Recovered
			Anaemia	貧血	2	N	TE	157	5	Y	None	Recovered
			Fatigue	疲労	3	Y	TE	157	5	Y	None	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	206	1	N	Not applicable	Death
106012	Hong Kong	75/M/A	Cystitis	膀胱炎	2	N	TE	7	7	N	None	Recovered
			Anaemia	貧血	2	Y	TE	29	2	Y	None	Recovered
			Constipation	便秘	1	N	TE	29	29	Y	None	Recovered
			Faeces discoloured	変色便	1	N	TE	29	29	N	None	Recovered
			Dizziness	浮動性めまい	1	N	TE	29	29	N	None	Recovered
			Anaemia	貧血	3	Y	TE	57	3	Y	Drug administration postponed	Recovered
			Hyperkalaemia	高カリウム血症	1	N	TE	57	23	N	None	Recovered
			Haematuria	血尿	1	N	TE	57	23	N	None	Recovered
			Gastroduodenal ulcer	胃十二指腸潰瘍	1	N	TE	73		N	None	Ongoing at time of death
			Haemorrhoids	痔核	1	N	TE	73	7	N	None	Recovered
			Muscular weakness	筋力低下	2	N	TE	77		N	None	Ongoing at time of death
			Sepsis	敗血症	2	N	TE	79	20	N	Not applicable	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	3	Y	TE	79		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	79		N	Drug permanently withdrawn	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	2	N	TE	80		N	None	Ongoing at time of death
			Convulsion	痙攣	2	N	TE	85		N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	4	Y	TE	90		N	Not applicable	Ongoing at time of death
			Pyrexia	発熱	2	N	TE	91	4	N	Not applicable	Recovered
			Diabetes mellitus	糖尿病	2	N	TE	91	16	N	Not applicable	Recovered
			Anxiety	不安	2	N	TE	94	13	N	Not applicable	Recovered
			Metastases to bone	骨転移	5	Y	TE	106	1	N	Not applicable	Death
133022	Poland	84/M/C	General physical health deterioration	全身健康状態低下	4	N	TE	77		N	None	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	3	Y	TE	77	8	N	Drug permanently withdrawn	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	5	Y	TE	84	1	N	Drug permanently withdrawn	Death
133029	Poland	56/M/C	Nausea	悪心	1	N	TE	2	2	Y	None	Recovered
			Asthenia	無力症	2	N	TE	2	3	Y	None	Recovered
			Urinary retention	尿閉	2	N	TE	53	4	N	None	Recovered
			Subileus	亜イレウス	3	Y	TE	63	5	Y	Drug administration postponed	Recovered
			Renal failure	腎不全	3	Y	TE	82	10	N	Drug permanently withdrawn	Death
			Renal failure	腎不全	5	Y	TE	91	1	N	Drug permanently withdrawn	Death
141002	Poland	60/M/C	Haematuria	血尿	2	Y	TE	10	27	N	None	Recovered
			Haematuria	血尿	3	Y	TE	40	11	N	None	Recovered with sequelae
			Haematuria	血尿	2	N	TE	50		N	None	Not recovered, but no changes expected
			Hydronephrosis	水腎症	2	Y	TE	56	5	N	Drug administration postponed	Recovered with sequelae

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	90	3	N	None	Recovered with sequelae
			Thrombocytopenia	血小板減少症	2	N	TE	92		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	2	N	TE	92		N	None	Ongoing at study termination / withdrawal
			Dyspnoea	呼吸困難	3	Y	TE	95	5	N	Not applicable	Death
			Dyspnoea	呼吸困難	5	Y	TE	99	1	N	Not applicable	Death
148005	Germany	63/M/C	Nausea	悪心	1	N	TE	27	1	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	57	38	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	57	29	Y	None	Recovered
			Nausea	悪心	1	N	TE	59	5	Y	None	Recovered
			Fatigue	疲労	2	N	TE	64		Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	85	1	Y	None	Recovered
			Anaemia	貧血	1	Y	TE	94	2	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	112		N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	114	4	Y	None	Recovered
			Nausea	悪心	1	N	TE	114	4	Y	None	Recovered
			Vomiting	嘔吐	2	N	TE	114	4	Y	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	129	1	N	None	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
149005	Germany	73/M/C	Bone pain	骨痛	1	N	TE	13	31	Y	None	Recovered
			Abdominal pain	腹痛	1	N	TE	31	13	Y	None	Recovered
			Nausea	悪心	1	N	TE	64	3	N	None	Recovered
			Fatigue	疲労	1	N	TE	64	5	N	Drug permanently withdrawn	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	64		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	1	N	TE	64	28	N	-	
			Insomnia	不眠症	1	N	TE	64	4	N	None	Recovered
			Fatigue	疲労	2	N	TE	68	13	N	Drug permanently withdrawn	Ongoing at time of death
			Fatigue	疲労	3	N	TE	80		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	91	24	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	114	2	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	115	1	N	Not applicable	Death
155010	Germany	80/M/C	Gastritis	胃炎	1	N	TE			N	None	Recovered
			General physical health deterioration	全身健康状態低下	1	N	TE	1	86	N	None	Recovered
			Gastritis	胃炎	2	N	TE	54		N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	120		N	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	1	N	TE	120		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	135		N	Not applicable	Ongoing at time of death
			Atrial fibrillation	心房細動	4	N	TE	203		N	Not applicable	Ongoing at time of death
			Sinusitis	副鼻腔炎	1	N	TE	203		N	Not applicable	Ongoing at time of death
			Cerebral haemorrhage	脳出血	4	Y	TE	203		N	Not applicable	Ongoing at time of death
			Epilepsy	てんかん	2	N	TE	203	2	N	Not applicable	Ongoing at time of death
			Pneumonia aspiration	嚥下性肺炎	4	Y	TE	203	2	N	Not applicable	Death
			Pneumonia aspiration	嚥下性肺炎	5	Y	TE	204	1	N	Not applicable	Death
172001	Brazil	75/M/C	Fatigue	疲労	2	N	TE	31		N	None	Not recovered, but no changes expected
			Dyspnoea	呼吸困難	1	N	TE	31	29	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	36	4	N	None	Recovered
			Nasal congestion	鼻閉	1	N	TE	38	22	N	None	Recovered
			Cachexia	悪液質	3	N	TE	59		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	N	TE	86	2	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	86	28	N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	87		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	113		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	212	1	N	Not applicable	Death
174003	Brazil	71/M/A	Weight decreased	体重減少	1	N	Pre	1	76	N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	4	15	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	41	17	N	None	Recovered
			Bone pain	骨痛	3	N	TE	41	4	N	None	Recovered
			Bone pain	骨痛	3	N	TE	41	17	N	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	2	N	TE	44		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	44	14	N	None	Recovered
			Constipation	便秘	2	N	TE	48	10	N	None	Recovered
			Nausea	悪心	2	N	TE	51	7	N	None	Recovered
			Bone pain	骨痛	2	N	TE	57		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	57		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	57		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	63	28	N	None	Recovered
			Nausea	悪心	1	N	TE	63	156	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	76	116	N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	99	43	N	None	Recovered
			Bone pain	骨痛	1	N	TE	105	1	N	None	Recovered
			Anaemia	貧血	3	N	TE	106	29	Y	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	106	29	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	134		Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	162	30	Y	None	Recovered
			Weight decreased	体重減少	3	N	TE	191		N	None	Ongoing at time of death
			Pneumonia	肺炎		N	TE	225		N	Not applicable	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	4	Y	TE	240	8	N	Not applicable	Death
			General physical health deterioration	全身健康状態低下	5	Y	TE	247	1	N	Not applicable	Death
181006	Brazil	75/M/B	Sepsis	敗血症	4	Y	TE	146	11	N	None	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hypernatraemia	高ナトリウム血症	4	N	TE	146		N	Drug administration postponed	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	146		N	None	Ongoing at time of death
			Renal failure acute	急性腎不全	4	N	TE	146		N	Drug permanently withdrawn	Ongoing at time of death
			Respiratory failure	呼吸不全	4	N	TE	146		N	Drug permanently withdrawn	Ongoing at time of death
			Sepsis	敗血症	5	Y	TE	156	1	N	None	Death
191006	Singapore	71/M/A	Hypoaesthesia	感覚鈍麻	1	N	Pre	-5		N	None	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	1	N	Pre	-4		N	None	Ongoing at time of death
			Myopathy	ミオパチー	1	N	Pre	-4		N	None	Ongoing at time of death
			Insomnia	不眠症	1	N	Pre	-4		N	None	Ongoing at time of death
			Urinary tract infection	尿路感染	2	N	Pre	1	7	N	None	Recovered
			Hyperkalaemia	高カリウム血症	2	N	Pre	1	28	N	None	Recovered
			Constipation	便秘	1	N	TE	16		Y	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	1	N	TE	16		Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	24	46	N	None	Recovered
			Headache	頭痛	1	N	TE	24		Y	None	Ongoing at time of death
			Urinary incontinence	尿失禁	2	N	TE	69		N	None	Ongoing at time of death
			Anal sphincter atony	肛門括約筋無緊張症	3	N	TE	118	59	N	Not applicable	Ongoing at time of death
			Somnolence	傾眠	3	N	TE	169		N	Not applicable	Ongoing at time of death
			Intestinal perforation	腸管穿孔	4	Y	TE	174		N	Not applicable	Ongoing at time of death
			Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	3	Y	TE	174		N	Not applicable	Ongoing at time of death
			Myocardial infarction	心筋梗塞	5	Y	TE	176	1	N	Not applicable	Death
207002	Australia	81/M/C	Anorexia	食欲不振	2	N	TE			N	None	Lost to follow-up
			Urinary incontinence	尿失禁	2	N	TE			N	None	Lost to follow-up
			Oedema peripheral	末梢性浮腫	1	N	TE	58		N	None	Lost to follow-up
			Swelling face	顔面腫脹	1	N	TE	58		N	None	Lost to follow-up
			Faecal incontinence	便失禁	1	N	TE	104		N	None	Ongoing at time of death
			Dementia	認知症	3	Y	TE	104	7	N	Drug permanently withdrawn	Recovered with sequelae

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	137	1	N	Not applicable	Death
213006	Australia	72/M/C	Constipation	便秘	1	N	TE			N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			N	None	Recovered
			Fatigue	疲労	1	N	TE	1	2	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	3	55	N	None	Recovered
			Ingrowing nail	嵌入爪	1	N	TE	18		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	29	3	Y	None	Recovered
			Fatigue	疲労	1	N	TE	57	3	Y	None	Recovered
			Constipation	便秘	1	N	TE	59	7	N	None	Recovered
			Fatigue	疲労	1	N	TE	85		Y	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	142		N	None	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	4	Y	TE	185	30	N	Not applicable	Recovered with sequelae
			Pneumonia	肺炎	3	Y	TE	188	5	N	Not applicable	Recovered
			Gastrointestinal haemorrhage	胃腸出血	3	Y	TE	196	2	N	Not applicable	Recovered
			Oral candidiasis	口腔カンジダ症	2	N	TE	200		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Postoperative wound infection	術後創感染	3	Y	TE	201	14	N	Not applicable	Recovered with sequelae
			Postoperative wound infection	術後創感染	2	N	TE	214		N	Not applicable	Ongoing at time of death
			Pulmonary embolism	肺塞栓症	4	Y	TE	220	5	N	Not applicable	Death
			Pulmonary embolism	肺塞栓症	5	Y	TE	224	1	N	Not applicable	Death
233003	UK	61/M/C	Anorexia	食欲不振	1	N	Pre	-13	22	N	None	Recovered with sequelae
			Fatigue	疲労	2	N	Pre	1	163	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre	1	29	N	None	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	29	36	Y	None	Recovered
			Bone pain	骨痛	2	N	Pre	29	36	N	None	Ongoing at time of death
			Ageusia	味覚消失	2	N	TE	29	36	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	58	4	N	None	Recovered
			Constipation	便秘	2	N	TE	60		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	64	25	N	None	Recovered
			Bone pain	骨痛	3	N	Pre	64		N	None	Ongoing at time of death
			Muscular weakness	筋力低下	3	N	TE	64		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	92	17	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Tachycardia	頻脈	1	N	TE	92		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	92		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	104	60	N	None	Recovered
			Anaemia	貧血	3	Y	TE	135	3	N	Drug administration postponed	Recovered
			Asthenia	無力症	3	N	TE	135	3	Y	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	138		N	Drug administration postponed	Ongoing at study termination / withdrawal
			Dysarthria	構語障害	1	N	TE	145		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	3	N	TE	152	12	N	None	Death
			Cardiac failure	心不全	4	Y	TE	152		N	Drug permanently withdrawn	Ongoing at time of death
			Pleural effusion	胸水	2	N	TE	152		N	Not applicable	Ongoing at time of death
			Nausea	悪心	2	N	TE	159	5	N	Not applicable	Ongoing at time of death

表 2.7.4.7- 14　死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study: Placebo

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	5	Y	TE	163	1	N	None	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
001023	Norway	62/M/C	Bone pain	骨痛	2	N	Pre	1		N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	29		Y	None	Ongoing at study termination / withdrawal
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	N	TE	57		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	TE	57		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Weight decreased	体重減少	1	N	TE	57		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	57	19	N	Drug permanently withdrawn	Death
			Metastases to liver	肝転移	3	Y	TE	57		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	75	1	N	Drug permanently withdrawn	Death
002006	Norway	66/M/C	Bone pain	骨痛	2	N	Pre			N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary tract infection	尿路感染	3	N	TE	10	10	N	None	Recovered
			Anaemia	貧血	2	N	TE	29	34	N	None	Recovered
			Bone pain	骨痛	1	N	Pre	29	29	N	None	Ongoing at study termination / withdrawal
			Ascites	腹水	1	N	TE	57	6	N	None	Recovered
			Bone pain	骨痛	2	N	Pre	57		N	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	Y	TE	62	18	N	Drug permanently withdrawn	Recovered with sequelae
			Fungal infection	真菌感染	2	N	TE	76	5	N	None	Recovered
			Anxiety	不安	2	N	TE	77		N	None	Not recovered, but no changes expected
			Sepsis	敗血症	4	Y	TE	79	5	N	Not applicable	Death
			Anaemia	貧血	2	N	TE	81	2	N	None	Recovered
			Sepsis	敗血症	5	Y	TE	83	1	N	Not applicable	Death
002013	Norway	69/M/C	Vision blurred	霧視	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Nausea	悪心	2	N	TE	2	5	Y	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Metastases to skin	皮膚転移	1	N	TE	57		N	None	Not recovered, but no changes expected
			Anorexia	食欲不振	2	N	TE	85		N	None	Ongoing at study termination / withdrawal
			Metastases to soft tissue	軟部組織転移	1	N	TE	86		N	None	Ongoing at time of death
			Cerebral haemorrhage	脳出血	3	Y	TE	100	38	Y	Drug permanently withdrawn	Death
			Anaemia	貧血	2	N	TE	110		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	111		Y	Not applicable	Ongoing at time of death
			Cerebral haemorrhage	脳出血	5	Y	TE	137	1	Y	Drug permanently withdrawn	Death
003018	Norway	71/M/C	Constipation	便秘	2	N	TE			N	Not applicable	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	2	N	TE	2	134	N	Not applicable	Recovered with sequelae
			Vomiting	嘔吐	1	N	TE	57	102	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	116	57	N	Not applicable	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	3	N	TE	135	24	N	Not applicable	Recovered with sequelae

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	2	N	TE	147	72	N	Not applicable	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	3	Y	TE	158	5	N	Not applicable	Recovered with sequelae
			Pelvic pain	骨盤痛	3	N	TE	162		Y	Not applicable	Ongoing at time of death
			Nausea	悪心	2	N	TE	172		N	Not applicable	Ongoing at time of death
			Weight decreased	体重減少	3	N	TE	172		N	Not applicable	Ongoing at time of death
			Musculoskeletal pain	筋骨格痛	3	Y	TE	172	38	N	Not applicable	Recovered with sequelae
			Gastric ulcer	胃潰瘍	3	N	TE	181		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	187	1	Y	Not applicable	Recovered
			Depression	うつ病	3	N	TE	208		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	218	1	N	Not applicable	Death
004001	Norway	60/M/C	Dysgeusia	味覚異常	1	N	TE	2	28	Y	None	Recovered
			Anaemia	貧血	1	N	TE	92	24	Y	None	Recovered
			Anaemia	貧血	1	N	TE	92	24	Y	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	92	113	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	120		Y	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Respiratory tract infection viral	ウイルス性気道感染	2	N	TE	134	11	N	None	Recovered
			Anaemia	貧血	2	N	TE	144		Y	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	2	N	TE	148	37	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	148	12	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	148	12	Y	None	Recovered with sequelae
			Pancytopenia	汎血球減少症	3	N	TE	155	5	Y	Not applicable	Recovered with sequelae
			Pancytopenia	汎血球減少症	3	Y	TE	159	11	Y	Not applicable	Recovered with sequelae
			Oedema	浮腫	2	Y	TE	159	11	Y	Not applicable	Recovered with sequelae
			Dyspnoea	呼吸困難	3	Y	TE	159	11	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	Y	TE	159	11	Y	Not applicable	Recovered with sequelae
			Pancytopenia	汎血球減少症	2	N	TE	169	16	Y	Not applicable	Recovered with sequelae
			Dyspnoea	呼吸困難	2	N	TE	169	16	Y	Not applicable	Recovered
			Pleural effusion	胸水	1	N	TE	170	15	Y	Not applicable	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pancytopenia	汎血球減少症	3	Y	TE	184	15	Y	Not applicable	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	3	Y	TE	184	15	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	Y	TE	184	15	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	Y	TE	184	15	Y	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	198	7	Y	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	198	7	Y	Not applicable	Recovered with sequelae
			Pancytopenia	汎血球減少症	4	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	204		Y	Not applicable	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	3	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Pleural effusion	胸水	2	Y	TE	204		Y	Not applicable	Ongoing at time of death
			Renal failure	腎不全	5	Y	TE	208	1	N	Not applicable	Death
005002	Norway	75/M/C	Bone pain	骨痛	1	N	TE			N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Lymphadenopathy	リンパ節症	1	N	TE	85		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	2	N	TE	162	36	N	Not applicable	Recovered
			Pneumonia	肺炎	3	Y	TE	169	15	N	Not applicable	Recovered
			Atrial fibrillation	心房細動	2	Y	TE	180	1	N	Not applicable	Recovered
			Bone pain	骨痛	3	Y	TE	197	7	N	Not applicable	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	198	6	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	1	N	TE	203		Y	Not applicable	Ongoing at time of death
			Pulmonary embolism	肺塞栓症	4	Y	TE	222	5	Y	Not applicable	Death
			Pulmonary embolism	肺塞栓症	5	Y	TE	226	1	Y	Not applicable	Death
006005	Norway	72/M/C	Diarrhoea	下痢	1	N	TE	3	1	Y	None	Recovered
			Pyrexia	発熱	2	Y	TE	22	7	N	None	Recovered
			Dehydration	脱水	2	Y	TE	22	7	N	None	Recovered
			Vomiting	嘔吐	1	Y	TE	38	1	N	None	Recovered
			Pyrexia	発熱	2	Y	TE	38	1	Y	None	Recovered
			Dehydration	脱水	2	Y	TE	38	6	Y	None	Recovered
			Musculoskeletal pain	筋骨格痛	2	Y	TE	38	6	N	None	Recovered
			Vomiting	嘔吐	2	Y	TE	62	11	Y	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dehydration	脱水	2	Y	TE	62	11	N	None	Recovered
			Bone pain	骨痛	2	Y	TE	62	11	N	None	Recovered with sequelae
			Bone pain	骨痛	3	Y	TE	85	15	N	None	Recovered with sequelae
			Dyspepsia	消化不良	2	N	TE	86		N	None	Ongoing at time of death
			Depression	うつ病	2	N	TE	99		N	None	Ongoing at time of death
			Pneumonia	肺炎	3	Y	TE	176	2	N	Not applicable	Death
			Bone pain	骨痛	3	Y	TE	176		N	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	5	Y	TE	177	1	N	Not applicable	Death
006008	Norway	70/M/C	Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	Pre	-1	29	N	None	Ongoing at time of death
			Hydronephrosis	水腎症	3	Y	Pre	-1	3	N	None	Recovered
			Constipation	便秘	2	N	TE	2	25	Y	None	Recovered
			Nausea	悪心	1	N	TE	2	6	Y	None	Recovered
			Fatigue	疲労	2	N	TE	2	6	N	None	Recovered
			Hyperhidrosis	多汗症	2	N	TE	2	6	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	17	11	N	None	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	Pre	28		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Small intestinal obstruction	小腸閉塞	3	Y	TE	55	3	N	Drug administration postponed	Recovered
			Death	死亡	5	Y	TE	60	1	N	Drug permanently withdrawn	Death
006055	Norway	63/M/C	Petechiae	点状出血	2	N	TE			N	None	Ongoing at study termination / withdrawal
			Nerve root compression	神経根圧迫	3	Y	Pre	-33	4	N	None	Recovered
			Groin pain	鼠径部痛	2	N	Pre	-2	3	N	None	Recovered
			Nerve root compression	神経根圧迫	3	Y	TE	1	4	N	None	Recovered
			Peripheral motor neuropathy	末梢性運動ニューロパチー	2	N	TE	1	4	N	None	Recovered
			Pyrexia	発熱	1	N	TE	23	3	N	None	Recovered
			Oedema peripheral	末梢性浮腫	3	Y	TE	24	4	N	None	Recovered with sequelae
			Hypoalbuminaemia	低アルブミン血症	2	N	TE	24	4	N	None	Ongoing at study termination / withdrawal
			Hypoaesthesia	感覚鈍麻	1	N	TE	24		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	27	8	N	None	Recovered with sequelae

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	2	N	TE	27	8	N	None	Ongoing at study termination / withdrawal
			Hypoalbuminaemia	低アルブミン血症	1	N	TE	27		N	None	Ongoing at study termination / withdrawal
			Cardiac failure	心不全	2	N	TE	28		N	None	Ongoing at study termination / withdrawal
			Pyrexia	発熱	1	N	TE	28	2	N	None	Recovered
			Pneumonia	肺炎	3	Y	TE	28	6	N	None	Recovered
			Dyspnoea	呼吸困難	1	N	TE	28	7	N	None	Recovered
			Pleural effusion	胸水	2	N	TE	28	7	N	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	30	3	N	None	Recovered
			Pulmonary hypertension	肺高血圧症	2	N	TE	32		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	34	5	N	None	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	1	N	TE	34		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	38	31	N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	52	18	N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Peripheral motor neuropathy	末梢性運動ニューロパチー	3	Y	TE	52	3	N	None	Recovered
			Urinary tract infection	尿路感染	2	N	TE	53	11	N	None	Recovered
			Thrombocytopenia	血小板減少症	4	Y	TE	66	2	Y	Drug administration postponed	Recovered with sequelae
			Hypokalaemia	低カリウム血症	1	N	TE	66		N	None	Ongoing at study termination / withdrawal
			Spinal cord compression	脊髄圧迫	3	Y	TE	66		N	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	3	N	TE	67	4	N	None	Ongoing at study termination / withdrawal
			Urinary tract infection	尿路感染	1	N	TE	67		N	None	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	N	TE	68		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	69		N	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	3	N	TE	70		N	None	Ongoing at study termination / withdrawal
			Thrombocytopenia	血小板減少症	4	N	TE	70	1	N	None	Ongoing at study termination / withdrawal
			General physical health deterioration	全身健康状態低下	3	N	TE	71		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	84	1	N	Not applicable	Death
008003	Norway	79/M/C	Nausea	悪心	2	N	Pre	1	25	N	None	Recovered
			Nausea	悪心	2	Y	TE	25	4	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	25		N	None	Ongoing at time of death
			Hypercalcaemia	高カルシウム血症	1	N	TE	25	2	N	None	Recovered
			Anaemia	貧血	2	N	TE	27	2	Y	None	Recovered
			Nausea	悪心	2	N	TE	28		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	35	25	N	Drug permanently withdrawn	Recovered
			Dehydration	脱水	2	N	TE	51		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	59	1	N	Not applicable	Death
008011	Norway	69/M/C	Nausea	悪心	1	N	TE			N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	1	N	TE			N	None	Recovered
			Fatigue	疲労	1	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE	2	2	N	None	Recovered
			Vomiting	嘔吐	1	N	TE	2	2	N	None	Recovered
			Tendonitis	腱炎	2	N	TE	35		N	None	Recovered
			Constipation	便秘	1	N	TE	37		N	None	Recovered
			Nausea	悪心	1	N	TE	37	5	N	None	Recovered
			Musculoskeletal stiffness	筋骨格硬直	2	N	TE	99	15	N	None	Recovered
			Pharyngitis	咽頭炎	1	N	TE	138	3	N	None	Recovered
			Pathological fracture	病的骨折	2	N	TE	149		N	Not applicable	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	149	9	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	2	N	TE	157	10	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	166	6	N	Not applicable	Recovered
			Vomiting	嘔吐	1	N	TE	167	22	N	None	Recovered
			Spinal cord compression	脊髄圧迫	3	N	TE	171	42	N	Not applicable	Ongoing at time of death
			Subileus	亜イレウス	2	Y	TE	181	4	N	Not applicable	Recovered
			Oesophageal pain	食道痛	1	N	TE	198	1	N	Not applicable	Recovered
			Cystitis	膀胱炎	1	N	TE	201	11	N	Not applicable	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	212	1	N	Not applicable	Death
011006	Czech Republic	68/M/C	Diarrhoea	下痢	1	N	TE	2	11	Y	None	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	150	256	Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	Y	TE	405		Y	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	4	Y	Post	405	2	Y	Not applicable	Death
			Pneumonia	肺炎	5	Y	Post	406	1	Y	Not applicable	Death
017003	Czech Republic	80/M/C	Cachexia	悪液質	4	Y	TE	115	10	N	None	Death
			Pneumonitis	肺臓炎	3	N	TE	115		N	None	Ongoing at time of death
			Cachexia	悪液質	5	Y	TE	124	1	N	None	Death
017004	Czech Republic	83/M/C	Angina pectoris	狭心症	3	Y	TE	105	15	N	None	Recovered with sequelae
			Depression	うつ病	2	N	TE	105	8	N	Drug administration postponed	Recovered
			Angina pectoris	狭心症	2	N	TE	119	184	N	None	Death
			Hypokalaemia	低カリウム血症	1	N	TE	119		N	None	Not recovered, but no changes expected

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Angina pectoris	狭心症	5	Y	TE	302	1	N	None	Death
017007	Czech Republic	80/M/C	Malignant neoplasm progression	悪性新生物進行	4	Y	TE	178	3	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	180	1	N	Not applicable	Death
017017	Czech Republic	77/M/C	General physical health deterioration	全身健康状態低下	4	Y	TE	151	2	N	Not applicable	Death
			General physical health deterioration	全身健康状態低下	5	Y	TE	152	1	N	Not applicable	Death
017018	Czech Republic	76/M/C	Bone pain	骨痛	1	Y	Pre	-61	10	N	None	Recovered
			Myocardial ischaemia	心筋虚血	4	Y	TE	146		N	Not applicable	Ongoing at time of death
			Myocardial infarction	心筋梗塞	5	Y	TE	154	1	N	Not applicable	Death
017027	Czech Republic	60/M/C	Anaemia	貧血	2	N	TE	79	43	N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	116	6	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	121	1	N	Drug permanently withdrawn	Death
017030	Czech Republic	86/M/C	Leukopenia	白血球減少症			TE			N	None	Recovered
			Anaemia	貧血	2	N	Pre	1		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anorexia	食欲不振	1	N	TE	28		N	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	Y	TE	50	8	N	None	Recovered
			Thrombocytopenia	血小板減少症	3	Y	TE	50	8	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	Y	TE	57		N	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	5	Y	TE	59	1	N	None	Death
017032	Czech Republic	57/M/C	Malignant neoplasm progression	悪性新生物進行	5	Y	TE	97	1	N	None	Death
020005	Sweden	71/M/C	Anorexia	食欲不振	2	N	TE			N	None	Ongoing at time of death
			Micturition urgency	尿意切迫	2	N	Pre			N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	1	4	Y	None	Recovered
			Fatigue	疲労	2	N	TE	1		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	1		Y	None	Not recovered, but no changes expected
			Musculoskeletal pain	筋骨格痛	1	N	TE	1	4	Y	None	Recovered
			Haematuria	血尿	2	N	TE	11		N	None	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	17	3	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	33	5	Y	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Constipation	便秘	3	N	TE	39		N	None	Ongoing at study termination / withdrawal
			Chills	悪寒	1	N	TE	54		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	Y	TE	75	14	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	91	22	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	112	1	N	Drug permanently withdrawn	Death
020015	Sweden	74/M/C	Nausea	悪心	1	N	Pre			N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE			N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	N	TE			Y	None	Ongoing at time of death
			Myalgia	筋痛	1	N	Pre			N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE			Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	19		Y	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cardiac failure congestive	うっ血性心不全	3	Y	TE	28	15	Y	Drug administration postponed	Recovered with sequelae
			Constipation	便秘	2	N	TE	28		Y	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	28	15	Y	None	Ongoing at time of death
			Cardiac failure congestive	うっ血性心不全	1	N	TE	42		Y	None	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE	42		Y	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	106	5	N	Drug permanently withdrawn	Death
024007	Sweden	63/M/C	Insomnia	不眠症	1	N	Pre	-2		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	Pre	-1		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	1	2	Y	None	Recovered
			Cystitis	膀胱炎	2	N	TE	30	41	N	None	Recovered
			Oedema	浮腫	2	N	TE	63	106	N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	75		N	None	Not recovered, but no changes expected
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	114		N	None	Not recovered, but no changes expected
			Erysipelas	丹毒	2	N	TE	128		N	None	Recovered
			Thrombophlebitis	血栓性静脈炎	1	N	TE	128		N	None	Recovered
			Bone pain	骨痛	3	Y	TE	138		N	None	Ongoing at time of death
			Metastases to liver	肝転移	3	N	TE	141	28	N	Not applicable	Death
			Anaemia	貧血	2	N	TE	158	4	Y	Not applicable	Recovered
			Metastases to liver	肝転移	5	Y	TE	168	1	N	Not applicable	Death
024017	Sweden	73/M/C	Bone pain	骨痛	2	N	TE	34		N	None	Not recovered, but no changes expected
			Nausea	悪心	1	N	TE	64	27	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	64		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	N	TE	117	30	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	204	1	N	Not applicable	Death
025004	Sweden	63/M/C	Fatigue	疲労	1	N	TE	31	-1	Y	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Upper respiratory tract infection bacterial	細菌性上気道感染	1	N	TE	48	12	N	None	Recovered
			Haematuria	血尿	3	Y	TE	82		N	Drug administration postponed	Ongoing at time of death
			Cardiac failure	心不全	4	Y	TE	90	2	N	Drug permanently withdrawn	Death
			Cardiac failure	心不全	5	Y	TE	91	1	N	Drug permanently withdrawn	Death
025014	Sweden	82/M/C	Haematuria	血尿	2	N	Pre			N	None	Recovered
			Fatigue	疲労	3	N	TE	29		N	Drug permanently withdrawn	Ongoing at time of death
			Hepatic failure	肝不全	3	Y	TE	29	9	N	Drug permanently withdrawn	Death
			Bone pain	骨痛	2	Y	TE	29		N	Drug permanently withdrawn	Ongoing at time of death
			Hepatic failure	肝不全	5	Y	TE	37	1	N	Drug permanently withdrawn	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
025015	Sweden	72/M/C	Fatigue	疲労	2	N	TE	57		N	None	Ongoing at study termination / withdrawal
			Lymphadenopathy	リンパ節症	2	N	TE	62		N	None	Ongoing at time of death
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	TE	62		N	None	Ongoing at study termination / withdrawal
			Metastases to liver	肝転移	5	Y	TE	88	1	N	Not applicable	Death
025020	Sweden	61/M/C	Bone pain	骨痛	2	Y	TE	42	3	N	None	Recovered
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	1	N	TE	70	71	N	None	Recovered
			Bone pain	骨痛	1	N	TE	127		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	132	8	N	None	Recovered
			Sepsis	敗血症	4	Y	TE	160	11	N	Not applicable	Recovered
			Spinal cord compression	脊髄圧迫	4	Y	TE	160	14	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	166		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	220	1	N	Not applicable	Death
026001	Sweden	78/M/C	Bone pain	骨痛	3	N	TE			N	None	Not recovered, but no changes expected

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	3		N	None	Not recovered, but no changes expected
			Haematuria	血尿	1	N	TE	106	4	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	114		N	None	Ongoing at time of death
			Dehydration	脱水	2	Y	TE	117	12	N	None	Recovered
			Confusional state	錯乱状態	2	Y	TE	117	12	N	None	Recovered with sequelae
			Urinary retention	尿閉	2	N	TE	118		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	137	2	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	138	1	N	Drug permanently withdrawn	Death
026002	Sweden	66/M/C	Oesophageal spasm	食道痙攣	1	N	TE			N	None	Recovered
			Bone pain	骨痛	3	Y	Pre	-2	8	N	Not applicable	Recovered with sequelae
			Polyneuropathy	多発ニューロパチー	1	Y	TE	91	4	N	None	Recovered with sequelae
			Faecal incontinence	便失禁	3	Y	TE	108	8	N	None	Recovered with sequelae
			Hyperglycaemia	高血糖	3	Y	TE	108	8	N	None	Recovered with sequelae

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Urinary incontinence	尿失禁	3	Y	TE	108	8	N	None	Recovered with sequelae
			Pancytopenia	汎血球減少症	2	N	TE	124	6	N	Drug permanently withdrawn	Ongoing at time of death
			Fall	転倒・転落	3	Y	TE	124		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	2	Y	TE	124	13	N	None	Death
			Urinary retention	尿閉	2	N	TE	124		N	Not applicable	Ongoing at time of death
			Mouth ulceration	口腔内潰瘍形成	2	N	TE	125		N	Not applicable	Ongoing at time of death
			Pancytopenia	汎血球減少症	3	Y	TE	129		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	136	1	N	None	Death
027002	Sweden	67/M/C	Hypertension	高血圧	2	N	TE	29		N	None	Not recovered, but no changes expected
			Onycholysis	爪甲離床症	2	N	TE	78	64	N	None	Recovered with sequelae
			Constipation	便秘	4	Y	Post	684	9	Y	Not applicable	Death
			Constipation	便秘	5	Y	Post	692	1	Y	Not applicable	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Multi-organ failure	多臓器不全	5	Y	Post	692	1	Y	Not applicable	Death
028002	Belgium	72/M/C	General physical health deterioration	全身健康状態低下	2	Y	Pre	-9	19	N	Not applicable	Recovered with sequelae
			Bone pain	骨痛	2	Y	Pre	-9	19	Y	Not applicable	Recovered with sequelae
			Anaemia	貧血	3	N	Pre	-1	2	N	None	Recovered
			Anal ulcer	肛門潰瘍	2	N	Pre	-1	88	N	None	Recovered
			General physical health deterioration	全身健康状態低下	1	N	Pre	10		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	1	N	Pre	10		Y	None	Not recovered, but no changes expected
			Anaemia	貧血	3	Y	TE	29	7	Y	Drug administration postponed	Recovered
			Weight decreased	体重減少	2	N	TE	29	28	N	None	Recovered
			Anorexia	食欲不振	3	N	TE	56	28	N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	56		N	None	Not recovered, but no changes expected
			Anaemia	貧血	2	Y	TE	83		Y	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			General physical health deterioration	全身健康状態低下	3	Y	TE	83	24	N	Drug permanently withdrawn	Death
			Anorexia	食欲不振	1	N	TE	83		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	87	20	N	None	Recovered
			Pathological fracture	病的骨折	3	Y	TE	91		N	Drug permanently withdrawn	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	105		N	Not applicable	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	5	Y	TE	106	1	N	Drug permanently withdrawn	Death
028003	Belgium	83/M/C	Nausea	悪心	1	N	TE	2	1	Y	None	Recovered
			Fatigue	疲労	1	N	TE	29		N	None	Ongoing at time of death
			Skin irritation	皮膚刺激	2	N	TE	50	15	N	None	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	55		Y	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	4	Y	TE	55		N	None	Ongoing at time of death
			Renal failure	腎不全	4	Y	TE	55		N	Drug permanently withdrawn	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pulmonary oedema	肺水腫	4	Y	TE	55		N	None	Ongoing at time of death
			Multi-organ failure	多臓器不全	4	Y	TE	59	6	N	None	Death
			Multi-organ failure	多臓器不全	5	Y	TE	64	1	N	None	Death
028004	Belgium	84/M/C	Transient ischaemic attack	一過性脳虚血発作	2	Y	Pre	-13	55	N	Not applicable	Recovered
			Urinary retention	尿閉	2	N	Pre	-7	6	N	None	Recovered
			Pruritus	そう痒症	1	N	TE	8	7	N	None	Recovered with sequelae
			Pruritus	そう痒症	1	N	TE	8	27	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	14	48	N	None	Recovered
			Urinary tract infection	尿路感染	1	N	TE	28	29	N	None	Recovered
			Confusional state	錯乱状態	1	N	TE	30		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	51		N	None	Ongoing at time of death
			Hypercholesterolaemia	高コレステロール血症	2	N	TE	51		N	None	Ongoing at time of death
			Inguinal hernia	鼠径ヘルニア	1	N	TE	55	14	N	None	Recovered
			Bone pain	骨痛	3	N	TE	57		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	93	1	N	Not applicable	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
028007	Belgium	65/M/C	Fatigue	疲労	1	N	TE	28		Y	None	Ongoing at study termination / withdrawal
			Feeling cold	冷感	1	N	TE	28	36	Y	None	Recovered
			Pallor	蒼白	1	N	TE	28		Y	None	Ongoing at study termination / withdrawal
			Pyrexia	発熱	2	N	TE	50	6	N	None	Recovered
			Urinary retention	尿閉	3	Y	TE	50	2	N	None	Recovered with sequelae
			Anaemia	貧血	3	N	TE	55	9	Y	None	Recovered with sequelae
			Pleurisy	胸膜炎	2	N	TE	56	23	N	None	Recovered
			Anaemia	貧血	2	N	TE	63		Y	None	Ongoing at study termination / withdrawal
			Tachycardia	頻脈	2	N	TE	91	15	N	None	Recovered
			Pleural effusion	胸水	2	N	TE	167	15	N	Not applicable	Recovered
			Paraesthesia	錯感覚	2	N	TE	168		N	None	Ongoing at study termination / withdrawal
			Lymphangiosis carcinomatosa	癌性リンパ管症	4	Y	TE	181	19	N	Not applicable	Recovered with sequelae
			Pleural effusion	胸水	4	Y	TE	181	2	N	Not applicable	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Lymphangiosis carcinomatosa	癌性リンパ管症	4	N	TE	199	5	N	Not applicable	Recovered with sequelae
			Lymphangiosis carcinomatosa	癌性リンパ管症	5	Y	TE	203	1	N	Not applicable	Death
033005	UK	83/M/C	Bone pain	骨痛	1	N	TE	1	3	Y	None	Recovered
			Myocardial infarction	心筋梗塞	4	Y	TE	82	3	N	None	Death
			Myocardial infarction	心筋梗塞	5	Y	TE	84	1	N	None	Death
033023	UK	69/M/C	Post-traumatic pain	外傷後疼痛	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE			N	None	Ongoing at time of death
			Muscular weakness	筋力低下	3	N	TE			N	None	Ongoing at time of death
			Pathological fracture	病的骨折	2	N	TE			N	None	Not recovered, but no changes expected
			Constipation	便秘	1	N	Pre	-673	882	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	28		N	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	85	65	N	None	Recovered with sequelae

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pathological fracture	病的骨折	3	Y	TE	149	20	Y	Drug administration postponed	Recovered
			Mobility decreased	運動性低下	2	N	TE	168	42	N	None	Ongoing at time of death
			Pathological fracture	病的骨折	2	N	TE	168		Y	None	Not recovered, but no changes expected
			Paraesthesia	錯感覚	1	Y	TE	175	5	N	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	178	7	N	None	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	178	32	N	None	Ongoing at time of death
			Upper limb fracture	上肢骨折	3	Y	TE	202		Y	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	5	Y	TE	209	1	N	Not applicable	Death
034004	UK	63/M/C	Nausea	悪心	1	N	TE	8		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	8		Y	None	Ongoing at time of death
			Oral candidiasis	口腔カンジダ症	1	N	TE	8		N	None	Ongoing at time of death
			Dizziness	浮動性めまい	1	N	TE	8		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cerebral ischaemia	脳虚血	4	Y	TE	43	5	N	None	Recovered with sequelae
			Anorexia	食欲不振	3	N	TE	53		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	92	9	N	Not applicable	Recovered
			Diarrhoea	下痢	3	N	TE	95	6	Y	Not applicable	Recovered
			Vomiting	嘔吐	3	N	TE	95	6	N	Not applicable	Recovered
			Anaemia	貧血	4	N	TE	98	2	N	Not applicable	Recovered
			Bone marrow failure	骨髄機能不全	4	Y	TE	98	9	N	Not applicable	Death
			Sinus tachycardia	洞性頻脈	1	N	TE	98		N	Not applicable	Ongoing at time of death
			Confusional state	錯乱状態	3	N	TE	98	2	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	2	N	TE	98	2	N	Not applicable	Recovered
			Rash	発疹	2	N	TE	98		N	None	Ongoing at time of death
			Haematemesis	吐血	3	N	TE	99	2	N	Not applicable	Recovered with sequelae
			Oesophagitis	食道炎	2	N	TE	99		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone marrow failure	骨髄機能不全	5	Y	TE	106	1	N	Not applicable	Death
035027	UK	68/M/C	Decreased appetite	食欲減退	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	1	3	Y	None	Recovered
			Constipation	便秘	2	N	TE	44		Y	None	Ongoing at time of death
			Intestinal obstruction	腸閉塞	4	Y	TE	54	2	Y	None	Death
			Intestinal obstruction	腸閉塞	5	Y	TE	55	1	Y	None	Death
035028	UK	70/M/C	Bone pain	骨痛	2	N	TE			N	None	Recovered
			Bone pain	骨痛	3	N	TE			N	None	Recovered
			Urine flow decreased	尿流量減少	1	N	TE	11	19	N	None	Recovered
			Bone pain	骨痛	2	N	TE	29		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	44	18	N	None	Recovered
			Decreased appetite	食欲減退	1	N	TE	44		N	None	Recovered
			Constipation	便秘	2	Y	TE	66	6	N	None	Recovered
			Confusional state	錯乱状態	2	N	TE	71	79	N	Not applicable	Death
			Constipation	便秘	1	N	TE	72	42	N	None	Recovered
			Anaemia	貧血	2	N	TE	141		Y	None	Ongoing at time of death
			Confusional state	錯乱状態	3	Y	TE	150	11	N	Not applicable	Death
			Confusional state	錯乱状態	5	Y	TE	160	1	N	Not applicable	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
037012	UK	67/M/C	Abdominal pain	腹痛	1	N	TE			N	None	Not recovered, but no changes expected
			Hiatus hernia	裂孔ヘルニア	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE			N	None	Recovered
			Pain in jaw	顎痛	1	N	TE			N	None	Ongoing at time of death
			Deep vein thrombosis	深部静脈血栓症	3	N	TE			Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	28	2	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	113		N	None	Ongoing at time of death
			Osteoarthritis	骨関節炎	1	N	TE	163		N	None	Not recovered, but no changes expected
			Dyspnoea exertional	労作性呼吸困難	1	N	TE	171		N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	198		N	None	Ongoing at time of death
			Head injury	頭部損傷	3	N	TE	212	1	N	None	Recovered with sequelae
			Disseminated intravascular coagulation	播種性血管内凝固	3	N	TE	214		N	None	Not recovered, but no changes expected

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	3	Y	TE	214		N	Not applicable	Ongoing at time of death
			Extradural haematoma	硬膜外血腫	5	Y	TE	214	1	N	Not applicable	Death
039005	UK	72/M/C	Constipation	便秘	3	N	TE	4	38	N	None	Recovered
			Nausea	悪心	3	N	TE	13	29	N	None	Recovered
			Nausea	悪心	3	N	TE	35	7	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	35		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	N	TE	35	8	N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	42	1	N	None	Death
039007	UK	68/M/C	Bone pain	骨痛	1	N	Pre			N	None	Ongoing at time of death
			Anaemia	貧血	1	Y	Pre	-23	2	N	Drug administration postponed	Recovered
			Decreased appetite	食欲減退	1	N	Pre	-11		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	-11		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	Pre	-11	5	N	None	Recovered
			Nausea	悪心	1	N	Pre	-4		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	1	N	Pre	-4		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	4	23	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	27		Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	29	36	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	60		Y	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	70	1	N	None	Recovered
			Anaemia	貧血	2	N	TE	92		Y	Drug administration postponed	Ongoing at time of death
			Joint injury	関節損傷	2	N	TE	94		N	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	95		Y	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	118	2	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	180	2	Y	Not applicable	Recovered
			Skin lesion	皮膚病変	3	N	TE	183		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	214	1	N	Not applicable	Death
039012	UK	82/M/C	Anaemia	貧血	3	N	TE			N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hyperchlorhydria	胃酸過多	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	2	N	Pre	-2	26	N	None	Recovered
			Hypoaesthesia	感覚鈍麻	2	N	Pre	-2		N	None	Ongoing at study termination / withdrawal
			Hypoaesthesia	感覚鈍麻	2	N	TE	8		N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	2	N	TE	8		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	24		N	None	Ongoing at time of death
			Pathological fracture	病的骨折	3	Y	TE	35	33	N	Drug administration postponed	Recovered
			Nausea	悪心	2	N	TE	71	86	Y	None	Ongoing at time of death
			Dry mouth	口内乾燥	3	N	TE	87	70	N	None	Ongoing at time of death
			Back injury	背部損傷	3	N	TE	91	66	N	None	Ongoing at time of death
			Diarrhoea	下痢	2	N	TE	125		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	156	1	N	None	Death
039027	UK	74/M/C	Nausea	悪心	2	N	TE	1		N	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	1		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	2	N	Pre	1		N	None	Ongoing at time of death
			Dizziness	浮動性めまい	2	N	TE	1		N	None	Ongoing at time of death
			Headache	頭痛	1	N	TE	1		N	None	Ongoing at time of death
			Hypoaesthesia	感覚鈍麻	1	N	TE	1		N	None	Ongoing at time of death
			Dehydration	脱水	3	Y	TE	8	7	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	18	20	N	Drug administration postponed	Death
			Renal failure	腎不全	3	Y	TE	18	1	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	N	TE	19	4	N	Drug administration postponed	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	37	1	N	Drug administration postponed	Death
040005	UK	67/M/C	Bone pain	骨痛	3	N	TE			N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	2	3	Y	None	Recovered
			Malaise	倦怠感	2	N	TE	2	3	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	2		N	None	Ongoing at study termination / withdrawal
			Diarrhoea	下痢	1	N	TE	29	4	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	29	4	N	None	Recovered
			Lower respiratory tract infection	下気道感染	3	N	TE	49	13	N	None	Recovered
			Anaemia	貧血	2	N	TE	57	56	Y	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	68	60	N	Drug permanently withdrawn	Death
			Anaemia	貧血	3	Y	TE	112	3	Y	None	Recovered
			Fatigue	疲労	3	Y	TE	112	3	Y	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	1	N	TE	114		Y	None	Ongoing at study termination / withdrawal

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Fatigue	疲労	2	N	TE	114		Y	Not applicable	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	127	1	N	Drug permanently withdrawn	Death
041008	UK	74/M/C	Anaemia	貧血	2	N	Pre	1	29	N	Drug administration postponed	Recovered
			Nausea	悪心	2	N	TE	1	3	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	1	3	N	None	Recovered
			Anaemia	貧血	2	Y	TE	29	4	N	Drug administration postponed	Recovered
			Acute myocardial infarction	急性心筋梗塞	4	Y	TE	29	4	N	Drug administration postponed	Recovered
			Anaemia	貧血	2	N	TE	32	19	N	Drug administration postponed	Recovered
			Lower respiratory tract infection	下気道感染	2	N	TE	35	13	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	50	4	N	Drug administration postponed	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	50	3	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	52		N	None	Ongoing at time of death
			Anaemia	貧血		Y	TE	76		N	Drug administration postponed	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	5	Y	TE	79	1	N	None	Death
041011	UK	58/M/C	Oral candidiasis	口腔カンジダ症	2	N	Pre	1		N	None	Recovered
			Metastases to bone	骨転移	2	N	TE	27	6	N	None	Recovered
			Anaemia	貧血	2	N	TE	29	84	Y	None	Ongoing at time of death
			Metastases to bone	骨転移	2	Y	TE	32	18	N	None	Recovered
			Metastases to bone	骨転移	2	N	TE	49		N	None	Not recovered, but no changes expected
			Oedema peripheral	末梢性浮腫	2	N	TE	57	57	N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Lower respiratory tract infection	下気道感染	3	Y	TE	63	6	N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	63	6	N	Drug administration postponed	Recovered
			Diabetes mellitus	糖尿病	2	N	TE	71	56	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	84	58	Y	Drug administration postponed	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	2	N	TE	85	79	N	Drug permanently withdrawn	Death
			Anaemia	貧血	1	N	TE	112	30	Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	113	38	N	None	Ongoing at time of death
			Memory impairment	記憶障害	1	N	TE	113		N	None	Ongoing at time of death
			Rales	ラ音	1	N	TE	113		N	None	Ongoing at time of death
			Dizziness postural	体位性めまい	2	N	TE	116		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Diabetes mellitus	糖尿病	1	N	TE	126		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	141		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	141	5	Y	Drug administration postponed	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	145		Y	Drug administration postponed	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	3	Y	TE	150		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	163	1	N	Drug permanently withdrawn	Death
042015	UK	72/M/C	Increased appetite	食欲亢進	1	N	TE			N	None	Recovered
			Somnolence	傾眠	2	N	TE			N	None	Recovered
			Diplopia	複視	3	N	TE	14	10	Y	None	Recovered
			Balance disorder	平衡障害	1	N	TE	14	10	N	None	Recovered
			Confusional state	錯乱状態	3	N	TE	14	10	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	15	15	Y	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	53	6	N	None	Recovered
			Agitation	激越	2	N	TE	114	2	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	115	1	N	None	Death
			Increased bronchial secretion	気管支分泌増加	2	N	TE	115	1	N	None	Recovered
042034	UK	75/M/C	Oedema peripheral	末梢性浮腫	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE			N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	141		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	141		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	172	1	N	Not applicable	Death
044005	UK	76/M/C	Cardiac failure congestive	うっ血性心不全	4	N	TE			N	Drug administration postponed	Death
			Fatigue	疲労	2	N	TE			Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	7	1	Y	None	Recovered
			Left ventricular dysfunction	左室機能不全	3	N	TE	54	73	N	Drug administration postponed	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Oedema peripheral	末梢性浮腫	1	N	TE	54	73	N	Drug administration postponed	Ongoing at time of death
			Dyspnoea	呼吸困難	3	N	TE	54	17	N	Drug administration postponed	Ongoing at time of death
			Troponin T increased	トロポニンＴ増加	4	N	TE	57	70	N	Drug administration postponed	Ongoing at time of death
			Pleural effusion	胸水	2	N	TE	57	70	N	Drug administration postponed	Ongoing at time of death
			Pulmonary embolism	肺塞栓症	3	Y	TE	57	3	N	Drug permanently withdrawn	Recovered with sequelae
			Pulmonary oedema	肺水腫	1	N	TE	58	69	N	Drug administration postponed	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	70	57	N	Drug administration postponed	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cardiac failure congestive	うっ血性心不全	5	Y	TE	126	1	N	Drug administration postponed	Death
047002	UK	81/M/C	Anaemia	貧血	3	N	TE	2	1	Y	None	Recovered
			Anaemia	貧血	3	N	TE	39	1	Y	None	Recovered
			Anaemia	貧血	3	N	TE	73	1	Y	None	Recovered
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	3	N	TE	85		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	2	N	TE	136		N	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	154	1	N	Not applicable	Death
049002	UK	73/M/C	Lower respiratory tract infection	下気道感染	3	Y	TE	9	11	N	None	Recovered
			Oral candidiasis	口腔カンジダ症	2	N	TE	57	53	Y	None	Recovered
			Paraesthesia	錯感覚	1	N	TE	100	30	N	None	Recovered
			Lower respiratory tract infection	下気道感染	2	Y	TE	109	3	N	Drug administration postponed	Recovered with sequelae
			Spinal cord compression	脊髄圧迫	4	Y	TE	129		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pneumonia	肺炎	4	Y	TE	135	7	N	Drug permanently withdrawn	Death
			Pneumonia	肺炎	5	Y	TE	141	1	N	Drug permanently withdrawn	Death
049007	UK	80/M/C	Nausea	悪心	2	N	TE	3		Y	None	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	3		Y	None	Ongoing at time of death
			Mucosal inflammation	粘膜の炎症	2	N	TE	29		Y	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	29		Y	None	Ongoing at time of death
			Fatigue	疲労	2	N	TE	120		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	128		N	None	Ongoing at time of death
			Headache	頭痛	2	N	TE	148	51	N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	176	3	N	Not applicable	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	198		N	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	3	Y	TE	198		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	198	12	N	Not applicable	Death
			Headache	頭痛	4	N	TE	198		N	None	Ongoing at time of death
			Urinary retention	尿閉	2	N	TE	204		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	209	1	N	Not applicable	Death
049008	UK	72/M/C	Decreased appetite	食欲減退	2	N	TE			N	None	Ongoing at time of death
			Lymphoedema	リンパ浮腫	1	N	Pre			N	None	Recovered
			Ear pain	耳痛	1	N	Pre	-7		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre	-3	5	N	None	Recovered
			Fatigue	疲労	2	N	TE	29		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	29	50	Y	None	Recovered
			Constipation	便秘	2	N	TE	40		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	40	2	N	None	Recovered with sequelae
			Palpitations	動悸	1	N	TE	54	4	N	Not applicable	Recovered
			Depressed mood	抑うつ気分	1	N	TE	54		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Vomiting	嘔吐	2	Y	TE	57	6	N	Drug administration postponed	Recovered
			Pyrexia	発熱	1	Y	TE	61	2	N	Drug administration postponed	Recovered
			Nausea	悪心	2	Y	TE	65	6	N	Drug administration postponed	Recovered with sequelae
			Vomiting	嘔吐	2	Y	TE	65	6	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	N	TE	67	1	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	89	1	N	Not applicable	Recovered
			Abdominal pain	腹痛	3	Y	TE	111		N	Not applicable	Ongoing at time of death
			Nausea	悪心	3	Y	TE	111		N	Not applicable	Ongoing at time of death
			Vomiting	嘔吐	3	Y	TE	111		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	111	11	N	Not applicable	Death
			Anaemia	貧血	2	N	TE	113		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	121	1	N	Not applicable	Death
051012	UK	73/M/C	Decreased appetite	食欲減退	1	N	TE	30		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	108	1	N	None	Death
055002	Netherlands	66/M/C	Lung infection	肺感染	2	N	TE	18	27	N	None	Recovered
			Anorexia	食欲不振	2	N	TE	54		Y	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	54		Y	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	59		Y	None	Ongoing at time of death
			Drug intolerance	薬物不耐性	4	Y	TE	71	3	N	None	Recovered with sequelae
			Pulmonary embolism	肺塞栓症	4	Y	TE	71		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	74	1	N	None	Death
060002	Spain	84/M/C	Anorexia	食欲不振	2	N	TE	29		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Cardiac failure	心不全	3	N	TE	100		N	None	Ongoing at study termination / withdrawal
			Dyspnoea	呼吸困難	2	N	TE	100		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	101	31	N	Not applicable	Ongoing at time of death
			Bronchitis	気管支炎	2	N	TE	107	2	N	None	Recovered
			Renal failure	腎不全	2	N	TE	107	3	N	None	Recovered
			Bronchitis	気管支炎	3	Y	TE	108		N	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	N	TE	109	5	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	113	11	Y	None	Ongoing at time of death
			Hyperuricaemia	高尿酸血症	1	N	TE	113		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	123		Y	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	129	1	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	131		N	Not applicable	Ongoing at time of death
			Death	死亡	5	Y	TE	137	1	N	Not applicable	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
060003	Spain	85/M/C	Bone pain	骨痛	3	N	TE	31	26	N	None	Ongoing at time of death
			Weight decreased	体重減少	2	N	TE	56	6	N	None	Ongoing at study termination / withdrawal
			Anorexia	食欲不振	2	N	TE	56	11	N	None	Recovered
			Bone pain	骨痛	2	N	TE	56		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	57		N	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	61		N	None	Ongoing at study termination / withdrawal
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	111	1	N	Not applicable	Death
060007	Spain	79/M/C	Nausea	悪心	1	N	Pre	-20	28	N	None	Recovered
			Anorexia	食欲不振	2	N	Pre	-20		N	None	Ongoing at time of death
			Haematuria	血尿	2	N	TE	5		N	None	Ongoing at time of death
			Vomiting	嘔吐	1	N	TE	6	4	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	6	12	N	Drug permanently withdrawn	Death
			Pyrexia	発熱	1	N	TE	7	2	N	None	Recovered
			Respiratory tract infection	気道感染	2	N	TE	7		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	3	N	TE	8		N	None	Ongoing at time of death
			Asthenia	無力症	1	N	TE	12	2	N	None	Ongoing at time of death
			Asthenia	無力症	3	N	TE	13		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	17	1	N	Drug permanently withdrawn	Death
063004	Spain	74/M/C	Abdominal pain upper	上腹部痛	1	N	TE	32	55	N	None	Recovered
			Somnolence	傾眠	2	N	TE	32	55	N	None	Recovered
			Anaemia	貧血	3	N	TE	58	29	N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	86		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	86	29	N	Not applicable	Ongoing at time of death
			Asthenia	無力症	1	N	TE	86		N	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	86		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	114		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	128	8	N	Drug permanently withdrawn	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	135	1	N	Drug permanently withdrawn	Death
074002	Italy	79/M/C	Muscle spasms	筋痙縮	1	N	Pre	-10	11	N	None	Recovered
			Diarrhoea	下痢	2	N	TE	28	8	N	None	Recovered
			Asthenia	無力症	2	N	TE	33	3	N	None	Recovered
			Pyrexia	発熱	1	N	TE	33	15	N	Drug administration postponed	Recovered
			Urinary tract infection	尿路感染	2	N	TE	46	39	N	None	Recovered
			Dry skin	皮膚乾燥	1	N	TE	75	10	Y	None	Recovered
			Asthenia	無力症	1	N	TE	84	83	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	131	29	Y	None	Recovered
			Neutropenia	好中球減少症	2	N	TE	131	29	Y	Drug permanently withdrawn	Recovered
			Thrombocytopenia	血小板減少症	1	N	TE	131	29	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	159	18	Y	None	Recovered
			Leukopenia	白血球減少症	4	N	TE	159	4	Y	None	Recovered
			Neutropenia	好中球減少症	4	N	TE	159	4	Y	Drug permanently withdrawn	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	3	N	TE	159	15	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	162	5	Y	None	Recovered
			Neutropenia	好中球減少症	1	N	TE	162	5	Y	Drug permanently withdrawn	Recovered
			Blood urea increased	血中尿素増加	1	N	TE	162	43	N	None	Recovered
			Asthenia	無力症	2	N	TE	166		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	173	8	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	180	8	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	183	5	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	187	32	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	187	8	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	194	11	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	204	15	Y	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	218	5	Y	None	Recovered
			Thrombocytopenia	血小板減少症	4	N	TE	218	5	Y	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	222	2	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	222	2	Y	None	Ongoing at time of death
			Bone marrow tumour cell infiltration	腫瘍細胞の骨髄浸潤	3	Y	TE	222	37	N	Not applicable	Death
			Anaemia	貧血	3	N	TE	223	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	223	2	Y	None	
			Neutropenia	好中球減少症	1	N	TE	223	5	Y	Not applicable	
			Thrombocytopenia	血小板減少症	4	N	TE	223	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	1	N	TE	224	2	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	225	8	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	225	1	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	1	N	TE	225	3	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	225	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	227	3	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	2	N	TE	227	3	Y	Not applicable	

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	4	N	TE	227	4	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	229	2	Y	None	
			Neutropenia	好中球減少症	3	N	TE	229	2	Y	Not applicable	
			Leukopenia	白血球減少症	2	N	TE	230	4	Y	None	
			Neutropenia	好中球減少症	2	N	TE	230	2	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	230	3	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	1	N	TE	231	3	Y	Not applicable	Recovered
			Anaemia	貧血	1	N	TE	232	4	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	232	4	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	233	2	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	2	N	TE	233	2	Y	Not applicable	Recovered
			Leukopenia	白血球減少症	2	N	TE	234	4	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	235	7	Y	None	Recovered
			Neutropenia	好中球減少症	1	N	Post	235	3	Y	-	
			Thrombocytopenia	血小板減少症	3	N	TE	235	2	Y	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	4	N	TE	236	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	237	7	Y	None	
			Neutropenia	好中球減少症	2	N	Post	237	2	Y	-	
			Neutropenia	好中球減少症	3	N	Post	238	5	Y	-	
			Thrombocytopenia	血小板減少症	3	N	TE	238	4	Y	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	241	2	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	241	3	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	242	8	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	2	N	Post	242	4	Y	Not applicable	Recovered
			Leukopenia	白血球減少症	2	N	TE	243	3	Y	None	
			Thrombocytopenia	血小板減少症	3	N	TE	243	2	Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	244		Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	1	N	TE	245	9	Y	None	
			Anaemia	貧血	1	N	TE	249		Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	2	N	TE	253	2	Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	1	N	Post	253	4	Y	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Leukopenia	白血球減少症	1	N	TE	254	3	Y	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	256		Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	2	N	Post	256		Y	None	Ongoing at time of death
			Bone marrow tumour cell infiltration	腫瘍細胞の骨髄浸潤	5	Y	TE	258	1	N	Not applicable	Death
075001	Italy	59/M/C	Strangury	有痛性排尿困難		N	TE	2	2	N	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	14	28	N	None	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	33	10	Y	Drug administration postponed	Recovered
			Vomiting	嘔吐	1	N	TE	33	10	Y	Drug administration postponed	Recovered
			Anorexia	食欲不振	1	N	TE	33	10	Y	Drug administration postponed	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	41		N	None	Ongoing at time of death
			Strangury	有痛性排尿困難	2	N	TE	78	1	N	None	Recovered
			Death	死亡	5	Y	TE	93	1	N	None	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
078001	Italy	76/M/C	Constipation	便秘	1	N	TE			N	None	Recovered
			Nausea	悪心	1	N	TE			N	None	Recovered
			Pyrexia	発熱	1	N	TE			N	None	Recovered
			Confusional state	錯乱状態	1	N	TE			N	None	Recovered
			Hyperhidrosis	多汗症	2	N	TE			N	None	Recovered
			Bone pain	骨痛	2	N	TE	2	11	Y	None	Recovered with sequelae
			Bone pain	骨痛	2	N	TE	38	21	N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	58	21	N	None	Ongoing at time of death
			Asthenia	無力症	2	N	TE	78	37	Y	None	Recovered
			Pyrexia	発熱	1	N	TE	78	29	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	78		N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	78	37	N	None	Recovered
			Fatigue	疲労	2	N	TE	127	14	N	None	Ongoing at time of death
			Depression	うつ病	2	N	TE	127		N	None	Ongoing at time of death
			Fatigue	疲労	3	N	TE	141		N	None	Ongoing at time of death
			Anaemia	貧血	3	Y	TE	147	2	Y	Drug permanently withdrawn	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	3	Y	TE	147	2	Y	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	149	14	Y	Drug permanently withdrawn	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	Y	TE	149	11	Y	Drug permanently withdrawn	Ongoing at time of death
			Anaemia	貧血	1	Y	TE	163		Y	Drug permanently withdrawn	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	163	15	N	Not applicable	Death
078003	Italy	74/M/C	Somnolence	傾眠	2	N	Pre	1		N	None	Ongoing at time of death
			Confusional state	錯乱状態	2	N	Pre	1		N	None	Ongoing at time of death
			Upper limb fracture	上肢骨折	2	N	TE	20	25	N	None	Recovered
			Asthenia	無力症	2	N	TE	49		Y	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	187		N	Not applicable	Ongoing at time of death
			Amnesia	健忘	2	N	TE	198		N	Not applicable	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	3	Y	TE	213	8	N	Not applicable	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			General physical health deterioration	全身健康状態低下	5	Y	TE	220	1	N	Not applicable	Death
078006	Italy	77/M/C	Pyrexia	発熱	1	N	TE	39	34	N	None	Recovered
			Pyrexia	発熱	1	N	TE	91	14	N	None	Recovered
			Anaemia	貧血	2	N	TE	104		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	104		Y	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	Y	TE	104	28	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	131	1	N	Drug permanently withdrawn	Death
080004	Italy	72/M/C	Weight decreased	体重減少	1	N	Pre	-13	13	N	None	Ongoing at time of death
			Weight decreased	体重減少	2	N	Pre	-1		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	Pre	-1	50	N	None	Recovered
			Bone pain	骨痛	3	N	TE	49	85	N	None	Recovered
			Fatigue	疲労	3	N	TE	133		N	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	133		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	161	1	N	Not applicable	Death
093002	Slovakia	81/M/C	Anaemia	貧血	2	N	TE	29	48	N	-	

