表 2.7.4.9－18　発現時期別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 Baseline <= to <= Day84 n (%)	 >= Day85 n (%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	53(11.0)	60(14.4)
Contusion	挫傷	12(2.5)	17(4.1)
Shunt stenosis	シャント狭窄	15(3.1)	11(2.6)
Skin abrasion	皮膚擦過傷	7(1.5)	4(1.0)
Wound	創傷	4(0.8)	2(0.5)
Shunt occlusion	シャント閉塞	1(0.2)	4(1.0)
Spinal compression fracture	脊椎圧迫骨折	2(0.4