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Nausea	悪心	2	N	TE	29	85	Y	None	Recovered
			Vomiting	嘔吐	1	N	TE	29	6	Y	None	Recovered
			Constipation	便秘	1	N	TE	56	58	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	56	4	Y	None	Recovered
			Anaemia	貧血	3	N	TE	76	10	N	-	
			Bone pain	骨痛	3	Y	TE	76	8	N	None	Recovered with sequelae
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	76		N	None	Ongoing at time of death
			Anaemia	貧血	1	N	TE	85	29	N	-	
			Diarrhoea	下痢	2	N	TE	85	5	Y	None	Recovered
			Anaemia	貧血	2	N	TE	113	31	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	Y	TE	143	5	N	Drug administration postponed	Recovered
			Bronchopneumonia	気管支肺炎	3	N	TE	150		N	None	Ongoing at time of death
			Cardiopulmonary failure	心肺不全	5	Y	TE	160	1	N	Not applicable	Death
104005	Hong Kong	73/M/A	Constipation	便秘	1	N	TE	1	29	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	64	2	Y	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pneumonia	肺炎	2	N	TE	87		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	3	Y	TE	87	18	N	Drug permanently withdrawn	Death
			Spinal cord compression	脊髄圧迫	5	Y	TE	104	1	N	Drug permanently withdrawn	Death
106005	Hong Kong	79/M/A	Decreased appetite	食欲減退	1	N	TE	29	85	Y	None	Recovered
			Dysuria	排尿困難	1	N	TE	29		N	None	Ongoing at time of death
			Nocturia	夜間頻尿	2	N	TE	29	57	N	None	Recovered
			Anaemia	貧血	3	Y	TE	113	3	Y	Drug administration postponed	Recovered with sequelae
			Constipation	便秘	2	N	TE	113	29	N	None	Recovered
			Sleep disorder	睡眠障害	1	N	TE	113	3	N	None	Recovered
			Spinal compression fracture	脊椎圧迫骨折	3	N	TE	115		N	None	Ongoing at time of death
			Sepsis	敗血症	3	Y	TE	155		N	Not applicable	Ongoing at time of death
			Lower respiratory tract infection	下気道感染	3	N	TE	156		N	Not applicable	Ongoing at time of death
			Haematuria	血尿	3	Y	TE	159		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	165	1	N	Not applicable	Death
106011	Hong Kong	79/M/A	Decreased appetite	食欲減退	1	N	TE	29	29	N	None	Recovered
			Abdominal pain upper	上腹部痛	1	N	TE	57	29	N	None	Recovered
			Liver function test abnormal	肝機能検査異常	3	Y	TE	57	13	N	Drug administration postponed	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	218	1	N	Not applicable	Death
133002	Poland	78/M/C	Pyrexia	発熱	1	N	TE	3	14	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	3	6	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	8	44	Y	None	Recovered
			Pathological fracture	病的骨折	2	Y	TE	43		N	None	Not recovered, but no changes expected
			Bone pain	骨痛	3	N	TE	51	53	Y	None	Recovered
			Oedema peripheral	末梢性浮腫	2	N	TE	72	34	N	None	Recovered
			Fatigue	疲労	3	N	TE	88	26	N	Drug permanently withdrawn	Ongoing at time of death
			Fatigue	疲労	4	N	TE	113		N	Drug permanently withdrawn	Ongoing at time of death
			Weight decreased	体重減少	2	N	TE	113		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	162	1	N	Not applicable	Death
133006	Poland	53/M/C	Bone pain	骨痛	2	N	TE	2	10	Y	None	Recovered
			Hypertension	高血圧	2	N	TE	29	29	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	50		N	None	Recovered
			Abdominal pain	腹痛	2	N	TE	71		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	140	29	N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	168		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	168		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	184	2	N	Not applicable	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	185	1	N	Not applicable	Death
133009	Poland	75/M/C	Alanine aminotransferase increased	アラニン・アミノトランスフェラーゼ増加	2	N	TE	85	29	N	None	Recovered
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	1	N	TE	85	29	N	None	Recovered
			Weight decreased	体重減少	1	N	TE	141	29	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	198	1	N	Not applicable	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
133011	Poland	66/M/C	Anaemia	貧血	2	N	Pre	1		N	None	Ongoing at time of death
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	2	N	Pre	1		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre	1		N	None	Not recovered, but no changes expected
			Tremor	振戦	4	Y	TE	25	1	Y	None	Recovered
			Confusional state	錯乱状態	4	Y	TE	25		Y	None	Ongoing at time of death
			Death	死亡	5	Y	TE	29	1	Y	None	Death
133012	Poland	67/M/C	Spinal cord compression	脊髄圧迫	3	Y	Pre	-35		N	Drug administration postponed	Ongoing at time of death
			Dyspnoea	呼吸困難	4	Y	TE	2	1	N	None	Death
			Dyspnoea	呼吸困難	5	Y	TE	2	1	N	None	Death
134001	Poland	57/M/C	Paralysis	麻痺	4	Y	Pre	-10		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	20	1	N	None	Death
137006	Poland	71/M/C	Anaemia	貧血	3	Y	TE	139	8	N	Not applicable	Recovered with sequelae
			Urinary tract infection	尿路感染	2	N	TE	157	8	N	Not applicable	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Haematuria	血尿	3	Y	TE	197	7	N	Not applicable	Recovered
			Anaemia	貧血	4	Y	TE	203		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	213	1	N	Not applicable	Death
139001	Poland	76/M/C	Anaemia	貧血	1	N	TE	29		N	None	Ongoing at time of death
			Malaise	倦怠感	3	N	TE	29		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	46	1	N	None	Death
139005	Poland	71/M/C	Oedema peripheral	末梢性浮腫	2	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	Pre			N	None	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	57	5	Y	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	120	1	N	None	Death
146004	Germany	77/M/C	Anaemia	貧血	2	N	TE	17	5	N	Drug administration postponed	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	17		Y	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			Multi-organ failure	多臓器不全	4	Y	TE	17	12	N	None	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	4	N	TE	21		N	Drug administration postponed	Ongoing at time of death
			Multi-organ failure	多臓器不全	5	Y	TE	28	1	N	None	Death
148009	Germany	71/M/C	Nasopharyngitis	鼻咽頭炎	1	N	Pre	-14	15	N	None	Recovered
			Anaemia	貧血	2	N	Pre	1	57	Y	Drug administration postponed	Recovered
			Fatigue	疲労	2	N	TE	8		N	None	Ongoing at time of death
			Bone pain	骨痛	3	Y	TE	29	4	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	57	4	Y	Drug administration postponed	Recovered
			Anaemia	貧血	1	N	TE	60	31	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	60	1	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	60	2	Y	None	Recovered
			Herpes zoster	帯状疱疹	3	Y	TE	96	12	Y	Drug administration postponed	Recovered
			Anaemia	貧血	2	Y	TE	98	1	Y	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	4	Y	TE	125	3	Y	Drug administration postponed	Recovered
			Syncope	失神	3	Y	TE	125	1	Y	Drug administration postponed	Recovered
			Pancytopenia	汎血球減少症		N	TE	140		Y	None	Ongoing at time of death
			Metastases to liver	肝転移	3	Y	TE	140	10	N	Drug permanently withdrawn	Death
			Epistaxis	鼻出血	2	N	TE	140	1	N	Not applicable	Recovered
			Metastases to liver	肝転移	5	Y	TE	149	1	N	Drug permanently withdrawn	Death
148019	Germany	65/M/C	Conjunctivitis	結膜炎	2	N	TE	2	8	N	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	29	1	Y	None	Recovered
			Nausea	悪心	1	N	TE	31	4	Y	None	Recovered
			Lymphadenopathy	リンパ節症	1	N	TE	32	1	Y	None	Recovered
			Bone pain	骨痛	1	N	TE	32	1	Y	None	Recovered
			Pleural effusion	胸水	1	N	TE	93		N	None	Ongoing at time of death
			Blood urea increased	血中尿素増加	2	N	TE	109	11	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Blood creatinine increased	血中クレアチニン増加	2	N	TE	113	7	N	None	Recovered
			Hydronephrosis	水腎症	3	Y	TE	113	2	N	None	Recovered
			Dyspnoea	呼吸困難	2	N	TE	113		N	None	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	119	4	N	None	Recovered
			General physical health deterioration	全身健康状態低下	2	N	TE	119		N	None	Ongoing at time of death
			Blood creatinine increased	血中クレアチニン増加	3	N	TE	119	4	N	None	Recovered
			Blood urea increased	血中尿素増加	3	N	TE	119	4	N	None	Recovered
			Hydronephrosis	水腎症	3	Y	TE	119	4	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	143	1	N	Drug permanently withdrawn	Death
152004	Germany	75/M/C	Bone pain	骨痛	1	N	TE			N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	1	N	TE	1		N	None	Ongoing at study termination / withdrawal
			Oedema peripheral	末梢性浮腫	1	N	TE	79		N	None	Recovered
			Bone pain	骨痛	3	Y	TE	79	14	N	Drug administration postponed	Recovered with sequelae

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Disturbance in attention	注意力障害	1	N	TE	79		N	None	Ongoing at study termination / withdrawal
			Insomnia	不眠症	1	N	TE	79		N	None	Recovered
			Pleural effusion	胸水	1	N	TE	79		N	None	Recovered
			Bone pain	骨痛	2	N	TE	92	37	N	None	Recovered with sequelae
			Pancytopenia	汎血球減少症	2	N	TE	128		N	None	Recovered with sequelae
			Nausea	悪心	1	N	TE	128	8	N	None	Recovered
			Vomiting	嘔吐	2	N	TE	128	8	N	None	Recovered
			Infection	感染	2	N	TE	128	8	N	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	128	8	N	None	Recovered
			Bone pain	骨痛	3	Y	TE	128	8	N	None	Recovered with sequelae
			Pneumonia primary atypical	原発性異型肺炎	3	Y	TE	147	22	N	Drug administration postponed	Recovered with sequelae
			Asthenia	無力症	2	N	TE	161		N	Drug permanently withdrawn	Ongoing at study termination / withdrawal
			General physical health deterioration	全身健康状態低下	5	Y	TE	195	1	N	None	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
170004	Brazil	78/M/C	Pathological fracture	病的骨折	3	N	TE	127		N	Drug administration postponed	Ongoing at time of death
			Urinary retention	尿閉	3	N	TE	156	1	N	None	Recovered
			Anaemia	貧血	2	N	TE	211		N	None	Ongoing at time of death
			Bone pain	骨痛	4	Y	TE	230		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	230	3	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	232	1	N	Drug permanently withdrawn	Death
173008	Brazil	67/M/C	Anaemia	貧血	2	N	Pre	1	33	N	Drug administration postponed	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	2	N	Pre	1	63	N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	33	2	N	Drug administration postponed	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	34	30	N	Drug administration postponed	Recovered
			Anaemia	貧血	3	N	TE	63	3	N	Drug administration postponed	Recovered
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	Pre	63		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	65	83	N	Drug administration postponed	Recovered
			Anorexia	食欲不振	2	N	TE	87	70	N	None	Ongoing at time of death
			Anaemia	貧血	3	N	TE	147	5	N	Drug administration postponed	Recovered
			Anorexia	食欲不振	3	N	TE	156		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	156		N	None	Ongoing at time of death
			Weight decreased	体重減少	3	N	TE	183		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	3	N	TE	184	11	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	1	N	TE	184	11	N	None	Ongoing at time of death
			Anaemia	貧血	4	N	TE	194	5	N	None	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	194	5	N	None	Ongoing at time of death
			Neutropenia	好中球減少症	4	N	TE	198		N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	N	TE	198		N	None	Ongoing at time of death
			Cerebrovascular accident	脳血管発作	4	Y	TE	198	4	Y	Not applicable	Death
			Cerebrovascular accident	脳血管発作	5	Y	TE	201	1	Y	Not applicable	Death
173009	Brazil	66/M/0	Bone pain	骨痛	2	N	Pre	-9		N	None	Ongoing at time of death
			General physical health deterioration	全身健康状態低下	4	Y	TE	29	20	N	Drug permanently withdrawn	Death
			General physical health deterioration	全身健康状態低下	5	Y	TE	48	1	N	Drug permanently withdrawn	Death
178007	Brazil	71/M/0	Hypercalcaemia	高カルシウム血症	3	N	Pre	1	88	Y	None	Recovered
			Neutropenia	好中球減少症	2	N	TE	29	29	Y	Drug administration postponed	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	2	N	TE	48	77	N	None	Ongoing at time of death
			Neutropenia	好中球減少症	3	N	TE	57	4	Y	Drug administration postponed	Recovered
			Neutropenia	好中球減少症	2	N	TE	60	65	Y	Drug administration postponed	Recovered
			Insomnia	不眠症	2	N	TE	78		N	None	Ongoing at time of death
			Pathological fracture	病的骨折	3	Y	TE	121	28	N	Drug administration postponed	Recovered
			Oedema peripheral	末梢性浮腫	1	N	TE	124		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	124	15	N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	138	25	N	None	Ongoing at time of death
			Dyspnoea	呼吸困難	2	N	TE	139	7	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	141	1	N	Not applicable	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	147	2	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	148		N	Not applicable	Lost to follow-up
			Device dislocation	医療機器位置異常	3	Y	TE	162	3	N	Not applicable	Recovered
			Procedural pain	処置による疼痛	3	Y	TE	162	3	N	Not applicable	Recovered
			Pneumonia	肺炎	3	Y	TE	165	3	N	Not applicable	Recovered
			Pulmonary embolism	肺塞栓症	3	Y	TE	165	3	N	Not applicable	Death
			Pneumonia	肺炎	4	Y	TE	167	28	N	Not applicable	Recovered
			Pulmonary embolism	肺塞栓症	4	Y	TE	167	63	N	Not applicable	Death
			Pulmonary embolism	肺塞栓症	5	Y	TE	229	1	N	Not applicable	Death
179006	Brazil	79/M/C	Nausea	悪心	1	N	Pre	-17	3	N	Not applicable	Recovered
			Cough	咳嗽	1	N	Pre	-6	5	N	Not applicable	Recovered
			Nausea	悪心	1	N	TE	34	99	N	None	Recovered
			Arthralgia	関節痛	1	N	TE	132		N	None	Recovered
			Bone pain	骨痛	1	N	TE	159	2	N	None	Recovered
			Myocardial infarction	心筋梗塞	5	Y	TE	244	1	N	Not applicable	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
181005	Brazil	74/M/C	Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	Pre	1		N	None	Ongoing at time of death
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	3	N	Pre	1		N	None	Ongoing at time of death
			Hypoglycaemia	低血糖症	3	Y	TE	29	2	N	None	Recovered
			Pneumonia	肺炎	2	Y	TE	30	16	N	Not applicable	Death
			Acute pulmonary oedema	急性肺水腫	2	Y	TE	30		N	Not applicable	Ongoing at time of death
			Pneumonia	肺炎	5	Y	TE	45	1	N	Not applicable	Death
201002	Australia	72/M/C	Dysphagia	嚥下障害	2	N	Pre	-7	70	N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	48	46	N	None	Recovered
			Muscle strain	筋挫傷	2	N	TE	49	15	N	None	Recovered
			Dysphagia	嚥下障害	1	N	Pre	63	71	N	None	Ongoing at time of death
			Peripheral sensory neuropathy	末梢性感覚ニューロパチー	2	N	TE	93	4	N	None	Recovered
			Lower respiratory tract infection	下気道感染	1	N	TE	99	8	N	None	Recovered
			Anaemia	貧血	3	Y	TE	132	9	N	Not applicable	Recovered
			Supraventricular tachycardia	上室性頻脈	2	Y	TE	132	1	N	Not applicable	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Abdominal distension	腹部膨満	3	Y	TE	132	9	N	Not applicable	Recovered with sequelae
			Oedema peripheral	末梢性浮腫	3	N	TE	132		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	132	39	N	Not applicable	Death
			Anxiety	不安	2	N	TE	132		N	Not applicable	Ongoing at time of death
			Dysphagia	嚥下障害	2	N	Pre	133		N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	1	N	TE	137	3	N	Not applicable	Recovered
			Abdominal distension	腹部膨満	2	N	TE	140		N	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	147		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	N	TE	161		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	170	1	N	Not applicable	Death
203007	Australia	70/M/C	Bone pain	骨痛	2	N	Pre	-7	63	N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	Pre	-7	63	N	None	Recovered
			Constipation	便秘	2	Y	Pre	-1	3	N	None	Recovered
			Anorexia	食欲不振	2	N	TE	3		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dysgeusia	味覚異常	1	N	TE	3		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	4	2	Y	None	Recovered
			Anaemia	貧血	2	N	TE	28	49	Y	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	28	29	N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	28	83	N	Not applicable	Death
			Fatigue	疲労	2	N	TE	35		N	None	Ongoing at time of death
			Nausea	悪心	1	N	TE	53	5	Y	None	Recovered
			Bone pain	骨痛	3	N	TE	56	3	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	56	3	N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	56	3	N	None	Recovered
			Bone pain	骨痛	1	N	TE	58		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	58		N	None	Ongoing at time of death
			Constipation	便秘	2	N	TE	66	8	N	Not applicable	Recovered
			Constipation	便秘	3	Y	TE	73	6	N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	76	3	Y	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	78		Y	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	110	1	N	Not applicable	Death
204001	Australia	76/M/C	Dyspnoea	呼吸困難	1	N	Pre	-392	366	N	None	Recovered
			Nausea	悪心	1	N	TE	1		Y	None	Ongoing at study termination / withdrawal
			Vomiting	嘔吐	1	N	TE	2		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	1	N	TE	2		Y	None	Ongoing at study termination / withdrawal
			Chills	悪寒	1	N	TE	6	1	Y	None	Recovered
			Diarrhoea	下痢	1	N	TE	8	1	Y	None	Recovered
			Constipation	便秘	1	N	TE	9		Y	None	Ongoing at study termination / withdrawal
			Contusion	挫傷	1	N	TE	10		N	None	Ongoing at study termination / withdrawal
			Gastroenteritis	胃腸炎	4	Y	TE	18	6	Y	None	Recovered with sequelae
			Renal failure acute	急性腎不全	2	Y	TE	18	6	Y	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Gastroenteritis	胃腸炎	3	N	TE	21	3	Y	None	Recovered with sequelae
			Anaemia	貧血	2	Y	TE	22	2	Y	None	Recovered
			Gastroenteritis	胃腸炎	2	N	TE	23	1	Y	None	Recovered with sequelae
			Bone pain	骨痛	1	N	TE	34		Y	None	Ongoing at time of death
			Mobility decreased	運動性低下	1	N	TE	34		Y	None	Ongoing at time of death
			Tremor	振戦	1	N	TE	34		Y	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	43	26	N	Not applicable	Ongoing at study termination / withdrawal
			Anaemia	貧血	2	N	TE	63	2	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	68	9	N	Not applicable	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	76		N	Not applicable	Ongoing at study termination / withdrawal
			Anxiety	不安	1	N	TE	79	1	Y	None	Recovered
			Anxiety	不安	1	N	TE	83	3	Y	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	116	1	N	Drug permanently withdrawn	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
205004	Australia	82/M/C	Bone pain	骨痛	2	N	TE			Y	None	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	3	N	Pre	1		N	None	Ongoing at time of death
			Urinary incontinence	尿失禁	2	N	TE	6		Y	None	Ongoing at time of death
			Fatigue	疲労	1	N	TE	33		Y	None	Ongoing at time of death
			Hydrocephalus	水頭症	4	Y	TE	107	20	N	Drug permanently withdrawn	Recovered with sequelae
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	127	14	N	Drug permanently withdrawn	Death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	140	1	N	Drug permanently withdrawn	Death
206001	Australia	83/M/C	Meniere's disease	メニエール病	2	N	TE	78	18	Y	Drug administration postponed	Recovered with sequelae
			Deep vein thrombosis	深部静脈血栓症	3	Y	TE	90	6	Y	None	Recovered with sequelae
			Constipation	便秘	1	N	TE	91	4	N	Drug administration postponed	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pollakiuria	頻尿	3	N	TE	189		N	Not applicable	Ongoing at time of death
			Anaemia	貧血	2	Y	TE	201		N	Not applicable	Ongoing at time of death
			Nausea	悪心	3	N	TE	201		N	Not applicable	Ongoing at time of death
			Pain	疼痛	3	N	TE	201		N	Not applicable	Ongoing at time of death
			Urinary tract infection	尿路感染	3	N	TE	201		N	Not applicable	Ongoing at time of death
			Hydronephrosis	水腎症	3	Y	TE	201		N	Not applicable	Ongoing at time of death
			Fluid overload	水分過負荷	3	N	TE	202		N	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	4	N	TE	202		N	Not applicable	Ongoing at time of death
			Lung consolidation	肺硬化	3	N	TE	202		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	212	1	N	Not applicable	Death
209003	Australia	56/M/C	Bone pain	骨痛	1	N	Pre	-22		N	None	Ongoing at time of death
			Oesophagitis	食道炎	1	N	TE	29		N	None	Ongoing at time of death
			Decreased appetite	食欲減退	1	N	TE	29		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Muscle spasms	筋痙縮	1	N	TE	57		N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	78		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	78		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	78		N	None	Ongoing at time of death
			Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1	N	TE	85		N	None	Ongoing at time of death
			Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	1	N	TE	85		N	None	Ongoing at time of death
			Breath sounds abnormal	呼吸音異常	1	N	TE	85		N	None	Ongoing at time of death
			Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1	N	TE	85		N	None	Ongoing at time of death
			Neuropathy peripheral	末梢性ニューロパチー	1	N	TE	88		N	None	Ongoing at time of death
			Spinal cord compression	脊髄圧迫	4	Y	TE	94	16	N	None	Recovered
			Burning sensation	灼熱感	1	N	TE	102	1	N	None	Recovered
			Rash	発疹	1	N	TE	103		N	None	Ongoing at time of death
			Pyrexia	発熱	1	N	TE	108	2	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	2	N	TE	109		N	Not applicable	Ongoing at time of death
			Diarrhoea	下痢	1	N	TE	109		N	Not applicable	Ongoing at time of death
			Radiation skin injury	放射線皮膚損傷	1	N	TE	109		N	Not applicable	Ongoing at time of death
			Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	3	Y	TE	109	7	N	Drug permanently withdrawn	Recovered
			Anxiety	不安	1	N	TE	109		N	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	138		N	Not applicable	Ongoing at time of death
			Ascites	腹水	1	Y	TE	149		N	Not applicable	Ongoing at time of death
			Epistaxis	鼻出血	1	N	TE	149	18	N	Not applicable	Recovered
			Dry skin	皮膚乾燥	1	N	TE	149		N	Not applicable	Ongoing at time of death
			Pruritus	そう痒症	1	N	TE	149		N	Not applicable	Ongoing at time of death
			Dyspnoea	呼吸困難	1	N	TE	153		N	None	Ongoing at time of death
			Rectal haemorrhage	直腸出血	1	N	TE	158		N	Not applicable	Ongoing at time of death
			Pitting oedema	圧痕浮腫	1	N	TE	158		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	158	9	N	Not applicable	Death
			Confusional state	錯乱状態	1	N	TE	158		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	166	1	N	Not applicable	Death
233005	UK	78/M/C	Nausea	悪心	1	N	TE	1	209	N	None	Ongoing at time of death
			Constipation	便秘	1	N	TE	29	181	Y	None	Ongoing at time of death
			Weight decreased	体重減少	1	N	TE	29	29	N	None	Recovered
			Anorexia	食欲不振	3	N	TE	29	113	Y	None	Ongoing at time of death
			Dehydration	脱水	3	N	TE	29	4	Y	Drug administration postponed	Recovered
			Malaise	倦怠感	2	Y	TE	32	6	Y	Drug administration postponed	Recovered
			Dehydration	脱水	3	Y	TE	32	6	Y	Drug administration postponed	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dehydration	脱水	2	Y	TE	45	5	Y	Drug administration postponed	Recovered
			Anaemia	貧血	3	Y	TE	53	3	Y	None	Recovered
			Hypertension	高血圧	3	N	TE	85	125	Y	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	134	3	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	136	3	Y	None	Recovered
			Dehydration	脱水	2	N	TE	136	3	Y	None	Recovered
			Dyspnoea	呼吸困難	3	N	TE	136	2	N	None	Recovered
			Anorexia	食欲不振	1	N	TE	141		Y	None	Ongoing at time of death
			Abdominal pain upper	上腹部痛	1	N	TE	167	3	Y	None	Recovered
			Anaemia	貧血	1	Y	TE	168	2	Y	None	Recovered
			Fatigue	疲労	2	N	TE	168		N	None	Ongoing at time of death
			Dehydration	脱水	2	Y	TE	168	2	Y	None	Recovered
			Anaemia	貧血	3	Y	TE	176	3	Y	Not applicable	Recovered
			Cough	咳嗽	2	N	TE	176	3	N	None	Recovered
			Cough	咳嗽	1	N	TE	176	3	N	Not applicable	Recovered
			Dyspnoea	呼吸困難	3	N	TE	176	3	Y	None	Recovered
			Anaemia	貧血	2	Y	TE	190		Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Neutropenia	好中球減少症	2	Y	TE	190		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	Y	TE	190		Y	Not applicable	Ongoing at time of death
			Abdominal pain	腹痛	1	N	TE	190	1	Y	Not applicable	Recovered
			Decreased appetite	食欲減退	3	N	TE	190		N	None	Ongoing at time of death
			Dehydration	脱水	3	Y	TE	190	4	Y	Not applicable	Recovered
			Hyperkalaemia	高カリウム血症	2	N	TE	190	20	Y	Not applicable	Recovered
			Bone pain	骨痛	2	N	TE	190		Y	Not applicable	Not recovered, but no changes expected
			Bone pain	骨痛	3	Y	TE	190	4	Y	Not applicable	Recovered
			Dizziness	浮動性めまい	2	N	TE	190		N	Not applicable	Not recovered, but no changes expected
			Anaemia	貧血	3	Y	TE	209		N	Not applicable	Ongoing at time of death
			Bronchopneumonia	気管支肺炎	5	Y	TE	209	1	N	Not applicable	Death
			Dehydration	脱水	3	Y	TE	209		Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Agitation	激越	2	N	TE	209	1	N	None	Ongoing at time of death
240002	USA	68/M/C	Anaemia	貧血	3	N	TE	33	6	Y	Drug administration postponed	Recovered with sequelae
			Pneumonia	肺炎	3	Y	TE	33	6	N	Drug administration postponed	Recovered
			Sepsis	敗血症	4	Y	TE	33	6	N	Drug administration postponed	Recovered
			Pleural effusion	胸水	2	N	TE	33	4	N	None	Recovered
			Hypotension	低血圧	3	N	TE	33	1	N	None	Recovered
			Anaemia	貧血	1	N	TE	38	48	Y	None	Recovered with sequelae
			Diarrhoea	下痢	1	N	TE	62		Y	None	Ongoing at time of death
			Muscle spasms	筋痙縮	1	N	TE	72	43	N	None	Recovered
			Anaemia	貧血	2	N	TE	85	97	Y	None	Recovered with sequelae
			Nausea	悪心	1	N	TE	114	3	N	None	Recovered
			Fatigue	疲労	2	N	TE	114		Y	None	Ongoing at time of death
			Haematuria	血尿	1	N	TE	133	7	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Leukopenia	白血球減少症	2	N	TE	139		Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	1	N	TE	139		Y	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	1	N	TE	139		Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	1	N	TE	140		N	None	Ongoing at time of death
			Contusion	挫傷	1	N	TE	140		N	None	Ongoing at time of death
			Bone pain	骨痛	2	N	TE	140		N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	170		N	None	Ongoing at time of death
			Leukopenia	白血球減少症	3	N	TE	180	3	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	3	Y	TE	180	6	Y	Not applicable	Recovered
			Urinary tract infection	尿路感染	1	N	TE	180	11	N	Not applicable	Recovered
			Bone pain	骨痛	3	N	TE	180	6	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	180	62	N	Not applicable	Death
			Haematuria	血尿	2	Y	TE	180	6	Y	Not applicable	Recovered
			Urinary retention	尿閉	2	Y	TE	180	6	Y	Not applicable	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pleural effusion	胸水	2	N	TE	180	24	N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	181	2	Y	None	Recovered with sequelae
			Dyspnoea	呼吸困難	1	N	TE	181	5	N	Not applicable	Recovered
			Anaemia	貧血	2	N	TE	182	50	Y	Not applicable	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	194		N	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	199	5	Y	Not applicable	Ongoing at time of death
			Abdominal pain	腹痛	2	N	TE	199	11	N	Not applicable	Recovered
			Diarrhoea	下痢	1	N	TE	199	11	N	Not applicable	Recovered
			Nausea	悪心	2	N	TE	199	11	N	Not applicable	Recovered
			Vomiting	嘔吐	2	N	TE	199	11	N	Not applicable	Recovered
			Asthenia	無力症	2	N	TE	199		N	Not applicable	Ongoing at time of death
			Arthralgia	関節痛	1	N	TE	199	11	N	Not applicable	Recovered
			Bone pain	骨痛	1	N	TE	199	11	N	Not applicable	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Dyspnoea	呼吸困難	3	N	TE	199	5	N	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	203		Y	Not applicable	Ongoing at time of death
			Skin laceration	皮膚裂傷	2	N	TE	205		N	Not applicable	Ongoing at time of death
			Haemorrhoids	痔核	1	N	TE	210	6	N	Not applicable	Recovered
			Convulsion	痙攣	2	N	TE	223	1	N	Not applicable	Recovered
			Subcutaneous abscess	皮下組織膿瘍	2	N	TE	227		N	Not applicable	Ongoing at time of death
			Insomnia	不眠症	1	N	TE	229		N	Not applicable	Recovered
			Anaemia	貧血	3	N	TE	231		Y	Not applicable	Ongoing at time of death
			Urinary retention	尿閉	2	N	TE	240	1	Y	Not applicable	Recovered
			Salivary hypersecretion	流涎過多	1	N	TE	241		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	241	1	N	Not applicable	Death
			Confusional state	錯乱状態	3	N	TE	241		N	Not applicable	Ongoing at time of death
240004	USA	56/M/C	Oedema peripheral	末梢性浮腫	1	N	TE	30	28	N	None	Recovered
			Supraventricular tachycardia	上室性頻脈	3	N	TE	55	1	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Mental status changes	精神状態変化	1	N	TE	55	1	N	None	Recovered
			Fatigue	疲労	1	N	TE	57		N	None	Ongoing at study termination / withdrawal
			Arthralgia	関節痛	1	N	TE	57	1	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	117	79	N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	117	79	N	None	Ongoing at study termination / withdrawal
			Cardiac murmur	心雑音	1	N	TE	119	35	N	None	Recovered
			Malignant neoplasm progression	悪性新生物進行	3	N	TE	156	487	N	Not applicable	Death
			Nocturia	夜間頻尿	1	N	TE	156	112	N	Not applicable	Recovered
			Bone pain	骨痛	3	N	TE	195		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	3	N	TE	195		N	None	Ongoing at study termination / withdrawal
			Depression	うつ病	1	N	TE	212	21	N	None	Recovered
			Anaemia	貧血	2	N	TE	216	9	Y	Not applicable	Recovered
			Pleural effusion	胸水	2	N	TE	216	3	N	Not applicable	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Pain	疼痛	3	N	TE	231		N	Not applicable	Ongoing at time of death
			Decreased appetite	食欲減退	2	N	TE	231		N	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	N	TE	642	1	N	Not applicable	Death
240006	USA	75/M/C	Constipation	便秘	1	N	TE			N	None	Recovered
			Bone pain	骨痛	1	N	Pre	-7	100	N	None	Recovered
			Cardiac murmur	心雑音	1	N	Pre	-2	35	N	None	Recovered
			Bone pain	骨痛	1	N	TE	31	63	N	None	Recovered
			Contusion	挫傷	1	N	TE	33		N	None	Ongoing at study termination / withdrawal
			Fatigue	疲労	3	N	TE	47	11	Y	None	Recovered
			Abdominal pain upper	上腹部痛	1	N	TE	64	25	N	None	Recovered
			Fatigue	疲労	1	N	TE	64		Y	None	Ongoing at time of death
			Oedema peripheral	末梢性浮腫	2	N	TE	64	60	N	None	Recovered
			Weight increased	体重増加	1	N	TE	64		N	None	Ongoing at study termination / withdrawal
			Bone pain	骨痛	2	N	TE	64	25	N	Drug administration postponed	Recovered
			Muscular weakness	筋力低下	1	N	TE	64		N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Bone pain	骨痛	4	Y	TE	88	6	N	Drug administration postponed	Recovered
			Spinal cord compression	脊髄圧迫	3	Y	TE	88	115	N	Drug permanently withdrawn	Recovered
			Anaemia	貧血	2	N	TE	109	33	Y	Not applicable	Recovered
			Thrombocytopenia	血小板減少症	2	N	TE	110	87	Y	Not applicable	Recovered
			Asthenia	無力症	2	N	TE	110		N	Not applicable	Ongoing at time of death
			Depression	うつ病	2	N	TE	110		N	Not applicable	Ongoing at time of death
			Fluid intake reduced	水分摂取量減少	2	N	TE	116	8	N	Not applicable	Recovered
			Cough	咳嗽	1	N	TE	118	17	N	None	Recovered
			Hypotension	低血圧	2	N	TE	120	55	N	Not applicable	Recovered
			Anorexia	食欲不振	2	N	TE	124		Y	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	Y	TE	145	203	N	Drug permanently withdrawn	Death
			Spinal cord compression	脊髄圧迫	3	N		202		N	Not applicable	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	347	1	N	Drug permanently withdrawn	Death
9017026	Czech Republic	62/ /	Bone pain	骨痛	2	N	TE	113	44	N	None	Recovered
			General physical health deterioration	全身健康状態低下	5	Y	TE	201	1	N	None	Death
9026014	Sweden	82/ /	Diarrhoea	下痢	1	N	TE	11	89	N	None	Recovered
			Anaemia	貧血	1	N	TE	20	16	N	None	Recovered
			Nausea	悪心	2	N	TE	20	12	Y	None	Recovered
			Rectal haemorrhage	直腸出血	1	N	TE	20	12	N	None	Recovered
			Asthenia	無力症	2	N	TE	20	51	N	None	Recovered
			Malnutrition	栄養障害	2	Y	TE	20	12	Y	Drug administration postponed	Recovered
			Hyponatraemia	低ナトリウム血症	3	N	TE	26	10	N	None	Recovered
			Metastases to liver	肝転移	3	N	TE	29	223	N	None	Death
			Malnutrition	栄養障害	1	N	TE	31	9	N	Drug administration postponed	Recovered
			Incontinence	失禁	3	N	TE	31		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	35	23	N	None	Ongoing at time of death
			Hyponatraemia	低ナトリウム血症	1	N	TE	35	64	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	1	N	TE	57	126	N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	3	N	TE	98	30	N	None	Recovered
			Hypokalaemia	低カリウム血症	1	N	TE	127	28	N	None	Recovered
			Muscular weakness	筋力低下	1	N	TE	155	29	N	None	Recovered
			Skin fragility	皮膚脆弱性	1	N	TE	155		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	175	9	N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	175	9	N	None	Recovered
			Anaemia	貧血	2	N	TE	182		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	183		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	203		N	Not applicable	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	205	2	N	Not applicable	Recovered
			Metastases to liver	肝転移	4	N	TE	251	40	N	None	Death
			Metastases to liver	肝転移	5	N	TE	290	1	N	None	Death
9049001	UK	65/ /	Fatigue	疲労	1	N	TE			Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	3	N	TE	29	8	N	Drug administration postponed	Recovered
			Nausea	悪心	2	N	TE	29	43	Y	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	3	N	TE	42	2	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	2	N	TE	43	50	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	92		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	98	1	N	Drug permanently withdrawn	Death
9050018	UK	71/ /	Paraesthesia oral	口の錯感覚	1	N	TE			N	None	Ongoing at time of death
			Contusion	挫傷	1	N	TE			N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE			Y	None	Recovered
			Paraesthesia	錯感覚	1	N	TE			N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	30	18	N	None	Recovered
			Fatigue	疲労	2	N	TE	30	18	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	106		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	144	30	N	Not applicable	Death
			Bone pain	骨痛	2	N	TE	147	11	N	Not applicable	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Anaemia	貧血	3	Y	TE	170		Y	Not applicable	Ongoing at time of death
			Thrombocytopenia	血小板減少症	3	Y	TE	170		Y	Not applicable	Ongoing at time of death
			Rectal haemorrhage	直腸出血	3	Y	TE	170		Y	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	173	1	N	Not applicable	Death
9074001	Italy	79/ /	Anaemia	貧血	1	N	TE	28	14	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	28	14	N	None	Recovered
			Blood potassium increased	血中カリウム増加	2	N	TE	42	14	N	None	Recovered
			Blood urea increased	血中尿素増加	1	N	TE	42		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	42	1	N	None	Recovered
			Asthenia	無力症	1	N	TE	74		N	None	Ongoing at time of death
			Somnolence	傾眠	1	N	TE	74	53	N	None	Recovered
			Hypercreatininaemia	高クレアチニン血症	1	N	TE	84	43	Y	None	Recovered
			Hyponatraemia	低ナトリウム血症	3	N	TE	84	14	N	-	
			Hyponatraemia	低ナトリウム血症	1	N	TE	98	14	N	-	
			Hyponatraemia	低ナトリウム血症	3	N	TE	112	15	N	-	
			Hyponatraemia	低ナトリウム血症	1	N	TE	127		N	None	Ongoing at time of death
			Syncope	失神	3	Y	TE	135	4	N	Not applicable	Death

表 2.7.4.7- 14　死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Main Study and Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Syncope	失神	5	Y	TE	138	1	N	Not applicable	Death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Placebo Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
9017026	Czech Republic	62/ /	Bone pain	骨痛	2	N	TE	113	44	N	None	Recovered
			General physical health deterioration	全身健康状態低下	5	Y	TE	201	1	N	None	Death
9026014	Sweden	82/ /	Diarrhoea	下痢	1	N	TE	11	89	N	None	Recovered
			Anaemia	貧血	1	N	TE	20	16	N	None	Recovered
			Nausea	悪心	2	N	TE	20	12	Y	None	Recovered
			Rectal haemorrhage	直腸出血	1	N	TE	20	12	N	None	Recovered
			Asthenia	無力症	2	N	TE	20	51	N	None	Recovered
			Malnutrition	栄養障害	2	Y	TE	20	12	Y	Drug administration postponed	Recovered
			Hyponatraemia	低ナトリウム血症	3	N	TE	26	10	N	None	Recovered
			Metastases to liver	肝転移	3	N	TE	29	223	N	None	Death
			Malnutrition	栄養障害	1	N	TE	31	9	N	Drug administration postponed	Recovered
			Incontinence	失禁	3	N	TE	31		N	None	Ongoing at time of death
			Anaemia	貧血	2	N	TE	35	23	N	None	Ongoing at time of death
			Hyponatraemia	低ナトリウム血症	1	N	TE	35	64	N	None	Recovered
			Anaemia	貧血	1	N	TE	57	126	N	None	Ongoing at time of death
			Hypokalaemia	低カリウム血症	3	N	TE	98	30	N	None	Recovered

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Placebo Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hypokalaemia	低カリウム血症	1	N	TE	127	28	N	None	Recovered
			Muscular weakness	筋力低下	1	N	TE	155	29	N	None	Recovered
			Skin fragility	皮膚脆弱性	1	N	TE	155		N	None	Ongoing at time of death
			Anorexia	食欲不振	2	N	TE	175	9	N	None	Ongoing at time of death
			Bone pain	骨痛	1	N	TE	175	9	N	None	Recovered
			Anaemia	貧血	2	N	TE	182		N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE	183		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	203		N	Not applicable	Ongoing at time of death
			Vomiting	嘔吐	2	N	TE	205	2	N	Not applicable	Recovered
			Metastases to liver	肝転移	4	N	TE	251	40	N	None	Death
			Metastases to liver	肝転移	5	N	TE	290	1	N	None	Death
9049001	UK	65/ /	Fatigue	疲労	1	N	TE			Y	None	Ongoing at time of death
			Neutropenia	好中球減少症	3	N	TE	29	8	N	Drug administration postponed	Recovered
			Nausea	悪心	2	N	TE	29	43	Y	None	Recovered
			Thrombocytopenia	血小板減少症	3	N	TE	42	2	N	None	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Placebo Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	2	N	TE	43	50	N	None	Ongoing at time of death
			Thrombocytopenia	血小板減少症	4	N	TE	92		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	98	1	N	Drug permanently withdrawn	Death
9050018	UK	71/ /	Paraesthesia oral	口の錯感覚	1	N	TE			N	None	Ongoing at time of death
			Contusion	挫傷	1	N	TE			N	None	Ongoing at time of death
			Anorexia	食欲不振	1	N	TE			N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE			Y	None	Recovered
			Paraesthesia	錯感覚	1	N	TE			N	None	Ongoing at time of death
			Nausea	悪心	2	N	TE	30	18	N	None	Recovered
			Fatigue	疲労	2	N	TE	30	18	N	None	Recovered
			Weight decreased	体重減少	2	N	TE	106		N	None	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	4	N	TE	144	30	N	Not applicable	Death
			Bone pain	骨痛	2	N	TE	147	11	N	Not applicable	Recovered
			Anaemia	貧血	3	Y	TE	170		Y	Not applicable	Ongoing at time of death

表 2.7.4.7- 14 死亡例の一覧（試験 BC1-06、2014 年 10 月 10 日データベースロック）（続き）

Treatment: Placebo Crossover: BAY 88-8223

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 11.0)	Adverse Events (AE) Preferred term (MedDRA version 11.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Thrombocytopenia	血小板減少症	3	Y	TE	170		Y	Not applicable	Ongoing at time of death
			Rectal haemorrhage	直腸出血	3	Y	TE	170		Y	Not applicable	Ongoing at time of death
			Malignant neoplasm progression	悪性新生物進行	5	Y	TE	173	1	N	Not applicable	Death
9074001	Italy	79/ /	Anaemia	貧血	1	N	TE	28	14	Y	None	Recovered
			Bone pain	骨痛	2	N	TE	28	14	N	None	Recovered
			Blood potassium increased	血中カリウム増加	2	N	TE	42	14	N	None	Recovered
			Blood urea increased	血中尿素増加	1	N	TE	42		N	None	Ongoing at time of death
			Bone pain	骨痛	3	N	TE	42	1	N	None	Recovered
			Asthenia	無力症	1	N	TE	74		N	None	Ongoing at time of death
			Somnolence	傾眠	1	N	TE	74	53	N	None	Recovered
			Hypercreatininaemia	高クレアチニン血症	1	N	TE	84	43	Y	None	Recovered
			Hyponatraemia	低ナトリウム血症	3	N	TE	84	14	N	-	
			Hyponatraemia	低ナトリウム血症	1	N	TE	98	14	N	-	
			Hyponatraemia	低ナトリウム血症	3	N	TE	112	15	N	-	
			Hyponatraemia	低ナトリウム血症	1	N	TE	127		N	None	Ongoing at time of death
			Syncope	失神	3	Y	TE	135	4	N	Not applicable	Death
			Syncope	失神	5	Y	TE	138	1	N	Not applicable	Death

Sex is identified as: M = Male.

Race is identified as: A = Asian, B = Black, C = Caucasian, O = Other.

The unit for "Age" is years.

Phase is identified as: Pre = Pre-Treatment, TE = Treatment-Emergent, Post = Post-Treatment

Source: 5.3.5.1.11 BC1-06_J-table 3/Table 1.4/2

表 2.7.4.7- 15 死亡例の一覧（試験 BC1-02、12 ヵ月報告）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events(AE) Preferred term (MedDRA version 7.0) or cause of death	Adverse Events(AE) Preferred term (MedDRA version 7.0)	Intensity	CTCAE grade	SAE	Relative week of AE	Duration of AE (day)	Related to study drug	Action taken with study treatment	Outcome
BAY 88-8223 (55)	104	76/M/C	Disease Progression (skeletal)					49.6		N		Death
	109	81/M/C	Disease Progression (skeletal)					27.1		N		Death
	206	82/M/C	Atrial fibrillation	心房細動	Moderate		N	8.6		N	None	Death
	301	62/M/C	Disease Progression (skeletal)					43.0		N		Death
	303	75/M/C	Disease Progression (skeletal, liver)					32.9		N		Death
	405	73/M/C	Liver insufficiency					20.4		N		Death
	501	60/M/C	Disease Progression (skeletal)					52.0		N		Death
	504	69/M/C	Disease Progression (skeletal)					33.1		N		Death
	511	86/M/C	Disease Progression (skeletal)					36.3		N		Death
	514	74/M/C	Disease Progression (skeletal), Urinary bladder tamponade					42.0		N		Death
	552	71/M/C	Myocardial infarction	心筋梗塞	Severe		Y	3.1	0	N	Drug permanently withdrawn	Death
	553	88/M/C	Disease Progression (skeletal)					42.6		N		Death

表 2.7.4.7- 15 死亡例の一覧（試験 BC1-02、12 ヵ月報告）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events(AE) Preferred term (MedDRA version 7.0) or cause of death	Adverse Events(AE) Preferred term (MedDRA version 7.0)	Intensity	CTCAE grade	SAE	Relative week of AE	Duration of AE (day)	Related to study drug	Action taken with study treatment	Outcome
	702	68/M/C	Carcinomatosis					33.9				Death
	803	72/M/C	Right lower lobe pneumonia					48.7				Death
Placebo	103	73/M/C	Pneumonia after outdoors and hypothermia					28.0				Death
	106	78/M/C	Disease Progression (skeletal)					16.7		N		Death
	108	64/M/C	Disease Progression (skeletal)					20.6		N		Death
	110	80/M/C	Disease Progression (skeletal)					42.6		N		Death
	203	61/M/C	Disease Progression (skeletal)					32.0		N		Death
	205	68/M/C	Atrial fibrillation	心房細動	Severe	4	Y	7.7	6	N	Drug permanently withdrawn	Death
			Sepsis	敗血症	Severe	4	Y	7.9	5	Uncer-tain	Drug administration postponed	Death
	302	78/M/C	Disease Progression (skeletal)					32.1		N		Death
	304	75/M/C	Disease Progression (skeletal)					22.1		N		Death
	404	67/M/C	Suspected rupture of aortic aneurism					33.0		N		Death

表 2.7.4.7- 15 死亡例の一覧（試験 BC1-02、12 ヵ月報告）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events(AE) Preferred term (MedDRA version 7.0) or cause of death	Adverse Events(AE) Preferred term (MedDRA version 7.0)	Intensity	CTCAE grade	SAE	Relative week of AE	Duration of AE (day)	Related to study drug	Action taken with study treatment	Outcome
	406	63/M/C	Disease Progression (skeletal)					12.4		N		Death
	502	73/M/C	Disease Progression (skeletal)					49.4		N		Death
	505	84/M/C	Disease Progression (skeletal), infection with fever					16.1		N		Death
	509	81/M/C	Disease Progression (skeletal)					26.6		N		Death
	513	74/M/C	Disease Progression (skeletal)					24.6		N		Death
	602	73/M/C	Disease Progression					42.6		N		Death
	801	72/M/C	Disease Progression (skeletal)					46.4		N		Death
	951	84/M/C	Disease Progression (skeletal)					41.7		N		Death

Sex is identified as: M = Male.

Race is identified as: C = Caucasian

The unit for "Age" is years.

Source: 5.3.5.1.6 A58302/Listing 14.3.2.1, 14.3.2.2, 16.2.4

表 2.7.4.7- 16 死亡例の一覧（試験 BC1-02、24 ヵ月報告）

Treatment (kBq/kg)	Subject ID	Age/Sex/Race	Cause of Death	Relative week of Death	Related to study drug	Outcome
BAY 88-8223 (55)	105	81/M/C	Desease progression (skeletal, liver)/Pancreas cancer	83.7	N	Death
	204	68/M/C	Desease progression (skeletal)	102.0	N	Death
	305	75/M/C	Desease progression (skeletal)	71.0	N	Death
	402	77/M/C	Cerebral vascular infarction	105.1	N	Death
	506	81/M/C	Desease progression (skeletal)	61.6	N	Death
	508	80/M/C	Desease progression (skeletal)	65.3	N	Death
	515	79/M/C	Desease progression (skeletal)	102.1	N	Death
	603	71/M/C	Myocardial infarction	52.7	N	Death
	805	65/M/C	Bronchopneumonia	102.4	N	Death
Placebo	101	60/M/C	Desease progression (skeletal, liver)	70.7	N	Death
	401	69/M/C	Desease progression (skeletal)	77.4	N	Death
	507	71/M/C	Desease progression (skeletal)	54.3	N	Death
	512	69/M/C	Desease progression (skeletal)	102.7	N	Death
	551	68/M/C	Desease progression (skeletal, liver, lung)	80.3	N	Death
	554	72/M/C	Desease progression (skeletal)	67.7	N	Death
	604	61/M/C		86.0		Death
	804	67/M/C	Desease progression (skeletal)cancer	71.1		Death
	806	78/M/C	Desease progression (skeletal)	68.3	N	Death
	807	67/M/C		86.4		Death

Sex is identified as: M = Male.

Race is identified as: C = Caucasian

The unit for "Age" is years.

Source: 5.3.5.1.6 A58302/Listing 16.2.4, 5.3.5.1.7 A58313/Appendix 3, List 3

表 2.7.4.7- 17 死亡例の一覧（試験 BC1-03、12 ヵ月報告）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 9.0) or Immediate Cause of Death / Cause of Death by Disease [a]	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Intensity	CTCAE grade	SAE	Relative Week of AE[b]	Duration of AE (day)	Related to study drug	Action taken to treat the event	Outcome
BAY 88-8223 (6)	1008	74/M/C	Cerebral haemorrhage / Cerebral haemorrhage					24.0[c]		Unlikely		Death
BAY 88-8223 (6)	1014	74/M/C	Skeletal metastases. Progression of metastatic prostate cancer / Disease progression					20.3[c]				Death
BAY 88-8223 (6)	1015	61/M/C	Skeletal metastases. Progression of metastatic prostate cancer / Disease progression					24.7[c]				Death
BAY 88-8223 (6)	1201	75/M/C	Disease progression	疾患進行	Severe		Y	11.9	0	Unlikely	None	Death
			Unknown / Disease progression					11.9[c]		Unlikely		Death
BAY 88-8223 (6)	1407	66/M/C	Cardiac arrest / Disease progression					21.6[c]		Unlikely		Death
BAY 88-8223 (6)	1601	75/M/C	Cardiopulmonary failure	心肺不全	Severe		Y	7.4	0	Unlikely	None	Death
			Heart and lung failure / Disease progression					7.4[c]		Unlikely		Death

表 2.7.4.7- 17 死亡例の一覧（試験 BC1-03、12 ヵ月報告）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 9.0) or Immediate Cause of Death / Cause of Death by Disease [a]	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Intensity	CTCAE grade	SAE	Relative Week of AE[b]	Duration of AE (day)	Related to study drug	Action taken to treat the event	Outcome
BAY 88-8223 (6)	1606	76/M/C	Disease progression	疾患進行		5	Y	15.9	0	Unlikely	None	Death
			Extreme fatigue / Disease progression					15.9[c]		Unlikely		Death
BAY 88-8223 (6)	1706	69/M/C	Fatigue	疲労		3	Y	6.4	37	Unlikely	Therapy	Death
BAY 88-8223 (6)	4008	81/M/C	Gastrointestinal haemorrhage	胃腸出血		2	Y	13.3	1	Unlikely	None	Death
			Acute haemorrhage from stomach / Disease progression					13.4[c]		Unlikely		Death
BAY 88-8223 (6)	5002	72/M/C	Metastatic prostate carcinoma / Disease progression					33.9[c]		Unlikely		Death
BAY 88-8223 (6)	7005	73/M/C	Progressive disease / Disease progression					26.0[c]		Unlikely		Death
BAY 88-8223 (28)	1010	82/M/C	Prostate cancer / Disease progression					22.4[c]		Unlikely		Death
BAY 88-8223 (28)	1016	49/M/C	Prostate cancer / Disease progression					20.3[c]		Unlikely		Death
BAY 88-8223 (28)	1102	68/M/C	Progression of disease / Disease progression					34.1[c]		Unlikely		Death

表 2.7.4.7- 17 死亡例の一覧（試験 BC1-03、12 ヵ月報告）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 9.0) or Immediate Cause of Death / Cause of Death by Disease [a]	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Intensity	CTCAE grade	SAE	Relative Week of AE[b]	Duration of AE (day)	Related to study drug	Action taken to treat the event	Outcome
			Progression of disease / Disease progression					34.1[c]		Unlikely		Death
BAY 88-8223 (28)	1311	75/M/C	Death without defined cause in the context of the terminal illness / Disease progression					50.0[c]		Unlikely		Death
BAY 88-8223 (28)	1313	74/M/C	Cardiac arrest	心停止		5	Y	7.3		Unlikely	Medication	Death
			Cardiac arrest / Possibly caused by coronary artery disease					7.3[c]		Unlikely		Death
BAY 88-8223 (28)	2301	68/M/C	General physical health deterioration	全身健康状態低下		4	Y	5.7	65	Unlikely	None	Death
			Tumour toxic multiple organ failure due to disease progression / Disease progression					15.0[c]		Unlikely		Death
BAY 88-8223 (28)	2302	69/M/C	Nausea	悪心		2	N	0.6	126	Unlikely	Medication	Death
			Vomiting	嘔吐		2	N	0.6	126	Unlikely	Medication	Death
			Weight decreased	体重減少		1	N	0.6	126	Unlikely	Medication	Death

表 2.7.4.7- 17 死亡例の一覧（試験 BC1-03、12 ヵ月報告）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 9.0) or Immediate Cause of Death / Cause of Death by Disease [a]	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Intensity	CTCAE grade	SAE	Relative Week of AE[b]	Duration of AE (day)	Related to study drug	Action taken to treat the event	Outcome
			Anorexia	食欲不振		2	N	1.1	122	Unlikely	Medication	Death
			Thrombocytopenia	血小板減少症		2	N	6.0	88	Possible	None	Death
			General physical health deterioration	全身健康状態低下	Severe		Y	3.9	103	Unlikely	Medication	Death
			Dyspnoea	呼吸困難		2	N	6.6	84	Unlikely	None	Death
			Anaemia	貧血		2	Y	8.0	74	Possible	Medication	Death
			Shoulder pain	肩部痛	Severe		Y	10.0	60	Unlikely	Medication	Death
			Oedema peripheral	末梢性浮腫	Mild		N	16.1	17	Unlikely	None	Death
			Disease progression	疾患進行		5	Y	12.9	40	Unlikely	None	Death
			Prostate cancer disease progression / Disease progression					18.6[c]		Unlikely		Death
BAY 88-8223 (28)	4001	80/M/C	Pneumonia / Disease progression, COPD					12.7[c]		Unlikely		Death
BAY 88-8223 (28)	6004	67/M/C	Metastatic prostate cancer / Disease progression					40.4[c]		Unlikely		Death
BAY 88-8223 (28)	7001	73/M/C	Constipation	便秘		2	N	0.6	22	Possible	Medication	Death
			Dizziness	浮動性めまい		1	N	1.0	19		None	Death
			Dyspnoea	呼吸困難		4	N	3.0	5	Possible	None	Death
			Oedema peripheral	末梢性浮腫		3	N	3.0	5	Possible	Other: EXAMINED	Death
			Disease progression	疾患進行		5	Y	3.7	0	Unlikely	None	Death
			Asthenia	無力症	Severe		N	2.0	12		None	Death

表 2.7.4.7- 17 死亡例の一覧（試験 BC1-03、12 ヵ月報告）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 9.0) or Immediate Cause of Death / Cause of Death by Disease [a]	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Intensity	CTCAE grade	SAE	Relative Week of AE[b]	Duration of AE (day)	Related to study drug	Action taken to treat the event	Outcome
			Malignant disease / Disease progression					3.7[c]		Unlikely		Death
BAY 88-8223 (28)	9003	81/M/C	Disease progression	疾患進行		5	Y	7.7	0	Unlikely	None	Death
			Disease progression / Disease progression					7.7[c]		Unlikely		Death
BAY 88-8223 (28)	9005	68/M/C	Intestinal perforation	腸管穿孔		4	Y	4.6	2	Unlikely	None	Death
			Bowel perforation / Disease progression					4.9[c]		Unlikely		Death
BAY 88-8223 (55)	1012	66/M/C	Prostate cancer / Disease progression					33.4[c]		Unlikely		Death
BAY 88-8223 (55)	1304	56/M/C	Evolution of the tumorage disease / Disease progression					23.9[c]		Unlikely		Death
BAY 88-8223 (55)	1702	64/M/C	Acute peritonitis / Acute peritonitis					17.1[c]		Unlikely		Death
BAY 88-8223 (55)	4005	65/M/C	Heart failure / Disease progression; coronary sclerosis					19.1[c]		Unlikely		Death
BAY 88-8223 (55)	5001	57/M/C	Metastatic prostate carcinoma / Disease progression					31.7[c]		Unlikely		Death
BAY 88-8223 (55)	6002	72/M/C	Infection	感染		4	Y	7.1	1	Unlikely	Medication	Death

表 2.7.4.7- 17 死亡例の一覧（試験 BC1-03、12 ヵ月報告）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 9.0) or Immediate Cause of Death / Cause of Death by Disease [a]	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Intensity	CTCAE grade	SAE	Relative Week of AE[b]	Duration of AE (day)	Related to study drug	Action taken to treat the event	Outcome
			Infection with normal ANC / Infection with normal ANC					7.3[c]		Unlikely		Death
			Renal failure acute	急性腎不全		4	Y	7.1	1	Unlikely	Medication	Death
BAY 88-8223 (55)	9002	70/M/C	Pulmonary oedema, LV dysfunction, mixed AVD / Disease progression					47.4[c]				Death
BAY 88-8223 (55)	9006	63/M/C	Disease progression / Disease progression					26.4[c]		Unlikely		Death
BAY 88-8223 (110)	1009	81/M/C	Prostate cancer / Disease progression					50.1[c]		Unlikely		Death
BAY 88-8223 (110)	1301	69/M/C	Multivisceral failure / Disease progression					40.0[c]		Unlikely		Death
BAY 88-8223 (110)	1303	73/M/C	Multivisceral failure / Disease progression					40.7[c]		Unlikely		Death
BAY 88-8223 (110)	1403	78/M/C	Cardiac arrest	心停止	Severe		Y	3.3	0	Unlikely	None	Death
			Worsening of health (due to cancer) / Heart attack, i.e. cardiac arrest					3.3[c]		Unlikely		Death

表 2.7.4.7- 17 死亡例の一覧（試験 BC1-03、12 ヵ月報告）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 9.0) or Immediate Cause of Death / Cause of Death by Disease [a]	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Intensity	CTCAE grade	SAE	Relative Week of AE[b]	Duration of AE (day)	Related to study drug	Action taken to treat the event	Outcome
BAY 88-8223 (110)	1603	58/M/C	Fatigue	疲労	Severe		Y	14.6	21	Unlikely	None	Death
			Extreme fatigue / Disease progression					17.6[c]		Unlikely		Death
BAY 88-8223 (110)	1605	64/M/C	Fatigue	疲労		4	Y	7.3	34	Unlikely	Therapy Other: BLOOD TRANSFUSION	Death
			Metastases to liver	肝転移	Severe		Y	11.6	4	Unlikely	None	Death
			Paraplegia	対麻痺		5	Y	11.6	4	Unlikely	None	Death
			Paraplegia, tetraplegia / Disease progression					12.1[c]		Unlikely		Death
BAY 88-8223 (110)	1609	60/M/C	Platelet count decreased	血小板数減少		2	N	14.0	91	Unlikely	None	Death
			Progression of disease / Disease progression					27.0[c]		Unlikely		Death
BAY 88-8223 (110)	1708	59/M/C	Acute peritonitis / Bad performance					36.0[c]		Unlikely		Death
BAY 88-8223 (110)	2201	71/M/C	Respiratory global insufficiency / Disease progression					44.7[c]		Unlikely		Death
BAY 88-8223 (110)	6001	71/M/C	Metastatic prostate cancer / Disease progression					43.6[c]		Unlikely		Death

表 2.7.4.7- 17 死亡例の一覧（試験 BC1-03、12 ヵ月報告）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 9.0) or Immediate Cause of Death / Cause of Death by Disease [a]	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Intensity	CTCAE grade	SAE	Relative Week of AE[b]	Duration of AE (day)	Related to study drug	Action taken to treat the event	Outcome
BAY 88-8223 (110)	7002	75/M/C	Disease progression – skeletal and lymph node metastases / Disease progression					21.0[c]		Unlikely		Death
BAY 88-8223 (110)	9004	78/M/C	Disease progression / Disease progression					31.9[c]				Death

Sex is identified as: M = Male.

Race is identified as: C = Caucasian

The unit for "Age" is years.

a: In case of adverse event with outcome death, preferred term of adverse events is listed. In case of death recorded on termination page, immediate cause of death and cause of death by disease are listed.

b: In case of missing dates, shortcuts after dates refer to whether month and day or just day (D) has been imputed. In case of death recorded on termination page, relative week of death is listed.

c: Relative week of death

Source: 5.3.5.1.8 A58307/Listing 14.3.2.1, 14.3.2.2, 14.3.2.16W.1, 16.2.4.16W.1

表 2.7.4.7- 18　死亡例の一覧（試験 BC1-03、24 ヵ月報告）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Immediate Cause of Death / Cause of Death by Disease	Relative Week of Death	Related to study drug	Outcome
BAY 88-8223 (6)	1004	63/M/C	Prostate cancer / Progression of metastatic prostate cancer (Skeletal)	80.3	Unlikely	Death
BAY 88-8223 (6)	1005	78/M/C	Prostate cancer / Progression of metastatic prostate cancer (Skeletal)	93.1	Unlikely	Death
BAY 88-8223 (6)	1017	61/M/C	Intra cerebral bleeding / Progression of metastatic prostate cancer (Brain)	54.6	Unlikely	Death
BAY 88-8223 (6)	1707	63/M/C	Acute respiratory and circulation insufficiency / Other than metastatic prostate cancer (Chronic heart insufficiency and chronic obstructive lung disease)	60.0	Unlikely	Death
BAY 88-8223 (6)	5003	73/M/C	Carcinomatosis / Progression of metastatic prostate cancer (Skeletal)	68.9	Unlikely	Death
BAY 88-8223 (6)	7007	77/M/C	Prostate cancer malignant disease / Progression of metastatic prostate cancer (Skeletal)	74.6	Unlikely	Death
BAY 88-8223 (6)	9001	73/M/C	Disease progression / Progression of metastatic prostate cancer (Skeletal)	70.9	Unlikely	Death
BAY 88-8223 (28)	1007	76/M/C	Prostate cancer / Progression of metastatic prostate cancer (Skeletal)	78.7	Unlikely	Death
BAY 88-8223 (28)	1027	62/M/C	Prostate cancer / Progression of metastatic prostate cancer (Skeletal Lymph Brain)	75.0	Unlikely	Death
BAY 88-8223 (28)	1101	70/M/C	Progression of disease / Progression of metastatic prostate cancer (Skeletal)	72.0	Unlikely	Death
BAY 88-8223 (28)	4011	67/M/C	PC with metastatis in lung / Progression of metastatic prostate cancer (Skeletal)	73.7	Unlikely	Death
BAY 88-8223 (55)	1003	59/M/C	Prostate cancer / Progression of metastatic prostate cancer (Skeletal)	61.4	Unlikely	Death
BAY 88-8223 (55)	1023	82/M/C	Prostate cancer / Progression of metastatic prostate cancer (Skeletal)	78.4	Unlikely	Death

表 2.7.4.7- 18　死亡例の一覧（試験 BC1-03、24 ヵ月報告）（続き）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Immediate Cause of Death / Cause of Death by Disease	Relative Week of Death	Related to study drug	Outcome
BAY 88-8223 (55)	4007	65/M/C	Pneumoni, Staphylococcus sepsis / Progression of metastatic prostate cancer (Skeletal)	57.6	Unlikely	Death
BAY 88-8223 (110)	1305	76/M/C	Death without defined cause in the context of the terminal illness / Progression of metastatic prostate cancer (Skeletal)	56.4	Unlikely	Death
BAY 88-8223 (110)	1308	58/M/C	Multivisceral failure / Progression of metastatic prostate cancer (Skeletal)	60.3	Unlikely	Death
BAY 88-8223 (110)	4002	74/M/C	Progressive cancer disease / Progression of metastatic prostate cancer (Skeletal)	68.0	Unlikely	Death
BAY 88-8223 (110)	4004	60/M/C	Progression of disease / Progression of metastatic prostate cancer (Skeletal Brain)	95.6	Unlikely	Death
BAY 88-8223 (110)	6005	74/M/C	Metastatic prostate cancer / Progression of metastatic prostate cancer (Skeletal)	65.6		Death
BAY 88-8223 (110)	7004	59/M/C	Prostate cancer / Progression of metastatic prostate cancer (Skeletal)	105.1	Unlikely	Death

Sex is identified as: M = Male.

Race is identified as: C = Caucasian

The unit for "Age" is years.

Source: 5.3.5.1.8 A58307/ Listing 16.2.4.16W.1, 5.3.5.1.9 A58314/Listing 14.3.2.24M.2

表 2.7.4.7- 19 死亡例の一覧（試験 BC1-04）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Adverse Events (AE) Preferred term (MedDRA version 9.0)	Intensity	CTCAE grade	SAE	Relative day of AE	Duration of AE (day)	Related to study drug	Specifica-tion of action	Outcome of AE
BAY 88-8223 (28)	804	68/M/C	Metastases to liver	肝転移	Severe		Y	73	6	Unlikely	None	Death
BAY 88-8223 (28)	904	78/M/C	Cardiac failure	心不全	Moderate		Y	78	-	Unlikely	Medication Therapy	Death
			Cardiac failure	心不全	Severe		Y	114	-	Unlikely	Medication Therapy	Death
BAY 88-8223 (28)	1402	71/M/C	Disease progression	疾患進行		5	Y	18	-	Unlikely	None	Death
BAY 88-8223 (55)	208	64/M/C	Metastatic squamous cell carcinoma	転移性扁平上皮癌		Severe	Y	34	70	Unlikely	None	Death
BAY 88-8223 (55)	903	73/M/C	Prostate cancer	前立腺癌	Severe		Y	153	-	Unlikely	Medication Therapy	Death
BAY 88-8223 (88)	401	82/M/C	Chest pain	胸痛		3	Y	54	3	Unlikely	Medication	Death

Sex is identified as: M = Male.

Race is identified as: C = Caucasian

The unit for "Age" is years.

Source: 5.3.4.2.1 A58308/Listing 16.2.4, 16.2.7.2

表 2.7.4.7- 20 死亡例の一覧（試験 BC1-09）

Treatment (kBq/kg)	Subject ID	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 12.1)	Adverse Events (AE) Preferred term (MedDRA version 12.1)	CTCAE grade	SAE	Relative Day of AE	Duration of AE	Related to study drug	Action taken with study treatment	Outcome of AE
BAY 88-8223 (55)	4004	73/F/C	Cardiac failure	心不全	5	Y	76	24	Unrelated	None	Death

Sex is identified as: F = Female.

Race is identified as: C = Caucasian, O = Other.

The unit for "Age" is years.

Source: 5.3.5.2.2 R-8779/Listing 16.2.4.1, 16.2.7.1, 16.2.7.2

表 2.7.4.7- 21 死亡例の一覧（試験 16430）

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 17.0)	Adverse Events (AE) Preferred term (MedDRA version 17.0)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
NO DATA AVAILABLE												

Sex is identified as: M = Male.

Race is identified as: A = Asian.

The unit for "Age" is years.

Phase is identified as: Pre = Pre-Treatment, TE = Treatment-Emergent, Post = Post-Treatment

Source: 5.3.5.2.8 16430_add 5/Table 1.4/2

表 2.7.4.7- 22 死亡例の一覧（試験 15354）

Treatment：Expansion Cohort

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 16.1)	Adverse Events (AE) Preferred term (MedDRA version 16.1)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
200030004	JPN	68/M/A	Upper respiratory tract infection	上気道感染	1	N	Pre	-5		N	DOSE NOT CHANGED	
			Upper respiratory tract infection	上気道感染	2	N	TE	8	16	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Cancer pain	癌疼痛	2	N	TE	27		N	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
			Gastric haemorrhage	胃出血	3	Y	Post	48	15	N	DRUG WITHDRAWN	RECOVERING/RESOLVING
			Tumour associated fever	腫瘍熱	1	N	Post	58		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Erythema	紅斑	2	N	Post	59		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Gastric haemorrhage	胃出血	2	N	Post	63		N	NOT APPLICABLE	RECOVERING/RESOLVING
			Lung infection	肺感染	2	Y	Post	65		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Nausea	悪心	2	N	Post	65		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Prostate cancer	前立腺癌	3	Y	Post	77		N	NOT APPLICABLE	
			Prostate cancer	前立腺癌	5	Y	Long	111	1	N	NOT APPLICABLE	FATAL
200030005	JPN	72/M/A	Hypoglycaemia	低血糖症	1	N	TE	2	1	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Vitreous haemorrhage	硝子体出血	2	N	TE	58		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED

表 2.7.4.7- 22 死亡例の一覧（試験 15354）（続き）

Treatment: Expansion Cohort

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 16.1)	Adverse Events (AE) Preferred term (MedDRA version 16.1)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Infection	感染	3	Y	TE	68		N	DOSE NOT CHANGED	
			Diabetes mellitus inadequate control	コントロール不良の糖尿病	3	N	TE	68		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Hypoaesthesia	感覚鈍麻	2	N	TE	68		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Constipation	便秘	1	N	TE	68		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Anaemia	貧血	3	N	TE	72	20	N	DOSE NOT CHANGED	RECOVERED/RESOLVED
			Infection	感染	1	Y	TE	75	21	N	DOSE NOT CHANGED	RECOVERING/RESOLVING
			Urinary retention	尿閉	2	N	TE	79		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Hypotension	低血圧	2	N	TE	92	1	N	DRUG INTERRUPTED	RECOVERED/RESOLVED
			Infection	感染	1	N	Post	96	11	N	DRUG INTERRUPTED	RECOVERED/RESOLVED
			Hepatic function abnormal	肝機能異常	3	N	Post	106		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Tumour associated fever	腫瘍熱	1	N	Post	106		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Prostate cancer	前立腺癌	4	Y	Post	109		N	NOT APPLICABLE	
			Prostate cancer	前立腺癌	5	Y	Post	118	1	N	NOT APPLICABLE	FATAL

表 2.7.4.7- 22 死亡例の一覧（試験 15354）（続き）

Treatment: Expansion Cohort

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 16.1)	Adverse Events (AE) Preferred term (MedDRA version 16.1)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
200030007	JPN	79/M/A	Haematuria	血尿	2	N	Pre	1		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Cancer pain	癌疼痛	3	N	TE	2		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Rectal haemorrhage	直腸出血	2	Y	TE	40		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Renal impairment	腎機能障害	3	N	TE	40		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Anaemia	貧血	3	N	TE	41		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Decubitus ulcer	褥瘡性潰瘍	2	N	TE	42		N	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
			Vomiting	嘔吐	1	N	TE	44		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Nausea	悪心	3	N	TE	44		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Rectal stenosis	直腸狭窄	3	N	TE	45		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Malaise	倦怠感	2	N	TE	48		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Delirium	譫妄	1	N	TE	49		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Hypocalcaemia	低カルシウム血症	3	N	TE	49		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Pyrexia	発熱	1	N	TE	49		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED

表 2.7.4.7- 22 死亡例の一覧（試験 15354）（続き）

Treatment: Expansion Cohort

Subject ID	Country	Age/ Sex/ Race	Adverse Events (AE) Preferred term (MedDRA version 16.1)	Adverse Events (AE) Preferred term (MedDRA version 16.1)	CTCAE grade	SAE	Phase	Relative Day of AE	Duration of AE	Related to study drug	Action Taken with Study Treatment	Outcome of AE
			Hypotension	低血圧	1	N	TE	49		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Prostate cancer	前立腺癌	3	Y	TE	49		N	NOT APPLICABLE	
			Lung infection	肺感染	3	Y	TE	58		N	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
			Prostate cancer	前立腺癌	5	Y	Post	59	1	N	NOT APPLICABLE	FATAL

Sex is identified as: M = Male.

Race is identified as: A = Asian.

The unit for "Age" is years.

Phase is identified as: Pre = Pre-Treatment, TE = Treatment-Emergent, Post = Post-Treatment, Long = Long-term Toxicities

Source: 5.3.3.2.6 15354_add 2/Table 1.4/2

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-001-001003	INCREASING CANCER RELATED BONE PAIN (CTC GRADE 2)[PT：癌疼痛] This 68 year old male patient experienced Increasing cancer related bone pain (CTC grade 2) 127 days after receiving first dose of study drug Alpharadin/placebo in this double blind, randomized, repeat dose, phase III, multicentre survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included atrial flutter, hypercholesterolaemia, hypertension, angina pectoris and lipomas.The event Increasing cancer related bone pain (CTC grade 2) is considered serious (hospitalized) and Listed for Alpharadin.The investigator assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor assessed the relationship to study drug as unrelated.
15245-001-001003	NAUSEA (CTC GRADE 3)[PT：悪心] VOMITING (CTC GRADE 3)[PT：嘔吐] Company causality assessment per License Partner Algeta:Events of NAUSEA (CTC GRADE 3) and VOMITING (CTC GRADE 3) are serious (hospitalization), listed and assessed by the Investigator and Sponsor as related to study drug.
15245-001-001003	ANEMIA (CTC GRADE 2)[PT：貧血] NAUSEA (CTC GRADE 3)[PT：悪心] VOMITING (CTC GRADE 3)[PT：嘔吐] INFECTION OF UNKNOWN ORIGIN (CTC GRADE 1)[PT：感染] INCREASED BONE PAIN (CTC GRADE 2)[PT：骨痛] This 68 year old male patient experienced ANEMIA (CTC GRADE 2), NAUSEA (CTC GRADE 3), VOMITING (CTC GRADE 3), INFECTION OF UNKNOWN ORIGIN (CTC GRADE 1) and INCREASED BONE PAIN (CTC GRADE 2) after using Alpharadin/placebo. The patient's medical history included lipoma, hypercholesterolemia, angina pectoris, atrial flutter and hypertension.The investigator considers the event of Nausea to be serious and probably related and the events of Anaemia, Vomiting, Infection of unknown origin and Increased bone pain to be serious and possiblyrelated to Alpharadin/placebo.The sponsor considers the event of Anaemia to be serious (hospitalized), possibly related and expected; the events of Nausea, Vomiting and Increased bone pain to be serious (hospitalized), unrelated and expected, and the event of Infection of unknown origin to be serious (hospitalized), unrelated and unexpected for Alpharadin.
15245-001-001003	ANEMIA (CTC GRADE 3)[PT：貧血] This 68 year old male patient experienced ANEMIA (CTC GRADE 3) and was hospitalized 46 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included lipomas, hypercholesterolemia, angina pectoris, atrial flutter and hypertension.The event ANEMIA (CTC GRADE 3) is considered serious (hospitalized) and Listed for Alpharadin.The investigator has assessed the relationship to study drug as possibly related but may also be related to the subject's advanced prostate cancer.The sponsor has assessed the relationship to study drug as possibly related.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-001-001003	INFECTION (CTC GRADE 2)[PT：感染] ANEMIA (CTC GRADE 2)[PT：貧血] VOMITING (CTC GRADE 2)[PT：嘔吐] This 68 year old male patient experienced INFECTION (CTC GRADE 2), ANEMIA (CTC GRADE 2) and VOMITING (CTC GRADE 2) and was hospitalized 51 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases. Relevant medical history was not provided.All events are serious (hospitalized). Event of INFECTION (CTC GRADE 2) is unlisted whereas events of ANEMIA (CTC GRADE 2) and VOMITING (CTC GRADE 2) are listed for Alpharadin. The investigator has assessed the relationship to study drug for the events of infection and vomiting as unrelated, but rather due to concurrent illness of prostate cancer. Causal assessment to study drug for the event of anemia is possibly related.The sponsor has assessed the relationship to study drug as unrelated for all the events.
15245-001-001012	INCREASED BONE PAIN IN BACK (CTC GRADE 2)[PT：脊椎痛] A 52 year old Caucasian male, enrolled in Phase III survival study BC1-06, experienced increased bone pain in his back which required overnight hospitalization 2 months and 13 days after initial administration of Alpharadin or placebo. A MRI showed skeletal metastases with no stenosis. Patient was treated with radiotherapy, lactulose, senna glycosides, metoclopramide, diazaepam and oxycodone hydrochloride. Patient recovered with sequela of skeletal back pain. Relevant medical history included bone pain in the back. Concomitant medications included prior docetaxel therapy, goserelin, ibuprofen, paracetamol with codeine, cetirizine hydrochloride and prednisolone. Increased bone pain in back was serious (hospitalization) and listed for Alpharadin. The investigator considers the event to be serious, and unrelated to Alpharadin/placebo. The sponsor has assessed the event to be serious and unrelated to Alpharadin.
15245-001-001012	CANCER RELATED BONE PAIN IN STERNUM (CTC GRADE)[PT：癌疼痛] Company causality assessment per License Partner Algeta:Event of CANCER RELATED BONE PAIN IN STERNUM is serious (hospitalized), listed and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to concurrent illness.
15245-001-001012	CANCER RELATED BONE PAIN IN THE BACK (CTC GRADE 2)[PT：骨痛] This 52 year old male patient experienced CANCER RELATED BONE PAIN IN THE BACK (CTC GRADE 2) and was hospitalized 47 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The subject had a relevant medical history of pain in back.The event CANCER RELATED BONE PAIN IN THE BACK (CTC GRADE 2) is considered serious (hospitalized) and Listed for Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-001-001014	SOMNOLENCE (CTC GRADE 3)[PT：傾眠] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-001-001014	BONE PAIN (CTC GRADE 2)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-001-001015	BRONCHITIS (CTC GRADE 2)[PT：気管支炎] 本症例には、プラセボが投与されていた。
15245-001-001015	CANCER RELATED BONE PAIN (CTC GRADE 3)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-001-001016	DROP FOOT LEFT LEG (CTC GRADE 2)[PT：腓骨神経麻痺] 試験薬は投与されていない。
15245-001-001019	UNSPECIFIED CHEST PAIN (CTC GRADE 2)[PT：胸痛] This study refers to a 70 year old Caucasian male with hormone-refractory prostate cancer with skeletal metastases who received Alpharadin or Placebo on 18-Sep-2009. The pt was admitted to hospital for observation due to UNSPECIFIED CHEST PAIN (CTC GRADE 2) on 28-Jan-2010. Medical history and concomitant conditions include cardiac infarction (1996), hypertension, hypercholesterolaemia, heart burn/ cardialgia, cancer related bone pain, bone fracture left leg (summer 2009) and retinal loosening. Concomitant medications include metoprolol, simvastatin, omeprazole, prednisolone, clopidogrel and goserelin. The subject received prior docetaxel therapy on 21-Jul-2009.UNSPECIFIED CHEST PAIN (CTC GRADE 2) is considered serious due to hospitalization and is not listed for Alpharadin. The investigator considered the event related to Alpharadin. Although the event occurred under active treatment with the suspect drug, company considers a causal involvement of Alpharadin to be highly unlikely as the pt's medical history of cardiac infarction (1996), hypertension, hypercholesterolaemia, heart burn/cardialgia are plausible explanations for the event.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-001-001019	ANEMIA (CTC GRADE 3)[PT：貧血] The investigator has assessed the relationship to study drug as possibly related due to the fact that the subject has had low haemoglobin since Feb 2010 (reported as an AE). The sponsor has assessed the relationship to study drug as possibly related.
15245-001-001020	ATRIAL FLUTTER (CTC GRADE 2)[PT：心房粗動] 本症例には、プラセボが投与されていた。
15245-001-001020	BONE PAIN (CTC GRADE 2)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-001-001021	PNEUMONITIS (CTC GRADE 2)[PT：肺臓炎] 試験薬は投与されていない。
15245-001-001022	SPINAL CORD CHANNEL COMPRESSION (CTC GRADE 3)[PT：脊髄除圧] REDUCED WALKING ABILITY (CTC GRADE 3)[PT：歩行障害] 本症例には、プラセボが投与されていた。
15245-001-001023	LIVER METASTASIS (CTC GRADE 3)[PT：肝転移] DISEASE PROGRESSION (CTC GRADE 4)[PT：前立腺癌] This 62 year old male patient experienced LIVER METASTASIS (CTC GRADE 3) and DISEASE PROGRESSION (CTC GRADE 4) 29 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included cancer related bone pain.The event LIVER METASTASIS (CTC GRADE 3) is considered serious (medically important event, hospitalized) and Unlisted for Alpharadin. The event DISEASE PROGRESSION (CTC GRADE 4) is considered serious (fatal, medically important event, hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated for both

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	events but rather due to concurrent illness.The sponsor has assessed the relationship to the study drug as unrelated for both events.
15245-001-001025	CHEST PAIN (CTC GRADE 2)[PT：骨痛] 試験薬は投与されていない。
15245-001-001027	NEUROPATHY - MOTOR AND SENSORY (CTC GRADE 4)[PT：末梢性感覚運動ニューロパチー] 本症例には、プラセボが投与されていた。
15245-001-001028	DEHYDRATION[PT：脱水] 本症例には、プラセボが投与されていた。
15245-001-001029	DEHYDRATION (GRADE 2)[PT：脱水] ANEMIA (CTC GRADE 3)[PT：貧血] This 66 year-old patient experienced and was hospitalized for dehydration (unlisted for Alpharadin) and anemia (listed) after Alpharadin/placebo was discontinued. The investigator has assessed the relationship to study drug probably related for anaemia and possibly related for dehydration and could not exclude the possibility that the study drug caused the anaemia. The sponsor has assessed the relationship to study drug as possibly related for both events.
15245-001-001029	ANEMI (CTC GRADE 3)[PT：貧血] THROMBOCYTOPENIA (CTC GRADE 3)[PT：血小板減少症] LEUCOCYTOPENIA (CTC GRADE 2)[PT：白血球減少症] This 66 year old male patient experienced ANEMI (CTC GRADE 3), THROMBOCYTOPENIA (CTC GRADE 3) and LEUCOCYTOPENIA (CTC GRADE 2) and was hospitalized 29 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included skeletal metastasis and bone pain due to skeletal metastases.The events ANEMI (CTC GRADE 3), THROMBOCYTOPENIA (CTC GRADE 3) and LEUCOCYTOPENIA (CTC GRADE 2) are considered serious (hospitalized) and Listed for Alpharadin. The investigator has assessed

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	the relationship to study drug as probably related for all three events.The sponsor has assessed the relationship to study drug as possibly related.
15245-001-001030	CONSTITUTIONAL SYMPTOM CONFUSION DUE TO MENINGEAL METASTASES (CTC GRADE 4)[PT：錯乱状態] 本症例には、プラセボが投与されていた。
15245-001-001030	DEATH DUE TO PNEUMONIA (CTCAE GRADE 5)[PT：肺炎] 本症例には、プラセボが投与されていた。
15245-001-001035	INFECTION (UNKNOWN ORIGIN) (CTC GRADE 2)[PT：感染] This clinical trial case report from a license partner refers to a 75 year old Caucasian male who was enrolled in a double blind, randomised, repeat dose, phase III, multicentre survival study of AlpharadinTM in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases, and received one study drug injection and experienced INFECTION OF UNKNOWN ORIGIN. X-Ray of thorax revealed the uncertain finding of possible infiltrate left side, lab data revealed a max CRP of 145 mg/l, leucocytes and neutrophils were whithin normal range. Patient was treated with cefotaxime, and recovered. Study medication was unchanged.The investigator has assessed the relationship to study drug as unrelated. The investigator stated that an alternative explanation was unknown.The reported event of INFECTION OF UNKNOWN ORIGIN is serious de to hospitalization and unexpected in the Investigator´s Brochure of Alpharadin.The sponsor has assessed the relationship to study drug as unrelated.
15245-001-001035	FRACTURA COLLI FEMORIS[PT：病的骨折] This 75 year old male patient experienced FRACTURA COLLI FEMORIS 66 days after the patient received the first dose of Alpharadin/placebo in this double blind, randomized, repeat dose, phase III, multicentre survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's medical history included prosthesis surgery left knee. The patient's concurrent condition included cancer related bone pain, nausea, hypertension and weight loss.The event FRACTURA COLLI FEMORIS is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated, but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-001-001035	THROMBOCYTOPENIA (CTC GRADE 2)[PT：血小板減少症] PAIN IN THE HIP (CTC GRADE 3)[PT：医療機器による疼痛] This 76 year old male patient experienced THROMBOCYTOPENIA (CTC GRADE 2) and PAIN IN THE HIP (CTC GRADE 3) and enrolled in a study of hormone-refractory prostate cancer with skeletal metastases. The patient's medical history included hospitalized 29 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of prosthesis surgery left knee. The patient's concurrent condition included cancer related bone pain, nausea, hypertension and weight loss.The event THROMBOCYTOPENIA (CTC GRADE 2) is considered serious (medically important event) and Listed for Alpharadin. The event PAIN IN THE HIP (CTC GRADE 3) [coded to 'Medical Device Complication' - MedDRA] is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated for the event of pain in the hip but rather due concurrent illness of fractura colli femoris and surgery. The investigator has assessed the relationship to study drug as possibly related for the event of thrombocytopenia.The company agrees with this and assesses the relationship to study drug as unrelated for the event pain in the hip and possibly related for the event of thrombocytopenia.
15245-001-001035	URINARY INFECTION (CTC GRADE 3)[PT：尿路感染] ANAEMIA (CTC GRADE 2)[PT：貧血] （本例は PMDA へ報告を行った症例である。弊社の見解を日本語で示す） 検査値等の詳細情報が不足しているが、本剤の投与後に発現していることを勘案し、時間的関連性の観点よりいずれの事象も本剤との因果関係は否定できないと考える。
15245-001-001035	URINARY RETENTION (CTC GRADE 3)[PT：尿閉] This 76-year-old male patient experienced URINARY RETENTION (CTC GRADE 3) and was hospitalized 77 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's medical history included prosthesis surgery left knee. The patient's concurrent condition included cancer related bone pain, nausea, hypertension and weight loss. The patient later died due to the prostate cancer.The event URINARY RETENTION (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due concurrent illness. The sponsor has assessed the relationship to study drug as unrelated.
15245-001-001038	THROMBOCYTOPENIA (CTC GRADE 3)[PT：血小板減少症] ANAEMIA (CTC GRADE 3)[PT：貧血] HEMORRHAGE-BLADDER (CTC GRADE 3)[PT：膀胱出血] PROSTATE CANCER WITH SKELETAL METASTASES[PT：骨転移] PROSTATE CANCER WITH SKELETAL METASTASES[PT：遠隔転移を伴う前立腺癌] 本症例には、プラセボが投与されていた。
15245-001-001041	DEHYDRATION (CTC GRADE 3)[PT：脱水] This 63 year old male patient experienced DEHYDRATION (CTC GRADE 3) and was hospitalized 2 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included skeletal metastases, hypertension, hypercholesterolemia, bone pain and bilateral lymph oedema.The event DEHYDRATION (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as possibly related. He stated that the reduced appetite and fluid intake occurred after the recent study drug application and may have

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	caused the dehydration.The company considers the event unrelated to study drug. It may have been consequence of reduced appetite and fluid intake which is often caused by underlying carcinoma.The sponsor has assessed the relationship to study drug as unrelated.
15245-001-001041	DEHYDRATION (CTC GRADE 2)[PT：脱水] ANAEMIA (CTC GRADE 2)[PT：貧血] REDUCED PHYSICAL CONDITION (CTC GRADE 2)[PT：無力症] This clinical trial case report (forwarded by Algeta) referring to a 64 year old male with known history of hypertension, hypercholesterolemia, bone pain due to skeletal metastases, pneumonia and lymph oedema both legs, enrolled in study BC1-06 (for patients with hormone-refractory prostate cancer with skeletal metastases) and received first dose of study medication Alpharadin (BAY 88-8223)/Placebo on 04-Jan-2011 to 26-Apr-2011(receiving date of last injection), prior to permanent discontinuation of study drug. Dehydration (hospitalized) and docetaxel therapy were reported prior to these events.Approximately one month after receiving last dose, patient experienced DEHYDRATION (CTCAE Grade 2) and REDUCED PHYSICAL CONDITION (CTCAE Grade 2) considered serious due to hospitalization and unlisted as per investigational brochures of Alpharadin (Bay 88-8223). ANEMIA (CTCAE Grade 2) was reported based on low hemoglobin level (8.8 g/dl), considered serious medically important / listed. The events were either resolved or resolved with sequelae.The investigator assessed the relationship to study drug as possibly related to DEHYDRATION, REDUCED PHYSICAL CONDITION and ANEMIA, sponsors concurs only for ANEMIA. Based on product safety profile, patient underlying medical condition / weak temporal relationship (an interval of one month) sponsor considered causality assessment for DEHYDRATION, REDUCED PHYSICAL CONDITION unrelated citing underlying metastatic malignancy is more plausible alternative explanation.
15245-002-002004	LEFT VENTRICULAR SYSTOLIC DYSFUNCTION[PT：左室機能不全] LOWER BACK AND RIGHT LEG PAIN (CTC GRADE 3)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-002-002006	SPINAL CORD COMPRESSION (CTC GRADE 3)[PT：脊髄圧迫] Company causality assessment per License Partner Algeta:Event of SPINAL CORD COMPRESSION (CTC GRADE 3), is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to progressive prostate cancer.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-002-002006	SEPSIS (CTC GRADE 4)[PT：敗血症] This 66 year old Caucasian male who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced SEPSIS (CTC GRADE 4) 23 days after the onset of study drug and subsequently died. Prior to the onset of the event, the subject received 3 study injections. The subject has no relevant medical history. SEPSIS (CTC GRADE 4) is considered serious (hospitalization, fatal) and unlisted for Alpharadin.The investigator's assessment of the relationship to study drug is unrelated but rather due to the subject's progressive prostate cancer. The subject was suffering with liver metastases (confirmed via a biopsy), skeletal and soft tissue metastases, bone marrow affection, anaemia and subsequently sepsis. The sponsor assessed the relationship to study drug as unrelated.
15245-002-002008	SKELETAL PAIN (CTC GRADE 3)[PT：骨痛] This 69 year old male patient experienced SKELETAL PAIN (CTC GRADE 3) and was hospitalized 5 days after receiving the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included low back pain and left hip pain.The event SKELETAL PAIN (CTC GRADE 3) is considered serious (hospitalized) and Listed for Alpharadin. The investigator has assessed the relationship to study drug as unrelated. An alternative explanation was not reported.The sponsor has assessed the relationship to study drug as unrelated.
15245-002-002008	HYPERGLYCAEMIA (CTC GRADE 4)[PT：高血糖] This case refers to a 69 year old male patient who enrolled in study BC1-06 who has been receiving Alpharadin or placebo for hormone-refractory prostate cancer since Oct-2009.From Apr 2010, prior to the onset of the event, the subject was reported to have been on insulin. On 04 Apr 2010 the subject was admitted to hospital due to HYPERGLICEMIA which is serious (hospitalized) and listed in the Investigator´s Brochure of Alpharadin. The investigator has assessed the relationship to study drug as unrelated, but rather due to concurrent illness. The investigator suspected the subject to have had a long-term hyperglycemia (high level of HbA1c (10.1%) suggests high levels of blood glucose over the previous weeks to months). Company considers the event to be unrelated for Alpharadin mostly because of the incompatible temporal condition.
15245-002-002008	INFECTION NOS (CTC GRADE 3)[PT：感染] This 69 year old male patient experienced INFECTION NOS (CTC GRADE 3) and was hospitalized 38 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event INFECTION NOS (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated, but rathe due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-002-002008	THROMBOCYTOPENIA (CTC GRADE 4)[PT：血小板減少症] ANAEMIA (CTC GRADE 4)[PT：貧血] The company has received a double blind, randomized phase III sponsored clinical trial report from (Algeta), referring a 69 year old Caucasian male patient (pt) enrolled in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases, received first dose of study medication (Alpharadin/Placebo) on 28-Oct-2009. No relevant information regarding past medical history including concomitant medications were provided. The patient did receive prior docetaxel therapy by Aug-2009.Prior hospitalizations due to hyperglycemia and infection (see Ref. cases /dates) were reported. Two months prior to the onset of the events the patient had received 06 study injections, therefore, action taken with study drug not applicable for reported events.Patient was hospitalized due to ANAEMIA (CTC grade 4) considered serious due to hospitalization and THROMBOCYTOPENIA (CTC grade 4) considered serious due to hospitalization and disability. Both events were considered listed as per

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	investigational brochures of Alpharadin (Bay 88-8223). Patient was transfused with 04 units red blood cells and 02 units of platelets. ANAEMIA was resolved on day two from onset date while patient was not recovered from THROMBOCYTOPENIA at the time of discharge. Two months later patient died from prostate cancer which was assessed as unrelated to the study drug. Of note, thrombocytopenia was ongoing at the time of death.The investigator causality assessment for ANAEMIA and THROMBOCYTOPENIA as possibly related to Alpharadin (Bay 88-8223)/placebo, sponsor (company) concurs. It is worth to mention that continuation of thrombocytopenia (till death), despite study drug was stopped and weak temporal association favors to assume underlying preexisting advanced metastatic disease as possible alternative explanation.
15245-002-002009	BACK PAIN (OSTEOPOROSIS)(CTC GRADE 3)[PT：背部痛] Company causality assessment per License Partner Algeta:Event of BACK PAIN (OSTEOPOROSIS) (CTC GRADE 3) is serious (hospitalized / medically significant), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to concurrent illness.
15245-002-002009	COMPRESSION FRACTURE LUMBAL COLUMN (CTC GRADE 3)[PT：病的骨折] This 74 year old male patient experienced COMPRESSION FRACTURE LUMBAL COLUMN (CTC GRADE 3) after the use of Alpharadin/Placebo. The patient's concurrent condition included back pain (osteoporosis).The investigator has assessed the relationship to study drug as unrelated but rather due to osteoporosis and not disease progression.The sponsor has assessed this event as serious (hospitalized), unrelated and unexpected for Alpharadin.
15245-002-002009	METASTATIC BONE PAIN (CTC GRADE 3)[PT：転移部痛] This 74 year old male patient experienced METASTATIC BONE PAIN (CTC grade 3) (previously TRAUMATIC FRACTURE OF TH11-L5) 132 days after receiving the first dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. Patient had no relevant medical history.The event METASTATIC BONE PAIN (CTC grade 3) is considered serious (hospitalized) and listed for Alpharadin.The investigator has assessed the event relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the event relationship to study drug as unrelated.
15245-002-002011	PAIN SKELETAL (CTC GRADE 3)[PT：骨痛] SUSPECT OF SEPTICEMIA (CTC GRADE 3)[PT：敗血症] 本症例には、プラセボが投与されていた。
15245-002-002013	HAEMORRHAGE CEREBRAL (CTC GRADE 3)[PT：脳出血] This 70 year old male patient experienced HAEMORRHAGE CEREBRAL (CTC GRADE 3) and was hospitalized 16 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient later died due to this event. The patient's medical history included constipation, pain skeletal and hypertension.The event HAEMORRHAGE CEREBRAL (CTC GRADE 3) is considered serious (fatal, hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as possibly related. The investigator stated that none of the subject's medical history could have been related to the

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	haemorrhage.The sponsor has assessed the relationship to study drug as possibly related.
15245-002-002014	WORSENING OF SKELETAL PAIN (CTC GRADE 3)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-002-002014	IMMINENT SPINAL CORD COMPRESSION (CTC GRADE 3)[PT：脊髄圧迫] 本症例には、プラセボが投与されていた。
15245-002-002014	INFECTION WITH ANC GRADE 2 (CTC GRADE 3)[PT：好中球減少性感染] 本症例には、プラセボが投与されていた。
15245-002-002015	HEMORRHAGE, CNS (CTC GRADE 2)[PT：脳出血] IMMINENT SPINAL CORD COMPRESSION (CTC GRADE 3)[PT：脊髄圧迫] DISEASE PROGRESSION (CTC GRADE 4)[PT：悪性新生物進行] 本症例には、プラセボが投与されていた。
15245-002-002017	SUPRAVENTRICULAR TACHYCARDIA (CTC GRADE 3)[PT：上室性頻脈] This 80 year old male patient experienced supraventricular tachycardia (CTC grade 3) and was hospitalized 23 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included hypertension, skeletal pain, paroxystic atrial fibrillation, aneurynm of the aorta and iliac, cuts sore left leg, urostomy, cysts in both kidneys and cancer vesica urinaria.The event supraventricular tachycardia (CTC grade 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-002-002017	ATRIAL FLUTTER (CTC GRADE 2)[PT：心房粗動] This 80 year old Caucasian male, who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced ATRIAL FLUTTER (CTC GRADE 2) 77 days after the last dose of study medication. Prior to onset of the event, the subject received 6 study injections.The subject's concurrent condition included hypertension, pain skeletal, paroxysmal atrial fibrillation, aneurysm of aorta and iliac, cancer vesica urinaria, cuts sore left leg, urostomy and cysts in both kidneys.ATRIAL FLUTTER (CTC GRADE 2) is considered serious (hospitalization) and unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated, but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-002-002018	WORSENING OF SKELETAL RELATED PAIN (CTC GRADE 3)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-002-002018	DISEASE PROGRESSION (CTC GRADE 3)[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-002-002018	BRAIN METASTASES (CTC GRADE 4)[PT：中枢神経系転移] 本症例には、プラセボが投与されていた。
15245-003-003001	ANEMIA (CTC GRADE 3)[PT：貧血] ANEMIA is considered serious due to hospitalization. The event is listed in the Investigator Brochure for Alpharadin/Placebo. In line with investigator, company assesses the event as possible associated with the study drug. However disease progression may provide a plausible alternative explanation for the event.
15245-003-003001	NEUTROPENIA (CTC GRADE 3)[PT：好中球減少症] Company causality assessment per License Partner Algeta:Event of NEUTROPENIA (CTC GRADE 3) is serious (hospitalized), listed and assessed by the Investigator and Sponsor as related to study drug.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-003-003003	LEFT PELVIS PAIN (CTCAE GRADE 2)[PT：骨痛] NAUSEA (CTCAE GRADE 3)[PT：悪心] 本症例には、プラセボが投与されていた。
15245-003-003003	SPINAL CORD COMPRESSION (CTC GRADE 3)[PT：脊髄圧迫] 本症例には、プラセボが投与されていた。
15245-003-003005	INFECTION - PULMONARY, PNEUMONIA (CTC GRADE 3)[PT：肺炎] This 59 year old male patient developed INFECTION - PULMONARY, PNEUMONIA (CTC GRADE 3) and was hospitalized 40 days after receiving the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included advanced prostate cancer.The event INFECTION - PULMONARY, PNEUMONIA (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-003-003005	PLEURAL EFFUSION (CTC GRADE 3)[PT：胸水] Company causality assessment per License Partner Algeta:Event of PLEURAL EFFUSION (CTC GRADE 3), is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to cancer progression.
15245-003-003007	URINARY FREQUENCY/URGENCY[PT：尿意切迫] Company causality assessment per License Partner Algeta:Event of URINARY FREQUENCY/URGENCY, is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-003-003010	PAIN IN PELVIS (CTC GRADE 3)[PT：骨痛] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-003-003011	VOMITING (CTC GRADE 3)[PT：嘔吐] PNEUMONIA (CTC GRADE 2)[PT：肺炎] METASTATIC BONE PAIN IN PELVIS (CTC GRADE 3)[PT：転移部痛] 本症例には、プラセボが投与されていた。
15245-003-003011	METASTATIC BONE PAIN[PT：転移部痛] 本症例には、プラセボが投与されていた。
15245-003-003013	SKELETAL PAIN IN PELVIS (CTC GRADE 3)[PT：骨痛] MULTIPLE FRACTURES (CTC GRADE 4)[PT：病的骨折] RAPIDLY PROGRESSING CANCER (CTC GRADE 4)[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-003-003014	MUSCULOSKELETAL PAIN (CTC GRADE 3)[PT：筋骨格痛] This 56 year old male patient experienced MUSCULOSKELETAL PAIN (CTC GRADE 3) and was hospitalized 35 days after receiving the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included prostate cancer. The event MUSCULOSKELETAL PAIN (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated, but rather due to disease progression.The sponsor has assessed the relationship to study drug as unrelated.
15245-003-003014	MUSCULOSKELETAL PAIN (CTC GRADE 3)[PT：筋骨格痛] This 56 year old male patient patient experienced / suffered from Musculoskeletal Pain (CTC grade 3) 62 days after the last received injection of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The subject had no relevant medical history.The event Musculoskeletal Pain (CTC grade 3) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated, but rather due to disease progression.The sponsor has assessed the relationship to study drug as unrelated.
15245-003-003015	FRACTURE (COSTAE)[PT：肋骨骨折] Company causality assessment per License Partner Algeta:Event of FRACTURE (COSTAE), is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-003-003015	MEDULLA (SPINAL) COMPRESSION (CTC 3)[PT：脊髄圧迫] MUSCULOSKELETAL PAIN IN THORAX COLUMNA AND OS ILIUM (CTC 3)[PT：骨痛] The case refers to a 73-year-old male patient in a double blind, randomised, repeat dose, phase III, multicentre survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. He experienced severe MEDULLA (SPINAL) COMPRESSION (CTC 3) and severe MUSCULOSKELETAL PAIN IN THORAX COLUMNA AND OS ILIUM (CTC 3) which are serious events due to hospitalization and are unlisted in the Investigator´s Brochure of Alpharadin. Relevant medical history included prostate cancer.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness for both events.The sponsor has assessed the relationship to study drug as unrelated for both events.
15245-003-003016	COMPRESSION FRACTURE L1 AND L2 (CTC GRADE 3)[PT：脊椎圧迫骨折] CONSTIPATION (CTC GRADE 3)[PT：便秘] （本例は PMDA へ報告を行った症例である。弊社の見解を日本語で示す） 「便秘」については、臨床経過等の詳細情報が不足しているが、本剤の投与後に発現していること並びに医師意見を勘案し、時間的関連性の観点より、本剤との因果関係は否定できないと考える。 「脊椎圧迫骨折」については、医師意見に同意できると考え、本剤との因果関係を否定できると考える。
15245-003-003016	MUSCULOSKELETAL PAIN LOWER BACK (CTC GRADE 3)[PT：筋骨格痛] This 78 year old Caucasian male, who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced MUSCULOSKELETAL PAIN LOWER BACK (CTC GRADE 3) 142 days after receiving the first dose of study drug. The subject's relevant medical history included compression fracture in L1 and L2 and bone metastases. MUSCULOSKELETAL PAIN LOWER BACK (CTC GRADE 3) is considered serious (hospitalization) and listed for Alpharadin. The investigator has assessed the relationship to study drug as unrelated.The sponsor has assessed event as listed and unrelated.
15245-003-003017	WORSENING MUSCULOSKELETAL PAIN IN BACK-LOWER BACK PAIN[PT：筋骨格痛] This 64 year old Caucasian male, who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced worsening musculoskeletal pain in back-lower back pain (CTCAE grade 2) (previously musculoskeletal pain in back-lower back pain) 106 days after taking first dose of study drug. The subject's relevant medical history included musculoskeletal pain and hypercholesterolemia.Musculoskeletal pain in back-lower back pain is considered serious (hospitalization) and unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated, but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-003-003017	MUSCULOSKELETAL PAIN (CTC GRADE 3)[PT：筋骨格痛] This 64 year old male patient experienced MUSCULOSKELETAL PAIN (CTC GRADE 3) and was hospitalized while in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event MUSCULOSKELETAL PAIN (CTC GRADE 3) is considered serious (hospitalized) and unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated, but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-003-003017	FRACTURES/FRACTURA COLLI FEMORIS (CTCAE GRADE 3)[PT：大腿骨頚部骨折] This 64 year old male patient experienced fractures/fractura colli femoris (CTC grade 4) and was hospitalized 55 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included arthritis. The event FRACTURES/FRACTURA COLLI FEMORIS (CTCAE GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to the subject falling on an icy ground.The Sponsor has assessed the relationship to study drug as unrelated.
15245-003-003018	MUSCULOSKELETAL PAIN (CTC GRADE 3)[PT：筋骨格痛] This 71 year old male patient experienced MUSCULOSKELETAL PAIN (CTC GRADE 3) and was hospitalized 15 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. Patient had no relevant medical history.The event MUSCULOSKELETAL PAIN is considered serious (hospitalized) and unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor considers the relationship to study drug as unrelated.
15245-003-003018	MUSCULOSKELETAL PAIN (CTC GRADE 3)[PT：筋骨格痛] This 71 year old male patient experienced musculoskeletal pain (CTC grade 3) and was hospitalized 29 days after the last dose received of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastasis. The patient's concurrent condition included hypertension.The event musculoskeletal pain (CTC grade 3) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator assessed the relationship to study drug as unrelated but rather due to prostate cancer.The sponsor assessed the relationship to study drug as unrelated.
15245-003-003018	PROSTATE CANCER WITH METASTASES[PT：遠隔転移を伴う前立腺癌] A 72 year old male Caucasian patient died due to PROSTATE CANCER WITH METASTASES 75 days after taking the last dose of study medication (Alpharadin- as complete study has been unblinded, patient allocated to Alpharadin) in a double blind, randomized, repeat dose, phase III, multicentre survival study of AlpharadinTM in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had relevant medical history of hypertension and completed his 06 study injections. History of prior two hospitalizations was positive due to musculoskeletal pain. (See ref cases #. ALG-BC1-06-0837and ALG-BC1-06-0845). PROSTATE CANCER WITH METASTASES [coded with (PT) of Prostate cancer / and (LLT) of progression of prostate cancer as per company coding conventions] is considered serious (fatal outcome)/ unlisted in the Investigators Brochure of Alpharadin. The investigator considers causal association unrelated to Alpharadin but rather due to concurrent illness (prostate cancer). The sponsor has assessed the relationship to study drug as unrelated.
15245-004-004001	EDEMA (CTC GRADE 3)[PT：浮腫] PLEURAL EFFUSION (CTC GRADE 2)[PT：胸水] PANCYTOPENIA (BLOOD/BONE MARROW-OTHER) (CTC GRADE 3)[PT：汎血球減少症] DYSPNEA (CTC GRADE 3)[PT：呼吸困難] This 61 year old male patient experienced developed EDEMA (CTC GRADE 3), PLEURAL EFFUSION (CTC GRADE 3), PANCYTOPENIA (BLOOD/BONE MARROW-OTHER) (CTC GRADE 3) and DYSPNEA (CTC GRADE 3) 12 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases. Patient had no relevant medical history. The event EDEMA (CTC GRADE 3) is considered serious (hospitalized, medically important event) and Unlisted for Alpharadin. The events PLEURAL EFFUSION (CTC GRADE 3) and DYSPNEA (CTC GRADE 3) are considered serious (hospitalized) and Unlisted for Alpharadin. The event PANCYTOPENIA (BLOOD/BONE MARROW-OTHER) (CTC GRADE 3) is considered serious (hospitalized) and Listed for

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	Alpharadin.The investigator has assessed the relationship to study drug as possibly related for the events of edema, pleural effusion, pancytopenia and dyspnea. It was later confirmed that the event of anemia was not a separate event and this event was deleted as an SAE. The anemia was already incorporated in the SAE term of pancytopenia. The investigator reported that the treatment related toxicity was considered as the most likely explanation, no other diagnosis was made. The subject did not have any history of cardiac/pulmonary disease and side effects were a possible explanation for the events pleural effusion and edema. The investigator stated the risk for edema from zoledronic acid was 0.1-1% and pleural effusion was not mentioned in the list of potential side effects.The sponsor has assessed the relationship of the events dyspnea, pleural effusion and edema as unrelated to study drug and the event pancytopenia as possibly related to study drug.
15245-004-004001	DYSPNEA (CTC GRADE 3)[PT：呼吸困難] EDEMA (CTC GRADE 3)[PT：浮腫] KIDNEY FAILURE[PT：腎不全] PANCYTOPENIA (CTC GRADE 4)[PT：汎血球減少症] PLEURAL EFFUSION (CTC GRADE 2)[PT：胸水] This 61 year old male patient experienced DYSPNEA, EDEMA, PANCYTOPENIA, PLEURAL EFFUSION and KIDNEY FAILURE while in this clinical study of Alpharadin in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event DYSPNEA is considered serious (hospitalized) and Unlisted for Alpharadin. The event EDEMA is considered serious (hospitalized) and Unlisted for Alpharadin. The event KIDNEY FAILURE is considered serious (fatal, hospitalized) and Unlisted for Alpharadin. The event PANCYTOPENIA is considered serious (medically important event) and Listed for Alpharadin. The event PLEURAL EFFUSION is considered serious (medically important event) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as possibly related for the events of dyspnea, edema, pancytopenia and pleural effusion. The events of anemia and thrombocytopenia were later confirmed as not separate events and were deleted as SAEs. Both events were incorporated in the SAE term of pancytopenia. It was reported that the events of edema and dyspnea were considered possibly related because the event of edema was detected at week 16 (visit date 02 Mar 2009), which was before a significant rise in prostate-specific antigen (PSA) and any other abnormalities associated with cancer progression were found. The event of dyspnea was also reported before any imaging abnormalities were detected. The investigator has assessed the relationship to study drug as unrelated for the event of kidney failure. In the investigators opinion the kidney failure was most likely related to bleeding and hypovolemia.Sponsor has assessed the relationship to study drug as related for pancytopenia and unrelated for all other events.
15245-004-004002	VOMITING (CTC GRADE 3)[PT：嘔吐] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-004-004002	BONE PAIN (CTC GRADE 3)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-004-004002	BONE PAIN (CTC GRADE 4)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-004-004007	BONE PAIN FROM SKELETAL METASTASES[PT：転移部痛] Company causality assessment per License Partner Algeta:Event of BONE PAIN FROM SKELETAL METASTASES, is serious due to hospitalization, listed and assessed by the Investigator and Sponsor as unrelated to study drug.
15245-005-005002	PNEUMONIA[PT：肺炎] ATRIAL FIBRILLATION (CTC GRADE 2)[PT：心房細動] ATRIAL FLUTTER[PT：心房粗動] Company causality assessment per License Partner Algeta:Event PNEUMONIA is serious due to hospitalization; events ATRIAL FIBRILLATION and ATRIAL FLUTTER are serious due to prolongation of hospitalization; all unexpected in the Investigator's Brochure of Alpharadin and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to concurrent illness.
15245-005-005002	BONE PAIN (CTC GRADE 3)[PT：骨痛] ANAEMIA (CTC GRADE 2)[PT：貧血] This 76 year old male patient experienced BONE PAIN (CTC GRADE 3) and ANAEMIA (CTC GRADE 2) and was hospitalized almost 2 months after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included osteo-arthritis in the right shoulder.The events BONE PAIN (CTC GRADE 3) and ANAEMIA (CTC GRADE 2) are considered serious (hospitalized) and Listed for Alpharadin. The investigator has assessed the relationship to study drug for bone pain as unrelated, but rather due to a concurrent illness. The relationship to study drug for anaemia has been assessed as possibly related.The sponsor has assessed the relationship to the study drug as unrelated for bone pain and as possibly related for anaemia.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-005-005002	HEART FAILURE DUE TO PULMONARY EMBOLISM (CTC GRADE 4)[PT：肺塞栓症] HEART FAILURE DUE TO PULMONARY EMBOLISM (CTC GRADE 4)[PT：心不全] （本例は PMDA へ報告を行った症例である。弊社の見解を日本語で示す） 肺塞栓症については、本剤の最終投与から約１ヶ月後に患者が肺炎で入院している事実、及び治験担当医の意見である本剤投与による長期的影響が確立されていないことを勘案し、因果関係を完全には否定できないと考える。 心不全については、肺塞栓症によるものと考えられ、肺塞栓症と同様の理由により、因果関係を完全には否定できないと考える。
15245-005-005003	BONE PAIN (CTC GRADE 2)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-006-006001	URINARY TRACT INFECTION (CTC GRADE 3)[PT：尿路感染] The investigator has assessed the relationship to study drug as unrelated. The sponsor has assessed the relationship to study drug as unrelated.
15245-006-006001	RENAL FAILURE (CTC GRADE 3)[PT：腎不全] Company causality assessment per License Partner Algeta:Event of RENAL FAILURE (CTC GRADE 3) is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to concurrent illness.
15245-006-006001	PAIN MUSCULOSKELETAL BONE (CTC GRADE 3)[PT：筋骨格痛] Company causality assessment per License Partner Algeta:Event of PAIN MUSCULOSKELETAL BONE (CTC GRADE 3), is serious due to hospitalization, listed and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-006-006002	FOOD POISONING (CTC GRADE 2)[PT：食中毒] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-006-006003	PAIN-MUSCULOSKELETAL-BACK (BONE PAIN) (CTC GRADE 2)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-006-006004	INFECTION UPPER RESPIRATORY (CTC GRADE 2)[PT：上気道感染] Company causality assessment per License Partner Algeta:Event of INFECTION UPPER RESPIRATORY (CTC GRADE 2), is serious due to hospitalization, listed and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-006-006005	DEHYDRATION (CTC GRADE 2)[PT：脱水] FEVER (CTC GRADE 2)[PT：発熱] This 72 year old male patient experienced DEHYDRATION (CTC GRADE 2) and FEVER (CTC GRADE 2) 22 days after receiving the first dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included prostate cancer.The events DEHYDRATION (CTC GRADE 2) and FEVER (CTC GRADE 2) are considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated for both events.The sponsor has assessed the relationship to study drug as unrelated for both events.
15245-006-006005	FEVER (CTC GRADE 2)[PT：発熱] VOMITING (CTC GRADE 1)[PT：嘔吐] DEHYDRATION (CTC GRADE 2)[PT：脱水] PAIN (MUSCULOSKELETAL) (CTC GRADE 2)[PT：筋骨格痛] This 73 year old male patient experienced FEVER (CTC GRADE 2), VOMITING (CTC GRADE 1), DEHYDRATION (CTC GRADE 2) and PAIN (MUSCULOSKELETAL) (CTC GRADE 2) and was hospitalized 10 days after taking the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included prostate cancer and skeletal metastases. The patient had previous event of dehydration and fever.Events of FEVER (CTC GRADE 2), DEHYDRATION (CTC GRADE 2) and PAIN (MUSCULOSKELETAL) (CTC GRADE 2) are unlisted in the Investigator's Brochure for Alpharadin whereas VOMITING (CTC GRADE 1) is listed. All events are serious (hospitalized).The investigator has assessed the relationship to study drug as possibly related for fever and dehydration because the study drug was administered a week before the events started, although the investigator does not believe that there is a causality. The investigator has assessed the relationship to the study drug for vomiting and pain as unrelated. The pain was expected to be caused by skeletal metastasis.The sponsor has assessed the relationship to study drug as unrelated for all events.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-006-006005	DEHYDRATION (CTC GRADE 2)[PT：脱水] PAIN (CTC GRADE 2)[PT：骨痛] VOMITING (CTC GRADE 2)[PT：嘔吐] The investigator has assessed the relationship to study drug as possibly related for vomiting, and unrelated for pain and dehydration.Company agrees with investigator and assesses the relationship to study drug as possibly related for the events of pain and vomiting (both expected) and unrelated for the event of dehydration (unexpected).
15245-006-006005	PAIN-MUSCULOSKELETAL-BONE (CTC GRADE 3)[PT：筋骨格痛] Company causality assessment per License Partner Algeta:Event of PAIN-MUSCULOSKELETAL-BONE (CTC GRADE 3), is serious due to hospitalization, listed and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-006-006005	INFECTION PULMONARY LUNG (PNEUMONIA) (CTC GRADE 5)[PT：肺炎] SKELETAL PAIN (CTC GRADE 3)[PT：骨痛] This 73 year old Caucasian male who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer, experienced skeletal pain and fatal infection pulmonary lung (pneumonia). The subject's relevant medical history included prostate cancer, skeletal/bone metastasis and dehydration. Skeletal pain is considered serious due to hospitalization and is listed for Alpharadin. Infection pulmonary lung (pneumonia) is considered serious due to hospitalization and its fatal nature and is unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated for both events but rather due to concurrent illness for both events.The sponsor assessed the relationship to study drug as unrelated.
15245-006-006008	BILATERAL HYDRONEPHROSIS (CTC GRADE 3)[PT：水腎症] 試験薬は投与されていない。
15245-006-006008	OBSTRUCTION, GI-ILEUM (GRADE 4)[PT：小腸閉塞] DEATH (UNKNOWN CAUSE), (CTC GRADE 5)[PT：死亡] Company causality assessment per License Partner Algeta:Events of DEATH (UNKNOWN CAUSE) (CTC GRADE 5), serious (fatal outcome) and OBSTRUCTION, GI-ILEUM (GRADE 4), serious (hospitalization), are unlisted and assessed by the Investigator and Sponsor as unrelated to study drug. An alternative explanation for the gastrointestinal obstruction was prostate cancer metastasis to the peritoneum.

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-006-006009	FATIGUE (CTC GRADE 3)[PT：疲労] DEHYDRATION (CTC GRADE 3)[PT：脱水] The investigator has assessed the relationship to study drug as related for both events. The sponsor has assessed the relationship to study drug as related for both events.
15245-006-006009	PROSTATE CANCER PROGRESSION (CTC GRADE 5)[PT：前立腺癌] CONSTIPATION (CTC GRADE 2)[PT：便秘] DEHYDRATION (CTC GRADE 2)[PT：脱水] CACHEXIA (CTC GRADE 2)[PT：悪液質] Company causality assessment per License Partner Algeta:Event of PROSTATE CANCER PROGRESSION (CTC GRADE 5) (unlisted), is serious due to fatal outcome; events of CONSTIPATION (CTC GRADE 2) (listed), DEHYDRATION (CTC GRADE 2) (unlisted) and CACHEXIA (CTC GRADE 2) (unlisted) are serious due to hospitalization and medical significance; all events are assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to concurrent illness.
15245-006-006010	NERVE ROOT COMPRESSION C5 (CTC GRADE 3)[PT：神経根圧迫] 試験薬は投与されていない。
15245-006-006010	LEUKOPENIA (REDUCED WBC) (CTC GRADE 3)[PT：白血球減少症] 試験薬は投与されていない。
15245-006-006010	DEATH UNKNOWN[PT：死亡] 試験薬は投与されていない。
15245-006-006011	BONE PAIN (CTC GRADE 2)[PT：骨痛] Company causality assessment per License Partner Algeta:Event of BONE PAIN (CTC GRADE 2), is serious due to hospitalization, listed and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-006-006011	MUSCULOSKELATAL-LOWER BACK PAIN-BONE[PT：骨痛] Company causality assessment per License Partner Algeta:Event of MUSCULOSKELATAL-LOWER BACK PAIN-BONE, is serious due to hospitalization/medically significant, listed and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-006-006012	HAEMORRHAGIC GLAUCOMA (CTC GRADE 3)[PT：緑内障] 本症例には、プラセボが投与されていた。
15245-006-006012	SPINAL CORD COMPRESSION (CTC GRADE 3)[PT：脊髄圧迫] 本症例には、プラセボが投与されていた。
15245-006-006013	PATHOLOGICAL FRACTURE CERVICAL COLUMNA, C2, TRAUMA (CTC GRADE 2)[PT：病的骨折] 本症例には、プラセボが投与されていた。
15245-006-006014	FRACTURE RIGHT FEMUR NECK-PATHOLOGICAL FRACTURE (CTC GRADE 3)[PT：病的骨折] 本症例には、プラセボが投与されていた。
15245-006-006014	DYSPNEA[PT：呼吸困難] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-006-006014	MUSCULOSKELETAL PAIN[PT：筋骨格痛] 本症例には、プラセボが投与されていた。
15245-006-006014	DEATH UNKNOWN[PT：死亡] 本症例には、プラセボが投与されていた。
15245-006-006016	MUSCULOSKELETAL BACK PAIN (CTC GRADE 3)[PT：筋骨格痛] Company causality assessment per License Partner Algeta:Event of MUSCULOSKELETAL BACK PAIN (CTC GRADE 3), is serious due to hospitalization, listed and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-006-006016	BLEEDING PROSTATE GLAND (CTC GRADE 3)[PT：前立腺出血] This 59 year old male patient experienced BLEEDING PROSTATE GLAND (CTC GRADE 3) and was hospitalized 20 days after receiving the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases. The patient's medical history was not provided.The event BLEEDING PROSTATE GLAND (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to local tumor growth which was the main cause for the event, supported by the disorder of the coagulation system which was treated with enoxaparin. The investigator reported local tumor progression as a contributing factor to the event.The sponsor has assessed the relationship to study drug as unrelated.
15245-006-006016	INFECTION-GENERAL-CATHETER RELATED (EPIDURAL CATHETER) (CTC GRADE 3)[PT：医療機器関連感染] This 60 year old male patient experienced INFECTION-GENERAL-CATHETER RELATED (EPIDURAL CATHETER) (CTC GRADE 3) 54 days after the last dose received of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases. The patient's concurrent condition included prostate cancer and skeletal metastases. Additionally the patient died due to prostate cancer with skeletal metastases however it was not reported as a serious adverse event as it occurred more than 12 weeks after last study drug injection.The event INFECTION-GENERAL-CATHETER RELATED (EPIDURAL CATHETER) (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug for the infection general catheter related and the death as unrelated but rather due to skeletal metastases.The sponsor assessed the relationship to the study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-006-006017	ANEMIA (CTC GRADE 3)[PT：貧血] PLATELETS DECREASE (CTC GRADE 4)[PT：血小板減少症] CEREBRAL BLEEDING (CTC GRADE 2)[PT：脳出血] Company causality assessment per License Partner Algeta:Events of ANEMIA (CTC GRADE 3) and CEREBRAL BLEEDING (CTC GRADE 2) are considered serious as medically significant; event of PLATELETS DECREASE (CTC GRADE 4) is serious due to hospitalization and as well as medically significant. Events ANEMIA and PLATELTEST DECREASED are listed for Alpharadin, whereas, CEREBRAL BLEEDING is unlisted. All events are assessed by the Investigator and Sponsor as possibly related to study drug.
15245-006-006018	FEVER (CTC GRADE 3)[PT：発熱] FEVER (CTC GRADE 2)[PT：発熱] The investigator considers the event serious and related to Alpharadin/placebo. Company considers the event serious, unrelated and expected for Alpharadin.
15245-006-006018	FEVER IN THE ABSENCE OF NEUTROPENIA[PT：発熱] Company causality assessment per License Partner Algeta:Event of FEVER IN THE ABSENCE OF NEUTROPENIA, is serious (medically significant), unlisted and assessed by the Investigator as possibly related to study drug since there is no explanation for the pt's fever attacks. The Sponsor assessed the event as unrelated to study drug.
15245-006-006018	SPINAL CORD COMPRESSION (CTC GRADE 2)[PT：脊髄圧迫] This 62 year old male patient experienced SPINAL CORD COMPRESSION (CTC GRADE 2) and was hospitalized 15 days after receiving the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included skeletal metastases, prostate cancer.The event SPINAL CORD COMPRESSION (CTC GRADE 2) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated, rather due to skeletal metastases.The sponsor has assessed the relationship to study drug as unrelated.
15245-006-006018	BONE PAIN RIGHT PELVIS (CTC GRADE 3)[PT：骨痛] Company causality assessment per License Partner Algeta:Event of BONE PAIN RIGHT PELVIS (CTC GRADE 3), is serious due to hospitalization/medically significant, listed and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-006-006019	ANEMIA (CTC GRADE 3)[PT：貧血] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-006-006019	ANEMIA (CTC GRADE 3)[PT：貧血] 本症例には、プラセボが投与されていた。
15245-006-006019	FEVER IN THE ABSENCE OF NEUTROPENIA[PT：発熱] PAIN MUSCULOSKELETAL JOINT[PT：関節痛] 本症例には、プラセボが投与されていた。
15245-006-006020	PAIN-MUSCULOSKELETAL-BONE-LUMBAL COLUMNA (CTC GRADE 3)[PT：脊椎痛] Company causality assessment per License Partner Algeta:Event of PAIN-MUSCULOSKELETAL-BONE-LUMBAL COLUMNA (CTC GRADE 3), is serious due to hospitalization/medically significant, listed and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-006-006020	PAIN-MUSCULOSKELETAL-BONE CERVICAL THORACIC AND LUMBAR COLUMNA (CTC GRADE 3)[PT：骨痛] Company causality assessment per License Partner Algeta:Event of PAIN-MUSCULOSKELETAL-BONE CERVICAL THORACIC AND LUMBAR COLUMNA (CTC GRADE 3), is serious due to hospitalization, listed and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-006-006021	METASTATIC SPINAL CORD COMPRESSION (CTC GRADE 3)[PT：脊髄圧迫] 試験薬は投与されていない。
15245-006-006021	WORSENING PAIN - MUSCULOSKELETAL-BACK (CTC 3)[PT：骨痛] METASTATIC SPINAL CORD COMPRESSION (CTC 3)[PT：腫瘍性圧迫] 試験薬は投与されていない。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-006-006021	DEATH UNKNOWN[PT：死亡] 試験薬は投与されていない。
15245-006-006024	PAIN-GASTROINTESTINAL (CTC GRADE 3)[PT：消化器痛] 試験薬は投与されていない。
15245-006-006026	PAIN-MUSCULOSKELETAL- BONE- STERNUM AND COSTAE DEXTER (CTC GRADE 3)[PT：骨痛] This 72 year old male patient experienced PAIN-MUSCULOSKELETAL- BONE- STERNUM AND COSTAE DEXTER (CTC GRADE 3) 8 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included prostate cancer and skeletal metastases.The event PAIN-MUSCULOSKELETAL- BONE- STERNUM AND COSTAE DEXTER (CTC GRADE 3) is considered serious (hospitalized) and Listed for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but considers the event to be due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-006-006026	OPIOID-OVERDOSE[PT：過量投与] The investigator considers the event to be serious and unrelated to Alpharadin/placebo. Company considers the event to be serious, unrelated and unexpected for Alpharadin.
15245-006-006026	PAIN-MUSCULOSKELETAL- BONE - BACK PAIN AND RIGHT HIP (CTC GRADE 3)[PT：骨痛] PAIN-MUSCULOSKELETAL- BONE - BACK PAIN AND RIGHT HIP (CTC GRADE 3) is considered serious due to hospitalization. The event is listed in the Investigator Brochure for Alpharadin. In line with investigator, company assesses the event as not associated with the study drug. Underlying disease of prostate cancer with skeletal metastases provides a plausible alternative explanation for the event.
15245-006-006027	PAIN-MUSCULOSKELETAL-BONE-BACK AND RIGHT SHOLDER (CTC GRADE 3)[PT：筋骨格痛] 試験薬は投与されていない。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-006-006028	CLOSTRIDIUM DIFFICILE INFECTION (CTC GRADE 1)[PT：クロストリジウム・ディフィシレ感染] 試験薬は投与されていない。
15245-006-006028	HEMORRHAGE GI-ESOPHAGUS[PT：食道出血] 試験薬は投与されていない。
15245-006-006029	PAIN-MUSCULOSKELETAL--BONE-CERVICAL THORACIC AND LUMBAR COLUMNA, BOTH SHOULDERS, RIGHT HIP AND LEG[PT：筋骨格痛] 本症例には、プラセボが投与されていた。
15245-006-006029	DYSPNEA (CTC GRADE 4)[PT：呼吸困難] 本症例には、プラセボが投与されていた。
15245-006-006030	METASTATIC SPINAL CORD COMPRESSION (CTC GRADE 3)[PT：腫瘍性圧迫] This 64 year old male patient experienced METASTATIC SPINAL CORD COMPRESSION (CTC GRADE 3) and was hospitalized 12 days after receiving the first dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included bone metastases and prostate cancer.The event METASTATIC SPINAL CORD COMPRESSION (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to bone metastasis.The sponsor has assessed the relationship to study drug as unrelated.
15245-006-006030	MULTIPLE METASTASIS IN CEREBRUM AND CEREBELLUM (CTC GRADE 3)[PT：中枢神経系転移] This 65 year old male patient experienced MULTIPLE METASTASIS IN CEREBRUM AND CEREBELLUM (CTC GRADE 3) and was hospitalized 25 days after receiving the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included prostate cancer and sleletal metastases.The event MULTIPLE METASTASIS IN CEREBRUM AND CEREBELLUM (CTC GRADE 3) is considered serious (hospitalized, medically important) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated, but rather due to concurrent illness.The sponsor has assessed the relationship to the study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-006-006032	PAIN MUSCULOSKELETAL RIGHT EXTREMITY RIGHT KNEE LOWER THIGH AND CALF (CTC GRADE 1)[PT：筋骨格痛] 試験薬は投与されていない。
15245-006-006036	MUSCULOSKELETAL-FRACTURE-PATELLA FRACTURE SINISTER (CTC GRADE 2)[PT：膝蓋骨骨折] Company causality assessment per License Partner Algeta:Event of MUSCULOSKELETAL-FRACTURE-PATELLA FRACTURE SINISTER (CTC GRADE 2), is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to an accident.
15245-006-006036	HEMATURIA (CTC GRADE 3)[PT：血尿] This 77 year old male patient experienced HEMATURIA (CTC GRADE 3) 56 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The subject had no relevant medical history.The event HEMATURIA (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to the study drug as unrelated but due to concurrent illness.The sponsor has assessed the relationship to the study drug as unrelated.
15245-006-006038	PAIN-MUSCULOSKELETAL-BONE-SACRUM (CTC GRADE 3)[PT：筋骨格痛] 試験薬は投与されていない。
15245-006-006038	INFECTION-PYELONEPHRITIS (CTC GRADE 3)[PT：腎盂腎炎] This 60 year old male patient developed INFECTION-PYELONEPHRITIS (CTC GRADE 3) 4 days after receiving the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The subject has a relevant medical history of prostate cancer, and skeletal metastasis.The event INFECTION-PYELONEPHRITIS (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor assessed the relationship to study drug as unrelated.
15245-006-006038	INFECTION WITH NORMAL ANC (CTC GRADE 3)[PT：感染] GENERAL PHYSICAL HEALTH DETERIORATION (CTC GRADE 3)[PT：全身健康状態低下] This 60 year old male patient experienced INFECTION WITH NORMAL ANC (CTC GRADE 3) and GENERAL PHYSICAL HEALTH DETERIORATION (CTC GRADE 3) 21 days after receiving latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included musculoskeletal pain, infection - pyelonephritis and skeletal metastasis.The event INFECTION WITH NORMAL ANC (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for alpharadin. The event GENERAL PHYSICAL HEALTH DETERIORATION (CTC GRADE 3) is considered serious (disability) and Unlisted for alpharadin. The

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	investigator has assessed the relationship to study drug as unrelated, rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-006-006038	PAIN MUSCULOSKELETAL BONE LOWER BACK AND PELVIS(CTC GRADE3)[PT：筋骨格痛] GENERAL DETERIORATION DUE TO PROGRESSION OF PRE-EXISTING CANCER (CTC GRADE 3)[PT：全身健康状態低下] GENERAL DETERIORATION DUE TO PROGRESSION OF PRE-EXISTING CANCER (CTC GRADE 3)[PT：前立腺癌] This study refers to a 60 year old Caucasian male with hormone-refractory prostate cancer with skeletal metastases who received Alpharadin or Placebo. The pt was admitted to hospital on 26-Apr-2010 for PAIN MUSCULOSKELETAL BONE LOWER BACK AND PELVIS (CTC GRADE 3). Hospitalization was prolonged from 07-May-2010 for GENERAL DETERIORATION DUE TO PROGRESSION OF PRE-EXISTING CANCER (CTC GRADE 3). Concomitant medications include oxycodone hydrochloride, paracetamol, lisinopril, albyl-enterosolubile, lactulose, sodium picosulfate and dexamethasone. The pt received prior docetaxel therapy on 30- Sep-2009.PAIN MUSCULOSKELETAL BONE LOWER BACK AND PELVIS and GENERAL DETERIORATION DUE TO PROGRESSION OF PRE-EXISTING CANCER are considered serious due to hospitalization/prolonged hospitalization. PAIN MUSCULOSKELETAL BONE LOWER BACK AND PELVIS is is listed for Alpharadin, whereas GENERAL DETERIORATION DUE TO PROGRESSION OF PRE-EXISTING CANCER is not listed for Alpharadin. The investigator assessed the relationship to study drug as not related; rather due to concurrent illness for both events to which the company agrees.
15245-006-006039	PAIN BONE COLUMNA AND BOTH HIPS (CTC GRADE 3)[PT：骨痛] PAIN BONE COLUMNA AND BOTH HIPS (CTC GRADE 3) is serious (hospitalized) and listed in the Investigator's Brochure for Alpharadin (Bay 88-8223). The investigator has assessed the relationship to study drug unrelated but rather due to concurrent illness. The sponsor has assessed the relationship to study drug as unrelated.
15245-006-006039	SPINAL CORD COMPRESSION (CTC GRADE 3)[PT：脊髄圧迫] This 72 year old male patient experienced SPINAL CORD COMPRESSION (CTC GRADE 3) and was hospitalized 32 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included skeletal metastases and prostate cancer.The event SPINAL CORD COMPRESSION (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug unrelated.
15245-006-006039	PROSTATE CANCER-SKELETAL METASTASES-DEATH (CTC GRADE 5)[PT：遠隔転移を伴う前立腺癌] PROSTATE CANCER-SKELETAL METASTASES-DEATH (CTC GRADE 5) is serious (fatal) and unlisted in the Investigator's Brochure for Alpharadin (Bay 88-8223). The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness. The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-006-006040	PAIN BONE LUMBAR COLUMNA[PT：脊椎痛] Company causality assessment per License Partner Algeta:Event of PAIN BONE LUMBAR COLUMNA, is serious due to hospitalization, listed and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-006-006040	VOMETING[PT：嘔吐] Company causality assessment per License Partner Algeta:Event of VOMITING, is serious due to hospitalization, listed and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-006-006040	VOMITING (CTC GRADE 3)[PT：嘔吐] The investigator considered event serious and unrelated to study drug, but rather to concurrent illness.Company considers the event vomiting serious, listed and unrelated to the drug.
15245-006-006040	VOMITING (CTC GRADE 2)[PT：嘔吐] Company causality assessment per License Partner Algeta:Event of VOMITING (CTC GRADE 2), is serious due to hospitalization, listed and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-006-006040	VOMITING (CTC GRADE3)[PT：嘔吐] Company causality assessment per License Partner Algeta:Event of VOMITING (CTC GRADE3), is serious due to hospitalization, listed and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-006-006040	BONE PAIN PELVIS (CTC GRADE 3)[PT：骨痛] Company causality assessment per License Partner Algeta:Event of BONE PAIN PELVIS (CTC GRADE 3), is serious due to hospitalization, listed and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-006-006040	GASTROENETRITIS CLOSTRIDIUM DIFICILLE (CTC GRADE 3)[PT：クロストリジウム菌性胃腸炎] WORSENING OF PROSTATE CANCER (CTC GRADE 3)[PT：前立腺癌] This clinical trial case report (forwarded by Algeta) referring to a 72 year old male with known history of prostate cancer and skeletal metastasis, prior docetaxel therapy(Nov-2009) and number of hospitalizations due to bone pain in lumbar column /pelvis and vomiting and nausea, enrolled in a double-blind, randomized, multiple dose, Phase III, multicentre study of Alpharadin in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases and received first dose of study medication Alpharadin (BAY 88-8223)/Placebo by March,2010. The Patient received five doses of study drug; the last injection was given two months prior to onset of the events. He was withdrawn from the study on request (01-Aug-2010). The patient experienced WORSENING OF METASTATIC PROSTATE CANCER (CTC Grade 3) considered serious (hospitalization / fatal outcome) and on the same day presented with vomiting, nausea and diarrhea, diagnosed as GASTROENTERITIS CLOSTRIDIUM DIFFICILLE (CTC Grade 3) considered serious(hospitalization). Clinical presentation (fever) and laboratory results revealed an infection (unknown origin), treated with ciprofloxacin. Patient was died on day four of admission; cause of death was reported as worsening of prostate cancer. The GASTROENTERITIS CLOSTRIDIUM DIFFICILLE was ongoing at the time of death.The investigator assessed the relationship to Alpharadin (BAY 88-8223)/Placebo as unrelated but rather due to concurrent illness for both events, sponsor (company) concurs citing incompatible relationship and underlying advanced metastatic disease favours same causality assessment (unrelated).
15245-006-006041	PNEUMONIA (CTC GRADE 2)[PT：肺炎] This 57 year old male patient developed PNEUMONIA (CTC GRADE 2) and was hospitalized 6 days after receiving the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included skeletal metastasis and prostate cancer.The event PNEUMONIA (CTC GRADE 2) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to the study drug as unrelated, but rather due to concurrent illness. The sponsor has assessed the relationship to the study drug as unrelated.
15245-006-006041	INFECTION OF UNKNOWN ORIGIN (CTC GRADE 3)[PT：感染] This 57 year old male patient developed an INFECTION OF UNKNOWN ORIGIN (CTC GRADE 3) and was hospitalized 5 days after receiving the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included skeletal metastases and prostate cancer.The event INFECTION OF UNKNOWN ORIGIN (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The Sponsor has assessed the relationship to study drug as unrelated.
15245-006-006041	INFECTION OF UNKNOWN ORIGIN (CTC GRADE 3)[PT：感染] This 57 year old male patient developed an INFECTION OF UNKNOWN ORIGIN (CTC GRADE 3) and was hospitalized 75 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included prostate cancer and skeletal metastases.The event INFECTION OF UNKNOWN ORIGIN (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness. The investigator stated that the subject has responded to antibiotics but may be pre-disposed to urinary tract infection due to urolothiasis.The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-006-006043	HEMATURI (CTC 2)[PT：血尿] 本症例には、プラセボが投与されていた。
15245-006-006045	BONE PAIN LEFT HIP AND THIGH (CTC GRADE 3)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-006-006045	FRACTURE LEFT FEMUR NECK-TRAUMATIC AND PATHOLOGICAL FRACTURE (CTC GRADE 3)[PT：外傷性骨折] FRACTURE LEFT FEMUR NECK-TRAUMATIC AND PATHOLOGICAL FRACTURE (CTC GRADE 3)[PT：病的骨折] 本症例には、プラセボが投与されていた。
15245-006-006046	FEVER (CTC GRADE 3)[PT：発熱] DYSPNOEA (CTC GRADE 2)[PT：呼吸困難] NEUTROPENIA (CTC GRADE 3)[PT：好中球減少症] This 76 year old male patient experienced FEVER (CTC GRADE 3), DYSPNOEA (CTC GRADE 2) and NEUTROPENIA (CTC GRADE 3) almost 2 months after receiving the first dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included prostate cancer and skeletal metastases.The event FEVER (CTC GRADE 3) is considered serious (hospitalized) and unlisted in the Investigator´s Brochure of Alpharadin. The events DYSPNOEA (CTC GRADE 2) and NEUTROPENIA (CTC GRADE 3) are considered serious (medically important events). DYSPNOEA is unlisted and NEUTROPENIA is listed in the Investigator´s Brochure of Alpharadin. The investigator has assessed the relationship to study drug as possibly related for all events.The sponsor has assessed the relationship to study drug as unrelated for fever and dyspnoea. The sponsor has assessed the relationship to study drug as possibly related for neutropenia.
15245-006-006046	ABDOMINAL PAIN (CTC GRADE 3)[PT：腹痛] This 76 year old male patient experienced abdominal pain (CTC Grade 3) and was hospitalized 40 days after receiving latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included prostate cancer and skeletal metastases.The event abdominal pain (CTC Grade 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-006-006046	INFECTION OF UNKNOWN ORIGIN (CTC GRADE 3)[PT：感染] This 76 year old male patient developed an infection of unknown origin (CTC grade 3) and was hospitalized 46 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included prostate cancer and skeletal metastases.The event infection of unknown origin (CTC grade 3) is considered serious (hospitalized) and unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-006-006047	NERVE ROOT COMPRESSION OF L2 DUE TO PROLAPSE OF LUMBAR DISC L2/L3 CTCAE GRADE 3[PT：神経根圧迫] NERVE ROOT COMPRESSION OF L2 DUE TO PROLAPSE OF LUMBAR DISC L2/L3 CTCAE GRADE 3[PT：椎間板突出] This 73 year old Caucasian male who enrolled in study BC1-06 and received Alpharadin/Placebo experienced nerve root compression of L2 due to prolapse of lumbar disc L2/L3 (split for coding purposes, as nerve root compression and prolapse of lumbar disc, due to Bayer coding conventions). The subject's relevant medical history included prostate cancer and skeletal metastases. Nerve root compression and prolapse of lumbar disc are considered serious (hospitalization) and are unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-006-006048	URINARY RETENTION (CTC GRADE 2)[PT：尿閉] 本症例には、プラセボが投与されていた。
15245-006-006048	PAIN LOWER BACK AND BOTH NATES (CTC GRADE 3)[PT：筋骨格痛] PAIN LOWER BACK AND BOTH NATES (CTC GRADE 3)[PT：背部痛] 本症例には、プラセボが投与されていた。
15245-006-006048	OEDEMA LEFT LEG (CTC GRADE 2)[PT：末梢性浮腫] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-006-006051	BONE PAIN RIGHT HIP/PELVIS (CTC GRADE 3)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-006-006052	BILATERAL HYDRONEPHROSIS (CTC GRADE 3)[PT：水腎症] This 74 year old male patient experienced Bilateral Hydronephrosis (CTC GRADE 3) and was hositalized 14 days after receiving the first dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included Prostate cancer and skeletal metastases.The event Bilateral Hydronephrosis (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for alpharadin. The investigator has assessed the event relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the event relationship to study drug as unrelated.
15245-006-006052	SEPSIS (CTC GRADE 3)[PT：敗血症] This 74 year old male patient developed sepsis (CTC grade 3) and was hospitalized 14 days after receiving the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastasis. The patient had a relevant medical history of prostate cancer with skeletal metastasis. The event sepsis (CTC grade 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator assessed the relationship to study drug as unrelated but rather due to concurrent illness.
15245-006-006052	URINARY RETENTION (CTC GRADE 3)[PT：尿閉] This 74 year old male patient experienced URINARY RETENTION (CTC GRADE 3) and was hospitalized 20 days after receiving latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included prostate cancer and skeletal metastases.URINARY RETENTION (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-006-006052	BONE PAIN (CTC GRADE 2)[PT：骨痛] UROSEPSIS (CTC GRADE 3)[PT：尿路性敗血症] This 74 year old male patient developed UROSEPSIS (CTC GRADE 3) and was hospitalized 54 days after receiving the last dose of Alpharadin/placebo in this clinical study of AlpharadinTM in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. Eleven (11) days later, hospitalization was prolonged due to BONE PAIN (CTC GRADE 2). The patient's concurrent condition included prostate cancer and skeletal metastases.The event UROSEPSIS (CTC GRADE 3) is considered serious (hospitalized) and unlisted for alpharadin. The event BONE PAIN (CTC GRADE 2) is considered serious (hospitalized) and listed for alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-006-006055	L4-S3 NERVE ROOT COMPRESSION (CTC GRADE 3)[PT：神経根圧迫] 試験薬は投与されていない。
15245-006-006055	PAIN RIGHT HIP DUE TO NERVE COMPRESSION (CTC GRADE 3)[PT：関節痛] WEAKNESS IN RIGHT LOWER EXTREMITY[PT：筋力低下] The case refers to a 63-year-old patient in a double-blind, randomized, repeat dose, phase III, multicentre survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. He experienced PAIN RIGHT HIP DUE TO NERVE COMPRESSION (CTC GRADE 3) which is a serious event due to hospitalization and is unlisted in the Investigator´s Brochure of Alpharadin. He also suffered from the non-serious event of WEAKNESS IN RIGHT LOWER EXTREMITY which is unlisted in the Investigator´s Brochure. The investigator assesses both events as unrelated but rather due to concurrent illness. The company agrees on that and considers the events not associated to the study drug.
15245-006-006055	DECLIVE EDEMA (CTC GRADE 3)[PT：脳浮腫] This 63 year old male patient experienced declive edema (CTC grade 3) and was hospitalized 24 days after receiving dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included hormone-refractory prostate cancer, skeletal metastases and atrial fibrillation.The event declive edema (CTC grade 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-006-006055	PNEUMONI (CTC GRADE 3)[PT：肺炎] This 63 year old male patient experienced Pneumoni (CTC Grade 3) and was hospitalized 28 days after receiving first dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included prostate cancer, skeletal metastases and atrial fibrillation.The event Pneumoni (CTC Grade 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-006-006055	WEAKNESS BOTH LOWER EXTREMITES DUE TO MOTOR NEUROPATHY (CTC GRADE 3)[PT：末梢性運動ニューロパチー] This 63 year old male patient experienced WEAKNESS BOTH LOWER EXTREMITIES DUE TO MOTOR NEUROPATHY (CTC GRADE 3) and was hospitalized 18 days after taking latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The subject's relevant medical history included prostate cancer, skeletal metastases and atrial fibrillation. The event WEAKNESS BOTH LOWER EXTREMITIES DUE TO MOTOR NEUROPATHY (CTC GRADE 3) is considered serious as the patient was hospitalized and is unlisted in the Reference Safety Document for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness. The investigator stated that the weakness of both lower extremities was due to increasing skeletal metastases Th12 - L2.The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-006-006055	THROMBOCYTOPENIA (CTC GRADE 4)[PT：血小板減少症] SPINAL CORD COMPRESSION L2 (CTC GRADE 3)[PT：脊髄圧迫] This 63 year old male patient experienced Spinal cord compression L2 (CTC grade 3) and was hospitalized 32 days after receiving last dose of study drug (Alpharadin/placebo) in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastasis. The patient also experienced thrombocytopenia (CTC grade 4). The patient's concurrent condition included prostate cancer, skeletal metastasis and atrial fibrillation.The event Spinal cord compression L2 (CTC grade 3) is considered serious (hospitalized) and Unlisted Alpharadin. The event thrombocytopenia (CTC grade 4) is considered serious (medically important event) and Listed for Alpharadin.The investigator has assessed the relationship to the study drug as possibly related for thrombocytopenia and unrelated for spinal cord compression L2. An alternative explanation for spinal cord compression L2 includes concurrent illness and an alternative explanation for the thrombocytopenia was reported as bone marrow infiltration due to disease progression.The Sponsor has assessed the relationship to study drug as possibly related for thrombocytopenia and unrelated for spinal cord compression L2.
15245-006-006055	PROGRESSIVE PROSTATE CANCER[PT：前立腺癌] This 64 year old male patient experienced PROGRESSION PROSTATE CANCER and died 50 days after receiving latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The subject has relevant medical history of prostate cancer and skeletal metastasis.The event PROGRESSIVE PROSTATE CANCER IS considered serious (fatal) and unlisted for alpharadin.The investigator has assessed the relationship to study drug as unrelated, but rather due to concurrent illness.The sponsor assessed the relationship to study drug as unrelated.
15245-007-007001	LIVER METASTASES (CTC GRADE 3)[PT：肝転移] 本症例には、プラセボが投与されていた。
15245-007-007001	EDEMA PENIS AND SCROTUM (AT CATHETER SITE) (CTC GRADE 2)[PT：カテーテル留置部位浮腫] 本症例には、プラセボが投与されていた。
15245-007-007003	RECURRENT PLEURAL EFFUSION (CTC GRADE 2)[PT：胸水] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-007-007003	PNEUMONIA, PAIN RIGHT HEMITHORAX (CTC GRADE 3)[PT：肺炎] PNEUMONIA, PAIN RIGHT HEMITHORAX (CTC GRADE 3)[PT：胸痛] 本症例には、プラセボが投与されていた。
15245-007-007003	CONFUSION DUE TO METASTASES (CTC GRADE 2)[PT：錯乱状態] INFECTION-OTHER (PNEUMONIA) (CTC GRADE 2)[PT：肺炎] MENINGEAL METASTASES (CTC GRADE 3)[PT：髄膜転移] 本症例には、プラセボが投与されていた。
15245-007-007003	本症例には、プラセボが投与されていた。
15245-007-007004	HIP PAIN BILATERAL (SKELETAL) (CTC GRADE 2)[PT：骨痛] HIP PAIN BILATERAL (SKELETAL) (CTC GRADE 2)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-007-007006	FATIGUE (CTC GRADE 3)[PT：疲労] 本症例には、プラセボが投与されていた。
15245-007-007007	URINARY INFECTION (CTC GRADE 3)[PT：尿路感染] HYDRONEPHROSIS RIGHT HAND SIDE (CTC GRADE 3)[PT：水腎症] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-007-007008	PNEUMONIA (CTC GRADE 2)[PT：肺炎] 本症例には、プラセボが投与されていた。
15245-007-007008	ANAEMIA-LOW HAEMOGLOBIN (HB 8.3 G/100 ML) (CTC GRADE 2)[PT：貧血] ANEMIA (CTC GRADE 3)[PT：貧血] 本症例には、プラセボが投与されていた。
15245-007-007008	SUICIDAL ATTEMPT (CTC 4)[PT：自殺企図] 本症例には、プラセボが投与されていた。
15245-007-007009	HAEMORRHAGE URETRA (CTC GRADE 3)[PT：尿道出血] 試験薬は投与されていない。
15245-007-007009	HYPERGLYCAEMIA (CTC GRADE 4)[PT：高血糖] HYPOKALAEMIA (CTC GRADE 4)[PT：低カリウム血症] POSSIBLE CARDIAC INFARCTION (CTC GRADE 2)[PT：心筋梗塞] 本症例には、プラセボが投与されていた。
15245-008-008001	FEMUR FRACTURE (CTC GRADE 3)[PT：大腿骨骨折] 試験薬は投与されていない。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-008-008001	INFECTION (CTC GRADE 3)[PT：処置後感染] 試験薬は投与されていない。
15245-008-008001	NAUSEA (CTC GRADE 2)[PT：悪心] Company causality assessment per License Partner Algeta:Event of NAUSEA (CTC GRADE 2), is serious due to hospitalization/medical significance, listed and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to disease progression.
15245-008-008001	PAIN RIGHT HIP/ FEMORIS (CTC GRADE 3)[PT：骨痛] This 66 year old male patient experienced from PAIN RIGHT HIP.The event PAIN RIGHT HIP/FEMORIS (CTC GRADE 3) is considered serious because the patient was hospitalized. The event is listed in the Investigator´s Brochure of Alpharadin.The reporting investigator assessed the causal relationship between event PAIN RIGHT HIP/FEMORIS (CTC GRADE 3) and treatment with study drug Alpharadin as unrelated, company concurs. The underlying prostate cancer with skeletal metastases and femur bone fracture may provide alternative explanations for the event.
15245-008-008003	NAUSEA (CTC GRADE 2)[PT：悪心] Company causality assessment per License Partner Algeta:Event of NAUSEA (CTC GRADE 2), is serious due to hospitalization, listed and assessed by the Investigator and Sponsor as unrelated to study drug.
15245-008-008003	DISEASE PROGRESSION (CTC GRADE 5)[PT：前立腺癌] The case refers to a 79-year-old mal patient in a double-blind, randomized, multiple dose, Phase III, multicentre study of Alpharadin in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases. He died due to DISEASE PROGRESSION (CTC GRADE 5) which is a serious event (fatal) and is unlisted in the Investigator´s Brochure of Alpharadin. The investigator has assessed the relationship to study drug as unrelated, but rather due to disease progression. The sponsor agrees on that and considers DISEASE PROGRESSION (CTC GRADE 5) not associated to Alpharadin/placebo.
15245-008-008007	BONE PAIN (CTC GRADE 3)[PT：骨痛] This 62 year old Caucasian male, who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced BONE PAIN (CTC GRADE 3) 42 days after receiving the last dose of study drug.The subject's relevant medical history includes increased pain in neck and sacrum.BONE PAIN (CTC GRADE 3) is considered serious (hospitalization) and listed for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to disease progression.The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-008-008007	INFECTION OF UNKNOWN ORIGIN (CTC GRADE 3)[PT：感染] The case refers to a 62-year-old male patient in a double blind, randomized, repeat dose, phase III, multicentre survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. He experienced INFECTION OF UNKNOWN ORIGIN (CTC GRADE 3) which is a serious event due to hospitalization and is unlisted in the Investigator´s Brochure of Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness. The company considers INFECTION OF UNKNOWN ORIGIN (CTC GRADE 3) not associated to Alpharadin/placebo.
15245-008-008008	ANEMIA (CTC GRADE 3)[PT：貧血] This study refers to a 74 year old Caucasian male with hormone-refractory prostate cancer with skeletal metastases who received Alpharadin or Placebo on 11-Jun-2009. The pt was admitted to hospital for ANEMIA (CTC GRADE 3) on 17-Aug-2009. Medical history and concurrent disease include hypercholesteremia, fatigue and weight loss (6 Kg) for the last two months, and low hemoglobin (06 Aug 9.4 g/dl). Concomitant medications include atorvastatin calcium, paracetamol, prednisolone and leuprorelin acetate. The pt received prior docetaxyl treatment.ANEMIA is considered serious due to hospitalization and is listed for Alpharadin. The investigator assessed the relationship to study drug as related. Based on implied temporal relationship and known product profile, company agrees with investigator and assessed event as possibly related.
15245-008-008008	REDUCED GENERAL HEALTH CONDITION (CTC GRADE 2)[PT：全身健康状態低下] Company causality assessment per License Partner Algeta:Event of REDUCED GENERAL HEALTH CONDITION (CTC GRADE 2), is serious (hospitalized), unlisted and assessed by the Investigator as possibly related to study drug. Sponsor assessed event as unrelated to study drug.
15245-008-008011	SPINAL CORD COMPRESSION (CTC GRADE 3)[PT：脊髄圧迫] This 69 year old male patient experienced SPINAL CORD COMPRESSION (CTC GRADE 3) and was hospitalized 9 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient did not have any relevant medical history.The event SPINAL CORD COMPRESSION (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated, but rather due to disease progression.The sponsor has assessed the relationship to study drug as unrelated.
15245-008-008011	SPINAL CORD COMPRESSION (CTC GRADE 4)[PT：脊髄圧迫] This 70 year old male patient experienced SPINAL CORD COMPRESSION (CTC GRADE 4) and was hospitalized 26 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's medical history included spinal cord compression. The event SPINAL CORD COMPRESSION (CTC GRADE 4) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated, rather due to disease progression.The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-008-008011	SUBILEUS (CTC GRADE 2)[PT：亜イレウス] This study refers to an 80 year old Caucasian male with hormone-refractory prostate cancer with skeletal metastases who received Alpharadin or Placebo. The pt was admitted to hospital on 22-Feb-2010 for SUBILEUS (CTC GRADE 2). The pt received prior docetaxel therapy on 30-Jun-2009.SUBILEUS is considered serious due to hospitalization and is not listed for Alpharadin. The investigator has assessed the relationship to study drug as unrelated, but rather due to disease progression, to which the company agrees.
15245-008-008011	DISEASE PROGRESSION[PT：悪性新生物進行] This 70 year old male patient experienced DISEASE PROGRESSION and died 72 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. Relevant medical history was not provided.The event DISEASE PROGRESSION is considered serious (fatal) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated.The sponsor has assessed the relationship to study drug as unrelated.
15245-008-008013	WORSENING ATRIAL FIBRILLATION (CTC GRADE 3)[PT：心房細動] This 78 year old male patient experienced Worsening Atrial Fibrillation (CTC grade 3) and was hospitalized 81 days after receiving the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included atrial fibrillation. The event Worsening Atrial Fibrillation (CTC grade 3) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-008-008014	INCREASED PAIN LEFT SIDE THORAX (CTC GRADE 2)[PT：筋肉痛] 本症例には、プラセボが投与されていた。
15245-008-008014	SUBTROCHANTER FRACTURE RIGHT HIP (CTC GRADE 3)[PT：病的骨折] 本症例には、プラセボが投与されていた。
15245-008-008014	GASTROENTERITIS NOROVIRUS (CTC GRADE 2)[PT：ノロウイルス性胃腸炎] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-008-008014	INFECTION RIGHT HIP, POST OPERATIVE (CTC GRADE 2)[PT：処置後感染] NORMAL ABSOLUTE NEUTROPHIL COUNT[PT：好中球数正常] 本症例には、プラセボが投与されていた。
15245-008-008014	DYSPNEA (CTC GRADE 3)[PT：呼吸困難] DISEASE PROGRESSION[PT：悪性新生物進行] 本症例には、プラセボが投与されていた。
15245-008-008015	BONE PAIN (CTC GRADE 3)[PT：骨痛] Company causality assessment per License Partner Algeta:Event of BONE PAIN (CTC GRADE 3), is serious due to hospitalization, listed and assessed by the Investigator and Sponsor as unrelated to study drug.
15245-008-008015	NAUSEA (CTC GRADE 3)[PT：悪心] The investigator considers the event to be serious and unrelated to Alpharadin/placebo. Company considers the event to be serious, unrelated and expected for Alpharadin.
15245-009-009001	CARDIAC DECOMPENSATION[PT：心不全] 本症例には、プラセボが投与されていた。
15245-010-010001	ANEMIA (CTC GRADE 2)[PT：貧血] METASTATIC BONE PAIN (CTC GRADE 2)[PT：転移部痛] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-010-010001	ANEMIA (CTC GRADE 3)[PT：貧血] 本症例には、プラセボが投与されていた。
15245-010-010001	ANEMIA (CTC GRADE 3)[PT：貧血] 本症例には、プラセボが投与されていた。
15245-010-010003	METASTATIC BONE PAIN (CTC GRADE 3)[PT：転移部痛] 本症例には、プラセボが投与されていた。
15245-010-010005	CACHEXIA TUMOROSA[PT：悪液質] 本症例には、プラセボが投与されていた。
15245-010-010008	ANAEMIA (CTC GRADE 3)[PT：貧血] This 75 year old male patient experienced anaemia (CTC Grade 3) and was hospitalized 47 days after receiving the last dose of study medication (Alpharadin/placebo) in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event ANAEMIA (CTC GRADE 3) is considered serious (hospitalized, disability) and listed for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to progression of cancer.The sponsor has assessed the relationship to study drug as unrelated.
15245-011-011003	PROGRESSION OF PROSTATE CANCER (CTC GRADE 2)[PT：前立腺癌] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-011-011006	THROMBOCYTOPENIA (CTC GRADE 4)[PT：血小板減少症] TERMINAL PNEUMONIA (CTC GRADE 5)[PT：肺炎] （本例は PMDA へ報告を行った症例である。弊社の見解を日本語で示す） これらの事象について、治験担当医は本治験薬との因果関係があると評価した。なお、「血小板減少症」について、「被験者は広範囲の骨転移を伴う非常に進行した前立腺癌があり、この影響により時折血小板減少症を来す可能性はあるが、極めて重度の血小板減少症が長期にわたり持続したことを考慮すると、試験薬との因果関係は否定できない。なお、脳出血はなかった。」とコメントした。 弊社は、「血小板減少症」については、本治験薬の製剤特性並びに時間的関連性を考慮すると本治験薬との因果関係は否定できないと考える。「肺炎」については、本剤の最終投与から約８か月半後に発現していること，又，本治験薬の投与終了後に実施された放射線療法により本事象が発現した可能性が考えられることから，本治験薬との因果関係は否定できると考える。
15245-011-011007	ANEMIA (CTC GRADE 3)[PT：貧血] 本症例には、プラセボが投与されていた。
15245-012-012001	TESTOSTERONE LEVEL ABNORMAL (CTC GRADE 1)[PT：血中テストステロン異常] 試験薬は投与されていない。
15245-012-012001	ANEMIA (CTC GRADE 3)[PT：貧血] This 61 year old male patient developed ANEMIA (CTC grade 3) and was hospitalized 29 days after receiving last dose of alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event ANEMIA (CTC grade 3) is considered serious (hospitalized) and Listed for alpharadin.The investigator has assessed the relationship to study drug as possibly related.The sponsor has assessed the relationship to study drug as possibly related.
15245-016-016001	PROSTATE CANCER PROGRESSION (CTC GRADE 3)[PT：前立腺癌] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-017-017003	CACHEXIA TUMOROSA (CTC GRADE 4)[PT：悪液質] Company causality assessment per License Partner Algeta:Event of CACHEXIA TUMOROSA is serious (fatal outcome / hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to concurrent illness.
15245-017-017004	ANGINA PECTORIS (CTC GRADE 3)[PT：狭心症] ANGINA PECTORIS (CTC GRADE 3) is considered serious due to hospitalization. The event is not listed in the product information for Alpharadin//PlaceboIn line with the investigator, company assesses the relationship to study drug as unrelated. Concomitant conditions of arterial hypertension and angina pectoris may provide plausible alternative explanations for the event. No further information is available.
15245-017-017005	ANAEMIA (CTC GRADE 4)[PT：貧血] This 81 year old male patient experienced ANAEMIA (CTC GRADE 4) 28 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's medical history included orchiectomy left due to tuberculosis.The event ANAEMIA (CTC GRADE 4) is considered serious (hospitalized) and Listed for Alpharadin.The investigator has assessed the relationship to study drug as unrelated, but considers the anaemia to be due to advanced metastatic disease of bone and bone marrow.The sponsor has assessed the relationship to study drug as unrelated.
15245-017-017007	DISEASE PROGRESSION (CTC 4)[PT：前立腺癌] The case refers to a 80-year-old male subject in a double blind, randomized, repeat dose, phase III, multicentre survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. He passed away due to DISEASE PROGRESSION (CTC 4) which is a serious event (hospitalization, fatal outcome) and is unlisted in the Investigator´s Brochure of Alpharadin.The investigator assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor assessed the relationship to study drug as unrelated.
15245-017-017009	SPINAL CORD COMPRESSION L3, L4 (CTC GRADE 3)[PT：脊髄圧迫] 本症例には、プラセボが投与されていた。
15245-017-017010	BURSITIS OLECRANI (CTC GRADE 2)[PT：滑液包炎] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-017-017010	PROSTATE CANCER PROGRESSION (CTC GRADE 5)[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-017-017013	DYSPEPSIA (CTC GRADE 1)[PT：消化不良] 試験薬は投与されていない。
15245-017-017013	CNS ISCHEMIA[PT：脳虚血] 本症例には、プラセボが投与されていた。
15245-017-017014	PROSTATE CANCER PROGRESSION[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-017-017016	URINARY INFECTION[PT：尿路感染] 本症例には、プラセボが投与されていた。
15245-017-017017	WORSENING OF MEDICAL STATUS (CTC 4)[PT：全身健康状態低下] The case refers to a 77-year-old male subject in a double blind, randomized, repeat dose, phase III, multicentre survival study of AlpharadinTM in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. He passed away due to WORSENING OF MEDICAL STATUS (CTC 4) which is a serious event (hospitalized and fatal outcome) and is unlisted in the Investigator´s Brochure of Alpharadin. The investigator has assessed the relationship to the study drug as unrelated but rather due to concurrent illness. The company agrees on that and considers WORSENING OF MEDICAL STATUS (CTC 4) not associated to study drug but to the underlying disease of prostate cancer and metastases to bone.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-017-017018	METASTATIC CHEST BONE PAIN (CTC GRADE 1)[PT：転移部痛] 試験薬は投与されていない。
15245-017-017018	CARDIAC INFARCTION[PT：心筋梗塞] WORSENING CARDIAC ISCHAEMIA (CTC GRADE 4)[PT：心筋虚血] This 77 year old male patient experienced WORSENING CARDIAC ISCHAEMIA (CTC GRADE 4) and was hospitalized 6 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient died over one week later due to CARDIAC INFARCTION. The patient's concurrent condition included metastatic bone pain, cardiac arrhythmia, cardiac ischemia, diabetes mellitus, hyperuricemia and hypertension arterial.The event CARDIAC INFARCTION is considered serious (fatal, hospitalized) and Unlisted for Alpharadin. The event WORSENING CARDIAC ISCHAEMIA (CTC GRADE 4) is considered serious (hospitalized, life threatening event) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated for both events but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated for both events.
15245-017-017027	DISEASE PROGRESSION (CTC GRADE 3)[PT：前立腺癌] This 60 year old male patient experienced Disease progression (CTC grade 3) and was hospitalized 32 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient later died due to the progression. The patient's concurrent condition included progression of prostate cancer.The event Disease progression (CTC grade 3) is considered serious (fatal, hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-017-017028	PHLEBOTHROMBOSIS OF RIGHT LEG (CTC GRADE 3)[PT：四肢静脈血栓症] INFECTION (CTC GRADE 3)[PT：ブドウ球菌感染] RENAL FAILURE (CTC GRADE 3)[PT：腎不全] 本症例には、プラセボが投与されていた。
15245-017-017030	THROMBOCYTOPENIA (CTC GRADE 3)[PT：血小板減少症] LEUCOPENIA (CTC GRADE 2)[PT：白血球減少症] WORSENING OF MEDICAL STATUS[PT：全身健康状態低下] This 86 year old Caucasian male who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced Thrombocytopenia (CTC Grade 3) and Leucopenia (CTC Grade 2) and was hospitalized 23 days after receiving the last dose of study drug. The patient later died due to Worsening of Medical Status.The subject's relevant medical history included hypertension, cardiac ischemia, central nervous system ischemia, diabetes mellitus, hypercholesterolemia, glaucoma, cataracts, deafness and metastatic bone pain.Worsening of Medical Status is considered serious (fatal) and unlisted for Alpharadin. Thrombocytopenia (CTC Grade 3) and Leucopenia (CTC Grade 2) are serious (hospitalization) and listed for Alpharadin.The investigator has assessed the relationship to study drug as unrelated for all events but rather due to concurrent illness.The sponsor has

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	assessed the relationship to study drug as unrelated for all events.
15245-017-017031	ULCUS-DUODENUM (CTC GRADE 2)[PT：十二指腸潰瘍] This 72 year old male patient experienced Ulcus duodenum (CTC grade 2) [PT duodenal ulcer] 15 days after receiving the last dose of Alpharadin/placebo in a clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. Relevant medical history was not provided. Patient was taking gliquidone, ibuprofen, perindopril, moduretic, allopurinol, estramustine phosphate sodium and zoledronic acid as concomitant medications, and did not receive prior docetaxel therapy. An endoscopy was performed and duodenal ulcer was confirmed. Patient improved in response to treatment and discharged.The event Ulcus duodenum (CTC grade 2) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator assessed the relationship to study drug as unrelated, but rather due to concurrent medication. The sponsor assessed the relationship to study drug as unrelated.
15245-017-017032	DISEASE PROGRESSION[PT：前立腺癌] This 57 year old male patient experienced DISEASE PROGRESSION and died 41 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event DISEASE PROGRESSION is considered serious (fatal) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-018-018004	GASTRITIS (CTC GRADE 1)[PT：胃炎] This 63 year old male patient experienced GASTRITIS (CTC GRADE 1) and was hospitalized 14 days after receiving latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event GASTRITIS (CTC GRADE 1) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated, but rather due to concomitant medications.The sponsor has assessed the relationship to study drug as unrelated.
15245-018-018004	PANCYTOPENIA (CTC GRADE 4)[PT：汎血球減少症] This study refers to a 63 year old Caucasian male with hormone-refractory prostate cancer with skeletal metastases who received Alpharadin or Placebo. The pt was admitted to hospital for PANCYTOPENIA (CTC GRADE 4) on 15-Feb-2010. Relevant medical history was reported as none. Concomitant medication includes calcium carbonate. The subject received prior docetaxel therapy on 17-Dec-2008. PANCYTOPENIA is considered serious due to hospitalization and is listed for Alpharadin. The investigator assessed the relationship to study drug as possibly related. Based on implied temporal relationship and known product profile, company agrees with investigator and assessed event as possibly related.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-020-020001	SEVERE BONE PAIN (CTC GRADE 3)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-020-020003	ANEMIA (CTC GRADE 2)[PT：貧血] THROMBOCYTOPENIA (CTC GRADE 3)[PT：血小板減少症] The investigator has assessed the relationship to study drug as related for both events. The sponsor has assessed the relationship to study drug as related for both events.
15245-020-020005	BONE PAIN (CTC GRADE 3)[PT：骨痛] This 72 year-old male patient enrolled in a non-Bayer-sponsored double-blind, randomized, Multiple Dose, Phase III, Multicentre Study of Alpharadin in the Treatment of Patients With Symptomatic Hormone Refractory Prostate Cancer With Skeletal Metastases experienced BONE PAIN (CTC GRADE 3) one month after start of study medication (one injection received). MR scan revealed progression in the backbone, both old and new metastases and mild spreading on spinal canal but not on medulla. No action was taken with study drug. The patient recovered.Event of BONE PAIN (CTC GRADE 3) is serious (hospitalized), regarded unlisted (initially regarded listed) and assessed by the Investigator as possibly related to study drug. Initial alternative explanation of concomitant medications was revised by investigator with follow-up received 12-Jan-2012.The sponsor assessed the relationship to study drug as unrelated.
15245-020-020005	WORSENING OF BONE PAIN (CTC GRADE 2)[PT：骨痛] This 72 year old male patient experienced WORSENING OF BONE PAIN (CTC GRADE 2) and was hospitalized 12 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases. The patient's medical history included Aortic aneurysm-Abdomen. The patient's concurrent condition included Hyperlipidemia, Amaurosis fugax and hypertension. The event WORSENING OF BONE PAIN (CTC GRADE 2) is considered serious (hospitalized) and Listed for Alpharadin.The investigator has assessed the relationship to study medication as unrelated. Concurrent illness was reported as alternative explanation.The sponsor has assessed the relationship to study drug as unrelated.
15245-020-020005	PROGRESSION OF PROSTATE CANCER[PT：前立腺癌] BAD GENERAL HEALTH[PT：全身健康状態低下] PAIN GENITALES[PT：生殖器痛] HEMATURIA[PT：血尿] This 72 year old male patient experienced PROGRESSION OF PROSTATE CANCER and was hospitalized 29 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases. The patient later died due to the progression. The patient's concurrent condition included hyperlipidemia, amaurosis fugax, hypertension and aortic aneurysm-abdomen. The event PROGRESSION OF PROSTATE CANCER is considered serious (fatal, hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	study drug as unrelated.
15245-020-020010	INCREASED BONE PAIN (CTC GRADE 3)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-020-020010	PROGRESSION OF CANCER (SKELETAL METASTASES)[PT：遠隔転移を伴う新生物] 本症例には、プラセボが投与されていた。
15245-020-020015	CONGESTIVE HEART FAILURE (CTC GRADE 3)[PT：うっ血性心不全] Company causality assessment per License Partner Algeta:Event of CONGESTIVE HEART FAILURE (CTC GRADE 3), is serious (hospitalized / medically significant), unlisted and assessed by the Investigator as possibly related to study drug. The Sponsor assessed the event as unrelated to study drug.
15245-020-020015	PROGRESSION OF PROSTATE CANCER[PT：前立腺癌] This 74 year old male patient experienced PROGRESSION OF PROSTATE CANCER and was hospitalized 33 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient died 4 days later due to the SAE. The patient had no relevant medical history.The event PROGRESSION OF PROSTATE CANCER (CTC GRADE 5) is considered serious (fatal, hospitalized) and Unlisted for alpharadin. The investigator has assessed the relationship to the study drug as unrelated but rather due to progression of underlying disease, prostate cancer.The sponsor has assessed the relationship to the study drug as unrelated.
15245-021-021001	PATHOLOGICAL FRACTURE OF THE LEFT HIP (COLLUM FEMORIS) (CTC GRADE 3)[PT：病的骨折] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-021-021001	INFECTION (CTC GRADE 3)[PT：感染] 本症例には、プラセボが投与されていた。
15245-021-021001	本症例には、プラセボが投与されていた。
15245-021-021002	EROSIVE DUODENITIS (CTC GRADE 3)[PT：びらん性十二指腸炎] This 63 year old male patient experienced EROSIVE DUODENITIS (CTC GRADE 3) and was hospitalized 3 days after receiving latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases. The patient's concurrent condition included Diarrhea, Constipation, and abdominal pain.The event EROSIVE DUODENITIS (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator had initially assessed the relationship to study drug as possibly related, however following the diagnosis the investigator assesssed the event as not related to study drug but probably due to treatment with diclofenac and betapred.The sponsor has assessed the relationship to study drug as unrelated.
15245-021-021002	NAUSEA (CTC GRADE 3)[PT：悪心] VOMITING (CTC GRADE 3)[PT：嘔吐] ANOREXIA (CTC GRADE 3)[PT：食欲減退] DEHYDRATION[PT：脱水] This study case report received from License Partner Algeta refers to a 63 year old male patient who was treated with Alpharadin for symptomatic hormone refractory prostate cancer with skeletal metastases. He experienced NAUSEA, VOMITING, ANOREXIA and DEHYDRATION 21 days after last injection. The patient´s medical history included complaints of abdominal problems, occasional constipation and diarrhea, and he has had an "erosive duodenitis" 18 days prior to the reported events.NAUSEA, VOMITING, ANOREXIA and DEHYDRATION (as a complication of nausea and vomiting) are considered serious due to hospitalisation. NAUSEA and VOMITING are expected according to the "expectedness event list for Alpharadin trials (14-Sep-2011)", ANOREXIA and DEHYDRATION are not expected.The Investigator cited the "erosive duodenitis" as alternative explanation for the reported events and assessed them accordingly and in line with the Sponsor as unrelated to Alpharadin. The Company follows this judgement.
15245-021-021002	WORSENING OF PROSTATE CANCER[PT：前立腺癌] This 63 year old male patient experienced WORSENING OF PROSTATE CANCER (CTC GRADE 3) and was hospitalized after receiving study medication (Alpharadin/placebo) in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The event WORSENING OF PROSTATE CANCER (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for alpharadin. The investigator assessed the relationship to study drug as unrelated but rather due to concurrent illness.The company agrees with the reporter.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-021-021003	DIARRHOEA CAUSING DEHYDRATION (CTC GRADE 2)[PT：下痢] DIARRHOEA CAUSING DEHYDRATION (CTC GRADE 2)[PT：脱水] This 63 year old male patient experienced DIARRHOEA CAUSING DEHYDRATION (CTC GRADE 2) (code split per coding requirements) and was hospitalized the same date as the latest received dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases. Medical history was not provided.The events DIARRHOEA CAUSING DEHYDRATION (CTC GRADE 2) (code split per coding requirements to diarrhea and dehydration) are considered serious (hospitalized) and Listed for diarrhea and unlisted for dehydration for Alpharadin. The investigator has updated the relationship to study drug from possibly related to unrelated. The investigator reported that the subject's wife has recovered after diarrhoea.The sponsor has assessed the relationship to study drug as unrelated.
15245-021-021003	FEVER OF UNKNOWN ORIGIN (CTC GRADE 2)[PT：発熱] Company causality assessment per License Partner Algeta:Event FEVER OF UNKNOWN ORIGIN (CTC GRADE 2), is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as related to study drug.
15245-022-022002	FREQUENT DIARRHEA (CTC GRADE 3)[PT：下痢] 本症例には、プラセボが投与されていた。
15245-022-022003	NON-SPECIFIED GENERAL INFECTION (CTC GRADE 2)[PT：感染] 本症例には、プラセボが投与されていた。
15245-022-022004	STERNUM FRACTURE (CTC GRADE 2)[PT：胸骨骨折] This 84 year old male patient experienced STERNUM FRACTURE (CTC GRADE 2) and was hospitalized 44 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event STERNUM FRACTURE (CTC GRADE 2) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated. An alternative explanation was not provided.The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-022-022005	NAUSEA (CTC GRADE 2)[PT：悪心] DEHYDRATION (CTC GRADE 2)[PT：脱水] VOMITING (CTC GRADE 2)[PT：嘔吐] 本症例には、プラセボが投与されていた。
15245-022-022005	FATIGUE (CTC GRADE 2)[PT：疲労] 本症例には、プラセボが投与されていた。
15245-022-022005	SEPSIS (CTC GRADE 4)[PT：敗血症] 本症例には、プラセボが投与されていた。
15245-022-022005	ANAEMIA (CTC GRADE 3)[PT：貧血] OBSTIPATION (CTC GRADE 3)[PT：便秘] SKELETAL PAIN (COLUNM) (CTC GRADE 3)[PT：脊椎痛] 本症例には、プラセボが投与されていた。
15245-022-022005	PROGRESSION OF PROSTATE CANCER[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-022-022008	HEMATURIA (CTC GRADE 1)[PT：血尿] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-022-022009	INCREASING PAIN (CTC GRADE 3)[PT：骨痛] This 76 year old male patient experienced Increasing Pain (CTC GRADE 3) (bone pain) 178 days after the first dose of Alpharadin/placebo in this double blind, randomized, repeat dose, phase III, multicenter survival study of AlpharadinTM in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.Increasing Pain (bone pain) is considered serious (hospitalized) and unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-022-022010	PROGRESSION OF DISEASE (CTC GRADE 3)[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-022-022010	MUCOSITIS (CTC GRADE 2)[PT：粘膜の炎症] 本症例には、プラセボが投与されていた。
15245-023-023002	HYDROCEPHALUS (CTC GRADE 2)[PT：水頭症] 本症例には、プラセボが投与されていた。
15245-023-023003	BACTERIAL SEPSIS (CTC GRADE 4)[PT：細菌性敗血症] （本例は PMDA へ報告を行った症例である。弊社の見解を日本語で示す） 本事象が本剤の最終投与から約 1 週間後に発現していることを勘案し、時間的関連性の観点より、本剤との因果関係は否定できないと考える。なお、本事象の発現時期は他の治療（一般的なインフルエンザに対するワクチンである fluarix）の実施時期と一致しているため、その影響も考えられる。
15245-024-024003	NEUTROPENIA (CTC GRADE 3)[PT：好中球減少症] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-024-024005	DISEASE PROGRESSION NOS (CTC GRADE 5)[PT：悪性新生物進行] 本症例には、プラセボが投与されていた。
15245-024-024006	INFECTION UNKNOWN ORIGIN (CTC GRADE 1)[PT：感染] 試験薬は投与されていない。
15245-024-024006	FEVER (CTC GRADE 1)[PT：発熱] 試験薬は投与されていない。
15245-024-024007	BONE PAIN (CTC GRADE 3)[PT：骨痛] LIVER METASTSES (CTC GRADE 5)[PT：肝転移] Company causality assessment per License Partner Algeta:Event of BONE PAIN (CTC GRADE 3), serious due to hospitalization, is listed for Alpharadin, whereas, LIVER METASTSES (CTC GRADE 5), serious due to hospitalization and fatal outcome, is unlisted. Both events were assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to disease progression of cancer with metastases.
15245-024-024009	MOTOR NEUROPATHY (CTC GRADE 3)[PT：末梢性運動ニューロパチー] 本症例には、プラセボが投与されていた。
15245-024-024009	CARDIAC INFARCTION (CTC GRADE 3)[PT：心筋梗塞] PROGRESSION OF PROSTATE CANCER (CTC GRADE 5)[PT：前立腺癌] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-024-024010	MOTOR NEUROPATHY (CTCAE GRADE 2)[PT：末梢性運動ニューロパチー] 試験薬は投与されていない。
15245-024-024011	BONE PAIN (CTC GRADE 2)[PT：骨痛] This 87 year old Caucasian male who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced BONE PAIN (CTC GRADE 2) 82 days after study drug was started. Prior to the onset of the event, the subject received 3 study injections.The subject's relevant medical history includes cardiac insufficiency and atrial fibrillation. BONE PAIN (CTC GRADE 2) is considered serious (hospitalization) and is listed for Alpharadin.The investigator assessed the relationship to study drug as unrelated, but rather due to progression of bone metastasis.The sponsor assessed the relationship to study drug as unrelated.
15245-024-024014	AURICULAR FIBRILLATION (CTC GRADE 2)[PT：心房細動] 本症例には、プラセボが投与されていた。
15245-024-024014	PROGRESSION OF PROSTATE CANCER[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-024-024016	BONE PAIN RELATED TO TRAUMA AFTER FALL[PT：骨痛] This case report was received by license partner Algeta and refers to a 73-year-old Caucasian male patient who received Alpharadin while enrolled in study BC1-06 titled 'A double blind, randomised, repeat dose, phase III, multicentre survival study of AlpharadinTM in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases'. Approx. 2 month after the last (6th) injection of Alpharadin the patient was admitted to hospital due to bone pain related to trauma after fall. The patient's relevant medical history included testicular cancer and angina pectoris. Concomitant medications were not reported.The event bone pain related to trauma after fall is considered serious due to hospitalization and is unlisted in the Investigator's Brochure of Alpharadin.The investigator has assessed the relationship to study drug as unrelated and cited trauma as alternative explanation.The sponsor has assessed the relationship to the study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-024-024017	PROGRESSION OF PROSTATE CANCER[PT：前立腺癌] Company causality assessment per License Partner Algeta:Event of PROGRESSION OF PROSTATE CANCER is serious (fatal outcome), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug.
15245-024-024022	RIGHT HIP FRACTURE (CTC GRADE 3)[PT：股関節部骨折] ANAEMIA (CTC GRADE 2)[PT：貧血] URINARY RETENTION (CTC GRADE 2)[PT：尿閉] 試験薬は投与されていない。
15245-024-024022	DISLOCATION AFTER HIP FRACTURE (CTC GRADE 3)[PT：医療機器位置異常] FEVER (CTC GRADE 3)[PT：発熱] VOMIT (CTC GRADE 3)[PT：嘔吐] PAIN (CTC GRADE 3)[PT：疼痛] 本症例には、プラセボが投与されていた。
15245-024-024022	PROGRESSION OF PROSTATE CANCER (CTC GRADE 3)[PT：前立腺癌] PNEUMONIA (CTC GRADE 4)[PT：肺炎] PULMONARY OEDEMA (CTC GRADE 4)[PT：肺水腫] PATHOLOGICAL LEFT HIP FRACTURE (CTC GRADE 3)[PT：病的骨折] SEPTICAEMIA (CTC GRADE 3)[PT：敗血症] 本症例には、プラセボが投与されていた。
15245-024-024023	BONE PAIN (CTCAE GRADE 2)[PT：骨痛] Company causality assessment per License Partner Algeta:Event of BONE PAIN (CTCAE GRADE 2) is serious (hospitalized), listed and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to skeletal metastasis.
15245-024-024024	PROGRESSION OF PROSTATE CANCER[PT：前立腺癌] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-024-024026	BONE PAIN (CTC GRADE 3)[PT：骨痛] FEVER (CTC GRADE 3)[PT：発熱] FATIGUE (CTC GRADE 3)[PT：疲労] 本症例には、プラセボが投与されていた。
15245-024-024026	PROGRESSION OF PROSTATE CANCER (CTC GRADE 3)[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-025-025001	ANEMIA (CTC GRADE 3)[PT：貧血] THROMBOCYTOPENIA (CTC GRADE 2)[PT：血小板減少症] Company causality assessment per License Partner Algeta:Events of ANEMIA (CTC GRADE 3) and THROMBOCYTOPENIA (CTC GRADE 2) are serious (hospitalized), listed and assessed by the Investigator and Sponsor as possibly related to study drug.
15245-025-025002	INFECTION CAUSED BY LISTERIA (CTC GRADE 2)[PT：リステリア症] 本症例には、プラセボが投与されていた。
15245-025-025002	DISEASE PROGRESSION IN PROSTATE CANCER (CTC GRADE 5)[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-025-025004	SEVERE HEART FAILURE (CTC GRADE 5)[PT：心不全] HAEMATURIA (CTC GRADE 3)[PT：血尿] This 64 year old Caucasian male who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer, experienced Haematuria and Severe heart failure 65 days after the onset of study drug. The subject's relevant medical history included sarcoidosis, hypertonia, arrhythmia and atrial fibrillation.Severe heart failure (fatal) is serious due to hospitalization and its fatal nature and is unlisted for Alpharadin. Haematuria is considered serious due to hospitalization and is unlisted for Alpharadin.The investigator assessed the relationship of both events to study drug as unrelated. The investigator confirmed that there was no evidence of disease progression. The sponsor

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	assessed the relationship to study drug as unrelated.
15245-025-025012	HYDRONEPHROSIS LEFT SIDE (CTC GRADE 2)[PT：水腎症] Company causality assessment per License Partner Algeta:Event of HYDRONEPHROSIS LEFT SIDE (CTC GRADE 2), is serious (hospitalized / medically significant), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to disease progression.
15245-025-025013	INFECTION (CTC GRADE 3)[PT：感染] This 72 year old male patient developed an INFECTION (CTC grade 3) and was hospitalized 19 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included hypertension.The event INFECTION (CTC grade 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated, but rather due to concurrent illness. The sponsor has assessed the relationship to study drug as unrelated.
15245-025-025013	FEVER[PT：発熱] Company causality assessment per License Partner Algeta:Event of FEVER is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to concurrent illness.
15245-025-025014	LIVER FAILURE (CTC GRADE 3)[PT：肝不全] PAIN RIGHT HIP[PT：関節痛] Company causality assessment per License Partner Algeta:Event of LIVER FAILURE (unlisted), serious due to hospitalization / fatal outcome and event of PAIN RIGHT HIP (listed), serious due to hospitalization, are assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to cancer progression.
15245-025-025015	PROSTATE CANCER PROGRESSION - LIVER METASTASES[PT：肝転移] PROSTATE CANCER PROGRESSION - LIVER METASTASES[PT：遠隔転移を伴う前立腺癌] This 73 year old male patient experienced PROSTATE CANCER PROGRESSION - LIVER METASTASES (code split per coding requirements) and died 27 days after receiving the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included angina pectoris, asthma and lumbar disc displacement.The events PROSTATE CANCER PROGRESSION - LIVER METASTASES (code split per coding requirements to prostate cancer progression and liver metastases) are considered serious (fatal) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated, but rather due to

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	concomitant illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-025-025020	BONE PAIN (CTC GRADE 2)[PT：骨痛] Company causality assessment per License Partner Algeta:Event of BONE PAIN (CTC GRADE 2), is serious (hospitalized), listed and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to concurrent illness.
15245-025-025020	SEPTICEMIA (CTC GRADE 4)[PT：敗血症] SPINAL CORD COMPRESSION L4 AND L5 (CTC GRADE 4)[PT：脊髄圧迫] Company causality assessment per License Partner Algeta:Events of SEPTICEMIA (CTC GRADE 4) and SPINAL CORD COMPRESSION L4 AND L5 (CTC GRADE 4) are serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-025-025020	DISEASE PROGRESSION (CTCAE GRADE 5)[PT：悪性新生物進行] A 61 year old Caucasian male, enrolled in a Phase III clinical trial, died due to disease progression 6.5 months after initial study medication (Alphardin/Placebo) administration. No autopsy was performed. The subject ‘s relevant medical history include prior docetaxel therapy, hypertension, lhermitte and angina pectoris. Concomitant medications include omeprazole, sodium picosulfate, lactulose, glyceryl trinitrate, ferroglycine sulfate complex, furosemide, magnesium hydroxide, morphine, fentanyl, paracetamol and amitriptyline. Death due to disease progression was serious (fatal) and unexpected for Alpharadin.The investigator has assessed the relationship to study drug as unrelated, but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-025-025022	DISEASE PROGRESSION (CTC GRADE 2)[PT：悪性新生物進行] This 61 year old male patient experienced disease progression (CTC grade 2) and was hospitalized 29 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient’s concurrent condition included sarcoidosis, hypertension and insomnia.The event disease progression (CTC grade 2) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated, but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-026-026001	DEHYDRATION (CTC GRADE 2)[PT：脱水] CONFUSION (CTC GRADE 2)[PT：錯乱状態] Company causality assessment per License Partner Algeta:Events of DEHYDRATION (CTC GRADE 2) and CONFUSION (CTC GRADE 2) are serious due to hospitalization, unlisted and assessed by the Investigator and Sponsor as unrelated to study drug.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-026-026001	DISEASE PROGRESSION[PT：前立腺癌] This 79 year old male patient experienced DISEASE PROGRESSION and was hospitalized 24 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient died 1 day later. The patient's concurrent condition included confusion, dehydration, compression fracture and collapsed vertebra.The event DISEASE PROGRESSION is considered serious (fatal, hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated.The sponsor has assessed the relationship to study drug as unrelated.
15245-026-026002	PAIN-OTHER-MUSCULOSKELETAL-BONE (CTC GRADE 3)[PT：骨痛] 試験薬は投与されていない。
15245-026-026002	MOTOR AND SENSORY NEUROPATHY (CTC GRADE 1)[PT：末梢性感覚運動ニューロパチー] This 66 year old male patient experienced MOTOR AND SENSORY NEUROPATHY (CTC GRADE 1) 91 days after receiving the first dose of Alpharadin/Placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included atrial fibrillation.The event MOTOR AND SENSORY NEUROPATHY (CTC GRADE 1) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated. Alternative explanation includes the subject's underlying disease.The sponsor has assessed the relationship to study drug as unrelated.
15245-026-026002	URINE AND FAECAL INCONTINENCE (CTC GRADE 3)[PT：尿失禁] URINE AND FAECAL INCONTINENCE (CTC GRADE 3)[PT：便失禁] HYPERGLYCEMIA (CTC GRADE 3)[PT：高血糖] This 66 year old male patient experienced URINE AND FAECAL INCONTINENCE (CTC GRADE 3) (coded twice to urine incontinence and fecal incontinence) and HYPERGLYCEMIA (CTC GRADE 3) 24 days after receiving the latest dose of study drug (Alpharadin/placebo) in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included lack of sensitivity in lower extremities, weakness in lower extremities, bone pain and atrial fibrillation.The events URINE AND FAECAL INCONTINENCE (CTC GRADE 3) (coded twice to urine incontinence and fecal incontinence) and HYPERGLYCEMIA (CTC GRADE 3) are considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug for all the events as unrelated, rather due to disease progression.The sponsor has assessed the relationship to study drug for all the events as unrelated.
15245-026-026002	UNDERLYING DISEASE (CTC GRADE 2)[PT：前立腺癌] PANCYTOPENIA (CTC GRADE 3)[PT：汎血球減少症] FALL ACCIDENT (CTC GRADE 3)[PT：事故] The case refers to a 66-year-old male patient in a double blind, randomized, repeat dose, phase III, multicentre survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had a relevant medical history of atrial fibrillation.Patient experienced PANCYTOPENIA (CTC GRADE 3) which is serious due to hospitalization and listed in the Investigator´s Brochure of Alpharadin. The patient also experienced a FALL ACCIDENT (CTC GRADE 3) which is serious (hospitalized) and unlisted for Alpharadin. The patient died from UNDERLYING DISEASE which is serious (fatal, hospitalized) and unlisted for Alpharadin.The investigator has assessed the relationship to study drug for all events as unrelated.The sponsor has assessed the

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	relationship to the study drug as unrelated for all the events.
15245-026-026003	DECREASED GENERAL CONDITION (CTC GRADE 2)[PT：全身健康状態低下] PNEUMONIA (CTC GRADE 3)[PT：肺炎] Company causality assessment per License Partner Algeta:Events DECREASED GENERAL CONDITION (CTC GRADE 2), serious (hospitalized) and PNEUMONIA (CTC GRADE 3), serious (hospitalized / medically significant), are unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to underlying disease.
15245-026-026005	HYDRONEPHROSIS (CTC GRADE 3)[PT：水腎症] This 67 year old male patient experienced HYDRONEPHROSIS (CTC GRADE 3) and was hospitalized 21 days after receiving the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included gout and hypertension.The event HYDRONEPHROSIS (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to underlying disease.The sponsor has assessed the relationship to study drug as unrelated.
15245-026-026005	DECREASED GENERAL CONDITION (CTC GRADE 1)[PT：全身健康状態低下] RECTAL BLEEDING (CTC GRADE 3)[PT：直腸出血] This 67 year-old caucasian male patient who was enrolled in a clinical study and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced DECREASED GENERAL CONDITION (CTC GRADE 1) and RECTAL BLEEDING (CTC GRADE 3). DECREASED GENERAL CONDITION (CTC GRADE 1) and RECTAL BLEEDING (CTC GRADE 3) are considered serious (hospitalization) and unlisted for Alpharadin. The investigator assessed the relationship to study drug as unrelated, but rather due to the underlying disease.The company agrees with this assessment.
15245-026-026005	URINARY TRACT INFECTION (CTC GRADE 3)[PT：尿路感染] Company causality assessment per License Partner Algeta:Event of URINARY TRACT INFECTION (CTC GRADE 3) is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to concurrent illness.
15245-026-026005	BONE PAIN (CTC GRADE 2)[PT：骨痛] DEHYDRATION (CTC GRADE 2)[PT：脱水] Company causality assessment per License Partner Algeta:Events of BONE PAIN (CTC GRADE 2) (listed) and DEHYDRATION (CTC GRADE 2) (unlisted) are serious (hospitalized) and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to underlying disease.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-026-026007	OCCLUSION OF J-STENT LEFT URETHER (CTC GRADE 2)[PT：医療機器閉塞] 試験薬は投与されていない。
15245-026-026009	FEVER (CTC GRADE 2)[PT：発熱] PAIN-NECK (CTC GRADE 2)[PT：頚部痛] 本症例には、プラセボが投与されていた。
15245-026-026009	FEVER OF BACTERIAL ORIGIN, UNKNOWN FOCUS (CTC GRADE 2)[PT：熱性感染症] 本症例には、プラセボが投与されていた。
15245-026-026010	SEIZURES DUE TO BRAIN METASTASES (CTC GRADE 4)[PT：中枢神経系転移] SEIZURES DUE TO BRAIN METASTASES (CTC GRADE 4)[PT：痙攣] Company causality assessment per License Partner Algeta:Event SEIZURES DUE TO BRAIN METASTASES (CTC GRADE 4), is serious (hospitalized / life threatening), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to underlying disease.
15245-026-026016	PNEUMONIA (CTC GRADE 3)[PT：肺炎] THROMBOCYTOPENIA (CTC GRADE 3)[PT：血小板減少症] This 72 year old male patient experienced PNEUMONIA (CTC Grade 3) and THROMBOCYTOPENIA (CTC Grade 3) and was hospitalized 25 days after receiving last dose of Alpharadin/placebo in this clinical study of AlpharadinTM in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. Patient had a medical history of impaired hearing.The event PNEUMONIA (CTC Grade 3) is considered serious (hospitalized) and Unlisted for alpharadin whereas event of THROMBOCYTOPENIA (CTC Grade 3) is considered serious (hospitalized) and Listed.The investigator has assessed the relationship to study drug as unrelated but rather due to underlying disease for pneumonia and probably related for thrombocytopenia.The Sponsor has assessed the relationship to study drug as unrelated for the event of pneumonia and possibly related for the event of thrombocytopenia.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-026-026017	FEVER (CTC GRADE 2)[PT：発熱] 本症例には、プラセボが投与されていた。
15245-027-027001	CIRCULATORY COLLAPSE[PT：循環虚脱] The case refers to a 73-year-old male patient in a double-blind, randomized, repeat dose, phase III, multicentre survival study of ALPHARADIN in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases.The patient experienced SYNCOPE (TWICE) which is a serious event because it was life-threatening and leaded to hospitalization. It is unlisted in the Investigator´s Brochure of Alpharadin.The investigator has assessed the relationship to study drug as unrelated. The investigator stated that the subject had bifascicular block when he entered the study and there was no known correlation between the study drug and cardiac arrhythmia.The sponsor has assessed the event relationship to the study drug as unrelated.
15245-027-027002	WORSENING OF CONSTIPATION (CTC GRADE 4)[PT：便秘] MULTIORGAN FAILURE (CTC GRADE 4)[PT：多臓器不全] （本例は PMDA へ報告を行った症例である。弊社の見解を日本語で示す） 「便秘」及び「多臓器不全」について、治験担当医は本治験薬との因果関係があると評価した。また、「本剤が便中に排泄されることにより下痢が生じる可能性があるということは予測していたが、本剤の通過により腸の神経系が損傷を受けるということが起こり得るのかという疑問もある。この疑問について答えられる者がいなかったことから、本事象との因果関係は否定しきれないと考えた。」とコメントした。 弊社は、いずれの事象も、本剤の最終投与から約 18 ヶ月後に発現していることを勘案し、時間的関連性が認められないことより、本剤との因果関係は否定できると考える。「便秘」については、併用薬であるモルヒネとの関連性が高いと考える。また、「多臓器不全」については、本剤の最終投与から本事象の発現までの間に下部腰椎および仙椎への放射線療法による治療を実施しており、放射線療法による影響とも考える。
15245-028-028001	ANEMIA (CTC GRADE 4)[PT：貧血] ANOREXIA (CTC GRADE 1)[PT：食欲減退] VOMITING (CTC GRADE 1)[PT：嘔吐] DYSPNEA (CTC GRADE 2)[PT：呼吸困難] This 63 year old male patient experienced ANEMIA (CTC GRADE 4), ANOREXIA (CTC GRADE 1), VOMITING (CTC GRADE 1) and DYSPNEA (CTC GRADE 2) and was hospitalized 28 days after taking the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included esophagitis, bone pain scapula, erection disorder, collapsed L4-L5 and osteoporosis.The event ANEMIA (CTC GRADE 4) is considered serious (hospitalized, disability) and Listed for Alpharadin. The events of ANOREXIA (CTC GRADE 1) and DYSPNEA (CTC GRADE 2) are considered serious (hospitalized) and Unlisted for Alpharadin. Event of VOMITING (CTC GRADE 1) is considered serious because the patient was hospitalized and Listed for Algeta-sponsored phase III multicenter study with alpharadin (BAY88-82. The investigator has assessed the relationship to study drug as possibly related for anemia. It was reported that anemia could have been also caused by massive bone metastases. The investigator has assessed the relationship to study drug as unrelated for anorexia, vomiting and dyspnea.The sponsor has assessed the relationship to study drug as possibly related for anemia because of the known product profile and unrelated for anorexia, vomiting and dyspnea.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-028-028001	ANEMIA (CTC GRADE 3)[PT：貧血] GENERAL DETERIORATION (CTC GRADE 3)[PT：全身健康状態低下] GENERAL DETERIORATION (CTC GRADE 3)[PT：全身健康状態低下] GENERAL DETERIORATION (CTC GRADE 3)[PT：全身健康状態低下] GENERAL DETERIORATION (CTC GRADE 3)[PT：全身健康状態低下] This 63 year old male patient experienced ANEMIA (CTC GRADE 3) and GENERAL DETERIORATION (CTC GRADE 3) (4 occurrences) while in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included oesophagitis, bone pain scapula, erection disorder, collapsed L4-L5, osteoporosis.The event ANEMIA (CTC GRADE 3) is considered serious (hospitalized) and Listed for Alpharadin. The events of GENERAL DETERIORATION (CTC GRADE 3) are considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to the study drug as possibly related for all events. The investigator clarified his assessment for general deterioration stating that although the subject's metastatic prostate cancer was very much progressed, the subject was still a dynamic person and was willing to get better. The subject had participated in other trials before. The rapid deterioration of the subject's general condition occurred quite unexpectedly, which is normally not seen in this type of prostate cancer patients.The sponsor has assessed the relationship to the study drug as possibly related for the event of anaemia and unrelated for general deterioration.
15245-028-028002	GENERAL DETERIORATION (CTC GRADE 2)[PT：全身健康状態低下] METASTATIC BONE PAIN (CTC GRADE 2)[PT：転移部痛] 試験薬は投与されていない。
15245-028-028002	ANEMIA (CTC GRADE 3)[PT：貧血] Company causality assessment per License Partner Algeta:Event of ANEMIA (CTC GRADE 3), is serious (hospitalized), listed and assessed by the Investigator and Sponsor as possibly related to study drug.
15245-028-028002	GENERAL DETERIORATION (CTC GRADE 3)[PT：全身健康状態低下] ANEMIA (CTC GRADE 2)[PT：貧血] HIP FRACTURE (CTC GRADE 3)[PT：病的骨折] This 73 year old male patient experienced GENERAL DETERIORATION (CTC GRADE 3), ANEMIA (CTC GRADE 2) and HIP FRACTURE (CTC GRADE 3) and was hospitalized 27 days after receiving the last dose of study medication (Alpharadin/placebo) in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient later died due to the general deterioration. The patient's concurrent condition included anemia.The event GENERAL DETERIORATION (CTC GRADE 3) is considered serious (fatal, hospitalized) and Unlisted for Alpharadin.. The event ANEMIA (CTC GRADE 2) is considered serious (hospitalized) and Listed for Alpharadin. The event HIP FRACTURE (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated for general deterioration and hip fracture, and as possibly related for anemia.The sponsor has assessed the relationship to study drug as unrelated for hip fracture and general deterioration and possibly related for the anaemia.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-028-028003	MULTIPLE ORGAN FAILURE (CTC GRADE 4)[PT：多臓器不全] RENAL INSUFFICIENCY[PT：腎不全] PULMONARY OEDEMA[PT：肺水腫] ANAEMIA[PT：貧血] DECREASED GENERAL STATUS[PT：全身健康状態低下] This 83 year old male patient experienced RENAL INSUFFICIENCY, PULMONARY OEDEMA, ANAEMIA and DECREASED GENERAL STATUS and was hospitalized 27 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient later developed MULTIPLE ORGAN FAILURE (CTC GRADE 4) which led to the patient's death. The patient's concurrent condition included hypertension arterial, Oedema lower limb, hydronephrosis and chronic obstructive pulmonary disease.The event MULTIPLE ORGAN FAILURE (CTC GRADE 4) is considered serious (fatal, hospitalized) and Unlisted for Alpharadin. The events RENAL INSUFFICIENCY, PULMONARY OEDEMA and DECREASED GENERAL STATUS are considered serious (hospitalized) and Unlisted for Alpharadin. The event ANAEMIA is considered serious (hospitalized) and Listed for Alpharadin.The investigator has assessed the relationship to study drug as unrelated for the events of renal insufficiency, pulmonary oedema, and decreased general status. The event of anaemia was assessed as possibly related. The event of multiple organ failure was assessed as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated for multiple organ failure, pulmonary oedema, renal insufficiency and decreased general status, and possibly related for anaemia.
15245-028-028004	TRANSIENT ISCHEMIC ATTACK (CTC GRADE 2)[PT：一過性脳虚血発作] 試験薬は投与されていない。
15245-028-028004	PROSTATE CANCER DISEASE[PT：前立腺癌] This 84 year old male patient experienced PROSTATE CANCER DISEASE and died 37 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. Relevant medical history was not provided.The event PROSTATE CANCER DISEASE is considered serious (fatal)and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated.Sponsor has assessed the relationship to study drug as unrelated.
15245-028-028005	PATHOLOGICAL FRACTURE OF RIGHT HUMERUS (CTC GRADE 3)[PT：病的骨折] POOR GENERAL CONDITION(CTC GRADE 3)[PT：全身健康状態低下] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-028-028005	PROGRESSION OF PRE-EXISTING CANCER[PT：悪性新生物進行] 本症例には、プラセボが投与されていた。
15245-028-028007	URINARY RETENTION (CTC GRADE 3)[PT：尿閉] Company causality assessment per License Partner Algeta:Event of URINARY RETENTION (CTC GRADE 3) is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to prostate cancer growth.
15245-028-028007	PULMONAL LYMPHANGITIS CARCINOMATOSA (CTC GRADE 4)[PT：癌性リンパ管症] PLEURAL EFFUSION (CTC GRADE 4)[PT：胸水] This 66 year old male patient was hospitalized for PULMONAL LYMPHANGITIS CARCINOMATOSA (CTC GRADE 4) and PLEURAL EFFUSION (CTC GRADE 4) 34 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient later died from PULMONAL LYMPHANGITIS CARCINOMATOSA. The patient had no relevant medical history.The event PULMONAL LYMPHANGITIS CARCINOMATOSA (CTC GRADE 4) is considered serious (fatal, life threatening event, hospitalized) and Unlisted for Alpharadin. The event PLEURAL EFFUSION (CTC GRADE 4) is considered serious because (life threatening event, hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated, but rather due to concurrent illness for both events.The sponsor has assessed the relationship to the study drug as unrelated for both events.
15245-029-029001	URINARY RETENTION (CTC GRADE 3)[PT：尿閉] 本症例には、プラセボが投与されていた。
15245-029-029001	DEGRADATION OF GENERAL STATUS (CTC GRADE 3)[PT：全身健康状態低下] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-029-029002	LOMBALGIA (CTC GRADE 3)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-029-029002	PROGRESSIVE DISEASE (CTC GRADE 3)[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-033-033001	PULMONARY EMBOLUS (CTC GRADE 5)[PT：肺塞栓症] 本症例には、プラセボが投与されていた。
15245-033-033002	ATRIAL FIBRILLATION (CTC GRADE 3)[PT：心房細動] URINARY TRACT INFECTION (CTC GRADE 2)[PT：尿路感染] 試験薬は投与されていない。
15245-033-033002	PAIN-MUSCULOSKELETAL-EXTREMITY-LIMB (CTC GRADE 2)[PT：筋骨格痛] 本症例には、プラセボが投与されていた。
15245-033-033005	MYOCARDIAL INFARCTION (CTC GRADE 4)[PT：心筋梗塞] Company causality assessment per License Partner Algeta:Event of MYOCARDIAL INFARCTION, is serious (hospitalized / fatal outcome), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-033-033006	BILATERAL LEG CELLULITIS[PT：蜂巣炎] CONSTIPATION[PT：便秘] This 76 year old Caucasian male who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer, experienced bilateral leg cellulitis and constipation after the onset of study drug. The subject's relevant medical history included prostate cancer with bone metastases, asbestosis and pathological bilateral neck of femur (NOF) fractures.Bilateral leg cellulitis and constipation are serious due to hospitalization and are unlisted for Alpharadin. The investigator assessed the relationship to study drug as unrelated but rather due to concomitant medications. The subject's constipation was due to the use of opiate analgesics used to treat bone pain.The sponsor assessed the relationship to study drug as unrelated for both events.
15245-033-033006	PNEUMONIA (CTC GRADE 3)[PT：肺炎] FRACTURE OF RIGHT HUMERUS (CTC GRADE 3)[PT：病的骨折] This 76 year old male patient experienced FRACTURE OF RIGHT HUMERUS (CTC GRADE 3) and PNEUMONIA (CTC GRADE 3) and was hospitalized 33 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases. The patient's medical history included pathological bilateral neck of femur (NOF) fractures. Both events recovered after treatment. The patient's concurrent condition included diarrhea - overflow due to constipation and prostate cancer with bone metastases. The events of FRACTURE OF RIGHT HUMERUS (CTC GRADE 3) and PNEUMONIA (CTC GRADE 3) are considered serious (hospitalized) and unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated for both events. Fracture of right humerus is due to concurrent illness and pneumonia is a community acquired infection.The sponsor has assessed the relationship to study drug as unrelated for both events.
15245-033-033011	HAEMATEMESIS (CTC GRADE 3)[PT：吐血] Company causality assessment per License Partner Algeta:Event of HAEMATEMESIS (CTC GRADE 3) is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to concomitant medications (NSAIDs).
15245-033-033012	METASTATIC BONE PAIN (CTC GRADE 3)[PT：転移部痛] Company causality assessment per License Partner Algeta:Event of METASTATIC BONE PAIN (CTC GRADE 3) is serious (hospitalized / disability), listed and assessed by the Investigator and Sponsor as unrelated to study drug; alternative explanation provided was due to prostate cancer.
15245-033-033012	PAIN-MUSCULOSKELETAL-BONE (CTC GRADE3)[PT：骨痛] This 73 year old male patient experienced PAIN-MUSCULOSKELETAL-BONE (CTC GRADE3) and was hospitalized 17 days after receiving the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event PAIN-MUSCULOSKELETAL-BONE (CTC GRADE3) is considered serious (hospitalized) and Listed for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-033-033014	PAIN - PULMONARY - CHEST/THORAX (CTC GRADE 3)[PT：胸痛] 本症例には、プラセボが投与されていた。
15245-033-033014	PROGRESSIVE PROSTATE CANCER[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-033-033017	PULMONARY THROMBOEMBOLUS[PT：肺塞栓症] 本症例には、プラセボが投与されていた。
15245-033-033019	POPLITEAL VEIN THROMBOSIS (CTC GRADE 2)[PT：深部静脈血栓症] Company causality assessment per License Partner Algeta:Event of POPLITEAL VEIN THROMBOSIS (CTC GRADE 2) is serious (hospitalization), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to concurrent illness.
15245-033-033019	PULMONARY EMBOLISM (CTC GRADE 3)[PT：肺塞栓症] This 72 year old Caucasian male, who was enrolled in study BC1-06 and has received four study injections of Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced PULMONARY EMBOLISM (CTC GRADE 3) (previously recurrence of pulmonary embolism (CTC grade 3)) 59 days after first administration of study drug. He was treated with Warfarin and recovered. Approximately three months before, he has experienced popliteal vein thrombosis. PULMONARY EMBOLISM (CTC GRADE 3) is considered serious due to medical significance and hospitalization, it is unexpected according to the Investigators Brochure for Alpharadin.The investigator has assessed the event as unrelated to the study drug, but rather due to concurrent illness.Given the patients underlying malignant disease with an increased risk of thromboembolic events as well as the previous popliteal vein thrombosis, the relationship to the study drug is considered unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-033-033022	PROGRESSIVE PROSTATE CANCER (CTC GRADE 2)[PT：前立腺癌] Company causality assessment per License Partner Algeta:Event of PROGRESSIVE PROSTATE CANCER (CTC GRADE 2), is serious due to hospitalization, listed and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-033-033023	PATHOLOGICAL FRACTURE OF RIGHT FEMUR (CTC GRADE 3)[PT：病的骨折] This 70 year old Caucasian male, who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced PATHOLOGICAL FRACTURE OF RIGHT FEMUR (CTC GRADE 3) 121 days after taking the first dose of study drug. The subject's concurrent condition included back pain and hypertension.PATHOLOGICAL FRACTURE OF RIGHT FEMUR (CTC GRADE 3) is considered serious (hospitalization) and is unlisted for Alpharadin.The investigator assessed the relationship to study drug as possibly related. The investigator stated that it was possible that the study drug might impair the subject's bone strength. However, the company disagrees and considers this event unrelated. A plausible alternative explanation is the patient's underlying disease.
15245-033-033023	PARAESTHESIA (LEFT HAND) (CTC GRADE 1)[PT：錯感覚] The case refers to a 70-year-old patient in a double blind, randomized, repeat dose, phase III, multicentre survival study of AlpharadinTM in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. He experienced PARAESTHESIA (LEFT HAND)(CTC GRADE 1) which is serious due to hospitalization and is unlisted in the Investigator´s Brochure of Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness. The investigator stated that the subject was known to have metastatic disease in lower cervical and upper thoracic spine. The left hand symptoms were due to left T1 nerve root compression by the metastatic disease. The company agrees on that and considers PARAESTHESIA (LEFT HAND)(CTC GRADE 1) not associated to Alpharadin/placebo.
15245-033-033023	PNEUMONIA (CTCAE GRADE 5)[PT：肺炎] BROKEN ARM (CTCAE GRADE 3)[PT：上肢骨折] This 70 year old male patient experienced BROKEN ARM (CTCAE GRADE 3) (requiring a hospitalization) and later died due to PNEUMONIA (CTCAE GRADE 5) while in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included advanced prostate cancer.The event PNEUMONIA (CTCAE GRADE 5) is considered serious (fatal) and Unlisted for Alpharadin. The event BROKEN ARM (CTCAE GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to the study drug as unrelated for pneumonia but rather due to concurrent illness and as possibly related for broken arm. The investigator stated that the radium 223 could impair bone strength thus the fracture was possibly related in the absence of other medical background.The sponsor has assessed the relationship to the study drug as unrelated for both events.
15245-033-033025	ANEMIA (CTC GRADE 2)[PT：貧血] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-033-033025	DISSEMINATED INTRAVASCULAR COAGULATION (CTC GRADE 3)[PT：播種性血管内凝固] ANAEMIA (CTC GRADE 3)[PT：貧血] RESPIRATORY FAILURE (CTC GRADE 4)[PT：呼吸不全] INTRACRANIAL BLEED[PT：頭蓋内出血] 本症例には、プラセボが投与されていた。
15245-033-033026	CHEST INFECTION (CTC GRADE 3)[PT：下気道感染] 本症例には、プラセボが投与されていた。
15245-033-033026	PAIN-MUSCULOSKELETAL-BACK (CTC GRADE 3)[PT：筋骨格痛] 本症例には、プラセボが投与されていた。
15245-033-033026	PAIN-MUSCULOSKELETAL-BACK (CTC GRADE 3)[PT：筋骨格痛] 本症例には、プラセボが投与されていた。
15245-033-033027	DRUG INDUCED VOMITING (CTC GRADE 3)[PT：嘔吐] This 58 year old Caucasian male who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced DRUG INDUCED VOMITING (CTC GRADE 3) 44 days after the administration of study drug. The subject has no relevant medical history.DRUG INDUCED VOMITING (CTC GRADE 3) is considered serious (hospitalization) and listed for Alpharadin.The investigator assessed the relationship to study drug as unrelated, but rather due to concomitant medication.The Sponsor assessed the event as unrelated to the study drug.
15245-033-033027	DEGENERATIVE CERVICAL DISC DISEASE (CTCAE GRADE 3)[PT：椎間板変性症] VOMITING (CTC GRADE 3)[PT：嘔吐] DIARRHOEA (CTC GRADE 3)[PT：下痢] This 58 year old male patient experienced DEGENERATIVE CERVICAL DISC DISEASE (CTC AE grade 3), VOMITING (CTC GRADE 3) and DIARRHOEA (CTC GRADE 3) 196 days after receiving the first dose and 56 days after the last dose received of Alpharadin/placebo in this double blind, randomised, repeat dose, phase III, multicentre survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event DEGENERATIVE CERVICAL DISC DISEASE (CTC AE grade 3) is considered serious (hospitalized) and unlisted for Alpharadin whereas the events of VOMITING

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	(CTC GRADE 3) and DIARRHOEA (CTC GRADE 3) are considered serious (prolonged hospitalization) and listed for Alpharadin.The investigator has assessed the events as unrelated to the study drug but rather due to concurrent illness.The sponsor considers the events unrelated to Alpharadin.
15245-033-033031	ACUTE URINARY RETENTION (CTC GRADE 2)[PT：尿閉] 本症例には、プラセボが投与されていた。
15245-033-033031	ANAEMIA (CTC GRADE 2)[PT：貧血] 本症例には、プラセボが投与されていた。
15245-034-034004	CNS CEREBROVASCULAR ISCHEMIA (CTC GRADE 3)[PT：脳虚血] Company causality assessment per License Partner Algeta:Event of CNS CEREBROVASCULAR ISCHEMIA (CTC GRADE 3) is serious (hospitalization), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to concurrent illness.
15245-034-034004	BONE MARROW FAILURE (CTC GRADE 4)[PT：骨髄機能不全] This 63 year old male patient experienced BONE MARROW FAILURE (CTC GRADE 4) and was hospitalized 70 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases. The patient's concurrent condition included cerebral vascular ischemia, hereditary non-polyposis colon cancer and cancer of transverse colon. The event BONE MARROW FAILURE (CTC GRADE 4) is considered serious (fatal, hospitalized, medically important event) and Unlisted for Alpharadin. The investigator assessed the relationship to study drug as unrelated but rather due to disease progression.The sponsor assessed the relationship to study drug as unrelated.
15245-034-034016	PYONEPHROSIS[PT：膿腎症] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-034-034016	RIGHT LOWER LOBE PNEUMONIA (CTC GRADE 3)[PT：大葉性肺炎] 本症例には、プラセボが投与されていた。
15245-034-034016	BLOCKED NEPHROSTOMY TUBE (CTC GRADE 3)[PT：医療機器閉塞] 本症例には、プラセボが投与されていた。
15245-034-034017	DISEASE PROGRESSION[PT：前立腺癌] This 83 year old male patient experienced disease progression and was hospitalized 16 days after taking the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient later died due to the progression. The patient's concurrent condition included cancer of the prostate, chronic pancreatitis, diabetes type II and anaemia.The event disease progression is considered serious (fatal, hospitalized, disabling) and Unlisted for Alpharadin.The investigator assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor assessed the relationship to study drug as unrelated.
15245-035-035006	CRANIAL NERVE PALSY (CTC GRADE 3)[PT：脳神経不全麻痺] This 62 year old male patient experienced CRANIAL NERVE PALSY (CTC GRADE 3) after the use of Alpharadin/placebo. The patient had no relevant medical history.The investigator previously considered the event to be serious and unrelated to Alpharadin/placebo but rather due to disease progression.The sponsor previously considered the event to be serious (medically significant), unrelated and unexpected for Alpharadin/placebo.
15245-035-035006	LOW BACK PAIN[PT：背部痛] Company causality assessment per License Partner Algeta:Event of LOW BACK PAIN, is serious due to hospitalization, listed and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-035-035011	LARGE BOWEL PERFORATION (CTC GRADE 3)[PT：大腸穿孔] RECTAL ABSCESS (CTC GRADE 3)[PT：直腸膿瘍] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-035-035013	BONE PAIN (CTC GRADE 3)[PT：骨痛] NAUSEA (CTC GRADE 3)[PT：悪心] 本症例には、プラセボが投与されていた。
15245-035-035015	NECK PAIN (BONE PAIN) (CTCAE GRADE 3)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-035-035016	SEVERE BACK PAIN (BONE PAIN) (CTC GRADE 3)[PT：骨痛] This study case report from a license partner refers to a 63 year old male patient who has received four injections of Alpharadin for hormone-refractory prostate cancer with skeletal metastases when experiencing SEVERE BACK PAIN (BONE PAIN) (CTC GRADE 3) approximately one month after the last injection. His medical history included osteoporosis and vertebral collapse at T8.SEVERE BACK PAIN (BONE PAIN) (CTC GRADE 3) is serious due to hospitalization, unexpected for Alpharadin according to the current Investigator´s Brochure (previously expected) and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to osteoporosis. Considering the presence of a plausible alternative explanation (osteoporosis), causality is regarded as unrelated.
15245-035-035016	VOMITING (CTC GRADE 3)[PT：嘔吐] DIARRHOEA (CTC GRADE 3)[PT：下痢] The company has received a double blind, randomized phase III sponsored clinical trial report from (Algeta), referring a 63 year old Caucasian male patient (pt) enrolled in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases, received first dose of study medication (Alpharadin/Placebo) on 27-Jan-2010. No relevant past medical history / details for concomitant medications were provided. The patient did not receive prior docetaxel.A prior hospitalization due to back pain (see Ref. case /dates) was reported. Patient was hospitalized due to VOMITING (CTC grade 3) and DIARRHOEA (CTC grade 3) after a four day history of severe DIARRHOEA, some nausea and VOMITING with poor appetite. Events were considered serious due to hospitalization, and listed as per investigational brochures of Alpharadin (Bay 88-8223). Patient responded well to rehydration and conservative management and recovered/ discharge. Prior to the onset of the event the patient had received 06 study injections, and action taken with study drug not applicable.The investigator causality assessment for VOMITING and DIARRHOEA as related to Alpharadin (Bay 88-8223)/placebo, sponsor (company) concurs.
15245-035-035016	DIARRHOEA (CTC GRADE 3)[PT：下痢] This is a study case was received by license partner Algeta and forwarded to Bayer Parma, which refers to a 63 year old Caucasian male patient with hormone-refractory prostate cancer with skeletal metastases who received Alpharadin within a double blind, randomised, repeat dose, phase III clinical trial; subject received 6 study injections.The subject experienced severe DIARRHOEA, serious due to hospitalization, listed on Investigator's Brochure for Alpharadin. The investigator has assessed the relationship to study drug as possibly related.The sponsor has assessed the relationship to study drug as possibly related.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-035-035017	SPINAL CORD COMPRESSION (CTC GRADE 3)[PT：脊髄圧迫] 本症例には、プラセボが投与されていた。
15245-035-035019	BACK PAIN (CTC GRADE 2)[PT：骨痛] This 67 year old male patient was hospitalized due to BACK PAIN (CTC GRADE 2), 106 days after initiating the study medication (Alpharadin/placebo) in this double blind, randomized, repeat dose; phase III, multicenter survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. History of using antibiotic treatment for UTI is positive.BACK PAIN (CTC GRADE 2) is considered serious (hospitalized) and unlisted according to updated Investigators Brochure of Alpharadin. The sponsor has assessed the relationship to the study drug as unrelated.The company agrees with investigators assessment and considers BACK PAIN (CTC GRADE 2) not associated with study medication.
15245-035-035019	URINARY TRACT INFECTION (CTC GRADE 3)[PT：尿路感染] This 67 year old male patient developed a URINARY TRACT INFECTION (CTC GRADE 3) and was hospitalized 12 days after receiving latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event URINARY TRACT INFECTION (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for alpharadin. The investigator has assessed the relationship to study drug as possibly related.The sponsor has assessed the relationship to study drug as unrelated.
15245-035-035022	BACK PAIN (BONE PAIN) (CTC GRADE 3)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-035-035023	GASTROINTESTINAL BLEED (CTC GRADE 3)[PT：胃腸出血] A 70 year old male patient was enrolled in clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases; and hospitalized due to GASTROINTESTINAL BLEED (CTC GRADE 3), 10 days after receiving latest dose of Study medication. The patient had no relevant medical history.The event GASTROINTESTINAL BLEED (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to the study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to the study drug as unrelated for gastrointestinal bleed.
15245-035-035023	C DIFFICILE DIARRHOEA (CTC GRADE 2)[PT：クロストリジウム・ディフィシレ大腸炎] Company causality assessment per License Partner Algeta:Event of C DIFFICILE DIARRHOEA (CTC GRADE 2) is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to docetaxel chemotherapy.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-035-035027	POSSIBLE BOWEL OBSTRUCTION (CTC GRADE 4)[PT：腸閉塞] This 69 year old male patient experienced a POSSIBLE BOWEL OBSTRUCTION (CTC GRADE 4) and died 27 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included COPD, diabetes and ischemic heart disease.The event POSSIBLE BOWEL OBSTRUCTION (CTC GRADE 4) is considered serious (fatal) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as possibly related for the event of possible bowel obstruction, and unrelated for the non serious events of vomiting and constipation.The sponsor has assessed the relationship to study drug as possibly related.
15245-035-035028	CONSTIPATION (CTC GRADE 2)[PT：便秘] Company causality assessment per License Partner Algeta:Event of CONSTIPATION (CTC GRADE 2), is serious due to hospitalization, listed and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-035-035028	CONFUSION RELATED TO PROGRESSIVE DISEASE (CTC GRADE 3)[PT：錯乱状態] This 71 year old male patient experienced Confusion related to progressive disease (CTC grade 3) and was hospitalized 10 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The subject later died due to the event. The subject did not have any relevant medical history.The event Confusion related to progressive disease (CTC grade 3) is considered serious (fatal, hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-035-035029	BONE PAIN IN BACK (CTC GRADE 3)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-035-035030	SPINAL CORD COMPRESSION (CTC GRADE 2)[PT：脊髄圧迫] 本症例には、プラセボが投与されていた。
15245-035-035031	BONE PAIN REQUIRING RADIOTHERAPY (CTC GRADE 4)[PT：骨痛] SEPSIS (CTC GRADE 4)[PT：敗血症] This 63 year old male patient who was treated with Alpharadin/placebo for hormone-refractory prostate cancer with skeletal metastases in a phase 3 clincial trial was hospitalised for bone pain requiring radiotherapy and in hospital was diagnosed with sepsis. Both events occurred 22 days after the 2nd dose of study medication. The patient has no relevant medical history.The event SEPSIS (CTC GRADE 4) is considered serious (hospitalized, life threatening event) and is unlisted in the investigator's brochure for Alpharadin. The event BONE PAIN

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	REQUIRING RADIOTHERAPY (GRADE 4) is considered serious (hospitalized) and unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated for both events, but rather due to concurrent illness. The sponsor has assessed the relationship to study drug as unrelated for both events.
15245-035-035033	CARDIAC ISCHAEMIA (CTC GRADE 4)[PT：心筋虚血] This 63 year old male patient experienced cardiac ischaemia (CTC Grade 4) and was hospitalized 49 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. Relevant medical history included raised cholesterol. The event cardiac ischaemia (CTC Grade 4) is considered serious (hospitalized, life threatening event) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness. The sponsor has assessed the relationship to study drug as unrelated.
15245-035-035037	PROGRESSIVE PROSTATE CANCER (CTC GRADE 5)[PT：悪性新生物進行] 本症例には、プラセボが投与されていた。
15245-036-036001	BONE PAIN (CTC GRADE 4)[PT：骨痛] This study case report from Algeta refers to a 82 year old Caucasian male, who was enrolled in a study of Alpharadin/Placebo in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases. 63 days after the first dose of study drug, he experienced BONE PAIN (CTC GRADE 4). The patient had no relevant medical history. BONE PAIN (CTC GRADE 4) is considered serious due to hospitalisation and disability; it is unexpected according to the "expectedness event list for Alpharadin trials (14-Sep-2011)". The Investigator assessed the relationship to study drug as unrelated, but rather due to concurrent illness. The Sponsor considered the relationship to study drug as unrelated as well, and the Company concurs.
15245-036-036001	ARRHYTHMIA (CTC GRADE 3)[PT：不整脈] This 83 year old male patient experienced ARRHYTHMIA (CTC GRADE 3) and was hospitalized 27 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases. The patient's concurrent condition included Paget's disease, hypertension and diabetes. The event ARRHYTHMIA (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness. The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-036-036003	SUSPECTED URINARY TRACT INFECTION (CTC GRADE 3)[PT：尿路感染] 本症例には、プラセボが投与されていた。
15245-036-036004	PULMONARY EMBOLISM (CTC GRADE 3)[PT：肺塞栓症] 本症例には、プラセボが投与されていた。
15245-036-036005	PNEUMONIA (CTC GRADE 3)[PT：肺炎] This 63 year old male patient developed PNEUMONIA (CTC GRADE 3) and was hospitalized 14 days after receiving the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. Relevant medical history included asthma.The event PNEUMONIA (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for alpharadin. The investigator has assessed the relationship to the study drug as unrelated but rather due to a chest infection.The Sponsor has assessed the relationship to study drug as unrelated.
15245-036-036005	PNEUMONIA (CTC GRADE 3)[PT：肺炎] A 64 year old Caucasian male patient, enrolled in a survival study, experienced PNEUMONIA resulting in hospitalization 7 months after initiation of Alpharin/placebo. Study medication was inactive for 1 month and 6 days prior to the event onset. Treatment included theophylline. Relevant medical history includes asthma. Concomitant medications include pregabalin, dicycloverine hydrochloride, duloxetine and tamsulosin. The patient did not receive prior docetaxel therapy. The investigator considers the event to be serious and unrelated to Alpharadin/placebo. Company considers the event to be serious, unrelated and unexpected for Alpharadin.
15245-036-036011	CONSTIPATION (CTC GRADE 3)[PT：便秘] 本症例には、プラセボが投与されていた。
15245-037-037007	RENAL FAILURE (CTC GRADE 3)[PT：腎不全] NAUSEA (CTC GRADE 1)[PT：悪心] VOMITING (CTC GRADE 1)[PT：嘔吐] RIGHT HYDRONEPHROSIS (CTC GRADE 3)[PT：水腎症] This 72 year old male patient experienced RENAL FAILURE (CTC GRADE 3), NAUSEA (CTC GRADE 1), VOMITING (CTC GRADE 1) and RIGHT HYDRONEPHROSIS (CTC GRADE 3) and was hospitalized 44 days after receiving last dose of study drug (Alpharadin/placebo) in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's medical history included transient ischaemic attack, restless leg syndrome, bronchitis, hypercholesterolemia and urinary frequency.The event RENAL FAILURE (CTC

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The event RIGHT HYDRONEPHROSIS (CTC GRADE 3) is considered serious (hospitalized, medically important event) and Unlisted for Alpharadin. The events NAUSEA (CTC GRADE 1) and VOMITING (CTC GRADE 1) are considered serious (hospitalized) and Listed for Alpharadin.The investigator has assessed the relationship to study drug for the events of renal failure and right hydronephrosis as unrelated. Alternative explanation was not provided. The investigator assessed the events of nausea and vomiting as possibly related to study drug.The sponsor has assessed the relationship to study drug as unrelated for the events of renal failure and right hydronephrosis, and as possibly related for the events of nausea and vomiting.
15245-037-037008	GASTRITIS SECONDARY TO IBUPROFEN (CTC GRADE 3)[PT：胃炎] Company causality assessment per License Partner Algeta:Event of GASTRITIS SECONDARY TO IBUPROFEN (CTC GRADE 3) is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to concomitant medication of ibuprofen.
15245-037-037012	ACUTE EXTRADURAL HAEMATOMA[PT：硬膜外血腫] THROMBOCYTOPENIA (CTC GRADE 3)[PT：血小板減少症] This 67 year old male patient experienced ACUTE EXTRADURAL HAEMATOMA and THROMBOCYTOPENIA (CTC grade 3) approximately 74 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's medical history included bilateral vasectomy. The patient's concurrent condition included metastatic prostate cancer, hormone implant, angina, hernia repair, neuropathy - fingers and toes, hypercholesterolemia, anorexia, constipation - intermittent, lethargy, headache - intermittent, intermittent vomiting, nausea and pain due to bone metastases.The event ACUTE EXTRADURAL HAEMATOMA is considered serious (fatal) and Unlisted for Alpharadin. The event THROMBOCYTOPENIA (CTC grade 3) is considered serious (medically important event) and Listed for Alpharadin. The investigator has assessed the relationship to study drug as unrelated, but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated for all events.
15245-037-037013	INFECTIVE BURSITIS (CTC 2)[PT：感染性滑液包炎] This 70 year old Caucasian male who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer, experienced infective bursitis (CTC 2) 37 days after the onset of study drug. The subject has a relevant medical history of back pain due to metastasis, pain in breasts, right knee replacement, bronchial asthma, gout, depression and arthritis in hands. Infective bursitis is considered serious due to hospitalization and unlisted for Alpharadin.The investigator has assessed the event relationship to the study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the event relationship to the study drug as unrelated.
15245-037-037018	BILATERAL LEG EDEMA (CTC GRADE 3)[PT：末梢性浮腫] SHINGLES (CTC GRADE 2)[PT：帯状疱疹] PROGRESSION OF METASTATIC PROSTATE CANCER (CTC GRADE 4)[PT：遠隔転移を伴う前立腺癌] CHEST INFECTION (CTC GRADE 3)[PT：下気道感染] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-037-037022	PROGRESSION OF METASTATIC PROSTATE CANCER[PT：遠隔転移を伴う前立腺癌] 試験薬は投与されていない。
15245-038-038003	BILATERAL LEG WEAKNESS (CTC GRADE 4)[PT：筋力低下] This 80 year old male patient experienced bilateral leg weakness (CTC grade 4) 28 days after the last dose received of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included prostate cancer and bone metastases.The event bilateral leg weakness (CTC grade 4) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-039-039005	PROGRESSION OF PROSTATE CANCER[PT：前立腺癌] This 72 year old male patient experienced PROGRESSION OF PROSTATE CANCER and died 15 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event PROGRESSION OF PROSTATE CANCER is considered serious (fatal) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated. The investigator had broken the treatment code following the death and cremation of the subject. The investigator reported that neither cord compression nor excruciating pain in his arms meet criteria of an SAE.The sponsor has assessed the relationship to study drug as unrelated.
15245-039-039007	ANEMIA (CTC GRADE 1)[PT：貧血] 試験薬は投与されていない。
15245-039-039007	ANAEMIA (CTC GRADE 3)[PT：貧血] This 69 year old male patient experienced ANAEMIA (CTC GRADE 3) and was hospitalized 118 days after receiving the first dose of study drug (Alpharadin/placebo) in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. Relevant medical history was not provided. Patient was previously hospitalized due to anemia.The event ANAEMIA (CTC GRADE 3) is considered serious (hospitalized) and Listed for Alpharadin. The investigator assessed the relationship to study drug as possibly related.The sponsor assessed the relationship to study drug as possibly related because it is a known complication of Alpharadin treatment.

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-039-039007	ANAEMIA (CTC GRADE 3)[PT：貧血] This 69 year old male patient experienced ANAEMIA (CTC GRADE 3) and was hospitalized 33 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. Relevant medical history was not provided.The event ANAEMIA (CTC GRADE 3) is considered serious (hospitalized) and Listed for Alpharadin.The investigator assessed the relationship to study drug as possibly related. The company cannot exclude ANAEMIA (CTC GRADE 3) to be related to the study drug because of the known product profile.The sponsor has assessed the relationship to study drug as possibly related.
15245-039-039007	PROGRESSION DISEASE[PT：悪性新生物進行] This 69 year old male patient experienced PROGRESSION DISEASE and died 67 days after receiving dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases. Relevant medical history was not provided.The event PROGRESSION DISEASE is considered serious (fatal) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated.The sponsor has assessed the relationship to study drug as unrelated.
15245-039-039011	BONE PAIN (CTC GRADE 3)[PT：骨痛] 試験薬は投与されていない。
15245-039-039011	NAUSEA (CTC GRADE 3)[PT：悪心] 本症例には、プラセボが投与されていた。
15245-039-039011	NAUSEA (CTC GRADE 3)[PT：悪心] 本症例には、プラセボが投与されていた。
15245-039-039011	PLEURAL EFFUSION (CTC GRADE 4)[PT：胸水] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-039-039012	FRACTURED IN LEFT HIP (CTC GRADE 3)[PT：病的骨折] Company causality assessment per License Partner Algeta:Event of FRACTURED IN LEFT HIP (CTC GRADE 3) is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to concurrent illness.
15245-039-039012	DISEASE PROGRESSION[PT：前立腺癌] This 83 year old male patient experienced DISEASE PROGRESSION and died 32 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event DISEASE PROGRESSION is considered serious (fatal) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated.The sponsor has assessed the relationship to study drug as unrelated.
15245-039-039015	HEMATURIA (CTC GRADE 3)[PT：血尿] INDUCED RADIATION CYSTITIS (CTC GRADE 3)[PT：放射線性膀胱炎] This 79 year old male patient experienced severe HEMATURIA (CTC GRADE 3) (hospitalized 1 day after last dose of Alpharadin/placebo) and severe INDUCED RADIATION CYSTITIS (CTC GRADE 3) (hospitalized 9 days after receiving last dose of Alpharadin/placebo) while in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The events HEMATURIA (CTC GRADE 3) and INDUCED RADIATION CYSTITIS (CTC GRADE 3) are considered serious (hospitalized for each event separately) and are listed in the Investigator´s Brochure of Alpharadin.The investigator has assessed the relationship to study drug for the event of HEMATURIA (CTC GRADE 3) as unrelated, but rather due to the subject's catheterization. The event of INDUCED RADIATION CYSTITIS (CTC GRADE 3) was reported as unrelated to study drug.HEMATURIA (CTC GRADE 3) could be caused by catheterization and INDUCED RADIATION CYSTITIS (CTC GRADE 3) is a common side effect of radiation therapy. Therefore the company considers the events unrelated to the study drug.
15245-039-039016	CORD COMPRESSION (CTC GRADE 3)[PT：脊髄圧迫] This 69 year old male patient experienced CORD COMPRESSION (CTC GRADE 3) and was hospitalized 7 days after receiving the first dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event CORD COMPRESSION (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to disease progression.The sponsor has assessed the relationship to study drug as unrelated.
15245-039-039017	ANEMIA (CTC GRADE 4)[PT：貧血] 試験薬は投与されていない。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-039-039020	PLEURAL EFFUSION (CTC GRADE 2)[PT：胸水] 本症例には、プラセボが投与されていた。
15245-039-039020	PROGRESSION OF DISEASE (DEATH)[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-039-039025	CRANIAL LESION (BRAIN METASTASES - CTC GRADE 3)[PT：中枢神経系転移] DISEASE PROGRESSION (CTC GRADE 3)[PT：ホルモン不応性前立腺癌] This 78 year old male patient experienced CRANIAL LESION (brain metastases - CTC GRADE 3) and was hospitalized 25 days after taking the last dose of study drug (Alpharadin/placebo) in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The hospitalization was prolonged due to DISEASE PROGRESSION (CTC GRADE 3) which the patient later died from. The patient had no relevant medical history.The event CRANIAL LESION (brain metastases - CTC GRADE 3) is considered serious (hospitalization) and DISEASE PROGRESSION is serious (fatal, hospitalized). Both events are unexpected for Alpharadin.The investigator has assessed the relationship between the events and study drug as unrelated, rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-039-039027	DEHYDRATION (CTC GRADE 3)[PT：脱水] This 74 year old Caucasian male, who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced DEHYDRATION (CTC GRADE 3) 8 days after taking the first dose of study drug. The subject had no relevant medical history.DEHYDRATION (CTC GRADE 3) is considered serious (hospitalization) and is unlisted for Alpharadin.The investigator assessed the relationship to study drug as unrelated.The sponsor assessed the relationship to study drug as unreled.
15245-039-039027	KIDNEY FAILURE (CTC GRADE 3)[PT：腎不全] DISEASE PROGRESSION (CTC GRADE 4)[PT：前立腺癌] The case refers to a 74-year-old male in a double blind, randomized, repeat dose, phase III, multicentre survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases.He died due to DISEASE PROGRESSION (CAUSE OF DEATH) which is considered serious (fatal, hospitalized). He also suffered from KIDNEY FAILURE (CTC GRADE 3) which is considered serious due to hospitalization. Both events are not listed in the Investigator Brochure for Alpharadin/placebo.The investigator has assessed the relationship to study drug as unrelated but rather due to disease progression for kidney failure. The investigator has assessed the relationship to the study drug as unrelated for disease progression.The sponsor has assessed the relationship to study drug as unrelated for both events.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-039-039028	SYNCOPE (CTC GRADE 3)[PT：失神] 本症例には、プラセボが投与されていた。
15245-040-040004	INTERMITTENT VOMITING (CTC GRADE 2)[PT：嘔吐] NAUSEA (CTC GRADE 2)[PT：悪心] This 68 year old male patient experienced Nausea (CTC grade 2) and intermittent vomiting (CTC grade 2)(previously reported vomiting (CTC grade 2)) 70 days after first dose of study drug (Alpharadin/placebo) in this clinical study of Alpharadin in the treatment of patients with hormone refractory prostate cancer with skeletal metastasis. The subject had no relevant medical history.The events of Nausea (CTC grade 2) and intermittent vomiting (CTC grade 2) are considered serious (hospitalized) and Listed for Alpharadin.The investigator has assessed the relationship to study drug as possibly related for both events. The investigator stated that fentanyl may have caused the nausea and vomiting.The sponsor has assessed the relationship to study drug as possibly related for both events.
15245-040-040005	ANAEMIA (CTC GRADE 3)[PT：貧血] This case refers to a 67-year-old male patient in a double blind, randomized, repeat dose, phase III, multicentre survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. Patient experienced ANAEMIA (CTC GRADE 3) 56 days after receiving latest dose of Alpharadin/placebo, which is considered serious due to hospitalization and is listed in the Investigator´s Brochure of Alpharadin. Patient had no relevant medical history.The investigator has assessed the relationship to study drug as possibly related for the anaemia.The sponsor has assessed the relationship to study drug as possibly related.
15245-040-040005	SKELETAL METASTASES (DISEASE PROGRESSION)[PT：骨転移] This 67 year old male patient experienced Skeletal metastases (disease progression) and died 71 days after the last dose of Alpharadin/placebo was received in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included Progression of pre-existing prostate cancer, pain lower back and neuropathy to groin and thighs.The event Skeletal metastases (disease progression) is considered serious (fatal) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated.The sponsor has assessed the relationship to study drug as unrelated.
15245-040-040006	CARDIOVASCULAR COLLAPSE (CTC GRADE 4)[PT：循環虚脱] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-040-040006	ATRIAL FIBRILLATION (CTC GRADE 3)[PT：心房細動] 本症例には、プラセボが投与されていた。
15245-040-040006	HEART FAILURE (CTC GRADE 3)[PT：心不全] 本症例には、プラセボが投与されていた。
15245-040-040007	CHEST PAIN (CTC GRADE 3)[PT：骨痛] This 69 year old male patient experienced chest pain (CTC grade 3) nearly one month after taking the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastasis. The patient had no relevant medical history.The event chest pain (CTC grade 3) is considered serious (hospitalized) and listed (under context of bone pain) for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-040-040008	BLEEDING (CTC GRADE 3)[PT：口腔内出血] （本例は PMDA へ報告を行った症例である。弊社の見解を日本語で示す） 「口腔内出血」はグレード 3 の血小板減少を伴っているものであり、血小板減少は本治験薬の副作用として周知のものであることを考慮すると、当該事象と本剤との因果関係は否定できないと考える。
15245-041-041001	MULTIPLE PULMONARY EMBOLI (CTC GRADE 4)[PT：肺塞栓症] 試験薬は投与されていない。
15245-041-041001	CHEST INFECTION (CTC GRADE 3)[PT：下気道感染] Company causality assessment per License Partner Algeta:Event of CHEST INFECTION (CTC GRADE 3) is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to concurrent illness.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-041-041001	BACK PAIN (METASTATIC BONE PAIN) (CTC GRADE 3)[PT：転移部痛] This 57 year old male patient experienced Back pain (metastatic bone pain) (CTC grade 3) and was hospitalized almost 1 month after receiving latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included low back pain.The event Back pain (metastatic bone pain) (CTC grade 2) is considered serious (hospitalized) and Listed for Alpharadin. The investigator has assessed the relationship to study drug as unrelated, but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-041-041003	ANAEMIA (CTC GRADE 3)[PT：貧血] Company causality assessment per License Partner Algeta:Event of ANAEMIA (CTC GRADE 3), is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as possibly related to study drug.
15245-041-041005	PATHOLOGICAL FRACTURE TO LEFT ACETABULUM (CTC GRADE 2)[PT：病的骨折] Company causality assessment per License Partner Algeta:Event of PATHOLOGICAL FRACTURE TO LEFT ACETABULUM (CTC GRADE 2) is serious (hospitalized / disability / medically significant), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to concurrent illness.
15245-041-041006	LOWER RESPIRATORY TRACT INFECTION (CTC GRADE 2)[PT：下気道感染] 試験薬は投与されていない。
15245-041-041006	CHEST INFECTION (CTC GRADE2)[PT：下気道感染] OPIATE TOXICITY (CTC GRADE 4)[PT：各種物質毒性] This 64 year old male patient developed a CHEST INFECTION (CTC GRADE 2) and was hospitalized 65 days after receiving latest dose of Alpharadin/placebo. The patient was also later hospitalized for OPIATE TOXICITY (CTC GRADE 4) 72 days after receiving latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's medical history included chest infection.The event CHEST INFECTION (CTC GRADE2) is considered serious (hospitalized, life threatening event) and Unlisted for Alpharadin. The event OPIATE TOXICITY (CTC GRADE 4) is considered serious (hospitalized, life threatening event, medically important event) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated, rather due to concurrent illness for the event chest infection. The investigator has assessed the relationship to study drug as unrelated, but rather due to concomitant medication for the event opiate toxicity.The sponsor has assessed the relationship to the study drug as unrelated for both events.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-041-041006	WORSENING PAIN LEFT SACRAL ILIAC JOINT RADIATING DOWN LEFT SIDE, PAIN LEFT ISCHIUM AND PAIN LEFT SIDE OF SACRUM (METASTATIC BONE PAIN) (CTC GRADE 3)[PT：転移部痛] This 64 year old Caucasian male, who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced worsening pain left sacral iliac joint radiating down left leg, pain left ischium and pain left side of sacrum (metastatic bone pain) (CTC GRADE of 3) 36 days after receiving the last dose of study drug. The subject's relevant medical history was not reported.Worsening pain left sacral iliac joint radiating down left leg, pain left ischium and pain left side of sacrum (metastatic bone pain) is considered serious (medically important event) and is unlisted for Alpharadin.The investigator has assessed the relationship to the study drug as unrelated, rather due to concurrent illness.The sponsor has assessed the relationship to the study drug as unrelated.
15245-041-041007	PROGRESSION OF DISEASE (CTC GRADE 4)[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-041-041008	NON ST ELEVATION MYOCARDIAL INFARCTION DUE TO ANGINA PECTORIS (CTC GRADE 4)[PT：急性心筋梗塞] ANAEMIA (CTC GRADE 2)[PT：貧血] This 74 year old male patient experienced NON ST ELEVATION MYOCARDIAL INFARCTION DUE TO ANGINA PECTORIS (CTC GRADE 4) (previously reported as NON ST ELEVATION MYOCARDIAL INFARCTION) and ANEMIA (CTC GRADE 2) and was hospitalized 29 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's medical history included myocardial infarction. The patient's concurrent condition included angina pectoris.The event NON ST ELEVATION MYOCARDIAL INFARCTION DUE TO ANGINA PECTORIS (CTC GRADE 4) is considered serious (hospitalized) and unlisted for Alpharadin. The event ANEMIA (CTC GRADE 2) is considered serious (hospitalized) and unlisted (previously listed) for Alpharadin according to the current "expectedness event list". The investigator has assessed the relationship to the study drug as unrelated for anaemia and for non ST elevation myocardial infarction due to angina pectoris.The sponsor has assessed the relationship to the study drug as unrelated for non ST elevation myocardial infarction due to angina pectoris and unrelated (previously possibly related) for anaemia.
15245-041-041008	ANAEMIA (CTC GRADE 3)[PT：貧血] This 74 year old Caucasian male who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer, experienced Anemia (CTC GRADE 3) 50 days after the onset of study drug. The subject's relevant medical history included angina pectoris and three myocardial infarctions. Anemia is considered serious due to hospitalization and is listed for Alpharadin.The investigator assessed the relationship to study drug as unrelated but rather due to concurrent illness.The Sponsor assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-041-041008	LOW HAEMOGLOBIN[PT：貧血] CHEST INFECTION[PT：下気道感染] Event of LOW HAEMOGLOBIN is serious (hospitalization) and listed in the Investigator's Brochure/Prescribing Information for Alpharadin (radium-223 chloride), whereas CHEST INFECTION is serious (hospitalization/fatal outcome) and unlisted. Investigator considered both events unrelated to study drug but rather due to concurrent illness. The sponsor assessed event of LOW HAEMOGLOBIN as possibly related to Alpharadin/Placebo, and CHEST INFECTION as unrelated to study drug.
15245-041-041009	HEMATURIA (CTC GRADE 2)[PT：血尿] 試験薬は投与されていない。
15245-041-041009	PROGRESSION OF DISEASE (CTC GRADE 2)[PT：前立腺癌] PANCYTOPENIA (CTC GRADE 2)[PT：汎血球減少症] 試験薬は投与されていない。
15245-041-041011	INTRACRANIAL EXTENSION OF SKULL VAULT METASTASES (CTC GRADE 2)[PT：骨転移] This 58 year old male patient experienced INTRACRANIAL EXTENSION OF SKULL VAULT METASTASES (CTC GRADE 2) 32 days after receiving the first dose of Alpharadin/placebo in this double blind, randomised, repeat dose, phase III, multicentre survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included metastases in skull.The event INTRACRANIAL EXTENSION OF SKULL VAULT METASTASES (CTC GRADE 2) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated, but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-041-041011	CHEST INFECTION (CTC GRADE 3)[PT：下気道感染] PROGRESSION OF DISEASE (CTC GRADE 3)[PT：前立腺癌] This study case report refers to a 58 year-old Caucasian male with hormone-refractory prostate cancer with skeletal metastases who received Alpharadin beginning 08-Oct- 2010. Relevant medical history includes skull metastases. Concomitant medications include fentanyl, methylphenidate, lansoprazole, oxycodone hydrochloride, bendroflumethiazide, clonazepam, solifenacin, tamsulosin, atenolol, total sennosides, bicalutamide, paracetamol, furosemide, metoclopramide, pregabalin and zoledronic acid. The patient received prior docetaxel therapy on 26-Jun-2010. He was admitted to hospital on 09-Dec-2010 due to CHEST INFECTION (CTC GRADE 3) and PROGRESSION OF DISEASE. CHEST INFECTION and PROGRESSION OF DISEASE are serious due to hospitalization and unlisted for study drug. The investigator considered both events unrelated to Alpharadin. The company concurs with this assessment and assumes an association with the underlying carcinoma.
15245-041-041011	CHEST INFECTION (CTC GRADE 3)[PT：下気道感染] PROGRESSION OF DISEASE (CTC GRADE 3)[PT：前立腺癌] This study case report refers to a 58 year-old Caucasian male with hormone-refractory prostate cancer with skeletal metastases who received Alpharadin beginning 08-Oct- 2010. Relevant medical history includes skull metastases. Concomitant medications include fentanyl, methylphenidate, lansoprazole, oxycodone hydrochloride, bendroflumethiazide, clonazepam, solifenacin, tamsulosin, atenolol, total sennosides, bicalutamide, paracetamol, furosemide, metoclopramide, pregabalin and zoledronic acid. The patient received prior docetaxel therapy on 26-Jun-2010. He was admitted to hospital on 09-Dec-2010 due to CHEST INFECTION (CTC GRADE 3) and PROGRESSION OF DISEASE. CHEST INFECTION and PROGRESSION OF DISEASE are serious due to hospitalization and unlisted for study drug. The investigator considered both events unrelated to Alpharadin. The company concurs with this assessment and assumes an association with the underlying carcinoma.

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-041-041011	BILATERAL LEG OEDEMA (CTC GRADE 3)[PT：末梢性浮腫] PROGRESSION OF DISEASE[PT：前立腺癌] This study report refers to a 58 year old male with hormone-refractory prostate cancer with skeletal metastases who experienced PROGRESSION OF DISEASE and BILATERAL LEG OEDEMA (CTC GRADE 3) and was hospitalized 38 days after receiving the last dose of Alpharadin or Placebo. The patient's concurrent conditions included intermittent urinary retention, gynaecomastia, fatigue, hypertension, metastatic bone pain right shoulder, cushingoid face, proximal myopathy of hips, parathesia right arm, right lateral rectus palsy, lower back pain (metastatic bone pain), bilateral lower rib pain (metastatic bone pain), pelvic pain (metastatic bone pain), right bundle branch block on ECG, urinary retention and overweight. Concomitant medications included methylphenidate, lansoprazole, oxycodone hydrochloride, bendroflumethiazide, clonazepam, solifenacin, tamsulosin, paracetamol, atenolol, bicalutamide, metoclopramide, pregabalin, fentanyl, furosemide, dexamethasone and docusate. The pt received prior docetaxel therapy on 26 Jun 2010.Serious events of PROGRESSION OF DISEASE (fatal) and BILATERAL LEG OEDEMA (hospitalized) are both unlisted for Alpharadin. The investigator assessed the relationship to study drug as unrelated but rather due to concurrent illness for both events.The sponsor assessed the relationship to study drug as unrelated for both events.
15245-041-041012	ORAL THRUSH (CTC GRADE 2)[PT：口腔カンジダ症] This clinical trial case report (forwarded by Algeta) referring to a 62 year old male (Caucasian) enrolled in a double-blind, randomized, multiple dose, Phase III, multicentre study of Alpharadin in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases and received first dose of study medication Alpharadin (BAY 88-8223)/Placebo by Dec 2010. Patient had received docetaxel therapy (June-2009) and relevant concomitant medications dexamethasone, fludrocortisones, frumil, rabeprazole, morphine sulphate, fentanyl patch and docusate sodium were reported. The Patient received five doses of study drug; the last injection was given a week (approx.) prior to the onset of the event. During the study course patient experienced a sore throat and pain on swallowing for 4-5 days and got hospitalized with diagnosis of ORAL THRUSH (CTC Grade 2), considered serious (hospitalization) / unlisted as per investigational brochures of Alpharadin (Bay 88-8223). Patient improved in response to treatment/discharged from hospital and study drug was kept as unchanged.The investigator assessed the causal relationship of event to Alpharadin (BAY 88-8223) therapy as unrelated but rather due to concurrent illness, sponsor (company) concurs citing underlying advanced metastatic disease / concomitant use of steroids are plausible alternative explanations.
15245-041-041012	ANAEMIA REQUIRING BLOOD TRANSFUSION (CTC GRADE 3)[PT：貧血] This 63 year old Caucasian male who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced ANAEMIA REQUIRING BLOOD TRANSFUSION (CTC GRADE 3) 57 days after the start of study drug. Prior to the onset of the event, the subject received 6 study injections.The subject's relevant medical history includes prostate cancer and bone metastases (Underlying disease). Anemia is considered serious (hospitalization) and listed for Alpharadin.The investigator assessed the relationship to study drug as possibly related, and also reported concurrent illness as the alternative explanation.The sponsor has assessed the relationship to study drug as possibly related.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-041-041012	PROGRESSION OF DISEASE (CTC GRADE 3)[PT：前立腺癌] This 63 year old male patient experienced PROGRESSION OF DISEASE (CTC GRADE 3) and was hospitalized 49 days after taking the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included metastatic prostate cancer.The event PROGRESSION OF DISEASE (CTC GRADE 3) is considered serious (hospitalized) and unlisted for Alpharadin. The patient was treated with radiotherapy and recovered on 05-Jul-2011. The investigator has assessed the relationship to study drug as unrelated, but rather due to concurrent illness.The sponsor assessed the event as unrelated to alpharadin.
15245-042-042002	PROGRESSION OF PROSTATE CANCER (CTC GRADE 3)[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-042-042002	DISEASE PROGRESSION (CTC GRADE 5)[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-042-042003	DECREASED HAEMOGLOBIN (CTCAE GRADE 2)[PT：ヘモグロビン減少] 本症例には、プラセボが投与されていた。
15245-042-042003	CONGESTIVE HEART FAILURE (CTC GRADE 3)[PT：うっ血性心不全] SPINAL CORD COMPRESSION (CTC GRADE 2)[PT：脊髄圧迫] 本症例には、プラセボが投与されていた。
15245-042-042004	SMALL BOWEL OBSTRUCTION (CTC GRADE 2)[PT：小腸閉塞] 試験薬は投与されていない。

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-042-042004	ANAEMIA (CTC GRADE 2)[PT：貧血] PATHOLOGICAL FRACTURE RIGHT CLAVICLE (CTC GRADE 2)[PT：病的骨折] 本症例には、プラセボが投与されていた。
15245-042-042004	DEATH - DISEASE PROGRESSION(CTC GRADE 5)[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-042-042010	GENERAL MALAISE: PROBABLY VIRUS INFECTION (CTC GRADE 2)[PT：倦怠感] 試験薬は投与されていない。
15245-042-042010	NEUROPATHIC PAIN (CTC GRADE 2)[PT：神経痛] 本症例には、プラセボが投与されていた。
15245-042-042014	PULMONARY EMBOLISM (GRADE 2)[PT：肺塞栓症] 試験薬は投与されていない。
15245-042-042015	DISEASE PROGRESSION[PT：悪性新生物進行] Company causality assessment per License Partner Algeta:Event of DISEASE PROGRESSION is serious (fatal outcome), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to concurrent illness.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-042-042020	HAEMATURIA (CTC GRADE 1)[PT：血尿] This 74 year old Caucasian male, who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced HAEMATURIA (CTC GRADE 1) 125 days after stdy drug was started. The subject's concurrent condition included hypertension, depression and urinary dysfunction. HAEMATURIA (CTC GRADE 1) is considered serious (hospitalization) and unlisted for Alpharadin.The investigator assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor assessed the relationship to study drug as unrelated.
15245-042-042020	HAEMATURIA (CTC GRADE 2)[PT：血尿] Company causality assessment per License Partner Algeta:Event of HAEMATURIA (CTC GRADE 2), is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-042-042020	ACUTE TUBULAR NECROSIS (CTC GRADE 3)[PT：腎尿細管壊死] The case refers to a 74-year-old male patient in a double blind, randomized, repeat dose, phase III, multicentre survival study of AlpharadinTM in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. He experienced ACUTE TUBULAR NECROSIS (CTC GRADE 3) which is serous due to hospitalization and unlisted in the Investigator´s Brochure of Alpharadin. The investigator has assessed the relationship to study drug as unrelated, but rather due to concurrent illness. The company considers ACUTE TUBULAR NECROSIS (CTC GRADE 3) not associated to Alpharadin/placebo but related to the underlying disease.The Sponsor has assessed the relationship to study drug as unrelated to study drug.
15245-042-042022	DISEASE PROGRESSION[PT：前立腺癌] 試験薬は投与されていない。
15245-042-042024	PYREXIA (CTC GRADE 3)[PT：発熱] VOMITING (CTC GRADE 3)[PT：嘔吐] CONFUSION (CTC GRADE 3)[PT：錯乱状態] 本症例には、プラセボが投与されていた。
15245-042-042024	DISEASE PROGRESSION[PT：悪性新生物進行] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-042-042025	URINARY RETENTION (CTC GRADE 3)[PT：尿閉] 本症例には、プラセボが投与されていた。
15245-042-042028	LEFT SIDED CHEST PAIN (CTC GRADE 3)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-042-042030	HAEMATURIA (CTC GRADE 3)[PT：血尿] The case refers to a 61-year-old male patient in a double blind, randomized, repeat dose, phase III, multicentre survival study of AlpharadinTM in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. He experienced HAEMATURIA (CTC GRADE 3) which is serious due to hospitalization and is unlisted in the Investigator´s Brochure of Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness. The cause of haematuria was not identified. The company considers HAEMATURIA (CTC GRADE 3) not associated to Alpharadin/placebo but related to the underlying carcinoma.
15245-042-042030	ACUTE RENAL FAILURE-OBSTRUCTIVE (CTC GRADE 3)[PT：急性腎不全] Company causality assessment per License Partner Algeta:Event of ACUTE RENAL FAILURE-OBSTRUCTIVE (CTC GRADE 3), is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-042-042030	CONSTIPATION (CTC GRADE 3)[PT：便秘] This 61 year old male patient experienced CONSTIPATION (CTC GRADE 3) and was hospitalized 39 days after receiving latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included hypercholesterolaemia and hypertension.The event CONSTIPATION (CTC GRADE 3) is considered serious (hospitalized) and Listed for Alpharadin. The investigator has assessment of the relationship to the study drug as unrelated but rather due concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-042-042030	URINARY TRACT INFECTION[PT：尿路感染] The investigator considers the event to be serious and unrelated to Alpharadin/placebo.Company considers the event to be serious, unrelated and unexpected for Alpharadin.

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-042-042031	WORSENING BACK PAIN (BONE PAIN) (CTC GRADE 3)[PT：骨痛] DEATH - DISEASE PROGRESSION (CTC GRADE 3)[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-042-042034	DISEASE PROGRESSION (DEATH)[PT：前立腺癌] This 75-year-old male patient, enrolled in a double blind study with Alpharadin/Placebo in the treatment of hormone-refractory prostate cancer with skeletal metastases, died from DISEASE PROGRESSION following 6 injections of the study medication. The event is unlisted in the Investigator's brochure for Alpharadin and considered unrelated to the study drug treatment by both, the investigator and the company, as the study medication is intended to increase survival time and to decrease symptoms of the underlying cancer, but cannot completely avoid the progression of the disase.
15245-042-042037	DEATH (CTC GRADE 5)[PT：死亡] 試験薬は投与されていない。
15245-042-042038	NON ST ELEVATION MYOCARDIAL INFARCTION (CTC GRADE 3)[PT：急性心筋梗塞] 本症例には、プラセボが投与されていた。
15245-042-042038	PULMONARY EMBOLISM (CTC GRADE 3)[PT：肺塞栓症] INFECTIVE EXACERBATION OF COPD (CTC 3)[PT：慢性閉塞性肺疾患] 本症例には、プラセボが投与されていた。
15245-042-042039	PULMONARY EMPHYSEMA[PT：肺気腫] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-042-042041	PATHOLOGICAL FRACTURE TO HIS LEFT FEMUR (CTC GRADE 3)[PT：病的骨折] This 81 year old male patient experienced PATHOLOGICAL FRACTURE TO HIS LEFT FEMUR (CTC AE grade 3) and was hospitalized 13 days after receiving the latest dose of Alpharading/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's relevant medical history included arthritis, spinal cord decompression, right knee replacement and chronic back pain.The event PATHOLOGICAL FRACTURE TO HIS LEFT FEMUR (CTC AE grade 3) is considered serious (hospitalized) and unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-042-042041	URINARY RETENTION (CTC GRADE 2)[PT：尿閉] CONFUSION (CTC GRADE 2)[PT：錯乱状態] DYSARTHRIA (CTC GRADE 2)[PT：構語障害] AGGRESSION (CTC GRADE 2)[PT：攻撃性] This 81 year old Caucasian male, who enrolled in study BC1-06 and received Alpharadin for hormone refractory prostate cancer with skeletal metastases, experienced URINARY RETENTION (CTC GRADE 2), CONFUSION (CTC GRADE 2), DYSARTHRIA (CTC GRADE 2), and AGGRESSION (CTC GRADE 2), 143 days after receiving the first dose of study drug. Medical history includes chronic back pain. Concomitant medications include dexamethasone, pregabalin, morphine, paracetamol, omeprazole and enoxaparin. The subject did not receive prior docetaxel therapy. Hospitalization was reported due to pathological fracture (See reference case number). URINARY RETENTION, CONFUSION, DYSARTHRIA and AGGRESSION are considered serious due to hospitalization and are all unlisted for Alpharadin.The investigator has assessed the events of urinary retention and dysartria as unrelated but rather due to concurrent illness. No explanation for confusion, agression and slurred speech was established.The sponsor assessed the relationship to study drug as unrelated for all events.
15245-043-043003	CHEST INFECTION (CTC GRADE 3)[PT：下気道感染] This 64 year old male patient experienced Chest infection (CTC Grade 3) and was hospitalized 17 days after receiving latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included hypertension and non-insulin dependent diabetes.The event Chest infection (CTC Grade 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-043-043003	BRAIN METASTASIS (CTC GRADE 4)[PT：中枢神経系転移] The case refers to a 64-year-old male patient in a double blind, randomised, repeat dose, phase III, multicentre survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. He experienced BRAIN METASTASES which is a serious event due to hospitalization and is unlisted in the Investigator´s Brochure of Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to disease progression. The company agrees and considers BRAIN METASTASES not associated to Alpharadin/placebo but related to the underlying carcinoma.
15245-043-043005	CHEST PAIN (BONE PAIN) (CTC GRADE 3)[PT：骨痛] This 67 year old male patient experienced CHEST PAIN (BONE PAIN) and was hospitalized 68 days after receiving last dose of Alpharadin/placebo in this clincial study of AlpharadinTM in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included high blood pressure, ischemic heart disease, angina pectoris and hypertension. The event CHEST PAIN (BONE PAIN) is considered serious (hospitalized) and Listed for Alpharadin.The investigator has not provided an assessment for the relationship to study drug.The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-043-043007	TURP REQUIRED FOR URINARY RETENTION (CTC GRADE 3)[PT：尿閉] This 61 year old male patient underwent TURP required for urinary retention (CTC grade 3) and was hospitalized 12 days after receiving the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's medical history included ex-smoker. The patient's concurrent condition included non insulin dependent diabetes, hypercholesterolemia and haematuria.The event TURP required for urinary retention (CTC grade 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-043-043011	DIZZYNESS (CTC GRADE 2)[PT：浮動性めまい] This 77 year old male patient experienced DIZZYNESS (CTC GRADE 2) and was hospitalized 36 days after first dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included unrinary stricture and diverticular disease.The event DIZZYNESS (CTC GRADE 2) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated, but rather due to concomitant medications.The sponsor has assessed the relationship to study drug as unrelated.
15245-043-043011	LOW HAEMOGLOBIN LEVELS (CTC GRADE 2)[PT：ヘモグロビン減少] This 78-year-old male patient enrolled in a clinical trial with Alpharadin to treat hormone-refractory prostate cancer with skeletal metastases, experienced LOW HEMOGLOBIN LEVELS (CTC GRADE 2), considered serious due to hospitalization. The event is listed in the Investigator's brochure for Alpharadin. The subject's relevant medical history includes diverticular disease and urinary stricture. The investigator has assessed the relationship to study drug as possibly related.The sponsor has assessed the relationship to study drug as related.
15245-043-043012	BACK PAIN (BONE PAIN) (CTC GRADE 3)[PT：骨痛] ACUTE RENAL FAILURE (CTC GRADE 3)[PT：急性腎不全] HYDRONEPHROSIS (CTC GRADE 3)[PT：水腎症] PULMONARY EMBOLUS (CTC GRADE 4)[PT：肺塞栓症] This 56 year old male patient experienced BACK PAIN (BONE PAIN) (CTC Grade 3), ACUTE RENAL FAILURE (CTC Grade 3, previously reported as grade 4) and HYDRONEPHROSIS (CTC grade 3) and was hospitalized 22 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. Approximately one week after the admission, the patient developed PULMONARY EMBOLUS (CTC Grade 4). The patient was treated and recovered from all events. The patient's concurrent condition included gluten/wheat intolerance.The events BACK PAIN (BONE PAIN) (CTC Grade 3), ACUTE RENAL FAILURE (CTC grade 3) and HYDRONEPHROSIS (CTC grade 3) are considered serious (hospitalized) and Unlisted for Alpharadin. The event of PULMONARY EMBOLUS (CTC Grade 4) is considered serious (life threatening) and unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness for back pain, acute renal failure, hydronephrosis and pulmonary embolism.The sponsor has assessed the relationship to study drug as unrelated for all the events.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-043-043015	URINARY RETENTION (CTC GRADE 3)[PT：尿閉] 本症例には、プラセボが投与されていた。
15245-043-043016	SPINAL CORD COMPRESSION (CTC GRADE 4)[PT：脊髄圧迫] 本症例には、プラセボが投与されていた。
15245-043-043017	RETENTION OF URINE (CTCAE GRADE 3)[PT：尿閉] 試験薬は投与されていない。
15245-043-043018	BRAIN METASTASES (CTCAE GRADE 5)[PT：中枢神経系転移] 本症例には、プラセボが投与されていた。
15245-044-044004	APHASIA (CTC GRADE 3)[PT：失語症] This 77 year old Caucasian male, who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced APHASIA (CTC GRADE 3) 76 days after receiving the first dose of study drug. The subject had no relevant medical history. APHASIA (CTC GRADE 3) is considered serious (hospitalization) and is unlisted for Alpharadin.The investigator has assessed the relationship to the study drug as unrelated, but rather due to concurrent illness.The Sponsor has assessed the relationship to study drug as unrelated.
15245-044-044004	HAEMATURIA (CTC GRADE 2)[PT：血尿] URINARY RETENTION (CTC GRADE 3)[PT：尿閉] This 77 year old male patient experienced Hematuria (CTC grade 2) and Urinary retention (CTC grade 2) and was hospitalized 65 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included metastatic prostate cancer. The events Hematuria (CTC grade 2) and Urinary retention (CTC grade 3)[severity was amended from previously reported CTC grade 2] are considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to the study drug as unrelated for both events, but rather due to concurrent illness.The sponsor

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	has assessed the relationship to study drug as unrelated for both events.
15245-044-044005	PULMONARY EMBOLISM (CTC GRADE 3)[PT：肺塞栓症] Company causality assessment per License Partner Algeta:Event of PULMONARY EMBOLISM (CTC GRADE 3), is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-044-044009	LEFT LEG DEEP VEIN THROMBOSIS (CTC GRADE 3)[PT：深部静脈血栓症] This 67 year old male patient experienced Left Leg Deep Vein Thrombosis (CTC Grade 3) and was hospitalized 24 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event Left Leg Deep Vein Thrombosis (CTC Grade 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to pelvic cancer-locally extensive prostate cancer.The sponsor has assessed the relationship to study drug as unrelated.
15245-044-044009	DISEASE PROGRESSION (CTC GRADE 4)[PT：悪性新生物進行] ANOREXIA (CTC GRADE 2)[PT：食欲減退] DEHYDRATION (CTC GRADE 3)[PT：脱水] DEEP VEIN THROMBOSIS (CTC GRADE 3)[PT：深部静脈血栓症] BOWEL PERFORATION (CTC GRADE 4)[PT：腸管穿孔] PATHOLOGICAL FRACTURE THROUGH RIGHT INFERIOR PUBIC RAMUS (CTC GRADE 2)[PT：病的骨折] This 67- year old male patient experienced disease progression (CTC grade 4) 34 days after taking the latest (i.e. 5th) dose of study drug (Alpharadin/placebo) in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient´s hospitalization was prolonged due to anorexia (CTC grade 2), dehydration (CTC grade 3), deep vein thrombosis (CTC grade 3, previously CTC grade 2), bowel perforation (CTC grade 4) and pathological fracture through right inferior pubic ramus (CTC grade 2, previously reported as grade 1). The patient had no relevant medical history.The events disease progression (CTC grade 4) and bowel perforation (CTC grade 4) are considered serious (hospitalized, life threatening event) and Unlisted for Alpharadin. The events anorexia (CTC grade 2), dehydration (CTC grade 3), deep vein thrombosis (CTC grade 3) and pathological fracture through right inferior pubic ramus (CTC grade 2) are considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness for all the events.The sponsor has assessed the relationship to study drug as unrelated for all the events.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-044-044009	LEFT LEG CELLULITIS (CTC GRADE 3)[PT：蜂巣炎] This 67 year old male patient developed LEFT LEG CELLULITIS (CTC GRADE 3) and was hospitalized 61 days after receiving last dose of study drug (Alpharadin/placebo) in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no medical history.The event LEFT LEG CELLULITIS (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-045-045001	HEMATURIA (CTC GRADE 3)[PT：血尿] 本症例には、プラセボが投与されていた。
15245-045-045001	HAEMATURIA[PT：血尿] 本症例には、プラセボが投与されていた。
15245-045-045001	PROSTATE CANCER PROGRESSION[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-045-045002	PROSTATE CANCER PROGRESSION (CTC GRADE 3)[PT：前立腺癌] 試験薬は投与されていない。
15245-045-045009	PATHOLOGICAL FRACTURE OF VERTEBRAE (T2 AND T5) (CTC GRADE 3)[PT：病的骨折] This 58 year old male patient was diagnosed with a PATHOLOGICAL FRACTURE OF VERTEBRAE (T2 AND T5) (CTC GRADE 3) and was hospitalized 8 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included bone metastases.The event PATHOLOGICAL FRACTURE OF VERTEBRAE (T2 AND T5) (CTC GRADE 3) is considered serious (hospitalized, disability) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-046-046002	ANAEMIA (CTC GRADE 3)[PT：貧血] The case refers to a 79-year-old male patient in a double blind, randomized, repeat dose, phase III, multicentre survival study of AlpharadinTM in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. He experienced ANAEMIA (CTC GRADE 3) which is serious due to hospitalization and is listed in the Investigator´s Brochure of Alpharadin. The investigator has assessed the relationship to study drug as possibly related. The company agrees to that because it is a known complication of the Alpharadin treatment.
15245-046-046004	ANAEMIA (CTC GRADE 3)[PT：貧血] Company causality assessment per License Partner Algeta:Event of ANAEMIA (CTC GRADE 3), is serious (medically significant), listed and assessed by the Investigator and Sponsor as related to study drug.
15245-046-046008	BRAIN METASTASES (CTCGRADE 4)[PT：中枢神経系転移] 本症例には、プラセボが投与されていた。
15245-046-046008	PULMONARY EMBOLISM (CTC GRADE 4)[PT：肺塞栓症] 本症例には、プラセボが投与されていた。
15245-047-047002	DISEASE PROGRESSION[PT：前立腺癌] This 81 year old male patient experienced DISEASE PROGRESSION and died 70 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included glaucoma, hypertension and skeletal pain.The event DISEASE PROGRESSION is considered serious (fatal) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated.The sponsor has assessed the relationship to study drug as unrelated.
15245-047-047003	URINARY RETENTION (CTC GRADE 3)[PT：尿閉] This 75 year old male patient experienced URINARY RETENTION (CTC GRADE 3) and was hospitalized 13 days after receiving the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included mass in prostate encrotching bladder - palpable mass.The event URINARY RETENTION (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to the tumour encroaching into his bladder which was present prior to entry into the trial. The investigator confirmed that event causality was not due to the study drug, study procedure, concomitant medication or concurrent illness.The

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	sponsor has assessed the relationship to study drug as unrelated.
15245-047-047006	CARDIAC ARREST[PT：心停止] 本症例には、プラセボが投与されていた。
15245-047-047007	ACUTE CONFUSION/AGITATION-CONFUSION (CTC GRADE 3)[PT：精神障害] ACUTE CONFUSION/AGITATION-CONFUSION (CTC GRADE 3)[PT：激越] DISEASE PROGRESSION[PT：前立腺癌] 試験薬は投与されていない。
15245-048-048001	BONE PAIN (CTC GRADE 3)[PT：骨痛] 試験薬は投与されていない。
15245-048-048001	CALCIUM SERUM LOW HYPOCALCEMIA (CTC GRADE 3)[PT：低カルシウム血症] Company causality assessment per License Partner Algeta:Event of CALCIUM SERUM LOW HYPOCALCEMIA (CTC GRADE 3), is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather the event was caused by the use of bisphosphonates (zoledronic acid).
15245-048-048001	CHEST INFECTION (CTC GRADE 3)[PT：下気道感染] Company causality assessment per License Partner Algeta:Event of CHEST INFECTION (CTC GRADE 3), is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-048-048001	DISEASE PROGRESSION[PT：悪性新生物進行] Company causality assessment per License Partner Algeta:Event of DISEASE PROGRESSION, is serious due to fatal outcome, unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-048-048003	BRAIN METASTASIS (CTC GRADE 4)[PT：中枢神経系転移] This 60 year old male patient experienced Brain metastasis (CTC grade 4) 24 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases.The event Brain metastasis (CTC grade 4) is considered serious (hospitalized, life threatening event) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-048-048004	FRACTURED NECK OF LEFT FEMUR (CTC GRADE 3)[PT：病的骨折] This 71 year old male patient experienced FRACTURED NECK OF LEFT FEMUR (CTC GRADE 3) after a fall and was hospitalized 28 days after receiving latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included hydronephrosis, hypertension and osteoarthritis right knee.The event FRACTURED NECK OF LEFT FEMUR (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to pure accidental circumstances.The sponsor has assessed the relationship to study drug as unrelated.
15245-048-048004	SPINAL CORD COMPRESSION (CTC GRADE 3)[PT：脊髄圧迫] This 71 year old male patient experienced SPINAL CORD COMPRESSION (CTC GRADE 3) and was hospitalized 55 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event SPINAL CORD COMPRESSION (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated, but rather due to disease progression.The sponsor has assessed the relationship to study drug as unrelated.
15245-048-048007	LOWER BACK PAIN (BONE PAIN) (CTC GRADE 3)[PT：脊椎痛] Company causality assessment per License Partner Algeta:Event of LOWER BACK PAIN (BONE PAIN) (CTC GRADE 3), is serious due to hospitalization, listed and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-048-048010	WORSENING PAIN (CTC GRADE 2)[PT：骨痛] This 77 year old male patient was hospitalized for worsening pain (CTC grade 2) 72 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastasis. The patient did not have any relevant medical history.Worsening pain (CTC grade 2) is considered serious (hospitalized) and listed for Alpharadin.The investigator assessed the relationship to study drug as unrelated but rather due to other disease.The sponsor assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-048-048012	PROGRESSION OF PROSTATE CANCER[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-049-049002	INFECTION (CHEST) (CTC GRADE 3)[PT：下気道感染] Company causality assessment per License Partner Algeta:Event of INFECTION (CHEST) (CTC GRADE 3), is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug.
15245-049-049002	INFECTION (CHEST) (CTC GRADE 2)[PT：下気道感染] Company causality assessment per License Partner Algeta:Event of INFECTION (CHEST) (CTC GRADE 2), is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug.
15245-049-049002	HOSPITAL ACQUIRED PNEUMONIA[PT：肺炎] SPINAL CORD COMPRESSION (CTC GRADE 4)[PT：脊髄圧迫] This 74 year old male patient experienced HOSPITAL ACQUIRED PNEUMONIA and SPINAL CORD COMPRESSION (CTC GRADE 4) and was hospitalized almost 1.5 months after taking last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient later died due to the pneumonia. The patient had no relevant medical history.The event HOSPITAL ACQUIRED PNEUMONIA is considered serious (fatal, hospitalized) and Unlisted for Alpharadin. The event SPINAL CORD COMPRESSION (CTC GRADE 4) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated for all events but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated for both events.
15245-049-049007	DISEASE PROGRESSION (CTC GRADE 3)[PT：悪性新生物進行] Company causality assessment per License Partner Algeta:Event of DISEASE PROGRESSION (CTC GRADE 3), is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-049-049007	DISEASE PROGRESSION (CTC GRADE 3)[PT：前立腺癌] PNEUMONIA (CTC GRADE 3)[PT：肺炎] This 80 year old male patient experienced DISEASE PROGRESSION (CTC GRADE 3) and PNEUMONIA (CTC GRADE 3) and was hospitalized 51 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient later died due to the disease progression. The patient's concurrent condition included osteoarthritis and atrial fibrillation.The event DISEASE PROGRESSION (CTC GRADE 3) is considered serious (fatal, hospitalized) and Unlisted for Alpharadin. The event PNEUMONIA (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated for the events of disease progression and pneumonia. An alternative explanation of disease progression was provided.The sponsor has assessed the relationship to study drug as unrelated.
15245-049-049008	PAIN LOWER BACK AND RIGHT HIP (BONE METASTASES) (CTC GRADE 3)[PT：転移部痛] Company causality assessment per License Partner Algeta:Event PAIN LOWER BACK AND RIGHT HIP (BONE METASTASES) (CTC GRADE 3), is serious due to hospitalization, listed and assessed by the Investigator and Sponsor as unrelated to study drug.
15245-049-049008	VOMITING (CTC GRADE 2)[PT：嘔吐] FEVER (CTC GRADE 1)[PT：発熱] Company causality assessment per License Partner Algeta:Event of VOMITING (CTC GRADE 2), serious due to hospitalization and medical significance is listed for Alpharadin, whereas, event of FEVER (CTC GRADE 1), serious due to hospitalization is unlisted. Both events are assessed by the Investigator and Sponsor as unrelated to study drug.
15245-049-049008	NAUSEA[PT：悪心] VOMITING[PT：嘔吐] Company causality assessment per License Partner Algeta:Events NAUSEA and VOMITING are serious due to hospitalization, listed and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concomitant medication.
15245-049-049008	NAUSEA (CTC GRADE 3)[PT：悪心] PAIN ABDOMINAL (CTC GRADE 3)[PT：腹痛] VOMITING (CTC GRADE 3)[PT：嘔吐] This 73 year old male patient experienced PAIN ABDOMINAL (CTC GRADE 3), NAUSEA (CTC GRADE 3) and VOMITING (CTC GRADE 3) and was hospitalized 83 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included bone pain and kidney stones.The event PAIN ABDOMINAL (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The events NAUSEA (CTC GRADE 3) and VOMITING (CTC GRADE 3) are considered serious (hospitalized) and Listed for Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concomitant medication.The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-050-050001	URINARY RETENTION (CTC GRADE OF 3)[PT：尿閉] 本症例には、プラセボが投与されていた。
15245-050-050001	ANEMIA (CTCAE GRADE 4)[PT：貧血] 本症例には、プラセボが投与されていた。
15245-050-050001	GASTRIC CARCINOMA (CTC GRADE 4)[PT：胃癌] 本症例には、プラセボが投与されていた。
15245-050-050002	DISEASE PROGRESSION OF PROSTATE CANCER[PT：前立腺癌] 試験薬は投与されていない。
15245-050-050003	DISEASE PROGRESSION DUE TO PROSTATE CANCER[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-050-050005	SPINAL CORD COMPRESSION (CTC GRADE 2)[PT：脊髄圧迫] STROKE (CTC GRADE 4)[PT：脳血管発作] Company causality assessment per License Partner Algeta:Events of SPINAL CORD COMPRESSION (CTC GRADE 2) and STROKE (CTC GRADE 4) are serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-050-050005	SPINAL CORD COMPRESSION (CTC GRADE 2)[PT：脊髄圧迫] NAUSEA (CTC GRADE 2)[PT：悪心] VOMITING (CTC GRADE 2)[PT：嘔吐] SPINAL CORD COMPRESSION (CTC GRADE 2), NAUSEA (CTC GRADE 2), and VOMITING (CTC GRADE 2) are considered serious due to hospitalization. SPINAL CORD COMPRESSION is unlisted in the Investigator Brochure for Alpharadin, while the other two events are listed. In line with investigator, company assesses the events as not associated with the study drug. The underlying prostate cancer with skeletal metastases and disease progression may provide an alternative explanation for the events.
15245-050-050005	DEATH DUE TO DISEASE PROGRESSION FROM PROSTATE CANCER[PT：前立腺癌] This 77 year old male patient died due to DEATH DUE TO DISEASE PROGRESSION FROM PROSTATE CANCER 48 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included constipation, nocturnal leg cramps, bone pain and loin pain.The event DEATH DUE TO DISEASE PROGRESSION FROM PROSTATE CANCER is considered serious (fatal) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated, but due to disease progression.The sponsor has assessed the relationship to study drug as unrelated.
15245-050-050009	BILATERAL HALF KNEE REPLACEMENT[PT：膝関節形成] Company causality assessment per License Partner Algeta:Event of BILATERAL HALF KNEE REPLACEMENT, is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-050-050016	BACK PAIN (LUMBAR REGION), (CTC GRADE 3)[PT：背部痛] 試験薬は投与されていない。
15245-050-050016	LEG WEAKNESS (CTC GRADE 3)[PT：筋力低下] BONE PAIN (CTC GRADE 3)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-050-050016	LUNG INFECTION (CTC GRADE 2)[PT：肺感染] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-050-050016	EPILEPTIC SEIZURE (CTC GRADE 3)[PT：てんかん] GENERAL DETERIORATION[PT：全身健康状態低下] 本症例には、プラセボが投与されていた。
15245-050-050018	LEG PAIN - NEUROPATHIC (CTC GRADE 2)[PT：神経痛] BACK PAIN (CTC GRADE 2)[PT：神経痛] 本症例には、プラセボが投与されていた。
15245-050-050019	DEHYDRATION (CTC GRADE 2)[PT：脱水] 試験薬は投与されていない。
15245-050-050019	INFECTION OF UNKNOWN ORIGIN (CTC GRADE 3)[PT：感染] This 70 year old male patient developed an Infection of unknown origin (CTC grade 3) 60 days after the first dose of study drug, Alpharadin/placebo in this double blind, randomized, repeat dose, phase III, multicentre survival study of AlpharadinTM in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's medical history included nausea, radiotherapy, vomiting and loose stools.The investigator considers the event to be serious and unrelated to Alpharadin/placebo.The Sponsor considers the event to be serious, unrelated and unexpected for Alpharadin.
15245-050-050019	TRANSIENT ISCHEMIC ATTACK (CTC GRADE 2)[PT：一過性脳虚血発作] This 70 year old male patient experienced TRANSIENT ISCHEMIC ATTACK (CTC GRADE 2) and was hospitalized 49 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's medical history included confusion due to a urinary tract infection and pulmonary embolism.The event TRANSIENT ISCHEMIC ATTACK (CTC GRADE 2) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor assessed the relationship to study drug as unrelated.
15245-050-050019	CONFUSION (CTC GRADE 3)[PT：錯乱状態] This 70 year old Caucasian male who enrolled in study BC1-06, and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced CONFUSION (CTC GRADE 3) 55 days after study drug was stopped. Prior to the onset of the event, the patient received 6 study injections.The subject's relevant medical history included two episodes of confusion, a urinary tract infection and pulmonary embolism.CONFUSION (CTC GRADE 3) is considered serious due to hospitalization and is unlisted for Alpharadin.The investigator assessed the relationship to study drug as unrelated, but rather due to concurrent illness; most likely urinary tract infection which is a frequent problem for the subject.The Sponsor assessed the relationship to study drug as serious, unrelated and unexpected.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-051-051001	DERANGED LIVER FUNCTIONS (CTC GRADE 4)[PT：肝機能検査異常] BRADYCARDIA (CTC GRADE 4)[PT：徐脈] 試験薬は投与されていない。
15245-051-051003	BILATERAL SUBDURAL HAEMATOMA (CTC GRADE 4)[PT：硬膜下血腫] SPINAL CORD COMPRESSION, T6 LEVEL, (CTC GRADE 4)[PT：脊髄圧迫] METASTATIC CANCER OF THE PROSTATE (CTC GRADE 5)[PT：遠隔転移を伴う前立腺癌] Company causality assessment per License Partner Algeta:Events of METASTATIC CANCER OF THE PROSTATE (CTC GRADE 5), serious due to fatal outcome, BILATERAL SUBDURAL HAEMATOMA (CTC GRADE 4) serious due to hospitalization / life-threatening and SPINAL CORD COMPRESSION, T6 LEVEL, (CTC GRADE 4) serious due to hospitalization, are all unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-051-051007	THECAL SAC COMPRESSION AT T9 (CTC GRADE 4)[PT：神経根圧迫] Company causality assessment per License Partner Algeta:Event of THECAL SAC COMPRESSION AT T9 (CTC GRADE 4) is serious (hospitalized / disability / life-threatening), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to concurrent illness.
15245-051-051007	BRAIN METASTASES (CTC GRADE 2)[PT：中枢神経系転移] Company causality assessment per License Partner Algeta:Event of BRAIN METASTASES (CTC GRADE 2), is serious (hospitalized / disability), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to disease progression.
15245-051-051010	ACUTE RENAL FAILURE (CTC GRADE 3)[PT：急性腎不全] This 68 year old male patient experienced ACUTE RENAL FAILURE (CTC grade 3) after the last dose of alpharadin (BAY88-8223). The patient's concurrent condition included high alcohol intake, peripheral neuropathy, dyspnoea, hypertension and type II diabetes.The event ACUTE RENAL FAILURE (CTC grade 3) is considered serious (hospitalized) and Unlisted for alpharadin.The investigator has assessed the relationship to study drug as unrelated, but rather due to disease progression.The sponsor has assessed the relationship to study drug as unrelated.
15245-051-051011	BILE DUCT OBSTRUCTION (CTC GRADE 2)[PT：胆管閉塞] The case refers to a 77-year-old male patient in a double blind, randomised, repeat dose, phase III, multicentre survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. He experienced BILE DUCT OBSTRUCTION (CTC GRADE 2) which is a serious event due to hospitalization and disabling and is unlisted in the Investigator´s Brochure of Alpharadin. The patient was discharged from hospital after 11 days and the outcome was reported as recovered with sequelae.The investigator has assessed the relationship to the study drug as unrelated. The investigator reported that the patient had a malignant mass obstruction in the common bile duct which was most likely due to the progression of metastatic disease. There is no real treatment

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	available and the subject is most likely to deteriorate soon. The sponsor has assessed the relationship to the study drug as unrelated.
15245-051-051012	DISEASE PROGRESSION[PT：悪性新生物進行] This 74 year old male patient experienced DISEASE PROGRESSION and died 52 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event DISEASE PROGRESSION is considered serious (fatal) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated, but rather due to disease progression.The sponsor has assessed the relationship to study drug as unrelated.
15245-051-051021	DISEASE PROGRESSION (PROSTATE CANCER)[PT：前立腺癌] The case refers to a 74-year-old male patient in a double blind, randomized, repeat dose, phase III, multicentre survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. He experienced DISEASE PROGRESSION (PROSTATE CANCER) which is serious due to hospitalization and is unlisted in the Investigator´s Brochure of Alpharadin. The investigator has assessed the relationship to study drug as unrelated. The company agrees with that and considers the underlying carcinoma to be related to DISEASE PROGRESSION.
15245-051-051021	DEHYDRATION (CTC GRADE 2)[PT：脱水] This study refers to a 74 year old Caucasian male with hormone-refractory prostate cancer with skeletal metastases who received Alpharadin or Placebo on 11-Mar-2010. The pt was admitted to hospital for DEHYDRATION (CTC GRADE 2) on 13-Jul-2010. Medical history and comorbidities include osteoarthritis, hyperlipidemia, diverticulitis, transurethral resection of prostate, peripheral neuropathy, dry throat, changes in taste, vertical fracture of (L) vertebral body, fatigue and back bone pain. Concomitant medications were not reported. Pt was previously hospitalized due to disease progression from 21-Apr-2010 to 27-Apr-2010. Pt received no prior docetaxel therapy.DEHYDRATION (CTC GRADE 2) is considered serious due to hospitalization and is not listed for Alpharadin. The investigator assessed the relationship to study drug as not related and noted that the loss of appetite might have caused the dehydration; company agrees with investigator, event not related to study drug.
15245-053-053001	DISEASE PROGRESSION[PT：前立腺癌] This 72 year old male patient experienced DISEASE PROGRESSION and died 51 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's medical history included elbow fracture due to fall, wrist fracture due to fall and a fall. The patient's concurrent condition included g-gt increased, pleural widening, mouth blisters, infarction of right eye, trauma to left eye, tonsillitis, left ventricular hypertrophy, supraventricular extra beats, glaucoma left eye, hearing loss, obstruction micturition, anemia, bladder diverticle, tumour pain, constipation, haemorrhoid, fatigue, dyspnea on effort, reflux oesophagitis, recurrent urinary tract infection, hepatitis, liver cirrhosis alcohol related, gastric ulcer, hypertension and aortal valve insufficiency.The event DISEASE PROGRESSION is considered serious (fatal) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated, rather due to prostate cancer disease progression.The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-053-053002	HAEMOGLOBIN (DECREASED) (CTC GRADE 3)[PT：ヘモグロビン減少] This 79 year old male patient experienced HAEMOGLOBIN (DECREASED) (CTC GRADE 3) and was hospitalized 30 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included metastatic prostate cancer.The event HAEMOGLOBIN (DECREASED) (CTC GRADE 3) is considered serious (hospitalized) and Listed for Alpharadin.The investigator has assessed the relationship to study drug as possibly related and also due to concurrent illness.The sponsor has assessed the relationship to study drug as possibly related.
15245-053-053004	SPINAL CORD COMPRESSION (CTC GRADE 3)[PT：脊髄圧迫] This 72 year old male patient developed SPINAL CORD COMPRESSION (CTC GRADE 3) and was hospitalized approximately 104 days after initiating Alpharadin in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastasis. The event of SPINAL CORD COMPRESSION (CTC GRADE 3) is considered serious due to hospitalization and persistent or significant disability/incapacity and is medically significant. It is unlisted in the Investigator´s Brochure of Alpharadin.The investigator assessed the relationship to study drug as unrelated but rather due to concurrent illness.The company agrees with this assessment.
15245-053-053004	RADICULAR SYNDROME LEFT BUTTOCK AND LEG (CTC GRADE 3)[PT：根症候群] This 72 year old male patient experienced Radicular syndrome left buttock and leg (CTC grade 3) and was hospitalized 10 days after receiving latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's medical history included threatened paraplegia. The patient's concurrent condition included metastases to the rib and T9 vertebre.The event Radicular syndrome left buttock and leg (CTC grade 3) is considered serious (hospitalized) and Unlisted for alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor assessed the relationship to study drug as unrelated.
15245-054-054001	ANAEMIA(CTC GRADE 2)[PT：貧血] Company causality assessment per License Partner Algeta:Event of ANAEMIA (CTC GRADE 2), is serious (hospitalized), listed and assessed by the Investigator and Sponsor as related to study drug.
15245-055-055002	PROGRESSION OF PROSTATE CANCER (CTC GRADE 5)[PT：前立腺癌] ACUTE REACTION TO NALOREX INJECTION (CTC GRADE 4)[PT：薬物不耐性] SUSPECTED PULMONARY EMBOLISM (CTC GRADE 4)[PT：肺塞栓症] PROGRESSION OF PROSTATE CANCER (CTC GRADE 5) is considered serious due to death occurred. SUSPECTED PULMONARY EMBOLISM (CTC GRADE 4) and ACUTE REACTION TO NALOREX INJECTION (CTC GRADE 4) are considered serious due to hospitalization/life-threatening. All events are unlisted in the Investigator Brochure for Alpharadin. The investigator has assessed the relationship to study drug as unrelated for all events. Alternative explanation for the events acute reaction to nalorex injection and progression of prostate cancer was reported as concomitant medication. For the event suspected pulmonary embolism the suspect's concurrent illness was reported as an alternative explanation.The sponsor has assessed the relationship to study drug as unrelated for all events.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-055-055007	CONFUSED (CTC GRADE 2)[PT：錯乱状態] 試験薬は投与されていない。
15245-055-055007	ANEMIA (CTC GRADE 3)[PT：貧血] 本症例には、プラセボが投与されていた。
15245-055-055007	PROGRESSION DISEASE[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-059-059004	DISEASE PROGRESSION[PT：前立腺癌] This 70 year old male patient died due to Disease progression 76 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases.The patient had no relevant medical history.The event Disease progression is considered serious (fatal) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated.The sponsor has assessed the relationship to study drug as unrelated.
15245-060-060002	ACUTE BRONCHITIS (CTC GRADE 3)[PT：気管支炎] UNKNOWN CAUSE OF DEATH (CTC GRADE 5)[PT：死亡] Company causality assessment per License Partner Algeta:Events of ACUTE BRONCHITIS (CTC GRADE 3), serious due to hospitalization and UNKNOWN CAUSE OF DEATH (CTC GRADE 5), serious due to fatal outcome, are unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather ACUTE BRONCHITIS was due to Klebsiella pneumoniae.
15245-060-060003	PROGRESSION OF DISEASE (CTC GRADE 5)[PT：前立腺癌] Company causality assessment per License Partner Algeta:Event PROGRESSION OF DISEASE (CTC GRADE 5) is serious (fatal outcome), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to clinical deterioration and PSA progression.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-060-060007	DISEASE PROGRESSION (CTC GRADE 4)[PT：前立腺癌] This 79 year old Caucasian male, who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced fatal disease progression (CTC grade 4) 6 days after the onset of study drug. The subject's relevant medical history included arterial hypertension. Disease progression (fatal) is considered serious (hospitalization/death) and is unlisted for Alpharadin.The investigator assessed the relationship to study drug as unrelated.The sponsor assessed the relationship to study drug as unrelated.
15245-060-060008	APHASIA (CTC GRADE 3)[PT：失語症] 本症例には、プラセボが投与されていた。
15245-060-060009	BLACK DIARRHEA (CTC GRADE 1)[PT：下痢] 本症例には、プラセボが投与されていた。
15245-060-060009	ACUTE CARDIAC INFARCTION (CTC GRADE 4)[PT：急性心筋梗塞] 本症例には、プラセボが投与されていた。
15245-060-060010	CHOLESTASIS (CTC GRADE 3)[PT：胆汁うっ滞] This study case report refers to a 75 year old male patient who developed CHOLESTASIS (CTC grade 3) and was hospitalized 29 days after first initiating treatment with study medication (Alpharadin/placebo) while in this clinical study of Alpharadin in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases. The patient's medical history included left humerus osteosynthesis, left shoulder surgery, left femur fracture.The patient's concurrent condition included metastatic bone pain, anal fistula surgery, arterial hypertension, vertigo, osteoporosis, alcoholism, hernia arthroplasty, disc herniation, hypercholesterolemia, chronic obstructive pulmonary disease. The event CHOLESTASIS (CTC grade 3) is considered serious (hospitalized) and Unlisted for alpharadin.The investigator has assessed the relationship to study drug as unrelated, but rather due to disease progression.The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-060-060010	DISEASE PROGRESSION NOS[PT：疾患進行] Company causality assessment per License Partner Algeta:Event of DISEASE PROGRESSION NOS, is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug.
15245-060-060010	DISEASE PROGRESSION NOS[PT：疾患進行] Company causality assessment per License Partner Algeta:Event of DISEASE PROGRESSION NOS, is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug.
15245-060-060012	CELLULITIS OF LEFT THIGH (CTC GRADE 3)[PT：蜂巣炎] 本症例には、プラセボが投与されていた。
15245-062-062004	VOMITING (CTC GRADE 1)[PT：嘔吐] 本症例には、プラセボが投与されていた。
15245-063-063002	GASTROENTERITIS (CTC GRADE 2)[PT：胃腸炎] This 64 year old male patient experienced GASTROENTERITIS (CTC GRADE 2) and was hospitalized 41 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included inguinal hernia and hypercholesterolaemia.The event GASTROENTERITIS (CTC GRADE 2) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the event relationship to study drug as unrelated, and considered the event as concurrent illness.The sponsor has assessed the event relationship to study drug as unrelated.
15245-063-063003	SPINAL CORD COMPRESSION (CTC GRADE 2)[PT：脊髄圧迫] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-063-063004	DISEASE PROGRESSION (CTC GRADE 3)[PT：前立腺癌] This 75 year old male patient experienced DISEASE PROGRESSION and died 21 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included arterial hypertension and hypercholesterolemia.The event DISEASE PROGRESSION is considered serious (fatal, hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to the study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to the study drug as unrelated.
15245-066-066004	PANCYTOPENIA (CTC GRADE 4)[PT：汎血球減少症] The case refers to a 79-year-old male patient in a double blind, randomized, repeat dose, phase III, multicentre survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. Patient experienced PANCYTOPENIA (CTC GRADE 4) which is a serious event due to hospitalization and medical significance. The subject's medical history includes venous thrombosis and metastatic bone pain.The event is listed in the Investigator´s Brochure of Alpharadin.The investigator has assessed the relationship to the study drug as probably related.The sponsor has assessed the relationship to study drug as possibly related.
15245-070-070002	HOSPITALIZATION DUE TO DISEASE PROGRESSION (CTC GRADE 4)[PT：悪性新生物進行] 本症例には、プラセボが投与されていた。
15245-070-070003	HEART FAILURE (CTC GRADE 3)[PT：心不全] RENAL FUNCTION FAILURE (CTC GRADE 3)[PT：腎不全] This 74 year old male patient experienced HEART FAILURE (CTC GRADE 3) and RENAL FUNCTION FAILURE (CTC GRADE 3) and was hospitalized 18 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included metastase bone pain, smoker, prostate benign hyperplasia, diabetes mellitus and arterial hypertension.The events HEART FAILURE (CTC GRADE 3) and RENAL FUNCTION FAILURE (CTC GRADE 3) are considered serious (hospitalized, medically important event) and unlisted for Alpharadin. The investigator has assessed the relationship to the study drug as unrelated for both events. The subject's heart failure was reported as due to hypertension. The raised creatinine levels were due to heart failure and renal function failure causing a creatinine alteration.The sponsor has assessed the relationship to the study drug as unrelated for both events.
15245-071-071002	SPINAL CORD COMPRESSION (CTC GRADE 3)[PT：脊髄圧迫] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-071-071006	RENAL INSUFFICIENCY (CTC GRADE 2)[PT：腎不全] ASTHENIA (CTC GRADE 2)[PT：無力症] ANOREXIA (CTC GRADE 2)[PT：食欲減退] CONSTIPATION (CTC GRADE 2)[PT：便秘] The case refers to a 77-year-old male patient in a double blind, randomized, repeat dose, phase III, multicentre survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. He experienced moderate RENAL INSUFFICIENCY (CTC GRADE 2) which is serious due to hospitalization and is listed in the Investigator´s Brochure of Alpharadin. He also suffered from moderate CONSTIPATION (CTC GRADE 2), ASTHENIA (CTC GRADE 2) and ANOREXIA (CTC GRADE 2) which are serious due to hospitalization and disabling and are listed in the Investigator´s Brochure of Alpharadin. The investigator has assessed the relationship to study drug as unrelated for all the events, but rather due to concurrent illness and regarding the event of asthenia and anorexia probably related to the underlying disease. The company agrees with that which is also supported by the incompatible temporal condition.
15245-071-071008	URINARY RETENTION (CTC GRADE 2)[PT：尿閉] SPINAL CORD COMPRESSION[PT：脊髄圧迫] 本症例には、プラセボが投与されていた。
15245-072-072001	HEART FAILURE (CTC GRADE 4)[PT：心不全] 本症例には、プラセボが投与されていた。
15245-074-074002	BONE MARROW NEOPLASTIC INFILTRATION (CTC GRADE 3)[PT：腫瘍細胞の骨髄浸潤] This 80 year old male patient experienced BONE MARROW NEOPLASTIC INFILTRATION (CTC GRADE 3), was hospitalized and later died while on active treatment in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included diabetes mellitus.The event Bone marrow neoplastic infiltration (CTC grade 3) is considered serious (fatal, hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated, but rather due to the underlying illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-075-075001	DEATH[PT：死亡] This 59 year old male patient experienced DEATH 16 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event DEATH is considered serious (fatal) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated. An alternative explanation for causality was trauma.The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-078-078001	G3 ANAEMIA (CTC GRADE 3)[PT：貧血] THROMBOCYTOPENIA (CTC GRADE 3)[PT：血小板減少症] PROGRESSION OF GENERAL CONDITION[PT：前立腺癌] This 77- year old male patient experienced G3 ANAEMIA (CTC GRADE 3) and THROMBOCYTOPENIA (CTC GRADE 3) and was hospitalized 34 days after receiving the last dose of a total of 5 injections of Alpharadin/placebo while in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient later died due to Progression of general condition. The patient had no relevant medical history.The investigator has assessed the relationship to study drug as possibly related for the anaemia and thrombocytopenia. The event of progression of general condition was assessed as not related to study drug, but rather due to concurrent illness.The event Progression of general conditions is serious (fatal) and unlisted for Alpharadin. The events G3 ANAEMIA (CTC GRADE 3) and THROMBOCYTOPENIA (CTC GRADE 3) are serious (hospitalized) and listed for Alpharadin.The sponsor has assessed the relationship to study drug as possibly related for the events of anaemia and thrombocytopenia. The sponsor has assessed the relationship to study drug as unrelated for the event of progression of general condition.
15245-078-078003	WORSENING OF GENERAL CONDITION (CTC GRADE 3)[PT：全身健康状態低下] This 75 year old Caucasian male who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer, experienced worsening of general condition and eventually died approximately 7 weeks after the study drug was discontinued. No relevant medical history was reported. Worsening of general condition is considered serious due to medically important event and the fatal outcome and is unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated, but rather due to prostate cancer.The Sponsor has assessed the relationship to study drug as unrelated.
15245-078-078006	BONE MARROW PROGRESSION (CTC GRADE 3)[PT：骨髄障害] This 77 year old male patient experienced Bone Marrow Progression (CTC GRADE 3) approximately 33 days after receiving the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event Bone Marrow Progression (CTC GRADE 3) is considered serious (hospitalized, fatal) and Unlisted for Alpharadin.The investigator amended the assessment of the relationship to study drug as unrelated. The investigator stated that the bone marrow progression is documented with radiological and laboratory test assessments.The sponsor has assessed the relationship with the study drug as unrelated.
15245-080-080001	DISEASE PROGRESSION[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-080-080004	DISEASE PROGRESSION[PT：前立腺癌] This clinical trial case report (forwarded by Algeta) referring to a 72 year old Caucasian male received study medication (Alpharadin/placebo) in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patients relevant medical history included seizure, HCV positive (hepatitis C virus), non confirmed positivity for treponema pallidum, kidney stones, duodenal ulcer and depression. The patient had received prior docetaxel therapy.The patient reported last visit (Mar-2011) with worsening of performance status considered grade 3 (not reported as separate event) followed recommendation of best supportive care / monthly follow up calls (unsuccessful) by

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	investigator. However, on 05-Aug-2011, the investigator was informed that the patient died on 20-Apr-2011, reported as DISEASE PROGRESSION. An autopsy was not performed and no additional information available.Prior to the onset of the event the subject received 04 study injections, the last injection being on Feb-2011 (70 days prior to reported event), therefore action taken with study drug considered as not applicable.Event DISEASE PROGRESSION is considered serious (fatal outcome) / unlisted as per investigational brochures of Alpharadin (Bay 88-8223).The investigator has assessed the relationship to study drug as unrelated, but rather due to underlying disease.The sponsor has assessed the relationship to study drug as unrelated.
15245-084-084002	BONE PAIN (CTC GRADE 2)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-084-084002	ANAEMIA (CTC GRADE 3)[PT：貧血] BONE PAIN (CTC GRADE 3)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-084-084002	BONE PAIN (CTC GRADE 3)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-084-084002	BONE PAIN (CTC GRADE 3)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-085-085001	OSTEOBLASTIC LESION L2, L3, DISC BULGING L1-L2, L2-L3 (CTC GRADE 2)[PT：骨痛] URINARY TRACT INFECTION (CTC GRADE 3)[PT：尿路感染] OSTEOBLASTIC LESION L2, L3, DISC BULGING L1-L2, L2-L3 (CTC GRADE 2)[PT：椎間板突出] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-085-085001	PNEUMONIA (CTC GRADE 1)[PT：肺炎] RESPIRATORY FAILURE (CTC GRADE 4)[PT：呼吸不全] 本症例には、プラセボが投与されていた。
15245-085-085003	DEEP VEIN THROMBOSIS OF THE LEFT LIMB (CTC GRADE 2)[PT：深部静脈血栓症] 試験薬は投与されていない。
15245-085-085003	HEMATURIA (CTC GRADE 2)[PT：血尿] RECTAL BLEEDING (CTC GRADE 2)[PT：直腸出血] 本症例には、プラセボが投与されていた。
15245-085-085003	RLL PNEUMONIA[PT：大葉性肺炎] URINARY SEPSIS (CTC GRADE 3)[PT：尿路性敗血症] GENERAL DETERIORATION (CTC GRADE 3)[PT：全身健康状態低下] 本症例には、プラセボが投与されていた。
15245-085-085004	BACK PAIN D6-D8 (CTC GRADE 2)[PT：脊椎痛] This 61 year old male patient experienced BACK PAIN D6-D8 (CTC GRADE 2) and was hospitalized 10 days after receiving first dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included multiple bone metastases.The event BACK PAIN D6-D8 (CTC GRADE 2) is considered serious (hospitalized) and Listed for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to the study drug as unrelated.
15245-085-085004	SPINAL CORD COMPRESSION L2-L4[PT：脊髄圧迫] Company causality assessment per License Partner Algeta:Event of SPINAL CORD COMPRESSION L2-L4 is serious (hospitalization), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to the progression of prostate cancer.

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-085-085004	GENERAL DETERIORATION (CTC GRADE 2)[PT：全身健康状態低下] PAIN ON RIGHT LEG (CTC GRADE 3)[PT：骨痛] This 62 year old male patient experienced General Deterioration (CTC Grade 2) and Pain on right leg (CTC Grade 3) and was hospitalized 73 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event General Deterioration (CTC Grade 2) is considered serious (hospitalized) and unlisted for Alpharadin whereas Pain on right leg (CTC Grade 3) is considered serious (hospitalized) and listed.The investigator has assessed the relationship to study drug as unrelated for both events but rather due to the progression of disease.The sponsor has assessed the relationship to study drug as unrelated for both events.
15245-085-085005	ANAEMIA (CTC GRADE 2)[PT：貧血] FATIGUE (CTC GRADE 2)[PT：疲労] 本症例には、プラセボが投与されていた。
15245-085-085005	UTI (CTC GRADE 2)[PT：尿路感染] 本症例には、プラセボが投与されていた。
15245-085-085005	MACROHEMATURIA (CTC GRDAE 2)[PT：血尿] WEAKNESS (CTC GRADE 2)[PT：無力症] 本症例には、プラセボが投与されていた。
15245-085-085005	GENERAL DETERIORATION (CTC GRADE 3)[PT：全身健康状態低下] STRONG PAIN (CTC GRADE 3)[PT：骨痛] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-086-086002	BONE PAIN (CTC GRADE 3)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-086-086002	ACUTE RENAL FAILURE (CTC GRADE 3)[PT：急性腎不全] 本症例には、プラセボが投与されていた。
15245-087-087002	BILATERAL LEG EDEMA (CTC GRADE 3)[PT：末梢性浮腫] This 69 year old male patient experienced BILATERAL LEG EDEMA (CTC GRADE 3) 44 days after receiving the first dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included peripheral vascular disease, pain in ribs, neuropathy sensory, fatigue, vertigo, hyperlipidemia, spondylosis cervicalis, tuberculosis pulmonary, carotid bilateral occlusion, hypermetropia, diabetes mellitus, obesity and hypertension essential.The event BILATERAL LEG EDEMA (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-087-087002	GENERAL DETERIORATION (CTC GRADE 4)[PT：全身健康状態低下] Company causality assessment per License Partner Algeta:Event of GENERAL DETERIORATION is serious (fatal outcome), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to concurrent illness.
15245-093-093001	BILIRUBIN ELEVATION (CTC GRADE 2)[PT：血中ビリルビン増加] BBONE PAIN (CTC GRADE 2)[PT：骨痛] WEIGHT LOSS (CTC GRADE 2)[PT：体重減少] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-093-093001	BONE PAIN (CTC GRADE 2)[PT：骨痛] CONSTIPATION (CTC GRADE 2)[PT：便秘] 本症例には、プラセボが投与されていた。
15245-093-093001	DISEASE PROGRESSION[PT：前立腺癌] PNEUMONIA (CTC GRADE 4)[PT：肺炎] 本症例には、プラセボが投与されていた。
15245-093-093002	BONE PAIN (CTC GRADE 3)[PT：骨痛] This study refers to an 81 year old Caucasian male with hormone-refractory prostate cancer with skeletal metastases who received Alpharadin or Placebo. The pt was admitted to hospital on 11-Jan-2010 for BONE PAIN (CTC GRADE 3). Relevant medical history includes bronchial asthma, arterial hypertension and a BWK 12 pathological fracture. Concomitant medications include fentanyl and morphine sulfate. The pt did not receive prior docetaxel therapy.BONE PAIN is considered serious due to hospitalization and is listed for Alpharadin. The investigator assessed the relationship to study drug as not related; but rather due to metastases, to which the company agrees.
15245-093-093002	ANEMIA (CTC GRADE 3)[PT：貧血] This 81 year old male patient developed ANEMIA (CTC GRADE 3) and was hospitalized 31 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included bone metastases. The event ANEMIA (CTC GRADE 3) is considered serious (hospitalized) and Listed for alpharadin. The investigator has assessed the relationship to study drug as unrelated, rather due to prostate cancer with bone metastases.The sponsor has assessed the relationship to study drug as unrelated.
15245-093-093002	CARDIOPULMONARY FAILURE[PT：心肺不全] This 81 year old male patient experienced CARDIOPULMONARY FAILURE and died 48 days after receiving latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included hypertension, bronchial asthma and prostate cancer.The event CARDIOPULMONARY FAILURE is considered serious (fatal) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated, but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-095-095001	CARDIO-PULMONARY FAILURE (CTC GRADE 4)[PT：心肺不全] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-096-096002	ANEMIA (CTC GRADE 3)[PT：貧血] 02-Nov-2010: ANEMIA (CTC GRADE 3) is serious (hospitalized) and listed in the Investigator's Brochure for Alpharadin (BAY 88-8223). The investigator has assessed the relationship of anemia to study drug as possibly related and the company concurs.The sponsor has assessed the relationship to study drug as possibly related.
15245-097-097001	SUDDEN DEATH (CTC GRADE 5) NOS[PT：突然死] 本症例には、プラセボが投与されていた。
15245-097-097002	WORSENING BACK BONE PAIN (CTC GRADE 3)[PT：脊椎痛] FATIGUE (CTC GRADE 3)[PT：疲労] This study refers to a 73 year old Caucasian male with hormone-refractory prostate cancer who received Alpharadin or Placebo on 06-Jul-2009. The pt was admitted to hospital for WORSENING BACK BONE PAIN (CTC GRADE 3) and FATIGUE (CTC GRADE 3) on 20-Oct-2009. Medical history and concurrent disease include hypertension. Concomitant medications include fentanyl, trandolapril, prednisone, bisoprolol fumarate, alprazolam and lactulose. The pt had not received prior docetaxel therapy.WORSENING BACK BONE PAIN and FATIGUE are considered serious due to hospitalization and are listed for Alpharadin. The investigator assessed the relationship to study drug for WORSENING BACK BONE PAIN as unrelated but rather due to concurrent illness and the event of FATIGUE was assessed by investigator as possibly related to study drug. Company assessed the relationship to study drug as unrelated for both events.
15245-097-097002	ANAEMIA (CTC GRADE 2)[PT：貧血] FATIGUE (CTC GRADE 3)[PT：疲労] ANOREXIA (CTC GRADE 3)[PT：食欲減退] This 74 year old male patient experienced ANAEMIA (CTC GRADE 2), FATIGUE (CTC GRADE 3) and ANOREXIA (CTC GRADE 3) and was hospitalized 50 days after receiving the last dose of study medication (Alpharadin/placebo) in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included hypertension.The events ANAEMIA (CTC GRADE 2) and FATIGUE (CTC GRADE 3) are considered serious (hospitalized) and Listed for Alpharadin. The event ANOREXIA (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as possibly related for the event of fatigue. The anaemia and anorexia were reported as unrelated but rather due to disease progression.The sponsor has assessed the relationship to study drug as unrelated for all three events.
15245-097-097004	CNS VASCULAR ISCHEMIA (CTC GRADE 4)[PT：脳虚血] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-097-097004	VOMITING (CTC GRADE 3)[PT：嘔吐] DIARRHOEA (CTC GRADE 3)[PT：下痢] URINARY INFECTION (CTC GRADE 3)[PT：尿路感染] FEVER (CTC GRADE 3)[PT：発熱] 本症例には、プラセボが投与されていた。
15245-097-097004	CARDIORESPIRATORY FAILURE[PT：心肺不全] 本症例には、プラセボが投与されていた。
15245-097-097006	SPINAL CORD STENOSIS (CTC GRADE 4)[PT：脊柱管狭窄症] This 73 year old male patient experienced SPINAL CORD STENOSIS (CTC GRADE 4) 2 days after taking the first dose of Alpharain/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included hypertension, depression, hypothyreosis and chronic heart ischemic disease. The event SPINAL CORD STENOSIS (CTC GRADE 4) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to prostate cancer metastases.The sponsor has assessed the relationship to study drug as unrelated.
15245-097-097007	ANEMIA (CTC GRADE 2)[PT：貧血] 本症例には、プラセボが投与されていた。
15245-097-097007	DISEASE PROGRESSION[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-097-097010	FATIGUE (CTC GRADE 2)[PT：疲労] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-097-097010	FATIGUE (CTC GRADE 3)[PT：疲労] 本症例には、プラセボが投与されていた。
15245-097-097010	DISEASE PROGRESSION (CTC GRADE 5)[PT：悪性新生物進行] 本症例には、プラセボが投与されていた。
15245-097-097014	ANAEMIA (CTC GRADE 3)[PT：貧血] 本症例には、プラセボが投与されていた。
15245-097-097014	URINARY BLEEDING (CTC GRADE 3)[PT：尿路出血] 本症例には、プラセボが投与されていた。
15245-097-097015	URETEROLITHIASIS L SIN (CTC GRADE 3)[PT：尿管結石] This 76 year old male patient experienced URETEROLITHIASIS L SIN (CTC GRADE 3) and was hospitalized 62 days after receiving last dose of study drug (Alpharadin/placebo) in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event URETEROLITHIASIS L SIN (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-099-099002	OBSTRUCTION OF LEFT URETERIC ORIFFICE DUE TO LOCAL PROGRESSION OF PROSTATE CANCER (CTC GRADE 3)[PT：前立腺癌] OBSTRUCTION OF LEFT URETERIC ORIFFICE DUE TO LOCAL PROGRESSION OF PROSTATE CANCER (CTC GRADE 3)[PT：尿管閉塞] This 70 year old male patient experienced obstruction of the left ureteric orifice due to local progression of prostate cancer (CTC Grade 3) while using Alpharadin/placebo. The patient's concurrent condition included prostate cancer and skeletal metastasis.The investigator considers the event serious and unrelated to Alpharadin/placebo, but rather due to prostate cancer.Sponsor considers the event serious (hospitalized), unrelated and unlisted for Alpharadin.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-099-099002	PROGRESSION OF BONE PAIN (CTC GRADE 2)[PT：骨痛] This study refers to a 70 year old Caucasian male with hormone-refractory prostate cancer with skeletal metastases who received Alpharadin or Placebo. The pt was admitted to hospital on 09-Jul-2010 for PROGRESSION OF BONE PAIN (CTC GRADE 2). Medical history was not provided. Concomitant medications include lacidipine, alfacalcidol, meloxicam, pregabalin, hydromorphone, prednisolone, fentanyl and omeprazole. The pt did not receive prior docetaxel therapy.PROGRESSION OF BONE PAIN is considered serious due to hospitalization and is listed for Alpharadin. The investigator assessed the relationship to study drug as unrelated, but rather due to progression of prostate cancer, to which the company agrees.
15245-103-103001	LEFT CHEST STAB WOUND (CTC GRADE 4)[PT：故意の自傷行為] INTENTIONAL OVERDOSAGE OF PARACETAMOL (CTCAE GRADE 4)[PT：有害事象なし] SEVERE DEPRESSION (CTC GRADE 4)[PT：うつ病] BILATERAL WRIST CUT WOUND (CTC GRADE 2)[PT：故意の自傷行為] This 74 year old male patient experienced LEFT CHEST STAB WOUND (CTC GRADE 4), INTENTIONAL OVERDOSAGE OF PARACETAMOL (CTC GRADE 4), BILATERAL WRIST CUT WOUND (CTC GRADE 2) and SEVERE DEPRESSION (CTC GRADE 4) and was hospitalized 20 days after receiving the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's medical history includes right scapular pain, right upper pelvic pain, hypertension, anaemia, nocturia and throat discomfort.The events INTENTIONAL OVERDOSAGE OF PARACETAMOL (CTC GRADE 4) and LEFT CHEST STAB WOUND (CTC GRADE 4) are considered serious (hospitalized, life threatening events) and Unlisted for Alpharadin. The events BILATERAL WRIST CUT WOUND (CTC GRADE 2) and SEVERE DEPRESSION (CTC GRADE 4) are considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated for all the events but due to a suicide attempt.The sponsor has assessed the relationship to study drug as unrelated for all the events.
15245-103-103002	CHEST INFECTION (CTC GRADE 3)[PT：下気道感染] This 76 year old male patient experienced Chest Infection (CTC grade 3) and was hospitalized 56 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included diabetes mellitus, hyperlipidemia, hypertension, ischemic heart disease and hearing impairment.The event Chest Infection (CTC grade 3) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to community acquired infection.The sponsor has assessed the event relationship to the study drug as unrelated.
15245-104-104005	PAIN (MUSCULOSKELETAL) CTC GRADE 3[PT：筋骨格痛] Company causality assessment per License Partner Algeta:Event of PAIN (MUSCULOSKELETAL) (CTC GRADE 3), is serious (hospitalized), listed and assessed by the Investigator and Sponsor as related to study drug.
15245-104-104005	SPINAL CORD COMPRESSION[PT：脊髄圧迫] The case refers to a 74-year-old male patient in a double blind, randomized, repeat dose, phase III, multicentre survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. He experienced SPINAL CORD COMPRESSION which is a serious event due to hospitalization and fatal outcome. It is unlisted in the Investigator´s Brochure of Alpharadin.The investigator has assessed the relationship to study drug as unrelated.The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-105-105003	GENERALIZED BONE PAIN (RELATED TO BONE METASTASES) (CTC GRADE 2)[PT：転移部痛] 本症例には、プラセボが投与されていた。
15245-105-105003	ANEMIA (CTC GRADE 3)[PT：貧血] CORD COMPRESSION (CTC GRADE 3)[PT：脊髄圧迫] 本症例には、プラセボが投与されていた。
15245-105-105004	CHEST PAIN (CTC GRADE 2)[PT：筋骨格系胸痛] This 70 year old Caucasian male, who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced chest pain (CTC GRADE 2) 8 days after taking latest dose of study drug and was hospitalized.The subject had no relevant medical history. Chest pain is considered serious (hospitalized) and is unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-105-105004	CHEST PAIN (CTC GRADE 2)[PT：胸痛] ANEMIA (CTC GRADE 3)[PT：貧血] This 70 year old Caucasian male who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced chest pain (CTC grade 2) and haemoglobin (Anemia) (CTC grade 3) 118 days after the administration of study drug. The subject's concurrent condition includes prostate cancer and multiple bone matastases, duodenal and gastric ulcer and inguinal hernia. Relevant medical history included hemorrhoid with haemorrhoidectomy. Chest pain (CTC grade 2) is considered serious (hospitalization) and is unlisted for Alpharadin. Haemoglobin (Anemia) (CTC grade 3) is considered serious (hospitalization) and listed for Alpharadin.The investigator has assessed the relationship to study drug as unrelated for both events, but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated for both events.
15245-105-105004	EPIGASTRIC PAIN (CTC GRADE 2)[PT：上腹部痛] URINARY AND BOWEL INCONTINENCE (CTC GRADE 2)[PT：尿失禁] HAEMATURIA (CTC GRADE 2)[PT：血尿] CHEST PAIN (CTC GRADE 2)[PT：筋骨格系胸痛] URINARY AND BOWEL INCONTINENCE (CTC GRADE 2)[PT：便失禁] This safety report refers to a 70 year old Caucasian male who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, and experienced URINARY AND BOWEL INCONTINENCE (CTC Grade 2) [coded to URINARY INCONTINENCE (CTC Grade 2) and BOWEL INCONTINENCE (CTC Grade 2)], HAEMATURIA (CTC Grade 2), EPIGASTRIC PAIN (CTC Grade 2) and CHEST PAIN (CTC Grade 2) and was hospitalized 29 days after receiving last dose of Alpharadin/placebo. The patient had no relevant medical history. Patient was previously hospitalized twice due to chest pain (see reference case numbers). Prior to the onset of the event the subject received 4 study injections.URINARY AND BOWEL INCONTINENCE (coded to URINARY INCONTINENCE and BOWEL INCONTINENCE), HAEMATURIA, EPIGASTRIC PAIN and CHEST PAIN are all considered serious (hospitalization) and unlisted for Alpharadin.The

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	investigator assessment of the relationship to study drug was unrelated for all the events, but rather due to concurrent illness. The sponsor has assessed the relationship to study drug as unrelated for all the events.
15245-105-105004	EXACERBATION OF CELLULITIS[PT：蜂巣炎] This 70 year-old male patient experienced EXACERBATION OF CELLULITIS CTC grade 3 (previously reported INFECTION (CELLULITIS) CTC grade 3) and was hospitalized approximately 2 month after receiving the last dose of study drug in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The event EXACERBATION OF CELLULITIS is considered serious (hospitalization) and is unlisted for Alpharadin. The investigator has assessed the relationship of the event to study drug as unrelated but rather due to concurrent illness of cellulitis. The sponsor has assessed the relationship of the event to study drug as unrelated.
15245-105-105004	ANAEMIA (CTC GRADE 3)[PT：貧血] HAEMATURIA (CTC GRADE 2)[PT：血尿] This study case report received from Algeta refers to a 70 year old male patient who was treated with Alpharadin for hormone-refractory prostate cancer and experienced anaemia (CTC grade 3) and haematuria (CTC grade 2) about two and a half months after last injection of the study drug. The patient was treated with blood transfusion and tranexamic and recovered after four days. Both events are considered serious due to hospitalisation. Anaemia and haematuria are unexpected in the investigator's brochure. The company concurs with the Investigator who considers both events as unrelated to Alpharadin but rather related to concurrent illness.
15245-106-106001	HAEMORRHAGE INTO BLADDER WALL (CTC GRADE 3)[PT：膀胱出血] ACUTE RETENTION OF URINE (CTC GRADE 3)[PT：尿閉] CYSTITIS (CTC GRADE 3)[PT：膀胱炎] 本症例には、プラセボが投与されていた。
15245-106-106002	MUSCULOSKELETAL PAIN (CTC GRADE 3)[PT：筋骨格痛] CONGESTIVE HEART FAILURE (CTC GRADE 3)[PT：うっ血性心不全] Company causality assessment per License Partner Algeta:Events of MUSCULOSKELETAL PAIN (CTC GRADE 3) and CONGESTIVE HEART FAILURE (CTC GRADE 3) are serious (hospitalization), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-106-106005	ANAEMIA[PT：貧血] This study case was received from license Partner and refers to a 79 year-old Asian male who developed grade 3 anaemia (haemoglobin: 7.2 g/dL) while enrolled in a phase III, multicentre survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. Prior to the onset of the event the patient received 4 study injections, the event occurred 4 weeks after the last injection. Study drug administration was postponed. The patient was treated with blood transfusion. The patient has a relevant medical history of anemia diagnosed in 2008. Concomitant medications include dexamethasone, diclofenac, doxasozin, phenazopyridine, rabeprazole and tramadol. The patient had not

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	received prior docetaxel therapy.Grade 3 anaemia is serious as it lead to prolonged hospitalization and is listed in the Investigator's Brochure of Alpharadin.The investigator has assessed the relationship to study drug as possibly related.The sponsor has assessed the relationship to study drug as related.
15245-106-106005	SEPSIS (CTC GRADE 3)[PT：敗血症] HAEMATURIA (CTC GRADE 3)[PT：血尿] PROSTATE CANCER, BONY METASTASES[PT：悪性新生物進行] The case refers to a 79-year-old male patient in a double blind, randomized, repeat dose, phase III, multicentre survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. He experienced HAEMATURIA (CTC GRADE 3) which is serious due to medical significance and is unlisted (previously reported as listed) in the Investigator´s Brochure of Alpharadin. The investigator considered it unrelated to the study drug. The company also assesses the event unrelated because of the incompatible temporal condition. The patient died due to SEPSIS (CTC GRADE 3) which is serious due to hospitalization and medical significance and its fatal outcome and which is unlisted (previously reported as listed) in the Investigator´s Brochure. The investigator considered it unrelated to Alpharadin/placebo. The company agrees due to the incompatible temporal relation. Also stated as cause of death was the event PROSTATE CANCER, BONY METASTASES which is serious due to its fatal outcome and is unlisted (previously reported as listed) in the Investigator´s Brochure under the context of the natural course of advanced carcinomas. The investigator assesses the event unrelated. The company considers it also not associated to the study drug but related to the underlying disease.
15245-106-106007	NERVE ROOT COMPRESSION (CTC GRADE 3)[PT：神経根圧迫] 試験薬は投与されていない。
15245-106-106011	DERANGED LIVER FUNCTION (CTC GRADE 3)[PT：肝機能異常] This 79 year old male patient experienced DERANGED LIVER FUNCTION (CTC GRADE 3) 29 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event DERANGED LIVER FUNCTION (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to pancreatic tumor.The sponsor has assessed the relationship to study drug as unrelated.
15245-106-106011	CANCER PROSTATE WITH BONE SECONDARY[PT：遠隔転移を伴う前立腺癌] Company causality assessment per License Partner Algeta:Event of CANCER PROSTATE WITH BONE SECONDARY is serious (fatal outcome), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-106-106012	ANAEMIA (CTC GRADE 2)[PT：貧血] 本症例には、プラセボが投与されていた。
15245-106-106012	ANAEMIA (CTC GRADE 3)[PT：貧血] 本症例には、プラセボが投与されていた。
15245-106-106012	CORD COMPRESSION (CTC GRADE 3)[PT：脊髄圧迫] PROSTATE CANCER (SKELETAL METASTASIS)[PT：骨転移] BONE PAIN (CTC GRADE 3)[PT：骨痛] ANAEMIA (CTC GRADE 4)[PT：貧血] 本症例には、プラセボが投与されていた。
15245-106-106016	COPD EXACERBATION(CTC GRADE 3)[PT：慢性閉塞性肺疾患] Company causality assessment per License Partner Algeta:Event of COPD EXACERBATION (CTC GRADE 3), is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-110-110002	UNCONTROLLED BONE PAIN (CTCAE GRADE 3)[PT：骨痛] （本例は PMDA へ報告を行った症例である。弊社の見解を日本語で示す） 「骨痛」について、治験担当医は本治験薬との因果関係があると評価した。弊社は、当該事象は原疾患（前立腺癌）の骨転移に基づくと考えるのが合理的であり、本剤との関連性はないと考える。
15245-111-111001	INTRACEREBRAL BLEEDING (CTC GRADE 3)[PT：脳出血] CONFUSIONAL STATE (CTC GRADE 3)[PT：錯乱状態] ANEMIA CTC GRADE 3[PT：貧血] This 71 year old Caucasian male who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer, experienced intracerebral bleeding (CTC grade 3), confusional state (CTC grade 3) and anemia (CTC grade 3) (7.8 g/dl) approximately 25 days after the fourth and last injection of study drug. The patient received treatment for the events and anemia (CTC grade 3) resolved on the same day whereas intracerebral bleeding (CTC grade 3) and confusional state (CTC grade 3) resolved with sequelae. Alpharadin was discontinued.The subject's relevant medical history included allergic rhinitis, sinus

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	curettage, bone pain, neuropathic pain, anemia, epigastric burn and arterial hypertension. Intracerebral bleeding (CTC grade 3) and confusional state (CTC grade 3) are serious due to hospitalization and life threatening nature and are unexpected in the Investigator's Brochure for Alpharadin. Anemia (CTC grade 3) is serious due to medical importance and is expected for AlpharadinThe investigator assessed the relationship to study drug as unrelated for all events but rather due to pre-existing prostate cancer.The sponsor has assessed the relationship to study drug as unrelated for all events.
15245-111-111002	PLEURAL EFFUSION (CTC GRADE 2)[PT：胸水] This 72 year old male patient experienced PLEURAL EFFUSION (CTC GRADE 2) 51 days after receiving the first dose of Alpharadin/placebo in this double-blind, randomized, multiple dose, phase III, multicentre study of Alpharadin in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases. The patient's concurrent condition included recurrent pleural effusion. The event PLEURAL EFFUSION (CTC GRADE 2) is considered serious (hospitalized) and listed in the Investigator´s Brochure of Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to the recurrent pleural effusion related to delayed toxicity from docetaxel. The company agrees on that and considers the event PLEURAL EFFUSION (CTC GRADE 2) unrelated to Alpharadin/placebo.
15245-111-111002	ACUTE PLEURAL EFFUSION (CTC GRADE 2)[PT：胸水] This 72 year old male patient experienced Acute Pleural Effusion (CTC grade 1) and was hospitalized 7 days after receiving latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included delayed docetaxel toxicity and recurrent pleural effusion.The event Acute Pleural Effusion (CTC grade 1) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to recurrent pleural effusion related to delayed toxicity from docetaxel.The sponsor has assessed the relationship to study drug as unrelated.
15245-111-111002	BILATERAL PULMONARY EMBOLISM (CTC GRADE 4)[PT：肺塞栓症] DEEP VEIN THROMBOSIS (CTC GRADE 3)[PT：深部静脈血栓症] This 73 year old male patient experienced Bilateral Pulmonary embolism CTC GRADE 4 (previously CTC GRADE 2) and deep vein thrombosis CTC GRADE 3 (previously CTC GRADE 2) 120 days after first dose of Alpharadin/placebo in this double blind, randomised, repeat dose, phase III, multicentre survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's medical history included thigh lipoma exeresis. The patient's concurrent condition included phlebitis, stomach pain, recurrent pleural effusion and anxiety.The events Bilateral Pulmonary embolism (CTC GRADE 4) and deep vein thrombosis (CTC GRADE 3) are considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to prostate cancer progression.The sponsor has assessed the relationship to study drug as unrelated.
15245-111-111002	DYSPNOEA (CTC GRADE 2)[PT：呼吸困難] This 73 year old male patient experienced Dyspnoea (CTC grade 2) and was hospitalized the same day of receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastasis. The patient's concurrent condition included recurrent pleural effusion, thigh lipoma exeresis, stomach pain, anxiety and phlebitis.The event Dyspnoea (CTC grade 2) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to pulmonary embolism.The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-111-111002	PLEURAL EFFUSION (CTC GRADE 2)[PT：胸水] This 73 year old male patient experienced PLEURAL EFFUSION (CTC GRADE 2) and was hospitalized 73 days after receiving last dose of study drug (Alpharadin/placebo) in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases.The patient's concurrent condition included acute pleural effusion, recurrent pleural effusion due to delayed toxicity from docetaxel, bilateral pulmonary embolism, dyspnea, thigh lipoma exeresis, stomach pain, anxiety and phlebitis.The event PLEURAL EFFUSION (CTC GRADE 2) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to recurrent pleural effusion due to delayed toxicity from docetaxel.The sponsor has assessed the relationship to study drug as unrelated.
15245-117-117008	ALZEIHMER'S DISEASE DECOMPENSATION (CTC GRADE 2)[PT：アルツハイマー型認知症] This 83 year old male patient experienced ALZEIHMER'S DISEASE DECOMPENSATION (CTC GRADE 2) and was hospitalized 16 days after taking the latest dose of study drug (Alpharadin/placebo) in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The subject had relevant medical history of Alzheimer's disease, dorsal pain, insomnia, anxiety and pollakiuria. The event ALZEIHMER'S DISEASE DECOMPENSATION (CTC GRADE 2) is considered serious as the patient was hospitalized and is unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated, but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-127-127001	RAPID DISEASE PROGRESSION[PT：前立腺癌] This 51 year old male patient died due to RAPID DISEASE PROGRESSION 32 days after receiving dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included osteonecrosis of jaw, left arm neuropathic pain and type 2 diabetes mellitus.The event RAPID DISEASE PROGRESSION is considered serious (fatal) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated.The sponsor has assessed the relationship to study drug as unrelated.
15245-128-128005	WORSENING OF ATRIAL FIBRILLATION (CTC GRADE 3)[PT：心房細動] EXACERBATION OF LEFT VENTRICULAR FAILURE (CTC GRADE 3)[PT：左室不全] 本症例には、プラセボが投与されていた。
15245-129-129002	GENERAL MUSCLE WEAKNESS[PT：筋力低下] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-129-129006	IMPENDING SPINAL CORD COMPRESSION (CTC GRADE 4)[PT：脊髄圧迫] PNEUMONIA[PT：肺炎] Pneumonia is considered serious due to death occurred. IMPENDING SPINAL CORD COMPRESSION (CTC GRADE 4) is considered serious due to hospitalization /life-threatening/disability. Both events are unlisted in the Investigator Brochure for Alpharadin. The investigator has assessed the relationship to study drug as unrelated for pneumonia and spinal cord compression, but rather due to progressive disease. The sponsor has assessed the relationship to the study drug as unrelated for both events.
15245-129-129007	ANAEMIA (CTC GRADE 3)[PT：貧血] ANAEMIA (CTC GRADE 3)[PT：貧血] This 81 year old male enrolled in clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases; while on active treatment with study drug (Alpharadin/placebo) developed ANAEMIA (CTC GRADE 3). The patient was known case of chronic anaemia (grade 2) prior to randomization; and taking erythropoietin (missed 2 injections). Patient concomitant medications include Metformin, alopurinol, glibenclamide, colchicine, acetylsalicylic acid, bisoprolol, amlodipine besylate and furosemide. The patient did not receive prior docetaxel therapy. The event ANAEMIA (CTC GRADE 3) is considered serious (medically important event) and listed for Alpharadin. As per provided information patient had two episodes of ANAEMIA(CTC GRADE 3) [29-Mar-2011 to 31-Mar-2011] and ANAEMIA (CTC GRADE 3) [26-Apr-2011 to 29-Apr-2011] in a month time. The investigator has assessed the relationship to study drug as unrelated for the first episode of anaemia and possibly related for the second episode as the subjects haemoglobin level dropped despite being on erythropoietin. A work up for anaemia is planned by the family physician if necessary (possibly rectal bleeding). The sponsor has assessed the relationship to study drug as possibly related for both episodes of anaemia.
15245-129-129007	ANAEMIA (CTC GRADE 3)[PT：貧血] This 81 year old Caucasian male, who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced ANAEMIA (CTC GRADE 3) 26 days after the study drug was stopped. The subject's relevant medical history included anaemia of chronic disease. Anaemia is considered serious due to medical importance and is listed for Alpharadin. The investigator has assessed the relationship to study drug as unrelated, rather due to anaemia of chronic disease. The sponsor assessed the relationship to study drug as unrelated.
15245-130-130003	GENERAL DETERIORATION PROGRESSION OF DISEASE[PT：前立腺癌] This 87 year old Black male, who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced GENERAL DETERIORATION PROGRESSION OF DISEASE 48 days after study drug was discontinued. Prior to the onset of the event , the subject received 1 study injection. The subject's concurrent conditions included hypertension, hypercholesteremia, weight loss, fatigue, weakness in lower extremities, urinary retention, anorexia, dysgeusia, chronic pain in pelvis, chronic pain in left shoulder, acute pain in right and left lower ribs, acute pain lower thoracic spine, arthritis in both hands and knees, atrial fibrillation and Chronic Obstructive Pulmonary Disease. Medical history included appendix surgery. GENERAL DETERIORATION PROGRESSION OF DISEASE is considered serious due to its fatal nature and is unlisted for Alpharadin. The Investigator assessed the relationship to study drug as possibly related. However, Company disagrees and considers this event to be unrelated. A Plausible alternative explanation and possible cause of death is the progression of the underlying disease of prostate cancer with skeletal metastases.

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-130-130004	FRACTURE (MUSCULOSKELETAL/SOFT TISSUE) (CTC GRADE 3 TO GRADE 2)[PT：股関節部骨折] （本例は PMDA へ報告を行った症例である。弊社の見解を日本語で示す） 「股関節部骨折」について、治験担当医は本治験薬との因果関係があると評価した。また、「骨折が起こるには、（正常、異常は問わず）骨へのストレス要因の存在が不可欠であり、また骨の状態が正常でも脆弱でも起こりうる。本事象に関して、本治験薬はストレス要因とはならないものの、骨転移部の骨の脆弱化に影響を及ぼしたことは否定できない。よって、初めの段階から骨折発現に関与していた可能性はある。」とコメントした。 本症例の原疾患は骨転移を有する進行性前立腺癌患者であり、骨転移は骨痛や骨折の原因となることが知られている。また、合併症に骨粗鬆症を有しており，臨床経過においてもラグの角につまずいたという外傷機転があることから、弊社は「股関節部骨折」と本試験薬との関連性はないと考える。
15245-130-130009	BONE PAIN (CTC GRADE 3)[PT：骨痛] Bone Pain (CTC grade 3) is considered serious due to hospitalization. The event is unlisted in the Investigator Brochure for Alpharadin. In line with investigator, company assesses the event as not associated with the study drug. The underlying condition of prostate cancer with skeletal metastases and possible disease progression provided plausible alternative explanations for the event.The sponsor has assessed the relationship to study drug as unrelated.
15245-133-133002	PATHOLOGICAL LEFT ARM FRACTURE (CTC GRADE 2)[PT：病的骨折] Company causality assessment per License Partner Algeta:Event of PATHOLOGICAL LEFT ARM FRACTURE (CTC GRADE 2) is serious (disability / medically significant), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to injury.
15245-133-133002	DISEASE PROGRESSION[PT：前立腺癌] Company causality assessment per License Partner Algeta:Event of DISEASE PROGRESSION is serious (fatal outcome), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to concurrent illness.
15245-133-133003	SECONDARY ANAEMIA TO BONE MARROW SUPPRESSION[PT：貧血] Company causality assessment per License Partner Algeta:Event of SECONDARY ANAEMIA TO BONE MARROW SUPPRESSION, is serious (hospitalized), listed and assessed by the Investigator and Sponsor as related to study drug.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-133-133003	SECONDARY ANEMIA TO BONE MARROW SUPRESSION (CTC GRADE 3)[PT：貧血] SECONDARY ANEMIA TO BONE MARROW SUPRESSION (CTC GRADE 3)[PT：骨髄機能不全] Company causality assessment per License Partner Algeta:Event of SECONDARY ANEMIA TO BONE MARROW SUPRESSION (CTC GRADE 3), is serious (hospitalized), listed and assessed by the Investigator and Sponsor as related to study drug.
15245-133-133003	ANAEMIA (CTC GRADE 4)[PT：貧血] This 78 year old male patient developed ANAEMIA (CTC GRADE 4) and was hospitalized 60 days after receiving the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included coronary heart disease.The event ANAEMIA (CTC GRADE 4) is considered serious (hospitalized) and Listed for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but probably due to prostate cancer.The sponsor has assessed the relationship to study drug as unrelated.
15245-133-133005	PARESIS OF LOWER (CTC GRADE 3)[PT：不全麻痺] Company causality assessment per License Partner Algeta:Event of PARESIS OF LOWER (CTC GRADE 3) is serious (disability), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to disease under study.
15245-133-133006	PROGRESSIVE CANCER (CTC GRADE 4)[PT：前立腺癌] This 54 year old Caucasian male who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced PROGRESSIVE CANCER (CTC GRADE 4), was hospitalized and later died 44 days after study drug was discontinued. The patient had received 6 study injections.The subject's relevant medical history was not provided. Concurrent conditions included low platelets and low hemoglobin.PROGRESSIVE CANCER (CTC GRADE 4) is considered serious (Hospitalized/Fatal) and unlisted for Alpharadin.The investigator assessed the relationship to study drug as unrelated but rather due to the underlying disease.The sponsor assessed the relationship to study drug as unrelated.
15245-133-133009	DEATH - DISEASE PROGRESSION[PT：悪性新生物進行] Company causality assessment per License Partner Algeta:Event DEATH - DISEASE PROGRESSION, serious due to fatal outcome, is unlisted and assessed by the Investigator and Sponsor as unrelated to study drug.
15245-133-133010	DETERIORATION OF PERFORMANCE STATUS (CTC GRADE 4)[PT：活動状態低下] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-133-133011	DEATH OF UNKNOWN REASON (CTC GRADE 5)[PT：死亡] CONFUSION (CTC GRADE 4)[PT：錯乱状態] TREMOR (CTC GRADE 4)[PT：振戦] This 66 year old male patient experienced DEATH OF UNKNOWN REASON (CTC GRADE 5), CONFUSION (CTC GRADE 4) and TREMOR (CTC GRADE 4) while on active treatment of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had not relevant medical history.The event DEATH OF UNKNOWN REASON (CTC GRADE 5) is considered serious (fatal) and Unlisted for Alpharadin. The event CONFUSION (CTC GRADE 4) is considered serious (disability) and Unlisted for Alpharadin. The event TREMOR (CTC GRADE 4) is considered serious (disability) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as possibly related for the events of confusion, tremor and death. The investigator reported that the relation between the death and study drug cannot be excluded.The sponsor has assessed the relationship to study drug as unrelated for all events.
15245-133-133012	SPINAL CORD COMPRESSION (CTC GRADE 3)[PT：脊髄圧迫] 試験薬は投与されていない。
15245-133-133012	DYSPNEA (CTC GRADE 3)[PT：呼吸困難] Company causality assessment per License Partner Algeta:Event DYSPNEA, is serious (fatal outcome), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to concurrent illness.
15245-133-133013	FATIGUE (CTC GRADE 3)[PT：疲労] 本症例には、プラセボが投与されていた。
15245-133-133017	BLEEDING FROM UPPER DIGESTIVE TRACT (CTC GRADE 2)[PT：上部消化管出血] This 61 year old Caucasian male who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer, experienced bleeding from upper digestive tract (CTC GRADE 2) 2 days after the onset of study drug. The patient recovered. No endoscopy was performed, the underlying reason for the haemorrhage was unknown.The subject's relevant medical history included hypertension. Bleeding from upper digestive tract is considered serious due to hospitalization and is unlisted for Alpharadin.The investigator assessed the relationship to study drug as unrelated, but rather due to bleeding from upper digestive tract.The sponsor assessed the relationship to the study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-133-133018	FATIGUE (CTC GRADE 4)[PT：疲労] This 73 year old male patient experienced FATIGUE (CTC GRADE 4) and was hospitalized 22 days after receiving latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases. Relevant medical history was not provided.The event FATIGUE (CTC GRADE 4) is considered serious (hospitalized, disability) and Listed for Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to the study drug as unrelated.
15245-133-133018	DISEASE PROGRESSION[PT：悪性新生物進行] Company causality assessment per License Partner Algeta:Event DISEASE PROGRESSION, is serious due to fatal outcome, unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-133-133019	PROSTATE CANCER PROGRESSION - DEATH (CTCAE GRADE 5)[PT：前立腺癌] This 77 year old male patient died due to PROSTATE CANCER PROGRESSION - DEATH (CTCAE GRADE 5) 73 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. Relevant medical history was reported as none.The event PROSTATE CANCER PROGRESSION - DEATH (CTCAE GRADE 5) is considered serious (fatal) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated.The sponsor has assessed the relationship to the study drug as unrelated.
15245-133-133020	DEHYDRATION (CTC GRADE 3)[PT：脱水] This 76 year old male patient experienced DEHYDRATION (CTC GRADE 3) and was hospitalized 8 days after taking first dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included Vomiting.The event DEHYDRATION (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as probably related.The sponsor has assessed the relationship to study drug as possibly related.
15245-133-133020	DISEASE PROGRESSION[PT：前立腺癌] Company causality assessment per License Partner Algeta:Event of DISEASE PROGRESSION is serious (fatal outcome), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to disease progression.
15245-133-133021	DISLOCATION OF NEPHROSTOMY (CTC GRADE 1)[PT：腎瘻造設] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-133-133021	ANEMIA (CTC GRADE 3)[PT：貧血] FATIGUE (CTC GRADE 4)[PT：疲労] 本症例には、プラセボが投与されていた。
15245-133-133021	DISEASE PROGRESSION[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-133-133022	DYSPNEA[PT：呼吸困難] 本症例には、プラセボが投与されていた。
15245-133-133025	LEACAGE OF THE AOTRAL GRAFT (CTC GRADE 2)[PT：動静脈グラフト部位出血] 試験薬は投与されていない。
15245-133-133025	PARAPLEGIA (CTC GRADE 3)[PT：対麻痺] 本症例には、プラセボが投与されていた。
15245-133-133025	ANEMIA (CTC GRADE 3)[PT：貧血] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-133-133025	PROSTATE CANCER PROGRESSION (CTCAE GRADE 5)[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-133-133026	HAEMATURIE (HAEMATURIA) (CTC GRADE 3)[PT：血尿] This 51 year old male patient experienced Haematurie (haematuria) (CTC grade 3) and was hospitalized 46 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event Haematurie (haematuria) (CTC grade 3) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-133-133029	SUBILEUS (CTC GRADE 3)[PT：亜イレウス] 本症例には、プラセボが投与されていた。
15245-133-133029	RENAL FAILURE (CTC GRADE 3)[PT：腎不全] 本症例には、プラセボが投与されていた。
15245-134-134001	NEUROPATHY MOTOR PARALYSIS[PT：末梢性運動ニューロパチー] NEUROPATHY MOTOR PARALYSIS[PT：麻痺] 試験薬は投与されていない。
15245-134-134001	PROSTATE CANCER PROGRESSION (CTC GRADE 5)[PT：前立腺癌] Company causality assessment per License Partner Algeta:Event of PROSTATE CANCER PROGRESSION (CTC GRADE 5), serious due fatal outcome, is unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to progression of underlying disease.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-135-135003	ANEMIA (CTC GRADE 3)[PT：貧血] Company causality assessment per License Partner Algeta:Event of ANEMIA (CTC GRADE 3) is serious (hospitalized), listed and assessed by the Investigator and Sponsor as related to study drug.
15245-135-135003	DISEASE PROGRESSION[PT：前立腺癌] This 62 year old male patient died due to DISEASE PROGRESSION 34 days after receiving latest dose of Alpharadin/placebo in this clinical study ofAlpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included Insomnia.The event DISEASE PROGRESSION is considered serious (fatal) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated.The sponsor has assessed the relationship to study drug as unrelated.
15245-135-135005	CEREBROVASCULAR ISCHEMIA (CTC GRADE 4)[PT：脳虚血] 本症例には、プラセボが投与されていた。
15245-137-137001	MUSCLE WEAKNESS EXTREMITY LOWER, PELVIC (CTC GRADE 3)[PT：筋力低下] 本症例には、プラセボが投与されていた。
15245-137-137001	CANCER PROGRESSION[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-137-137003	PROSTATE CANCER PROGRESSION[PT：前立腺癌] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-137-137006	ANAEMIA (CTC GRADE 3)[PT：貧血] This 71 year old male patient experienced ANAEMIA (CTC GRADE 3) and was hospitalized on the patient's day of last study drug (Alpharadin/placebo) injection in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. Relevant medical history was not provided.The event ANAEMIA (CTC GRADE 3) is considered serious (hospitalized) and Listed for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to prostate cancer.The sponsor has assessed the relationship to study drug as unrelated.
15245-137-137006	HAEMATURIA (CTC GRADE 3)[PT：血尿] ANEMIA (CTC GRADE 4)[PT：貧血] Company causality assessment per License Partner Algeta:Events of HAEMATURIA (unlisted) and ANEMIA (listed) are serious (hospitalization) and assessed by the Investigator and Sponsor as unrelated to study drug. Alternative explanation provided was cancer progression and anemia was considered due to haematuria.
15245-137-137006	PROSTATE CANCER[PT：前立腺癌] Company causality assessment per License Partner Algeta:Event of PROSTATE CANCER is serious (fatal outcome), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug.
15245-137-137008	BONE PAIN WORSENING (CTC GRADE 2)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-137-137010	WORSENING OF BONE PAIN (CTC GRADE 2)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-137-137010	ANAEMIA (CTC GRADE 3)[PT：貧血] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-137-137010	ANAEMIA (CTC GRADE 3)[PT：貧血] 本症例には、プラセボが投与されていた。
15245-137-137010	ANAEMIA (CTC GRADE 2)[PT：貧血] 本症例には、プラセボが投与されていた。
15245-137-137012	COMPRESSION FRACTURE OF T4 (CTC GRADE 3)[PT：病的骨折] 本症例には、プラセボが投与されていた。
15245-137-137012	PROSTATE CANCER PROGRESSION[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-139-139001	PROGRESSION OF PROSTATE CANCER (CTC GRADE 5)[PT：前立腺癌] Company causality assessment per License Partner Algeta:Event of PROGRESSION OF PROSTATE CANCER (CTC GRADE 5) is serious (fatal outcome), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug.
15245-139-139002	ISCHAEMIC STROKE (CTC GRADE 3)[PT：虚血性脳卒中] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-139-139005	ANEMIA (CTC GRADE 2)[PT：貧血] The case refers to a 71-year-old male patient in a double blind, randomized, repeat dose, phase III, multicentre survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. He experienced ANEMIA (CTC GRADE 2) which is a serious event due to hospitalization and is listed in the Investigator´s Brochure of Alpharadin. The investigator has assessed the relationship to study drug as possibly related. The company can also not exclude that ANEMIA (CTC GRADE 2) is associated to the study drug.
15245-139-139005	PROSTATE CANCER PROGRESSION[PT：前立腺癌] Company causality assessment per License Partner Algeta:Event of PROSTATE CANCER PROGRESSION is serious (fatal outcome), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to disease progression.
15245-139-139006	ANEMIA (CTC GRADE 2)[PT：貧血] Company causality assessment per License Partner Algeta:Event of ANEMIA (CTC GRADE 2) is serious (hospitalized), listed and assessed by the Investigator and Sponsor as related to study drug.
15245-139-139009	PANCYTOPENIA (CTCAE GRADE 3)[PT：汎血球減少症] Company causality assessment per License Partner Algeta:Event of PANCYTOPENIA (CTCAE GRADE 3) is serious (medically significant), listed and assessed by the Investigator and Sponsor as related to study drug.
15245-139-139009	LEUCKOCYTOPENIA (CTC GRADE 3)[PT：白血球減少症] Company causality assessment per License Partner Algeta:Event of LEUCKOCYTOPENIA (CTC GRADE 3) is serious (medically significant), listed and assessed by the Investigator and Sponsor as related to study drug.
15245-139-139012	THROMBOPHLEBITIS OF LEFT LOWER LIMB (CTC GRADE 2)[PT：血栓性静脈炎] 試験薬は投与されていない。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-141-141002	HEMATURIA (CTCAE GRADE 2)[PT：血尿] HEMATURIA (CTCAE GRADE 3)[PT：血尿] 本症例には、プラセボが投与されていた。
15245-141-141002	RIGHT HYDRONEPHROSIS (CTC GRADE 2)[PT：水腎症] 本症例には、プラセボが投与されていた。
15245-141-141002	ANAEMIA (CTC GRADE 3)[PT：貧血] 本症例には、プラセボが投与されていた。
15245-141-141002	DYSPNOE[PT：呼吸困難] 本症例には、プラセボが投与されていた。
15245-141-141003	FRACTURE OF RIGHT FEMORAL BONE (CTC GRADE 3)[PT：病的骨折] 本症例には、プラセボが投与されていた。
15245-141-141004	PROSTATE CANCER PROGRESSION[PT：前立腺癌] This 68 year old male patient died due to Prostate Cancer Progression 60 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The subject had no relevant medical history.The event Prostate Cancer Progression is considered serious (fatal) and Unlisted for Alpharadin. Investigator has assessed the relationship to study drug as unrelated.The sponsor assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-141-141005	BREATHS HELD[PT：呼吸不全] This 66 year old Caucasian male patient died from “Breaths held” 63 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. No relevant medical history was not provided.The event Breaths held is considered serious (fatal) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated, but rather due to concomitant illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-144-144002	BENIGN BLADDER TUMOR (CTC GRADE 3)[PT：膀胱の良性新生物] This 77 year old male patient experienced BENIGN BLADDER TUMOR (CTC GRADE 3) and was hospitalized 22 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event BENIGN BLADDER TUMOR (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to the underlying prostate cancer.The sponsor has assessed the relationship to study drug as unrelated.
15245-144-144004	PNEUMONIA (CTC GRADE 3)[PT：肺炎] This 68 year old male patient developed PNEUMONIA (CTC GRADE 3) and was hospitalized 2 days after receiving the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event PNEUMONIA (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for alpharadin. The investigator has assessed the relationship to study drug as unrelated, rather due to concurrrent illness.Sponsor has assessed the relationship to study drug as unrelated.
15245-146-146001	HERPES ZOSTER (CTC GRADE 2)[PT：帯状疱疹] This 70 year old male patient experienced HERPES ZOSTER (CTC GRADE 2) and was hospitalized 29 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's medical history included thyroidectomy.The event HERPES ZOSTER (CTC GRADE 2) is considered serious (hospitalized) and Unlisted for alpharadin. The investigator has assessed the relationship to study drug as unrelated.Sponsor has assessed the relationship to study drug as unrelated.
15245-146-146004	MULTIPLE ORGAN FAILURE (CTC GRADE 4)[PT：多臓器不全] This 77-year-old male patient enrolled in a clinical study with Alpharadin/placebo for patients with hormone-refractory prostate cancer with skeletal metastases, developed MULTIPLE ORGAN FAILURE (CTC Grade 4) (previously ″general deterioration″) which is considered serious due to fatal outcome and hospitalization. The patient had relevant medical history of hypertension, disturbance of micturation, cardiac pacemaker, kidney left cystis, cystis liver 9mm seg V and cholecystolithiasis.The event is unlisted in the Investigator´s Brochure for Alpharadin.The investigator has assessed the relationship to study drug as unrelated. The investigator also states that the symptoms of anaemia, fibrinolysis and blood clotting which were caused by a depression of the bone marrow, most probably caused by the previous chemotherapy (taxotere) as it is a known side effect of the therapy.The Sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-148-148005	ANAEMIA (CTC GRADE 2)[PT：貧血] 本症例には、プラセボが投与されていた。
15245-148-148005	DEATH DUE TO TUMOR PROGRESSION[PT：新生物進行] 本症例には、プラセボが投与されていた。
15245-148-148007	EMESIS (CTC GRADE 3)[PT：嘔吐] NAUSEA (CTC GRADE 3)[PT：悪心] DIARRHEA (CTC GRADE 3)[PT：下痢] 本症例には、プラセボが投与されていた。
15245-148-148009	SEVERE PAIN IN PELVIS & LEGS (CTC GRADE 3)[PT：骨痛] SEVERE PAIN IN PELVIS & LEGS (CTC GRADE 3)[PT：骨痛] This 71 year old Caucasian male, who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced SEVERE PAIN IN PELVIS & LEGS (CTC GRADE 3) 29 days after receiving the first dose of study drug. The subject's relevant medical history included lung embolism, fatigue, pelvic and spinal pain, incontinence, maxilla necrosis, slipped disc, anaemia and erythrocytes low. SEVERE PAIN IN PELVIS & LEGS (CTC GRADE 3) was split for coding purposes to SEVERE PAIN IN PELVIS (PELVIC BONE PAIN) and SEVERE PAIN IN LEGS (LOWER EXTREMITY BONE PAIN). Both events are serious (hospitalization) and are listed for Alpharadin under the context of bone pain.The investigator has assessed the relationship to study drug as possibly related.The sponsor assessed the relationship to study drug as possibly related.
15245-148-148009	ANAEMIA (CTC GRADE 3)[PT：貧血] Company causality assessment per License Partner Algeta:Event of ANAEMIA (CTC GRADE 3) is serious (hospitalized), listed and assessed by the Investigator and Sponsor as related to study drug.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-148-148009	HERPES ZOSTER (CTC GRADE 3)[PT：帯状疱疹] ANEMIA (CTC GRADE 2)[PT：貧血] This 71 year old male was hospitalized for HERPES ZOSTER (CTC GRADE 3) 7 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The hospitalization was prolonged due to ANEMIA (CTC GRADE 2). The patient's concurrent condition included erythrocytes low, liver cyst, pain pelvis bone, haematocrit low, HB low, slipped disc, necrosis maxilla, incontinence, pain spine bone, fatigue, lung embolism left basal and scoliose.The event HERPES ZOSTER (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The event ANEMIA (CTC GRADE 2) is considered serious (hospitalized) and Listed for Alpharadin. The investigator has assessed the relationship to study drug as possibly related for both events. The investigator stated that herpes zoster was considered possibly related to the study drug as herpes zoster can be triggered by cytotoxic tumour therapy. The sponsor has assessed the relationship to study drug as unrelated for the event of Herpes Zoster and possibly related for the event of anaemia.
15245-148-148009	SYNCOPE (CTC GRADE 3)[PT：失神] ANEMIA (CTC GRADE 4)[PT：貧血] This 71 year old male patient experienced SYNCOPE (CTC GRADE 3) and ANEMIA (CTC GRADE 4) and was hospitalized 36 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's medical history included Iron low, CRP high, LDH high, total ALP high, erythrocytes decreased, haematocrit low, radical prostatectomy with urethrovesical anastamosis, pallative transurethral prostatectomy, abdominal wall catheter, low haemoglobin, necrosis maxilla and lung embolism.The patient's concurrent condition included scoliose, liver cyst, osteonecrosis, slipped disc, incontinence, pelvic and spine bone pain, fatigue and pallative tumour relaps removal. The event SYNCOPE (CTC GRADE 3) is considered serious because (hospitalized) and Unlisted for Alpharadin. The event ANEMIA (CTC GRADE 4) is considered serious (hospitalized) and Listed for Alpharadin. The investigator assessed the relationship to the study drug as possibly related for both events. The investigator also reported that the reason for syncope was the profound anaemia which in turn can be triggered by tumor therapies.The sponsor has assessed the relationship to study drug as possibly related for both events.
15245-148-148009	RAPIDLY PROGRESSIVE LIVER METASTASIS[PT：肝転移] Event RAPIDLY PROGRESSIVE LIVER METASTASIS (CTC GRADE 3) is serious (hospitalization/fatal outcome) and unlisted in the Investigator's Brochure/Prescribing Information for Alpharadin (radium-223 chloride). Investigator has assessed the relationship to the study drug as unrelated, rather due to progressing tumor. The sponsor considered the event unrelated.
15245-148-148012	ACUTE CORONARY SYNDROME (CTC GRADE 3)[PT：急性冠動脈症候群] Company causality assessment per License Partner Algeta:Event of ACUTE CORONARY SYNDROME (CTC GRADE 3), is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to concurrent illness.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-148-148012	PROGRESSIVE ANGINA PECTORIS (CTC GRADE 3)[PT：狭心症] This 73 year old male patient experienced PROGRESSIVE ANGINA PECTORIS (CTC GRADE 3) and was hospitalized 5 days after taking the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's medical history included stent insertion. The patient's concurrent condition included vascular coronary heart disease. The event PROGRESSIVE ANGINA PECTORIS (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for alpharadin. The investigator assessed the relationship to study drug as unrelated, but rather due to the subject's known cardiac history.The sponsor assessed the relationship to study drug as unrelated.
15245-148-148014	CATARACT SURGERY (CTC GRADE 3)[PT：白内障手術] Company causality assessment per License Partner Algeta:Event of CATARACT SURGERY (CTC GRADE 3) is serious (hospitalization), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug.
15245-148-148015	LYMPH NODE METASTASES (CTC GRADE 3)[PT：リンパ節転移] 本症例には、プラセボが投与されていた。
15245-148-148019	HYDRONEPHROSIS RIGHT GRADE II (CTC GRADE 3)[PT：水腎症] This 65 year old male patient experienced hydronephrosis right grade II (CTC grade 3) and was hospitalized 113 days after start of treatment with Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastasis. The patient's concurrent condition included hypertonia, diabetes mellitus, sinus bradycardia and cirrhosis of the kidney. The event hydronephrosis right grade II (CTC grade 3) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor assessed the relationship to study drug as unrelated.
15245-148-148019	BILATERAL HYDRONEPHROSIS (CTC GRADE 3)[PT：水腎症] This 65 year old male patient experienced Bilateral hydronephrosis (CTC grade 3) and was hospitalized 6 days after receiving the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included diabetes mellitus, sinus bradycardia, shrinkage of left kidney and hypertonia.The event Bilateral hydronephrosis (CTC grade 3) is considered serious (hospitalized) and Unlisted for alpharadin.The investigator has assessed the relationship to study drug as unrelated, but rather due to concurrent illness/tumour progression.The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-148-148019	RESPIRATORY INSUFFICIENCY DUE TO TUMOR PROGRESSION[PT：呼吸不全] RESPIRATORY INSUFFICIENCY DUE TO TUMOR PROGRESSION[PT：前立腺癌] This 65 year old male patient died from respiratory insufficiency due to tumor progression 31 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included hypertonia, diabetes mellitus, shrinkage of left kidney and sinus bradycardia.The events of respiratory insufficiency due to tumor progression (code split per coding requirements to respiratory insufficiency and progression of prostate cancer) are considered serious (fatal) and Unlisted Alpharadin. The investigator assessed the relationship to study drug as unrelated.The sponsor assessed the relationship to study drug as unrelated.
15245-148-148021	WORSENING ABSENCE OF APPETITE (CTC GRADE 3)[PT：食欲減退] DYSPHAGIA (CTC GRADE 3)[PT：嚥下障害] WORSENING FATIGUE (CTC GRADE 3)[PT：疲労] INCREASE IN PSA (CTC GRADE 3)[PT：前立腺特異性抗原増加] 本症例には、プラセボが投与されていた。
15245-149-149004	BONE PAIN-METASTASES (CTC GRADE 3)[PT：転移部痛] 本症例には、プラセボが投与されていた。
15245-149-149005	PROGRESSION OF PROSTATE CANCER[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-149-149006	PARESIS OF LEFT ARM (CTC GRADE 3)[PT：不全単麻痺] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-149-149006	GENERAL PHYSICAL HEALTH DETERIORATION (CTC GRADE 3)[PT：全身健康状態低下] GASTRITIS (CTC GRADE 3)[PT：胃炎] 本症例には、プラセボが投与されていた。
15245-149-149009	APLASTIC ANEMIA (CTC GRADE 3)[PT：再生不良性貧血] （本例は PMDA へ報告を行った症例である。弊社の見解を日本語で示す） 本事象の発現は本治験薬の最終投与約 1 年後であるが、本治験薬の投与継続中に輸血が必要となっている状況を勘案し、時間的関連性の観点より、本治験薬との因果関係は否定できないと考える。しかしながら、本症例の原疾患は骨転移を有する前立腺癌であり、造血障害の危険因子を併せ持っているため、その影響も考えられる。
15245-150-150002	WORSENING OF PAIN LUMBAR REGION (BONE PAIN) (CTC GRADE 3)[PT：骨痛] This 72 year old Caucasian male who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer, experienced worsening of pain lumbar region. The subject's relevant medical history included pain in lumbar region, gonarthrosis, spondylosis, coxarthrosis, obstipation and vertebroplasty. Worsening of pain lumbar region is considered serious due to hospitalization and is listed for Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor assessed the relationship to study drug as unrelated.
15245-150-150002	RADIX IRRITATION SYNDROM LWK5[PT：腰髄神経根障害] Company causality assessment per License Partner Algeta:Event of RADIX IRRITATION SYNDROM LWK5 is serious (hospitalization), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-150-150002	URINARY RETENTION (CTC 2)[PT：尿閉] The case refers to a 72-year-old male patient in a double blind, randomized, repeat dose, phase III, multicentre survival study of AlpharadinTM in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. He experienced moderate URINARY RETENTION (CTC 2) which is serious due to hospitalization and is unlisted in the Investigator´s Brochure of Alpharadin. The investigator has assessed the relationship to the study drug as unrelated but rather a concurrent illness. The company agrees on that and considers URINARY RETENTION (CTC 2) not associated to Alpharadin/placebo but related to the underlying disease.
15245-150-150002	BONE PAIN (CTC GRADE 3)[PT：骨痛] This 72 year old male patient experienced BONE PAIN (CTC grade 3) and was hospitalized 43 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's medical history included vetebroplastie. The patient's concurrent condition included obstipation, coxarthrosis, spondylosis, gonathrosis and pain lumbar section.The event BONE PAIN (CTC grade 3) is considered serious (hospitalized) and Listed for Alpharadin. The investigator has assessed the relationship to the study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to the study drug as

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	unrelated.
15245-150-150003	HYDRONEPHROSIS (CTC GRADE 2)[PT：水腎症] The investigator considers the event serious and unrelated to Alpharadin/placebo.Company considers the event serious, unrelated and unexpected for Alpharadin.
15245-150-150003	HYDRONEPHROSIS BOTH SIDES (CTC GRADE 2)[PT：水腎症] This 70 year old Caucasian male who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer, experienced hydronephrosis both sides 141 days after the onset of study drug. The complete study has been unblinded. The patient received Alpharadin.The subject's relevant medical history included double J stent inserted due to hydronephrosis, diabetes mellitus, arterial hypertension, hyperlipidaemia, cerebral apoplex, spondylosis arthrosis and heart insufficiency grade I. Hydronephrosis both sides, is considered serious due to hospitalization and is unlisted for Alpharadin.The investigator has assessed the event relationship to study drug as unrelated but rather due to concurrent illness. The sponsor has assessed the relationship to study drug as unrelated.
15245-151-151002	URINE RETENTION (CTC GRADE 3)[PT：尿閉] 本症例には、プラセボが投与されていた。
15245-151-151002	BONE PAIN CHEST, WORSENING (CTC GRADE 3)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-151-151002	ABSCESS AT NECROSIS OF LOWER JAW (CTC GRADE 3)[PT：顎膿瘍] ABSCESS AT NECROSIS OF LOWER JAW (CTC GRADE 3)[PT：顎骨壊死] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-151-151003	BONE PAIN (CTC GRADE 4)[PT：骨痛] 試験薬は投与されていない。
15245-151-151005	URINARY RETENTION (CTC GRADE 3)[PT：尿閉] This 83 year old Caucasian male who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced urinary retention (CTC grade 3) 18 days after the last dose of study drug.The subject's concurrent condition diabetes mellitus (type II), hypertension arterial, renal cell carcinoma, hypothyroidism, hypoacusis of both ears and glaucoma both eyes, metastatic bone pain, hyperuricemia, liver cysts and lower urinary tract syndrome. Medical history includes nephrectomy of the left kidney and inguinal hernia herniotomy.Urinary retention (CTC grade 3) is considered serious (hospitalization) and are unlisted for Alpharadin.The investigator assessed the relationship to study drug as unrelated but rather due to concurrent illness of lower urinary tract syndrome (LUTS).The sponsor assessed the relationship to study drug as unrelated.
15245-151-151005	HYPOGLYCEMIA (CTC GRADE 3)[PT：低血糖症] The investigator considers the event HYPOGLYCEMIA to be serious and unrelated to Alpharadin but rather due to concurrent illness of diabetes mellitus.Company considers the event to be serious, unrelated and unexpected for Alpharadin. Diabetes mellitus type II is an alternative possible explanation.
15245-152-152001	PAIN LEFT KIDNEY (CTC GRADE 3)[PT：腎臓痛] This study case report was received by license partner Algeta and refers to a 79 year old Caucasian male who was enrolled in study BC1-06 entitled 'A double blind, randomised, repeat dose, phase III, multicentre survival study of AlpharadinTM in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases'. The patient suffered PAIN LEFT KIDNEY (CTC grade 3) and was hospitalzied 15 days after starting treatment with Alpharadin. It was the first and last injection prior to the event onset. A retrograde pyelography revealed a stone in the left ureter. The patient's medical history included urolithiasis, metastatic prostate cancer and hypertension. Concomitant medications included finasteride, felodipine, fentanyl and trospium chloride. PAIN LEFT KIDNEY (CTC grade of 3) is considered serious (hospitalization, disability) and is unexpected in the Investigator's Brochure for Alpharadin.The investigator has assessed the relationship to the study drug as unrelated, but rather due to concurrent illness of urolithiasis.The sponsor has assessed the relationship to the study drug as unrelated.
15245-152-152003	INCREASING PAIN (CTC GRADE 3)[PT：骨痛] This 49 year old male patient enrolled in a double blind, randomized, repeat dose, phase III, multicentre survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. Relevant medical history included prostate cancer, bone metastases, perforation of the colon, necrosis of the jaw, renal failure, resection of the colon, spinal cord compression, depression, anxiety disorder and pain due to bone metastases and taking number of concomitant medications.During the study course, patient experienced INCREASING PAIN (CTC Grade 3) [MedDRA PT- Bone pain] and was hospitalized 28 days after receiving the last dose of study medication. The event INCREASING PAIN (CTC GRADE 3)

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	is considered serious (hospitalized) and amended to Unlisted for Alpharadin based on reference safety information (Source: reference safety info- dated 14-Sep-2011). The investigator has assessed the relationship of the event to the study drug as unrelated, but rather due to concurrent illness, bone metastases and due to the fact that the last administration of the drug was three weeks before the event started.The sponsor has assessed the relationship to study drug as unrelated.
15245-152-152003	PAIN DUE TO BONE METASTASES LUMBAR COLUMN (CTC GRADE 3)[PT：転移部痛] This 50 year old male patient experienced PAIN DUE TO BONE METASTASES LUMBAR COLUMN (CTC GRADE 3) and was hospitalized 2 month after receiving latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases.The patient has a relevant medical history of prostate cancer and bone metastases, perforation of colon, necrosis of jaw, renal failure, resection of colon, spinal cord compression, depression, anxiety disorder, pain due to bone metastases, protusion of spinal disc, fracture, walk impairment due to spinal cord compression.The event PAIN DUE TO BONE METASTASES LUMBAR COLUMN (CTC GRADE 3) is considered serious (hospitalized, medically important event) and unlisted for alpharadin. The investigator has assessed the relationship to study drug as unrelated, but rather due to progressive disease.The sponsor has assessed the relationship to study drug as unrelated, but rather due to progressive disease.
15245-152-152004	INCREASING PAIN (CTC GRADE 3)[PT：骨痛] This 75 year old male patient experienced INCREASING PAIN (CTC GRADE 3) and was hospitalized while receiving study medication (Alpharadin/placebo) in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent conditions included prostate cancer and bone metastases. The event INCREASING PAIN (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for alpharadin. The investigator assessed the relationship to study drug as unrelated but rather due to progression of disease. The sponsor has assessed the relationship to study drug as unrelated.
15245-152-152004	INCREASING PAIN (CTC GRADE 3)[PT：骨痛] This 75 year old male patient experienced INCREASING PAIN (CTC GRADE 3) (confirmed as bone pain) and was hospitalized one month after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had relevant medical history of prostate cancer and bone metastases. The event INCREASING PAIN (CTC GRADE 3) (bone pain) is considered serious (hospitalized) and Listed for alpharadin. The investigator has assessed the relationship to study drug as unrelated, but rather due to progressive disease.The sponsor has assessed the relationship to study drug as unrelated.
15245-152-152004	PAIN OTHER BONE METASTASIS (CTC GRADE 3)[PT：転移部痛] This 75 year old male patient experienced PAIN OTHER BONE METASTASIS (CTC Grade 3) and was hospitalized 15 days after receiving latest dose of Alpharadin (randomized to Alpharadin) in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included prostate cancer and bone metastasis.The event PAIN OTHER BONE METASTASIS (CTC Grade 3) is considered serious (hospitalized) and Unlisted for alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to progressive disease.The Sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-152-152004	ATYPICAL PNEUMONIA WITH DYSPNOE (CTCAE GRADE 3)[PT：異型肺炎] ATYPICAL PNEUMONIA WITH DYSPNOE (CTCAE GRADE 3)[PT：呼吸困難] This 75 year-old caucasian male who was enrolled in a clinical study and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced ATYPICAL PNEUMONIA WITH DYSPNEA (CTC GRADE 3) 147 days after start of study drug. He recovered with sequelae (asthenia).The subject's relevant medical history was reported as prostate cancer and bone metastases (underlying disease). ATYPICAL PNEUMONIA WITH DYSPNEA is considered serious (hospitalization) and unexpected for Alpharadin.The investigator assessed the relationship to study drug as unrelated, but rather due to concurrent illness.The company agrees with this assessment as the temporal condition of the event is incompatible.
15245-152-152004	GENERAL DETERIORATION OF HEALTH DUE TO PROSTATE CANCER (CTC GRADE 5)[PT：全身健康状態低下] This 76 year old male patient experienced GENERAL DETERIORATION OF HEALTH DUE TO PROSTATE CANCER (CTC GRADE 5) (previously reported as GENERAL DETERIORATION) and died 83 days after receiving last dose of Alpharadin/placebo (patient was randomized to Alpharadin) in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. Relevant medical history was not reported.The event GENERAL DETERIORATION OF HEALTH DUE TO PROSTATE CANCER (CTC GRADE 5) is considered serious (fatal) and unlisted for alpharadin. The investigator has assessed the relationship to study drug as unrelated, and considered it rather due to progressive disease.The company agrees with this assessment.
15245-154-154001	CORONARY ARTERY DISEASE (CTC GRADE 3)[PT：冠動脈疾患] 試験薬は投与されていない。
15245-154-154001	CORONARY ARTERY DISEASE (CTC GRADE 2)[PT：冠動脈疾患] This 65 year old male patient experienced coronary artery disease (CTC grade 2) and was hospitalized 38 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's medical history included stent implantation. The patient's concurrent condition included hypercholesterolemia and prostate cancer.The event coronary artery disease (CTC grade 2) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated.The sponsor has assessed the relationship to study drug as unrelated.
15245-154-154002	NEOPLASTIC EPIDURAL SPINAL CORD COMPRESSION (CTC GRADE 3)[PT：腫瘍性圧迫] Company causality assessment per License Partner Algeta:Event of NEOPLASTIC EPIDURAL SPINAL CORD COMPRESSION (CTC GRADE 3) is serious (hospitalization), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to progression of disease.

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-154-154002	SUSPECTED NEUROBORRELIOSIS WITH FACIAL PALSY (CTC GRADE 3)[PT：神経ボレリア症] FACIAL PALSY BY SUSPECTED BORELIOSIS[PT：第７脳神経麻痺] This 72 year old Caucasian male enrolled in this double blind, randomized, repeat dose; phase III, multicenter survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases was hospitalized due to SUSPECTED NEUROBORRELIOSIS WITH FACIAL PALSY (CTC GRADE 3), 29 days after the last Alpharadin injection (of overall five). He experienced two weeks prior to this FACIAL PALSY, which was associated with the neuroborreliosis. Approximately three months after last study drug dose, the patient died due to prostate cancer. The subject's concurrent condition included prostate cancer and mild apoplexy. Concomitant medications were oxycodone, diclofenac and paracetamol.SUSPECTED NEUROBORRELIOSIS WITH FACIAL PALSY (CTC GRADE 3) was split to SUSPECTED NEUROBORRELIOSIS and FACIAL PALSY BY SUSPECTED NEUROBORRELIOSIS due to coding conventions. The event SUSPECTED NEUROBORRELIOSIS is considered serious due to medical significance and hospitalization, unexpected according to the updated Investigators Brochure of Alpharadin; FACIAL PALSY BY SUSPECTED NEUROBORRELIOSIS serious due to prolonged hospitalization, disability and medical significance, considered expected for Alpharadin (previously “Bell's palsy”, unexpected). The investigator has assessed the relationship of the events SUSPECTED NEUROBORRELIOSIS WITH FACIAL PALSY and FACIAL PALSY BY SUSPECTED NEUROBORRELIOSIS as unrelated to study medication but rather due to concurrent illness.The sponsor has assessed the relationship to the study drug as unrelated. The company agrees with Investigator's assessment and considers the events not associated with study medication.
15245-154-154004	ACUTE PRERENAL FAILURE (CTC GRADE 2)[PT：急性腎前性腎不全] This 63 year old male patient experienced ACUTE PRERENAL FAILURE (CTC GRADE 2) and was hospitalized 25 days after receiving the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included hypercholesterolemia and hypertension. The event ACUTE PRERENAL FAILURE (CTC GRADE 2) is considered serious (hospitalized) and Unlisted for alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to exsiccosis.The sponsor has assessed the relationship to study drug as unrelated.
15245-154-154004	SPONTANEOUS BACTERIAL PERITONITIS (CTC GRADE 3)[PT：細菌性腹膜炎] TUMOUR PROGRESSION (CTC GRADE 2)[PT：前立腺癌] This 63 year old male patient developed SPONTANEOUS BACTERIAL PERITONITIS (CTC GRADE 3) and was hospitalized 30 days after receiving the last dose of study drug (Alpharadin/placebo) in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient was later found to have TUMOUR PROGRESSION (CTC GRADE 2) which prolonged the hospitalization. The patient's concurrent condition included hypercholesterolemia and hypertension.The events SPONTANEOUS BACTERIAL PERITONITIS (CTC GRADE 3) and TUMOUR PROGRESSION (CTC GRADE 2) are considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated, but rather due to concurrent illness for both events.The sponsor has assessed the relationship to study drug as unrelated for both events.
15245-155-155004	OBSTIPATION (CTC GRADE 1)[PT：便秘] This 63 year old male patient experienced OBSTIPATION (CTC GRADE 1) and was hospitalized 26 days after receiving the first dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event OBSTIPATION (CTC GRADE 1) is considered serious (hospitalized) and Listed for Alpharadin.The investigator has assessed the relationship to study drug as unrelated, but rather due to concomitant treatment with fentanyl.The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-155-155006	PERIPROSTHETIC INFECTION OF THE RIGHT HIP JOINT (CTC GRADE 3)[PT：医療機器関連感染] 本症例には、プラセボが投与されていた。
15245-155-155007	MASS LESION AT ANASTOMOSIS BETWEEN NEOBLADDER AND URETHRA (CTC GRADE 2)[PT：尿路の良性新生物] 本症例には、プラセボが投与されていた。
15245-155-155010	DEATH CAUSED BY ASPIRATION PNEUMONIA (CTC GRADE 4)[PT：誤嚥性肺炎] CEREBRAL BLEEDING (CTC GRADE 4)[PT：脳出血] 本症例には、プラセボが投与されていた。
15245-157-157002	DYSPNEA (CTC GRADE 3)[PT：呼吸困難] 試験薬は投与されていない。
15245-157-157002	ANAEMIA[PT：貧血] The investigator considers the event to be serious and possibly related to Alpharadin/placebo.Company considers the event to be serious, possibly related and expected for Alpharadin.
15245-169-169004	MYOCARDIAL INFARCTION[PT：心筋梗塞] 試験薬は投与されていない。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-170-170004	WORSENING BONE PAIN (CTC GRADE 4)[PT：骨痛] PROSTATE CANCER PROGRESSION (CTC GRADE 4)[PT：前立腺癌] This 78 year old male patient experienced PROSTATE CANCER PROGRESSION (CTC GRADE 4) and WORSENING BONE PAIN (CTC GRADE 4) and was hospitalized 74 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient later died due to prostate cancer progression. The patient had no relevant medical history.The event PROSTATE CANCER PROGRESSION (CTC GRADE 4) is considered serious (fatal, hospitalized) and Unlisted for Alpharadin. The event WORSENING BONE PAIN (CTC GRADE 4) is considered serious (hospitalized) and Listed for Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated for both events.
15245-172-172001	DISEASE PROGRESSION (CTCAE GRADE 5)[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-173-173008	CEREBRAL VASCULAR ACCIDENT(CTC GRADE 4)[PT：脳血管発作] （本例は PMDA へ報告を行った症例である。弊社の見解を日本語で示す） 本事象が本剤の最終投与後に発現していることを勘案し、時間的関連性の観点より、本剤との因果関係は否定できないと考える。
15245-173-173009	WORSENING ON CLINICAL PERFORMANCE (CTC GRADE 4)[PT：全身健康状態低下] This 66 year old male patient experienced WORSENING OF CLINICAL PERFORMANCE nearly one month after taking the only study dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastasis. The patient had no relevant medical history.The event worsening of clinical performance is considered serious (fatal, life threatening event) and Unlisted in the Investigator´s Brochure of Alpharadin.The investigator assessed the relationship to study drug as unrelated but rather due to prostate cancer.The sponsor assessed the relationship to study drug as unrelated.
15245-173-173011	WORSENING OF CLINICAL PERFORMANCE (CTC 5)[PT：活動状態低下] The case refers to a 62-year-old male patient in a double blind, randomized, repeat dose, phase III, multicentre survival study of AlpharadinTM in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The complete study has been unblinded. The patient received Alpharadin. He experienced WORSENING OF CLINICAL PERFORMANCE (CTC 5) which is serious due to life-threatening character and fatal outcome and is unlisted in the Investigator´s Brochure of Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to the prostate cancer. The company agrees on that and considers WORSENING OF CLINICAL PERFORMANCE (CTC 5) not associated to Alpharadin but to the underlying carcinoma.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-174-174003	BACK BONE PAIN WORSENING (CTC GRADE 3)[PT：脊椎痛] 本症例には、プラセボが投与されていた。
15245-174-174003	ECOG PERFORMANCE STATUS WORSENED (CTC GRADE 4)[PT：全身健康状態低下] 本症例には、プラセボが投与されていた。
15245-178-178001	SEPTIC SHOCK[PT：敗血症性ショック] 試験薬は投与されていない。
15245-178-178007	FEMUR FRACTURE (CTC GRADE 3)[PT：病的骨折] ANEMIA (CTC GRADE 3)[PT：貧血] This clinical trial case report (forwarded by Algeta) referring to a 71-year-old Latino male enrolled in a double-blind, randomized, multiple dose, Phase III, multicentre study of Alpharadin in the treatment of patients with symptomatic hormone refractory prostate cancer with skeletal metastases and did receive first dose of study medication Alpharadin (BAY 88-8223)/Placebo in Feb-2011. Prior to the onset of the events the subject received 4 study injections, the last injection being on 02 May 2011.Patient did not receive prior docetaxel therapy. Patient had no relevent medical history. Relevant concomitant medications included paracetamol, codeine and cyproterone.An X-ray performed revealed FEMUR FRACTURE (CTC GRADE 3) (confirmed as pathological fracture). The patient had surgery to repair the fracture. The event resolved. The study drug was postponed for femur fracture.Event FEMUR FRACTURE (CTC GRADE 3) was considered serious (medically significant, hospitalization) and unlisted as per investigational brochures of Alpharadin. The patient also experienced ANEMIA (CTC grade 3) which prolonged hospitalisation. He was treated with a blood transfusion. The event resolved and the subject was discharged from hospital.ANEMIA is considered serious (hospitalization) and is listed in the Investigator’s Brochure for Alpharadin.The investigator has assessed the relationship to study drug for both events as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated for both events.
15245-178-178007	POST PROCEDURAL/OPERATION PAIN (CTC GRADE 3)[PT：処置による疼痛] PNEUMONIA (CTC GRADE 4)[PT：肺炎] PULMONARY EMBOLISM (CTC GRADE 5)[PT：肺塞栓症] DISLOCATION OF PROSTHESIS (CTC GRADE 3)[PT：医療機器位置異常] This 72-year-old male patient experienced POST PROCEDURAL/OPERATION PAIN (CTC GRADE 3) and DISLOCATION OF PROSTHESIS (CTC GRADE 3) resulting in a hospitalization 75 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	patient also developed PULMONARY EMBOLISM (CTC GRADE 5) and PNEUMONIA (CTC GRADE 4) prolonging the hospitalization. The patient later died due to the pulmonary embolism. The subject had a relevant medical history of bone metastases, fracture femur and surgery for correction of fracture and prosthesis.The event PULMONARY EMBOLISM (CTC GRADE 5) is considered serious (fatal, hospitalized) and unlisted for Alpharadin. The events DISLOCATION OF PROSTHESIS (CTC GRADE 3), POST PROCEDURAL/OPERATION PAIN (CTC GRADE 3) and PNEUMONIA (CTC GRADE 4) are considered serious (hospitalized) and unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated for all the events. The investigator stated that the bone pain was a post procedural or operation pain because of the disposition of prosthesis.The sponsor has assessed the relationship to study drug as unrelated for all events.
15245-179-179001	ANEMIA (CTC GRADE 2)[PT：貧血] Company causality assessment per License Partner Algeta:Event of ANEMIA (CTC GRADE 2) is serious (hospitalized), listed and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to the underlying disease of prostate cancer metastatic, advanced hormone refractory with bone marrow infiltration by neoplasm.
15245-179-179001	ANEMIA (CTC GRADE 2)[PT：貧血] This 77 year old male patient experienced ANEMIA (CTC GRADE 2) and was hospitalized in this clinical study double-blind, randomized, Multiple Dose, Phase III, Multicentre Study of Alpharadin in the Treatment of Patients With Symptomatic Hormone Refractory Prostate Cancer With Skeletal Metastases. The event ANEMIA (CTC GRADE 2) is considered serious (hospitalized) and unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug unrelated.
15245-179-179001	ASTENIA (CTC GRADE 2)[PT：無力症] This 77 year old male patient experienced ASTENIA (CTC GRADE 2) and was hospitalized 35 days after receiving latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event ASTENIA (CTC GRADE 2) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-179-179001	FATIGUE (CTC GRADE 3)[PT：疲労] This 77 year old male patient experienced FATIGUE (CTC GRADE 3) and was hospitalized 85 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event FATIGUE (CTC GRADE 3) is considered serious (hospitalized) and Listed for Alpharadin. The investigator has assessed the relationship to the study drug as unrelated, rather due to concurrent illness.The sponsor has assessed the relationship to the study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-179-179003	URINARY TRACT INFECTION (CTC GRADE 3)[PT：尿路感染] 試験薬は投与されていない。
15245-179-179003	ADVANCED UNDERLYING DISEASE (METASTATIC HORMONE REFRACTORY CANCER)[PT：遠隔転移を伴う前立腺癌] 試験薬は投与されていない。
15245-179-179005	URINARY TRACT INFECTION (CTCAE GRADE 3)[PT：尿路感染] 試験薬は投与されていない。
15245-179-179006	CARDIAC ISCHAEMIA / INFARCTION[PT：心筋虚血] CARDIAC ISCHAEMIA / INFARCTION[PT：心筋梗塞] This 80 year old male patient experienced CARDIAC ISCHAEMIA / INFARCTION (code split per coding requirements) and died 84 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included Dyslipidemia.The events CARDIAC ISCHAEMIA / INFARCTION (code split to cardiac ischemia and cardiac infarction per coding requirements) are considered serious (fatal) and Unlisted for alpharadin. The investigator has assessed the relationship to study drug as unrelated, but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-179-179008	ASTHENIA[PT：無力症] 試験薬は投与されていない。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-181-181001	PROGRESSION OF METASTATIC PROSTATE CANCER[PT：遠隔転移を伴う前立腺癌] 試験薬は投与されていない。
15245-181-181005	HYPOGLYCEMIA (CTC GRADE 3)[PT：低血糖症] ACUTE PULMONARY EDEMA (CTC GRADE 2)[PT：急性肺水腫] PNEUMONIA (CTC GRADE 2)[PT：肺炎] This 75 year old male patient experienced HYPOGLYCEMIA (CTC GRADE 3) and was hospitalized 29 days after receiving dose of Alpharadin/placebo while in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. One day later the patient developed ACUTE PULMONARY EDEMA (CTC GRADE 2) and PNEUMONIA (CTC GRADE 2) prolonging the hospitalization. The patient later died due to the pneumonia. The patient's concurrent condition included depression, asthenia, systemic arterial hypertension and diabetes mellitus II.The events HYPOGLYCEMIA (CTC GRADE 3) and ACUTE PULMONARY EDEMA (CTC GRADE 2) are considered serious (hospitalized) and Unlisted for Alpharadin. The event PNEUMONIA (CTC GRADE 2) is considered serious (fatal, hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug for all events as unrelated. Hypoglycemia and pneumonia were considered due to concurrent illness and acute pulmonary edema was considered due to acute renal failure.The sponsor has assessed the relationship to study drug as unrelated for all events.
15245-181-181006	WORSENING PAIN IN LEFT HIP - (BONE PAIN) (CTC GRADE 3)[PT：骨痛] SEPSIS (CTC GRADE 4)[PT：敗血症] 本症例には、プラセボが投与されていた。
15245-181-181048	ANAEMIA (CTC GRADE 3)[PT：貧血] WORSENING HIP BONE PAIN (CTC GRADE 3)[PT：骨痛] This 70 year old male patient experienced worsening hip bone pain (CTC grade 3) and anaemia (CTC grade 3) and was hospitalized 36 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The events worsening hip bone pain (CTC grade 3) and anaemia (CTC grade 3) are considered serious (hospitalized) and Listed for Alpharadin. The investigator has assessed the relationship to study drug as unrelated. Alternative explanation for the events was unknown.The sponsor has assessed the relationship to study drug as unrelated for both events.
15245-181-181048	THROMBOCYTOPENIA (CTC GRADE 4)[PT：血小板減少症] This 71 year old Caucasian male, who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer, experienced Thrombocytopenia (CTC 4) while using Alpharadin/placebo. The subject's relevant medical history included of prostate cancer.Thrombocytopenia is considered serious due to hospitalization and the life-threatening nature of the event and is listed for Alpharadin.The investigator has assessed the relationship to study drug as unrelated. An alternative explanation for the event was reported as unknown.The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-191-191006	CHRONIC OBSTRUCTIVE LUNG DISEASE EXACERBATION (CTC GRADE 3)[PT：慢性閉塞性肺疾患] INTESTINAL PERFORATION (CTC GRADE 4)[PT：腸管穿孔] MYOCARDIAL INFARCTION[PT：心筋梗塞] 本症例には、プラセボが投与されていた。
15245-200-200002	CHEST PAIN (CTC GRADE 3)[PT：非心臓性胸痛] 試験薬は投与されていない。
15245-201-201002	SUPRAVENTRICULAR TACHYCARDIA (CTC GRADE 2)[PT：上室性頻脈] DECREASED HEMOGLOBIN (CTC GRADE 3)[PT：ヘモグロビン減少] ABDOMINAL DISTENTION (CTC GRADE 3)[PT：腹部膨満] This 72 year old male patient experienced SUPRAVENTRICULAR TACHYCARDIA (CTC GRADE 2), DECREASED HEMOGLOBIN (CTC GRADE 3) and ABDOMINAL DISTENTION (CTC GRADE 3) 27 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included inguinal hernia, osteoarthritis, prostate cancer, abdominal aortic aneurysm, hypertension and chronic obstructive pulmonary disease. The events SUPRAVENTRICULAR TACHYCARDIA (CTC GRADE 2) is and ABDOMINAL DISTENTION (CTC GRADE 3) are considered serious (hospitalized) and Unlisted for alpharadin. The event DECREASED HEMOGLOBIN (CTC GRADE 3) is considered serious (disability) and Unlisted for alpharadin. The investigator has assessed the relationship to study drug as unrelated for all events. An alternative assessment was provided of concomitant medications.The sponsor has assessed the relationship to study drug as unrelated for all events.
15245-201-201002	DISEASE PROGRESSION (PROSTATE CANCER)[PT：前立腺癌] This 72 year old male patient died due to DISEASE PROGRESSION (PROSTATE CANCER) 65 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included prostate cancer, inguinal hernia, osteoarthritis, abdominal aortic aneurysm, hypertension and chronic obstructive pulmonary disease (bronchitis).The event DISEASE PROGRESSION (PROSTATE CANCER) is considered serious (fatal) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated.The sponsor has assessed the relationship to study drug as unrelated.
15245-202-202003	PAIN MANAGEMENT FOR INCREASING PAIN (BONE) DUE TO PATHOLOGICAL FRACTURE (CTC GRADE 3)[PT：骨痛] PAIN MANAGEMENT FOR INCREASING PAIN (BONE) DUE TO PATHOLOGICAL FRACTURE (CTC GRADE 3)[PT：病的骨折] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-203-203004	HYPOPHOSPHATEMIA (CTC GRADE 4)[PT：低リン酸血症] Company causality assessment per License Partner Algeta:HYPOPHOSPHATEMIA (CTC GRADE 4) is serious (hospitalization), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but probably related to renal osteomalacia, secondary hyperparathyroidism and nutritional deficiency.
15245-203-203006	BONY PAIN SECONDARY TO NEW CERVICAL SPINE METASTASES (CTC GRADE 3)[PT：転移部痛] BONY PAIN SECONDARY TO NEW CERVICAL SPINE METASTASES (CTC GRADE 3)[PT：転移部痛] 本症例には、プラセボが投与されていた。
15245-203-203006	DECREASED MOBILITY[PT：運動性低下] 本症例には、プラセボが投与されていた。
15245-203-203007	WORSENING CONSTIPATION WITH OVERFLOW SYMPTOMS (CTC GRADE 2)[PT：便秘] 試験薬は投与されていない。
15245-203-203007	WORSENING CONSTIPATION WITH OVERFLOW SYMPTOMS (CTC GRADE 3)[PT：遺糞] WORSENING CONSTIPATION WITH OVERFLOW SYMPTOMS (CTC GRADE 3)[PT：便秘] This 70 year old male patient experienced WORSENING CONSTIPATION WITH OVERFLOW SYMPTOMS (CTC GRADE 3) (code split per coding requirements) and was hospitalized 45 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included metastatic prostate cancer, hypothyroidism, gout, rheumatoid arthritis, coronary artery disease, atrial fibrillation, hypertension, gastro-oesophageal reflux and constipation with overflow symptoms.The events WORSENING CONSTIPATION WITH OVERFLOW SYMPTOMS (CTC GRADE 3) (code split to constipation and overflow symptoms per coding requirements) are serious (hospitalized) and listed and unlisted respectively for Alpharadin. The investigator has assessed the relationship to the study drug as unrelated but rather due to concomitant medication, most likely endone and oxycontin.The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-203-203007	PROGRESSIVE DISEASE[PT：前立腺癌] This 70 year old male patient experienced progressive disease and died 82 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included metastatic prostate cancer.The event progressive disease is considered serious (fatal) and Unlisted for Alpharadin. The investigator assessed the relationship to study drug as unrelated.The sponsor assessed the relationship to study drug as unrelated.
15245-204-204001	ACUTE RENAL FAILURE (CTC GRADE 2)[PT：急性腎不全] ACUTE GASTROENTERITIS (CTC GRADE 4)[PT：胃腸炎] ANAEMIA (CTC GRADE 2)[PT：貧血] （本例は PMDA へ報告を行った症例である。弊社の見解を日本語で示す） これらの事象は、本剤の投与後に発現していることを勘案し、時間的関連性の観点より本剤との因果関係は否定できないと考える。
15245-204-204001	OVERWHELMING DISEASE BURDEN[PT：前立腺癌] This 76 year old male patient experienced overwhelming disease burden resulting in death 7 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patient's with hormone-refractory prostate cancer with skeletal metastasis. Relevant medical history was not provided.The event overwhelming disease burden is considered serious (fatal, hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated (previously related). The gastrointestinat tract disturbance, nausea/vomiting and anemia were considered as part of his end stage progression.The sponsor has assessed the event relationship to study drug as unrelated.
15245-205-205004	HYDROCEPHALUS WITH INTRAVENTRICULAR BLEED (CTC GRADE 4)[PT：脳室内出血] PROGRESSIVE DISEASE (CTC GRADE 4)[PT：前立腺癌] HYDROCEPHALUS WITH INTRAVENTRICULAR BLEED (CTC GRADE 4)[PT：水頭症] The case refers to a 82-year-old male patient in a double blind, randomised, repeat dose, phase III, multicentre survival study of AlpharadinTM in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases.He experienced HYDROCEPHALUS WITH INTRAVENTRICULAR BLEED (CTC GRADE 4) which is serious due to hospitalization and life-threatening characteristics. It is unlisted in the Investigator´s Brochure of Alpharadin. In July 2010 the patient died due to PROGRESSIVE DISEASE (CTC GRADE 4) which is serious (fatal, hospitalization) and unlisted.The investigator has assessed the relationship to the study drug as unrelated for both events but rather due to progressive disease.The company agrees on that and considers HYDROCEPHALUS WITH INTRAVENTRICULAR BLEED (CTC GRADE 4) and PROGRESSIVE DISEASE (CTC GRADE 4) unrelated to Alpharadin/placebo.The sponsor has assessed the relationship to the study drug as unrelated for both.
15245-206-206001	DVT-LEFT LOWER LEG (CTC GRADE 3)[PT：深部静脈血栓症] This 84 year old male patient experienced DVT-LEFT LOWER LEG (CTC GRADE 3) and was hospitalized greater than one month after taking the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The subject has a relevant medical history of prostate cancer with bone metastases. The event DVT-LEFT LOWER LEG (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as possibly related.The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-206-206001	LEFT HYDRONEPHROSIS (CAUSING ACUTE RENAL FAILURE) (CTC GRADE 3)[PT：水腎症] PROGRESSION METASTATIC PROSTATE CANCER[PT：遠隔転移を伴う前立腺癌] ANEMIA (CTC GRADE 2)[PT：貧血] This 84 year old male patient was hospitalized for Left Hydronephrosis (causing acute renal failure) (CTC grade 3) and ANEMIA (CTC grade 2) 35 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient later died from Progression Metastatic Prostate Cancer 46 days after receiving last dose of study drug. The patient has a medical history of deep vein thrombosis, prostate cancer, bone metastases and ureteral catheterization.The event Progression Metastatic Prostate Cancer is considered serious (fatal) and unlisted for Alpharadin. The event Left Hydronephrosis (causing acute renal failure) (CTC grade 3) is considered serious (hospitalized) and unlisted for Alpharadin whereas ANEMIA (CTC grade 2) is considered serious (hospitalized) and listed.The investigator has assessed the relationship to study drug as unrelated for the progression metastatic prostate cancer, anaemia and the left hydronephrosis (causing acute renal failure), but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated for all the events.
15245-207-207001	OBSTRUCTING RENAL CALCULI (CTC GRADE 3)[PT：腎結石症] 試験薬は投与されていない。
15245-207-207002	WORSENING OF DEMENTIA (CTC GRADE 3)[PT：認知症] 本症例には、プラセボが投与されていた。
15245-207-207002	PROSTATE CANCER WITH BONE METASTASES[PT：遠隔転移を伴う前立腺癌] 本症例には、プラセボが投与されていた。
15245-208-208001	PROGRESSIVE PROSTATE CANCER[PT：前立腺癌] 試験薬は投与されていない。

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-208-208004	ACUTE DEHYDRATION (CTC GRADE 2)[PT：脱水] 試験薬は投与されていない。
15245-208-208004	EXACERBATION OF DEPRESSION (CTC GRADE 3)[PT：うつ病] PAIN: MUSCULOSKELETAL (CTC GRADE 3)[PT：筋骨格痛] The investigator has assessed the relationship to study drug as unrelated for both events. The sponsor has assessed the relationship to study drug as unrelated for both events.
15245-208-208007	ANAEMIA (CTC GRADE 2)[PT：貧血] 試験薬は投与されていない。
15245-209-209001	FATIGUE (CTC GRADE 3)[PT：疲労] BONE PAIN[PT：骨痛] Company causality assessment per License Partner Algeta:Events of FATIGUE and BONE PAIN are serious (hospitalized), listed and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to prostate cancer.
15245-209-209001	GENERAL DETERIORATION OF PROSTATE CANCER (CTC GRADE 2)[PT：前立腺癌] GENERAL DETERIORATION OF PROSTATE CANCER (CTC GRADE 2) is considered serious due to hospitalization. The event is unlisted in the Investigator Brochure. The investigator has assessed the relationship to study drug as unrelated, but rather due to underlying condition. Company concurs.
15245-209-209002	DYSPNOEA (CTC GRADE 3)[PT：呼吸困難] Company causality assessment per License Partner Algeta:Event of DYSPNOEA (CTC GRADE 3) is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-209-209003	SPINAL CORD COMPRESSION (CTC GRADE 4)[PT：脊髄圧迫] This 56 year old male patient experienced SPINAL CORD COMPRESSION (CTC GRADE 4) and was hospitalized 3 days after receiving the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included chest wall pain, lethargy and bone pain. The event SPINAL CORD COMPRESSION (CTC GRADE 4) is considered serious (hospitalized) and Unlisted for alpharadin. The investigator assessed the relationship to study drug as unrelated, rather due to metastatic prostate cancer. The sponsor has assessed the relationship to the study drug as unrelated.
15245-209-209003	AST (INCREASED ASPARTATE AMINOTRANSFERASE) (CTC GRADE 3)[PT：アスパラギン酸アミノトランスフェラーゼ増加] Company causality assessment per License Partner Algeta:Event of AST (INCREASED ASPARTATE AMINOTRANSFERASE) (CTC GRADE 3) is serious (hospitalized), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug but rather due to concurrent illness.
15245-209-209003	ASCITES (CTC GRADE 1)[PT：腹水] This 56 year old male patient developed ASCITES (CTC GRADE 1) and was hospitalized 65 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's medical history included pneumonia. The patient's concurrent condition included diarrhea, headache, flushing, insomnia, weight loss, nocturia, haematuria, bone pain, lethargy, chest wall pain, dyspnoea and constipation.The event ASCITES (CTC GRADE 1) is considered serious (hospitalized) and Unlisted for alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness. The sponsor has assessed the relationship to study drug as unrelated.
15245-209-209003	TERMINAL PROSTATE CANCER (CTC GRADE 4)[PT：前立腺癌] Company causality assessment per License Partner Algeta:Event of TERMINAL PROSTATE CANCER, is serious (hospitalized / fatal outcome), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug.
15245-212-212001	ATRIAL FIBRILLATION (CTC GRADE 2)[PT：心房細動] 本症例には、プラセボが投与されていた。
15245-212-212001	DEHYDRATION (CTC GRADE 3)[PT：脱水] FATIGUE (CTC GRADE 3)[PT：疲労] BONE PAIN (CTC GRADE 3)[PT：骨痛] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-213-213002	PAIN-MUSCULOSKELETAL-BONE[PT：骨痛] Company causality assessment per License Partner Algeta:Event of PAIN-MUSCULOSKELETAL-BONE is serious (hospitalized), listed and assessed by the Investigator and Sponsor as unrelated to study drug, but rather related to progressive disease.
15245-213-213006	NEURO - OTHER, SPINAL CORD COMPRESSION (CTC GRADE 4)[PT：脊髄圧迫] PNEUMONIA[PT：肺炎] GASTROINTESTINAL BLEED (CTC GRADE 3)[PT：胃腸出血] POST OPERATIVE WOUND INFECTION (CTC GRADE 3)[PT：術後創感染] 本症例には、プラセボが投与されていた。
15245-213-213006	PULMONARY EMBOLISM[PT：肺塞栓症] 本症例には、プラセボが投与されていた。
15245-213-213008	LACERATION LEFT FINGER (CTC GRADE 3)[PT：裂傷] Laceration left finger (CTC grade 3, previously 2) is considered serious due to hospitalization. The event is unlisted in the Investigator for Brochure Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to the injury. Company concurs.
15245-213-213009	FEBRILE NEUTROPENIA (CTC GRADE 3)[PT：発熱性好中球減少症] 本症例には、プラセボが投与されていた。
15245-214-214003	ABDOMINAL PAIN POST INSERTION JJ STENT (CTC GRADE 3)[PT：処置による疼痛] This 69 year old male patient experienced ABDOMINAL PAIN POST INSERTION JJ STENT (CTC GRADE 3) and was hospitalized 12 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event ABDOMINAL PAIN POST INSERTION JJ STENT (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to expected soft tissue disease progression. The patient had hydronephrosis which was not related to the study drug administration, but presumed to be related to extension of the prostate cancer out of the pelvic lymph nodes causing the uterine

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	obstruction.The sponsor has assessed the relationship to study drug as unrelated.
15245-214-214003	PAIN DUE TO PROGRESSION OF DISEASE (CTC GRADE 3)[PT：癌疼痛] PAIN DUE TO PROGRESSION OF DISEASE (CTC GRADE 3)[PT：癌疼痛] This 69 year old male patient experienced PAIN DUE TO PROGRESSION OF DISEASE (CTC GRADE 3) and was hospitalized 61 days after receiving latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event PAIN DUE TO PROGRESSION OF DISEASE (CTC GRADE 3) (code split per coding requirements) is considered serious (hospitalized) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness. The sponsor has assessed the relationship to study drug as unrelated.
15245-230-230002	BONE PAIN (CTC GRADE 3)[PT：骨痛] This 66 year old male patient experienced BONE PAIN (CTC Grade 3) an was hospitalized 10 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had no relevant medical history.The event BONE PAIN (CTC Grade 3) is considered serious (hospitalized) and Listed for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-230-230002	PATHOLOGICAL RIGHT FEMUR FRACTURE (CTC GRADE 3)[PT：病的骨折] This 67 year old male patient experienced pathological right femur fracture (CTC Grade 3) and was hospitalized 28 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included multiple bone metastases.The event pathological right femur fracture (CTC Grade 3) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-230-230002	BONE PAIN LEFT HIP (CTC GRADE 3)[PT：骨痛] This 67 year old male patient experienced BONE PAIN LEFT HIP (CTC grade 3) 76 days after the last received dose of Alpharadin in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. He underwent a left intramedullary nail (previously reported as the event) and recovered with sepuelae. The patient's concurrent condition included metastatic bone disease.The reported event BONE PAIN LEFT HIP (CTC grade 3) is considered serious due to hospitalisation, it is amended to unlisted (based on guideline dated 14-sep-2011) / according to the Investigator´s Brochure for Alpharadin.The Investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The Sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-230-230003	UROSEPSIS (CTC GRADE 3)[PT：尿路性敗血症] HYPOGLYCAEMIA (CTC GRADE 4)[PT：低血糖症] 試験薬は投与されていない。
15245-230-230003	CONSTIPATION (CTC GRADE 3)[PT：便秘] The case refers to a 73-year-old male patient in a double blind, randomized, repeat dose, phase III, multicentre survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. He experienced CONSTIPATION (CTC Grade 3) which is considered serious due to hospitalization. The event is listed in the Investigator´s Brochure for Alpharadin. The event occurred about 50 days after the last study drug injection. The investigator has assessed the relationship with study drug as unrelated but rather due to concomitant medications Panadein Co or oxycodone hydrochloride. The company agrees on that.The sponsor has assessed the relationship to study drug as unrelated.
15245-230-230003	DISEASE PROGRESSION NOS[PT：疾患進行] Company causality assessment per License Partner Algeta:Event of DISEASE PROGRESSION NOS is serious (fatal outcome), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug.
15245-230-230005	INFECTION WITH UNKNOWN CAUSE (CTC GRADE 3)[PT：感染] This 64 year old Caucasian male who was enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced infection with unknown cause (symptom: febrile with shortness of breath) 6 days after the 3rd dose of study drug. The patient had no relevant medical history.Infection with unknown cause is considered serious as the patient was hospitalised and is unlisted in the investigator's brochure for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-230-230005	HYPERGLYCEMIA (CTC GRADE 4)[PT：高血糖] This 64 year old male patient experienced HYPERGLYCEMIA (CTC GRADE 4) 77 days after receiving the first dose of Alpharadin/placebo (altogether 3 injuections) in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included overweight. The event HYPERGLYCEMIA (CTC GRADE 4) is considered serious (medically significant; previously reported as life-threatening/disabling) and Unlisted for Alpharadin.The investigator assessed the relationship to study drug as unrelated (initially as possibly related) but rather due to concomitant medication of dexamethasone.The company agrees, additionally considering the concomitant drug Goserelin hyperglycemia (onset of diabetes or worsening glycemic control has been reported in males) and the patient´s overweight as potential causes or contributors.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-233-233001	SPINAL CORD COMPRESSION (CTC GRADE 4)[PT：脊髄圧迫] This 75 year old male patient experienced SPINAL CORD COMPRESSION (CTC GRADE 4) and was hospitalized 33 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. Relevant medical history was not provided.The event SPINAL CORD COMPRESSION (CTC GRADE 4) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated but rather due to prostate cancer.The sponsor has assessed the relationship to study drug as unrelated.
15245-233-233001	WORSENING ATRIAL FIBRILLATION (CTC GRADE 3)[PT：心房細動] （本例は PMDA へ報告を行った症例である。弊社の見解を日本語で示す） 合併症（高血圧、高コレステロール血症、末梢性動脈疾患）や既往歴（冠動脈バイパス術、深部静脈血栓）などの背景因子によるものが大きいと考えるが、本治験薬の最終投与から約 6 週間後の発現であること、及び報告者の意見も考慮し、本治験薬との因果関係は否定できないと考える。
15245-233-233001	CONGESTIVE HEART FAILURE (CTC GRADE 3)[PT：うっ血性心不全] This 75 year old male patient experienced CONGESTIVE HEART FAILURE (CTC GRADE 3) and was hospitalized 61 days after receiving last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's medical history included previous hydronephrosis. The patient's concurrent condition included prostate cancer, bone metastases, high blood pressure, atrial fibrillation, ischemic heart disease and DVT. Patient later died due to prostate cancer (skeletal metastases).The event CONGESTIVE HEART FAILURE (CTC GRADE 3) is considered serious due to hospitalization and disability/incapacity and is Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as possibly related. However, Company disagrees as the patient's concurrent conditions are plausible alternative explanations for the event.
15245-233-233002	SEPSIS (CTC GRADE 4)[PT：敗血症] This 70 year old male patient developed SEPSIS (CTC GRADE 4) 5 days after taking their only dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included mild hypertension.The event SEPSIS (CTC GRADE 4) is considered serious (hospitalized, life threatening event) and Unlisted for Alpharadin. The investigator has assessed the relationship to study drug as possibly related. The investigator reported that it is difficult to exclude this potential association as the subject's symptoms started within 24 hours of receiving study drug.The sponsor has assessed the relationship to study drug as unrelated.
15245-233-233002	C. DIFFICILE INFECTION (CTC GRADE 4)[PT：クロストリジウム・ディフィシレ感染] The case refers to a 70-year-old male patient in a clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. He experienced C. DIFFICILE INFECTION which is serious due to hospitalization and is unlisted in the Investigator´s Brochure of Alpharadin. The investigator assessed the event unrelated to study drug. The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-233-233002	DIARHHOEA (CTC GRADE 3)[PT：下痢] BILATERAL PLEURAL EFFUSION (CTC GRADE 1)[PT：胸水] The company has received a double blind, randomized phase III sponsored clinical trial report from (Algeta), referring a 70 year old Caucasian male patient (pt) enrolled in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases, received first dose of study medication (Alpharadin/Placebo) on 23-Dec-2009. The patient (pt) relevant medical history included prostate cancer with bony metastases, prior hospitalization due to Clostridium difficile infection (see ref cases/dates), and taking number of concomitant medications. The patient did receive prior docetaxel therapy by Nov-2007.Prior to the onset of the event the patient received 01 study injection, later the study drug was discontinued (previously) due to the SAE of Clostridium difficile infection therefore, action taken with study drug was not applicable for currently reported events. Patient was admitted to hospital due to DIARRHEA (CTC grade 3), subsequent weaknesses and complications including BILATERAL PLEURAL EFFUSION (CTC grade 1). Both events were considered serious (hospitalization). Event DIARRHEA was considered listed as per investigational brochures of Alpharadin (Bay 88-8223) while BILATERAL PLEURAL EFFUSION was unlisted. DIARRHEA was resolved with sequelae of general deterioration on day eight from the onset date, while patient recovered with sequelae of general weakness and poor performance status from BILATERAL PLEURAL EFFUSION. The investigator causality assessment for DIARRHEA and BILATERAL PLEURAL EFFUSION as probably related to the study drug Alpharadin (Bay 88-8223)/placebo.Right now, based on clinical presentation, patient medical history and incompatible latency period between the onset of the event / date of last dose of drug administration, sponsor (company) is not in alignment with investigator assessment and considered both events as unrelated citing underlying preexisting advanced metastatic disease is more plausible alternative explanation.
15245-233-233002	SEPSIS[PT：敗血症] Company Causality Asessment per Licence Partner Algeta:Event SEPSIS is serious (fatal outcome) and unlisted for Alpharadin. Investigator has assessed the relationship to study drug as possibly related. The sponsor has assessed the relationship to study drug as unrelated.
15245-233-233003	ANAEMIA (CTC GRADE 3)[PT：貧血] 本症例には、プラセボが投与されていた。
15245-233-233003	ANAEMIA (CTC GRADE 3)[PT：貧血] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-233-233003	HEART FAILURE (CTC GRADE 4)[PT：心不全] ANAEMIA[PT：貧血] 本症例には、プラセボが投与されていた。
15245-233-233005	DEHYDRATION (CTC GRADE 2)[PT：脱水] GENERAL MALAISE (CTC GRADE 2)[PT：倦怠感] DEHYDRATION (CTC GRADE 3)[PT：脱水] The case refers to a 78-year-old male patient in a double blind, randomized, repeat dose, phase III, multicentre survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. He experienced GENERAL MALAISE (CTC GRADE 2), DEHYDRATION (CTC GRADE 3) and DEHYDRATION which are serious due to medical significance and hospitalization. The investigator has assessed the relationship to study drug for all events as possibly related. The investigator concluded that following the study injection, the subject had general weakness and decreased appetite, and his oral intake reduced. This may have caused dehydration and raised serum creatinine. The company considers the events unrelated to the study drug. The increased oral intake and the resulting events could also be caused by the underlying disease.
15245-233-233005	LOW HAEMOGLOBIN (CTC GRADE 3)[PT：ヘモグロビン減少] This 79 year old Caucasian male, who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, experienced LOW HAEMOGLOBIN (CTC GRADE 3) 53 days after receiving the first study injection. Prior to the onset of the event, the subject received 1 study injection.The subject's relevant medical history includes metastatic prostate cancer. LOW HAEMOGLOBIN (CTC GRADE 3) is considered serious (hospitalization) and listed for Alpharadin.The investigator has assessed the relationship to study drug as probably related. The sponsor has assessed the relationship to study drug as related.
15245-233-233005	ANAEMIA (CTC GRADE 3)[PT：貧血] This 79 year old male patient experienced ANAEMIA (CTC GRADE 3) 136 days after initial dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included metastatic prostate cancer.The event ANAEMIA (CTC GRADE 3) is considered serious (hospitalized) and Listed for Alpharadin.The investigator has assessed the relationship to study drug as possibly related.The sponsor has assessed the relationship to study drug as possibly related.
15245-233-233005	ANAEMIA (CTC GRADE 1)[PT：貧血] DEHYDRATION (CTC GRADE 2)[PT：脱水] The company has received a double blind, randomized phase III sponsored clinical trial report from (Algeta), referring a 79 year old Caucasian male patient (pt) enrolled in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases, received first dose of study medication (Alpharadin/Placebo) on 25-Jan-2010. Patient has received 05 study injections prior to the onset dates of events and last injection was given approximately 1 month prior to events onset. The action taken with study drug was not applicable. The patient (pt) relevant medical history included metastatic prostate cancer and taking number of concomitant medications. Patient did not receive docetaxel therapy. He was previously hospitalized once due to dehydration twice due to low hemoglobin (see ref cases/dates).During the study course patient was admitted to hospital due to shortness of breath (considered as symptom of the ANAEMIA) secondary to ANAEMIA (CTC grade 1) [previously reported] and

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	DEHYDRATION (CTC grade 2). Both events were considered serious (hospitalization). Event ANAEMIA was considered listed as per investigational brochures of Alpharadin (Bay 88-8223) while DEHYDRATION was unlisted. Patient had improved /recovered in response to treatment on day two from the date of onset.The investigator has assessed the relationship to the study drug Alpharadin (Bay 88-8223)/placebo as possibility related for both events, sponsor (company) concurs citing underlying preexisting advanced metastatic disease / prior hospitalization for the same reasons are plausible alternative explanations.
15245-233-233005	ANAEMIA (CTC GRADE 3)[PT：貧血] DRY COUGH[PT：咳嗽] SHORTNESS OF BREATH[PT：呼吸困難] The investigator considers the event serious and probably related to Alpharadin/placebo.Company considers the event serious, expected and related to Alpharadin.
15245-233-233005	DEHYDRATION (CTC GRADE 3)[PT：脱水] BONE PAIN (CTC GRADE 3)[PT：骨痛] ANAEMIA (CTC GRADE 2)[PT：貧血] NEUTROPENIA (CTC GRADE 2)[PT：好中球減少症] THROMBOCYTOPENIA (CTC GRADE 1)[PT：血小板減少症] This 79 year old male patient experienced Dehydration (CTC Grade 3), Bone pain (CTC grade 3), Anaemia (CTC grade 2), Neutropenia (CTC grade 2) and Thrombocytopenia (CTC grade 1) and was hospitalized 22 days after the last received study dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient's concurrent condition included metastatic prostate cancer and right bundle branch block. The event Dehydration (CTC Grade 3) is considered serious (hospitalized) and Unlisted for Alpharadin whereas the events of Bone pain (CTC grade 3) (hospitalized), Anaemia (CTC grade 2) (hospitalized/disability), Neutropenia (CTC grade 2) (hospitalized/disability) and Thrombocytopenia (CTC grade 1) (hospitalization/medically important) are considered serious and Listed for Alpharadin.The investigator has assessed the relationship to study drug as probably related for dehydration and bone pain. The investigator assessed the relationship to study drug as possibly related for anaemia, neutropenia and thrombocytopenia. The investigator states that dehydration was a recurrent problem during the study trial period, thus assessing the event of dehydration as probably related to the study drug.The sponsor has assessed the relationship to study drug as unrelated for the events of dehydration and bone pain and possibly related for the events of anaemia, neutropenia and thrombocytopenia.
15245-233-233005	ANAEMIA (CTC GRADE 3)[PT：貧血] DEHYDRATION (CTC GRADE 3)[PT：脱水] BRONCHOPNEUMONIA (CTC GRADE 5)[PT：気管支肺炎] （本例は PMDA へ報告を行った症例である。弊社の見解を日本語で示す） 治験担当医は、「気管支肺炎」及び「貧血」について本治験薬との因果関係はないと評価し、「脱水」について因果関係があると評価した。なお、「貧血」について、「従前より患っており恐らく原疾患進行による」とコメントした。 弊社は、「貧血」及び「脱水」については、時間的関連性が認められないことから本剤との因果関係はないと考える。本剤よりもむしろ原疾患に起因すると考える。「気管支肺炎」については、疾患進行による全身状態低下の寄与が考えられるものの、好中球減少の関与を勘案すると、本剤との因果関係は完全には否定できないと考える。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-234-234005	CEREBRAL VASCULAR ACCIDENT (CTC GRADE 4)[PT：脳血管発作] The investigator has assessed the relationship to study drug as related. The sponsor has assessed the relationship to study drug as possibly related.
15245-234-234005	WORSENING ANAEMIA (CTC GRADE 3)[PT：貧血] This 59 -year old male patient experienced WORSENING ANAEMIA (CTC grade 3)(previously reported as Anaemia (CTC Grade 3)), 28 days after the last of totally 3 injections of study treatment (Alpharadin/placebo) in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient was hospitalized 2 days later for a blood transfusion. The action taken with study drug was permanently discontinued.The patient's concurrent condition included metastatic prostate cancer and anaemia.The patient had received prior docetaxel therapy. The event Anaemia (CTC Grade 3) is serious (hospitalized, medically important event) and unlisted for Alpharadin (previously listed).The investigator has assessed the relationship to study drug as possibly related.The sponsor has assessed the relationship to study drug as possibly related.
15245-234-234005	DISEASE PROGRESSION[PT：前立腺癌] This 59 year old Caucasian male, who enrolled in study BC1-06 and received Alpharadin/Placebo for hormone refractory prostate cancer with skeletal metastases, died of DISEASE PROGRESSION 55 days after receiving the last dose of study drug. It was reported that cause of death was metastatic prostate cancer (disease progression).The subject's relevant medical history included metastatic prostate cancer (underlying disease). DISEASE PROGRESSION is considered serious (Fatal) and is unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated. The sponsor has assessed the relationship to study drug as unrelated.
15245-240-240002	SEPSIS (CTC GRADE 4)[PT：敗血症] SUSPECTED PNEUMONIA (CTC GRADE 3)[PT：肺炎] This safety report refers to a 68 year old Caucasian male who enrolled in study BC1-06 and received study medication (first dose Dec-2009) for hormone refractory prostate cancer with skeletal metastases, and was hospitalized due to SEPSIS (CTC Grade 4) and SUSPECTED PNEUMONIA (CTC Grade 3), onset was reported 33 days from the last dose.Relevant medical history /concomitant medications included bone metastases, chronic aortic stenosis, coronary artery disease, status post bypass, anaemia and Pancytopenia (probably due to chemotherapy), and use of goserelin, zoledronic acid, rosuvastatin, loratadine, acetylsalicylic acid, metoprolol, pantoprazole, oxycodone, dexamethasone and magnesium hydroxide as concomitant medications. Patient had received prior docetaxel therapy in Jan-2005. Prior to the onset of the event the subject received 01 study injection(s). At the time of this report the study drug was postponed.SEPSIS (CTC Grade 4) and SUSPECTED PNEUMONIA (CTC Grade 3) are considered serious (hospitalization) and both are unlisted for Alpharadin. Action taken with study drug was postponed for both events. Later the patient was discharged and the outcome was considered resolved for both events.The investigator has assessed the relationship to study drug as unrelated, rather due to concurrent illness. The investigator also reported that although sepsis was never microbiologically confirmed, the subject was clinically septic and hypotensive. He also responded to antibiotics and fluids. The discharge summary stated that no obvious pneumonia could be seen, although his left lower lobe infiltrates certainly could be an early community-acquired pneumonia. His pleural effusion was however rather small and not considered a serious adverse event.The sponsor has assessed the relationship to study drug as unrelated for both events.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-240-240002	PROGRESSIVE DISEASE RESULTING IN DEATH (CTC GRADE 4)[PT：前立腺癌] Company causality assessment per License Partner Algeta:Event of PROGRESSIVE DISEASE RESULTING IN DEATH is serious (fatal outcome), unlisted and assessed by the Investigator and Sponsor as unrelated to study drug, but rather due to progression of prostate cancer.
15245-240-240002	PERSISTENT HAEMATURIA (CTC GRADE 2)[PT：血尿] THROMBOCYTOPENIA (CTC GRADE 3)[PT：血小板減少症] URINARY RETENTION (CTC GRADE 2)[PT：尿閉] The company has received a double blind, randomized phase III sponsored clinical trial report from (Algeta), referring a 68 year old male enrolled in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases.Patient received first dose of study medication (Alpharadin/Placebo) on 23 Dec 2009 and initial report was received on '24-Jun-2010' not 04-Oct-2010, (changes can not be made due to system limitations). Patient has received 6 study injections (the last injection being given 10 days earlier from the onset dates of event). Action taken with study drug is not applicable.The patient (pt) relevant medical history included prostate cancer with bone metastases, coronary artery bypass graft, aortic valve replacement, anemia and radiation cystitis, prior radiation therapy/ docetaxel therapy and concomitant medications. Concurrent condition included worsening of 'cervical neck pain' required ibuprofen (not considered serious adverse event and CT scan revealed pre-generative cervical spondylosis)During the course patient experienced PERSISTENT HAEMATURIA (CTC grade 2), URINARY RETENTION (CTC grade 2) considered serious (hospitalization). On the day of hospitalization THROMBOCYTOPENIA (CTC grade 3) was observed and considered serious (hospitalization). PERSISTENT HAEMATURIA and URINARY RETENTION were unlisted as per investigational brochures of Alpharadin (Bay 88-8223) while THROMBOCYTOPENIA is listed.Patient was improved in response to treatment. As per report provide, patient was improved /recovered in response to treatment on day six from onset.The investigator has assessed the relationship to the study drug as possibly related for PERSISTENT HAEMATURIA, URINARY RETENTION and probably related THROMBOCYTOPENIA citing PERSISTENT HAEMATURIA was related to THROMBOCYTOPENIA that was probably related to the study drug. URINARY RETENTION was related to blood in urine which was secondary to the study drug induced due to THROMBOCYTOPENIA. Right now, company has assessed the causal relationship to the study drug as unrelated for the events of PERSISTENT HAEMATURIA, URINARY RETENTION and possibly related for the event of THROMBOCYTOPENIA pending additional information.
15245-240-240006	INCREASING BONE PAIN (CTC GRADE 4)[PT：骨痛] ADVANCING PROSTATE CANCER (CTC GRADE 4)[PT：悪性新生物進行] CORD COMPRESSION (CTC GRADE 3)[PT：脊髄圧迫] This 75 year old male patient experienced INCREASING BONE PAIN (CTC GRADE 4) and was hospitalized 25 days after receiving the last dose of study medication (Alpharadin/placebo) in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. One day later the patient was diagnosed with SPINAL CORD COMPRESSION (CTC grade 3). The patient was also confirmed to having ADVANCING PROSTATE CANCER (CTC GRADE 4) and later died due to the advancing prostate cancer. The patient's concurrent condition included congestive heart failure, drug allergy, hypercholesterolemia and hypertension.The event INCREASING BONE PAIN (CTC GRADE 4) is considered serious (hospitalized) and unlisted for Alpharadin. The event ADVANCING PROSTATE CANCER (CTC GRADE 4) is considered serious (fatal, hospitalized, medically significant) and unlisted for Alpharadin. The event SPINAL CORD COMPRESSION (CTC grade 3) is considered serious (hospitalized) and unlisted for Alpharadin. The investigator has assessed the relationship to the study drug as unrelated for the events, but rather due to concurrent illness.The sponsor

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	has assessed the relationship to the study drug as unrelated for all events.
15245-240-240010	SEVERE BACK PAIN (CTC GRADE 3)[PT：骨痛] 本症例には、プラセボが投与されていた。
15245-242-242001	DEHYDRATION (CTC GRADE 3)[PT：脱水] This 80 year old male patient experienced Dehydration (CTC grade 3) and was hospitalized 51 days after receiving the last dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases.The patient's medical history included erectile dysfunction, urinary incontinence, degenerative arthritis, left hip replacement, tremor, thoracic kyphosis, fatigue, back pain, edema bilateral lower extremity, dry skin, bilateral hip pain, and constipation. The patient's concurrent condition included right lower extremity deep vein thrombosis, pulmonary embolism, radiation pneumonitis, spermatocele, squamous cell cancer left cheek, squamous cell cancer scalp, squamous ell cancer left upper back, compression fracture T-spine, vertebral collapse, osteonecrosis of mandible and hyperlipidemia.The event Dehydration (CTC grade 3) is considered serious (hospitalized) and Unlisted for Alpharadin.The investigator has assessed the relationship to study drug as unrelated, but rather due to effects of radiations.The sponsor has assessed the relationship to study drug as unrelated.
15245-242-242001	DEHYDRATION (CTC GRADE 3)[PT：脱水] This clinical trial case report (forwarded by Algeta) referring to an 80 year old male with known history of right lower extremity deep vein thrombosis, pulmonary embolism, radiation pneumonitis, erectile dysfunction, spermatocele, urinary incontinence, squamous cell cancer left cheek, squamous cell cancer scalp, degenerative arthritis, left hip replacement, squamous cell cancer left upper back, compression fractures T-Spine, tremor, thoracic kyphosis, vertebral collapse, osteonecrosis/osteomyelitis of mandible, fatigue, constipation, back pain, hyperlipidermia, edema-bilateral lower extremity, dry skin and bilateral hip pain and prior history of hospitalization due to dehydration, in a double blind, randomized, repeat dose, phase III, multicentre survival study of patients with hormone-refractory prostate cancer with skeletal metastases and received Alpharadin (BAY 88-8223)/Placebo. Patient experienced DEHYDRATION (CTC Grade 3), considered serious (hospitalization) / unlisted as per investigational brochures of Alpharadin (Bay 88-8223). Patient improved in response to treatment.The investigator has assessed the relationship to study drug as unrelated to study medications, rather due to concurrent illness. The sponsor (company) concurs with investigator assessment (unrelated) citing patient's underlying metastatic disease, multiple concurrent conditions, previously reported hospitalization due to 'dehydration' and concomitant medications are reasonable contributory factors.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-245-245001	LETHARGY (CTC GRADE 3)[PT：嗜眠] 試験薬は投与されていない。
15245-251-251003	PLEURAL EFFUSION (CTC GRADE 2)[PT：胸水] 試験薬は投与されていない。
15245-251-251003	EXACERBATION OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (CTC GRADE 3)[PT：慢性閉塞性肺疾患] LYMPHOPENIA (CTC GRADE 4)[PT：リンパ球減少症] EXACERBATION OF CONGESTIVE HEART FAILURE (CTC AE GRADE 3)[PT：うっ血性心不全] 試験薬は投与されていない。
15245-251-251003	NON ST ELEVATION MYOCARDIAL INFARCTION (CTC GRADE 4)[PT：急性心筋梗塞] EXACERBATION OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (CTC GRADE 3)[PT：慢性閉塞性肺疾患] 本症例には、プラセボが投与されていた。
15245-251-251003	EPISTAXIS (CTC GRADE 2)[PT：鼻出血] 本症例には、プラセボが投与されていた。
15245-251-251003	EXACERBATION OF CHRONIC RESPIRATORY FAILURE (CTC GRADE 3)[PT：慢性呼吸不全] EXACERBATION OF CONGESTIVE HEART FAILURE (CTC GRADE 3)[PT：うっ血性心不全] EXACERBATION OF COPD (CTC GRADE 3)[PT：慢性閉塞性肺疾患] ORTHOSTATIC HYPOTENSION (CTC GRADE 3)[PT：起立性低血圧] 本症例には、プラセボが投与されていた。

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-251-251003	PNEUMONIA (CTC GRADE 4)[PT：肺炎] MULTIORGAN FAILURE[PT：多臓器不全] 本症例には、プラセボが投与されていた。
15245-253-253001	SYNCOPE (CTC GRADE 3)[PT：失神] This 73 year old male patient experienced SYNCOPE (CTC GRADE 3) and was hospitalized 12 days after receiving the latest dose of Alpharadin/placebo in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The subject has a relevant medical history of hypertension, carotid artery stenosis, status post carotid artery endarterectomy and metastatic prostate cancer.The event SYNCOPE (CTC GRADE 3) is considered serious (hospitalized) and Unlisted for alpharadin. The investigator has assessed the relationship to study drug as unrelated to the study drug. Several of the concomitant medications may have syncope and dizziness associated with them. However, the subject had been taking them for some time prior to the onset of the event, therefore the investigator states that the event may not be related to the concomitant medications.The sponsor has assessed the relationship to study drug as unrelated.
15245-9006-9006051	BONE PAIN LEFT HIP/PELVIS (CTC GRADE 3)[PT：骨痛] This license partner study case report refers to an 88 year old male patient who was treated with Alpharadin for hormone-refractory prostate cancer with sceletal metastasis for about five months and experienced BONE PAIN LEFT HIP/PELVIS (CTC GRADE 3).The reported event is considered serious due to hospitalisation, it is unexpected according to the Investigator´s Brochure for Alpharadin.The investigator has assessed the relationship to study drug as unrelated, but rather due to concurrent illness.The sponsor considers BONE PAIN RIGHT HIP / PELVIS as unrelated. The company concurs with this assessment, citing the patient´s underlying malignant disease as valid alternative explanation.
15245-9017-9017026	DETERIORATION OF THE SUBJECT'S GENERAL CONDITION (CTC GRADE 5)[PT：全身健康状態低下] This study case report received from license partner Algeta refers to a 62 year-old Caucasian male patient who was enrolled in a phase III study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases and developed DETERIORATION OF THE SUBJECT'S GENERAL CONDITION (CTC grade 5) (previously reported as worsening of medical status). The patient had no relevant medical history.The investigator reported the event to be unrelated to study drug but rather due to concurrent illness.DETERIORATION OF THE SUBJECT'S GENERAL CONDITION (CTC grade 5) is serious due to hospitalization and fatal outcome and is unexpected in the Investigator's Brochure of Alpharadin.The sponsor has assessed the relationship to study drug as unrelated.The event occurred 45 days after the last dose of study medication. Regarding the plausible alternative explanation of the underlying prostate cancer with skeletal metastases the event is assessed as unrelated to Alpharadin.
15245-9020-9020006	SPINAL CORD COMPRESSION (CTC GRADE 4)[PT：脊髄圧迫] This study case report refers to a 71 year old male patient who had experienced urinary retention and had fallen several times and was hospitalized for SPINAL CORD COMPRESSION (CTC Grade 4) (amended from previously reported event of MEDULLA COMPRESSION and primarily URINARY RETENTION) after receiving study medication while in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient had been randomized to placebo and eligible for crossover treatment. The patient's concurrent condition included gout, hypertension, mild nausea, mild muscle spasm, hot flushes and metastatic pain.The event SPINAL CORD COMPRESSION (CTC Grade 4) is considered serious (hospitalized, disability) and unlisted for Alpharadin. The investigator has assessed the relationship to study drug as unrelated, but rather due to concurrent illness.The Sponsor has

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	assessed the relationship to study drug as unrelated.
15245-9020-9020006	PNEUMONIA (CTC GRADE 3)[PT：肺炎] This study case report refers to a 71 year old male patient who developed PNEUMONIA while being treated with Alpharadin (patient was initially receiving placebo in this study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases, but was eligible for cross over treatment and had received study medication prior to event). After receiving treatment with tazocin, the patient had recovered. The event PNEUMONIA is considered serious (hospitalized) and Unlisted for ALPHARADIN. The investigator has assessed the relationship to study drug as unrelated, but rather due to infection.The sponsor has assessed the relationship to study drug as unrelated.
15245-9025-9025017	WORSENING ATRIAL FIBRILLATION (CTC GRADE 1)[PT：心房細動] 本症例には、プラセボが投与されていた。
15245-9025-9025017	LUXATION OF THE HIP (PROTESES) (CTC GRADE 1)[PT：医療機器位置異常] 本症例には、プラセボが投与されていた。
15245-9025-9025017	CONCUSSION (CTC GRADE 2)[PT：脳振盪] This study case report received from license partner Algeta refers to a 72 year old male patient with a medical history of hypertension, glaucoma left eye and atrial fibrillation who was enrolled in this study for treatment of hormone-refractory prostate cancer with skeletal metastases with Alpharadin / Placebo. He initially received Placebo and experienced after cross over and 15 days after the first dose of Alpharadin a CONCUSSION (CTC grade 2) after he accidentally fell on his head. The patient recovered after two days.CONCUSSION is considered serious due to hospitalisation, it is unexpected according to the ″expectedness event list for Alpharadin trials (14-Sep-2011)″.The Investigator and the Sponsor assessed the reported event as unrelated to Alpharadin.Company agrees, accepting the patients fall as plausible alternative explanation.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-9025-9025017	UPPER RESPIRATORY TRACT INFECTION (CTC GRADE 2)[PT：上気道感染] This study case report refers to a 73 year old male patient who developed a UPPER RESPIRATORY TRACT INFECTION (CTC Grade 2) while being treated with study drug in this clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient was initially treated wtih placebo but was eligible for cross over treatment and received study drug. The patient's relevant medical history included hypertension, glaucoma, atrial fibrialltion, hypocalcemia, erysipelas, urinary urgency, bone pain, inflammation dental, fatigue, skin lesion right ear and urinary retention.The event UPPER RESPIRATORY TRACT INFECTION (CTC Grade 2) is considered serious (hospitalized) and Unlisted in the Investigator's Brochure for ALPHARADIN.The investigator has assessed the relationship to study drug as unrelated.The sponsor has assessed the relationship to study drug as unrelated.
15245-9025-9025018	OBSTIPATION (CTC GRADE 1)[PT：便秘] 本症例には、プラセボが投与されていた。
15245-9025-9025018	PROGRESSION OF PROSTATE CANCER[PT：前立腺癌] 本症例には、プラセボが投与されていた。
15245-9026-9026014	NUTRITION PROBLEMS (CTC GRADE 2)[PT：栄養障害] （本例は PMDA へ報告を行った症例である。弊社の見解を日本語で示す） 本剤投与後に発現している時間的関連性及び治験担当医の評価を勘案し、本剤との因果関係は否定できないと考える。しかしながら、悪心、食欲喪失による影響、以前の前立腺に対する放射線療法および抗凝固療法の影響によりこの数年間で間欠的に生じていた直腸出血、原疾患の進行による可能性も考えられる。
15245-9033-9033026	MUSCULO-SKELETAL FRACTURE HIP (CTC GRADE 3)[PT：股関節部骨折] This 71-year-old Caucasian male patient who received 5 doses of Alpharadin (radium 223) in indication hormone-refractory prostate cancer with skeletal metastases, in the course of a clinical study, experienced musculo-skeletal-fracture hip (CTC grade 3) 7 month after the last dose. The patient has a relevant medical history of osteopenia and osteoporosis. It was reported that the patient was not receiving any concomitant medications that may have contributed to the fracture i.e. corticosteroids, proton pump inhibitor. The investigator has assessed the relationship to study drug as possibly related with the rationale that "any fracture is possibly related given mechanism of action of the study drug".Musculo-skeletal-fracture hip is serious due to hospitalization and is unexpected in the investigator's brochure for Alpharadin.The information provided in this case is very limited. It is not known whether the patient experienced a fall or other trauma, and it was unknown whether it was a pathologic or traumatic fracture. The patient's skeletal metastases however, were described as widespread with diffuse bony involvement. Therefore it can be concluded that the patient's bone metastases increased the risk to experience a fracture and can be considered

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	as an alternative explanation. The event is assessed as unrelated to study drug in agreement with the sponsor of the study.
15245-9033-9033028	FRACTURE LEFT FEMUR (CTCAE GRADE 3)[PT：大腿骨骨折] （本例は PMDA へ報告を行った症例である。弊社の見解を日本語で示す） 本事象は、本剤の 2 回目の投与から約 10 日後に発生しており、時間的関連性から本剤との因果関係を完全には否定できないと考える。しかしながら、原疾患は骨転移を有する進行性前立腺癌患者であり、骨転移は骨痛や骨折の原因となることが知られていることから原疾患の骨転移による可能性も考えられる。
15245-9033-9033028	FRACTURE OF LEFT INTERNAL FEMORAL PLATE AND ENDOPROSTHETIC REPLACEMENT(CTC GRADE 3)[PT：大腿骨骨折] FRACTURE OF LEFT INTERNAL FEMORAL PLATE AND ENDOPROSTHETIC REPLACEMENT(CTC GRADE 3)[PT：骨折内固定] （本例は PMDA へ報告を行った症例である。弊社の見解を日本語で示す） 「大腿骨骨折」及び「骨折内固定」について、治験担当医は本治験薬との因果関係はないと評価した。 弊社も、原疾患は骨転移を有する進行性前立腺癌患者であり、骨転移は骨痛や骨折の原因となることが知られていることから、「大腿骨骨折」及び「骨折内固定」は原疾患に基づき発現したと考えられ、本試験薬の関連性はないと考える。
15245-9035-9035026	CHOLECYSTITIS (CTC GRADE 3)[PT：胆嚢炎] （本例は PMDA へ報告を行った症例である。弊社の見解を日本語で示す） 「胆嚢炎」について治験担当医は本治験薬との因果関係があると評価した。弊社は、臨床経過および検査所見より、「胆嚢炎」は胆石によるものであり本治験薬との因果関係は否定できると考える。
15245-9035-9035030	NON-CANCER RELATED BACK PAIN (CTC GRADE 2)[PT：背部痛] This 64 year old male patient was diagnosed with NON-CANCER RELATED BACK PAIN (CTC grade 2) (previously reported SUSPECTED SPINAL CORD COMPRESSION (CTC grade 2)) while enrolled in this clinical study of Alpharadin/Placebo in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. It was reported that a MRI was performed to exclude spinal cord compression but there was an acquired degenerative spinal stenosis at L3 and L4 levels similar to previous examination. Prior to the onset of the event the patient received 4 study injections, the last injection being approx. 7 weeks prior to the onset of the event. No action was taken with study drug. The patient was previously hospitalised due to spinal cord compression in Dec 2010. Treatment included nitrofurantoin. NON-CANCER RELATED BACK PAIN (CTC grade 2) is serious (disability) and is unexpected in the Investigator's Brochure of Alpharadin. The investigator has assessed the relationship to study drug as unrelated but but rather due to concurrent illness.The Sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-9042-9042038	MUSCULOSKELETAL CHEST PAIN (CTCAE GRADE 3)[PT：筋骨格系胸痛] This study report refers to a 76-year-old Caucasian male patient who was enrolled in a double blind, randomized, repeat dose, phase III, multicenter survival study of AlpharadinTM in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patients relevant medical history included hypertension, Hypercholesterolemia and COPD and no concomitant medication was reported. The patient did not have prior docetaxel therapy. The patient was previously hospitalized due to Non-ST elevation myocardial infarction and again due to pulmonary embolism and infective exacerbation of COPD (see ref. case numbers).The investigator was informed (via patients wife) for patient hospitalization due to MUSCULOSKELETAL CHEST PAIN (CTCAE GRADE 3). The subject was discharged with codeine for pain relief. The event is considered serious (hospitalization) / and is unlisted in the Investigators Brochure of Alpharadin.The investigator has assessed the events relationship to study drug as unrelated but rather due to concurrent illness. The Sponsor has assessed the relationship to study drug as unrelated. No reason is seen to deviate from the investigator's assessment and causal association with study medication is excluded.
15245-9048-9048014	ISCHEMIC RIGHT FOOT (CTC GRADE 3)[PT：末梢性虚血] This 73 year old male patient enrolled in a clinical study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. Patient was randomized to placebo. The patient was eligible for cross over treatment with Alpharadin and received 3rd dose on 25-Jan-2011.The patient experienced ISCHEMIC RIGHT FOOT (CTC GRADE 3) (amended from previously reported NECROTIC TOE) and was hospitalized 18 days after receiving 3rd dose of Alpharadin. The patient's concurrent condition included prostate cancer with bone metastases.The event ISCHEMIC RIGHT FOOT (CTC GRADE 3) is considered serious (hospitalized) and unlisted in the Investigator's Brochure for Alpharadin. The investigator assessed the event as unrelated to study drug, but rather to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.
15245-9049-9049001	DISEASE PROGRESSION (CTCAE GRADE 5)[PT：前立腺癌] This study case report refers to a 66 year old male patient with hormone-refractory prostate cancer with skeletal metastases. The patient received 6 injections of Placebo from 27-May-2009 to 14-Oct-2009. The patient was eligible for cross over treatment with Alpharadin and received three injections of study drug. Approximately one month after the last dose, the patient had DISEASE PROGRESSION (CTCAE GRADE 5) on 17-Jul-2012 and died the same day. DISEASE PROGRESSION is considered serious due to fatal outcome and is unlisted for Alpharadin. The investigator assessed the relationship to study drug as unrelated. Since the reported event reflects the "natural course" of the malignant progredient underlying disease, causality is considered unrelated for Alpharadin.
15245-9050-9050018	RECTAL BLEEDING (CTC GRADE 3)[PT：直腸出血] THROMBOCYTOPENIA (CTC GRADE 3)[PT：血小板減少症] ANAEMIA (CTC GRADE 3)[PT：貧血] PROGRESSION OF PROSTATE CANCER[PT：悪性新生物進行] This study case report refers to a 71 year old male patient who developed RECTAL BLEEDING (CTC grade 3), THROMBOCYTOPENIA (CTC grade 3) and ANAEMIA (CTC grade 3) 37 days after receiving latest dose of Alpharadin in this study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. The patient was initially randomized to placebo but was eligible for cross over treatment with Alpharadin and received study drug. During hospitalisation the patient died due to PROGRESSION OF PROSTATE CANCER and not due to rectal bleeding, thrombocytopenia or anaemia. The events were ongoing at the time of death. The patient has a relevant medical history of musculoskeletal and neuropathic pain, lower limb oedema, anxiety and bruising to arms. The patient received concomitantly acetylsalicylic acid but administration dates were not provided.All reported events are considered serious due to hospitalisation, PROGRESSION OF PROSTATE CANCER additionally due to fatal outcome. Only THROMBOCYTOPENIA is expected according to the Investigators Brochure for

表 2.7.4.7- 23 因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
	Alpharadin, the remaining events are unexpected.The investigator has assessed the relationship of the events rectal bleeding, thrombocytopenia and anaemia to study drug as possibly related, and progression of prostate cancer as unrelated but rather due to prostate cancer. The investigator has assessed the relationship of the event rectal bleeding as possibly related to treatment with aspirin and the events thrombocytopenia, anaemia and progression of prostate cancer as unrelated to treatment with aspirin. The investigator reported that the cause of rectal bleeding was unknown at this point but that prostate cancer progression, local recurrence and prior radiation therapy were all possibilities. The sponsor has assessed the relationship of the events rectal bleeding, thrombocytopenia and anaemia to the study drug as possibly related, and progression of prostate cancer as unrelated.The company concurs with this assessment.
15245-9074-9074001	SYNCOPE (CTC GRADE 3)[PT：失神] （本例は PMDA へ報告を行った症例である。弊社の見解を日本語で示す） 「失神」について、治験担当医は本治験薬との因果関係はないと評価した。弊社は、当該事象は他の要因により発現した可能性が高いと考えられるが、臨床経過等の詳細情報が不足していること、また本治験薬の最終投与 3 週間後に発現しており治療効果が投与終了後 1～2 ヵ月存続することが予想されていることを考慮すると、本治験薬との因果関係は完全には否定できないと考える。
15245-9137-9137002	SPINAL CORD COMPRESSION (CTC GRADE 2)[PT：脊髄圧迫] 本症例には、プラセボが投与されていた。
15245-9191-9191003	SCROTAL OEDEMA (CTCAE GRADE 3)[PT：陰嚢浮腫] 本症例には、プラセボが投与されていた。
15245-9191-9191003	SCROTAL OEDEMA (CTC GRADE 3)[PT：陰嚢浮腫] EDEMA LIMB (CTC GRADE 2)[PT：末梢性浮腫] This 80 year old male patient experienced SCROTAL OEDEMA (CTC GRADE 3) and EDEMA LIMB (CTC GRADE 2) and was hospitalized 27 days after receiving first dose of cross over treatment of Alpharadin in this double blind, randomised, repeat dose, phase III, multicentre survival study of Alpharadin in the treatment of patients with hormone-refractory prostate cancer with skeletal metastases. This study was previously unblinded. The patient was initially randomized to placebo.The patient's concurrent condition included chronic atrial fibrillation and hypertensive heart disease.The events SCROTAL OEDEMA (CTC GRADE 3) and EDEMA LIMB (CTC GRADE 2) are considered serious (hospitalized) and Unlisted for alpharadin. The investigator has assessed the relationship to study drug as unrelated, but rather due to concurrent illness.The sponsor has assessed the relationship to study drug as unrelated.

表 2.7.4.7- 23　因果関係判定根拠に関する治験依頼者の見解（試験 BC1-06）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15245-9240-9240003	PANCYTOPENIA[PT：汎血球減少症] This study case report received from license partner Algeta refers to a 71 year old Caucasian male patient who received 6 injections of Alpharadin for prostate cancer with skeletal metastases after unblinding of study and subsequent cross over and experienced PANCYTOPENIA (previously reported as PANCYTOPENIA (WITH GRADE 3 THROMBOCYTOPENIA)) more than 1 year after the last injection of Alpharadin. A bone marrow biopsy showed marrow involved by metastatic prostate carcinoma, marrow fibrosis and cells showed reactivity for cytokeratin (AE1/AEK), PSA and PSAP on immunostains. The event is serious due to medical significance and is listed in the Investigator's Brochure of Alpharadin.The investigator has assessed the relationship to study drug as possibly related.The License Partner assessed the relationship as possibly related.

表 2.7.4.7- 24　因果関係判定根拠に関する治験依頼者の見解（試験 16430）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
16430- 200010002	蜂窩織炎(CTCAE Grade 2) [PT：蜂巣炎] ゾレドロン酸による顎骨壊死から当該事象の発現に至ったとの医師意見に同意できると考え、弊社も本剤との因果関係を否定できると考える。
16430- 200010003	腰痛 (CTCAE Grade 2) [PT：背部痛] MRI 検査の結果から腰椎圧迫骨折の疑いの所見が確認されており、高齢者であることを勘案すると、本事象は偶発的に発現したとの医師意見に同意できると考え、弊社も本剤との因果関係を否定できると考える。
16430- 200040001	肺炎の悪化(CTCAE Grade 2)[PT：肺炎] 本剤投与開始以前から存在する肺炎が偶発的に悪化したと考えられるとの医師意見に同意できると考え、弊社も本剤との因果関係を否定できると考える。
16430- 200090002	汎血球減少症 (CTCAE Grade 3) [PT：汎血球減少症] 時間的関連性及び本剤の安全性プロファイルを考慮すると、本剤との因果関係を否定できないと考える。
16430- 200090004	骨痛増悪 (CTCAE Grade 2) [PT：骨痛] 当該事象について、治験担当医は、「治験参加後に急激な骨痛増悪が認められた為時間的な関連性を否定できず、因果関係は否定できないと判断した」とコメントした。当該事象発現時の検査所見において、多発骨転移と転移巣の増大が確認されており、弊社は、当該事象は本剤の治療対象である前立腺癌（骨転移を伴う）の進行によるものと考えられることから、本剤との因果関係を否定できると考える。
16430- 200090005	Anaemia (CTCAE Grade 3) [PT：貧血] Anaemia (CTCAE Grade 3) [PT：貧血] 当該事象について、治験担当医は、「治験薬投与5回目以降に貧血があり、副作用による骨髄抑制を考え治験薬との因果関係は否定できない。」とコメントした。ヘモグロビン値が本剤の投与以前より低値であったこと、並びに、同時にPSA上昇が認められ、治験担当医により原疾患進行と判断されていることから、弊社は、当該事象は原疾患の進行が原因と考え、本剤との因果関係を否定できると考える。
16430- 200120001	原疾患の悪化 (CTCAE Grade 3) [PT：前立腺癌] 「前立腺癌（原疾患の悪化）」は、原疾患進行の自然経過と考えられることから本剤との因果関係を否定できると考える。

表 2.7.4.7- 24　因果関係判定根拠に関する治験依頼者の見解（試験 16430）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
16430- 200120005	骨痛の悪化（worsening of bone pain, CTCAE Grade 3）[PT：骨痛] 本剤の治療対象である前立腺癌（骨転移を伴う）の進行によると考えられ、本剤との因果関係を否定できると考える。
16430- 200120005	血小板減少症[PT：血小板減少症] 当該事象について、治験担当医は、「治験薬投与前から PSA、ALP、骨型 ALP は上昇傾向にあり、当該事象発現時に更なる上昇を来したことから、自然経過により原疾患が悪化したと判断した。原疾患の悪化による影響で DIC を疑うため、当該事象について治験薬との因果関係は否定できる」とコメントした。弊社も治験担当医の意見に同意できると考え、当該事象と本剤との因果関係を否定できると考える。
16430- 200160003	Worsening of bone pain（CTCAE Grade 3）[PT：骨痛] 本剤の治療対象である前立腺癌（骨転移を伴う）の進行によると考えられ、本剤との因果関係を否定できると考える。
16430- 200180004	腫瘍疼痛（腰部）の悪化（tumor pain（lumbar）Exacerbation, CTCAE Grade 2）[PT：腫瘍疼痛] 本剤の治療対象である前立腺癌（骨転移を伴う）の進行によると考えられ、本剤との因果関係を否定できると考える。
16430- 200180006	腫瘍疼痛（腰部）の悪化（CTCAE Grade 3）[PT：腫瘍疼痛] 本剤の治療対象である前立腺癌（骨転移を伴う）の進行によると考えられ、本剤との因果関係を否定できると考える。
16430- 200190001	骨痛の悪化[PT：骨痛] 本剤の治療対象である前立腺癌（骨転移を伴う）の進行によると考えられ、本剤との因果関係を否定できると考える。

表 2.7.4.7- 24　因果関係判定根拠に関する治験依頼者の見解（試験 16430）（続き）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
16430- 200190001	食欲不振[PT：食欲減退] 当該事象について、治験担当医は、「今回の事象は原疾患の悪化に伴う症状であり治験薬との因果関係はないと考える」とコメントした。弊社も治験担当医の意見に同意できると考え、当該事象と本剤との因果関係を否定できると考える。
16430- 200190003	腎機能障害の悪化[PT：腎機能障害] 当該事象について、治験担当医は、「今回の事象は、前立腺がんの急激な進行による食欲不振によりおこったものであり、治験薬との因果関係はないと判断する」とコメントした。被験者は元々合併症として腎機能障害を有しており、弊社も治験担当医の意見に同意できると考え、当該事象と本剤との因果関係を否定できると考える。

表 2.7.4.7- 25　因果関係判定根拠に関する治験依頼者の見解（試験 15354）

被検者番号	因果関係判定根拠に関する治験依頼者の見解
15354- 200010003	ＡＳＴ増加（CTCAE Grade 3）[PT：アスパラギン酸アミノトランスフェラーゼ増加] ＡＬＴ増加（CTCAE Grade 3）[PT：アラニンアミノトランスフェラーゼ増加] これらの事象が発現した翌日の CT 検査にて肝転移増悪が確認されたこと、並びに本剤最終投与から約 7 週間が経過しており時間的関連性が認められないことから、これらの事象と本剤との因果関係を否定できると考える。
15354- 200020007	Bone pain [PT：骨痛] 本剤の治療対象である前立腺癌（骨転移を伴う）の進行によると考えられ、本剤との因果関係を否定できると考える。
15354- 200020009	Progression of bone pain（CTCAE Grade 3）[PT：骨痛] 本剤の治療対象である前立腺癌（骨転移を伴う）の進行によると考えられ、本剤との因果関係を否定できると考える。
15354- 200030004	Gastric haemorrhage(CTCAE Grade 3) [PT：胃出血] Lung infection(CTCAE grade 2) [PT：肺感染] Progression of prostate cancer（CTCAE grade 5)[PT：前立腺癌] 「胃出血(G3)」について、出血部位において治験開始時から認められていた肝転移巣が胃に浸潤していることが CT により確認されていること、並びに最終投与から 6 週間以上経過しており時間的関連性が認められないことから本剤との因果関係を否定できると考える。「肺臓炎（G2）」について、最終投与から 8 週間以上経過しており時間的関連性が認められないことから本剤との因果関係を否定できると考える。「前立腺癌の悪化（G3）」については、原疾患進行の自然経過と考えられることから本剤との因果関係を否定できると考える。
15354- 200030005	Infections（CTCAE Grade 3）[PT：感染] Progression of prostate cancer（CTCAE Grade 5）[PT：前立腺癌] 「感染症（G3）」について、本剤最終投与前後の好中球数は保たれており好中球数減少による免疫力低下は考えにくいこと、並びに医師意見のように基礎疾患の糖尿病による易感染状態であった可能性があることから、偶発的なものと考え、本剤との因果関係を否定できると考える。「前立腺癌の進行（G5）」については、原疾患進行の自然経過と考えられることから本剤との因果関係を否定できると考える。
15354- 200030007	Rectal haemorrhage（CTCAE Grade 2）[PT：直腸出血] Progression of prostate cancer（CTCAE Grade 5）[PT：前立腺癌] Lung infection（CTCAE Grade 3）[PT：肺炎] CT 検査により、前立腺癌の膀胱直腸浸潤及び傍大動脈リンパ節転移が確認されている。「直腸出血」は、治験医により直腸浸潤が原因と判断されていることから、本剤との因果関係を否定できると考える。また、「前立腺癌の進行」は、原疾患進行の自然経過と考えられることから本剤との因果関係を否定できると考える。「肺炎」についても、原疾患の進行に伴う全身状態の悪化から感染をきたしたと考えられるため、本剤との因果関係は否定できると考える。

2.7.5　参考文献

2.7 臨床概要における参考文献の掲載先を以下に示す。

2.7.1 生物薬剤学試験及び関連する分析法；「参考文献一覧」の項

2.7.2 臨床薬理試験；「参考文献一覧」の項

2.7.3 臨床的有効性；「参考文献一覧」の項

2.7.4 臨床的安全性；「参考文献一覧」の項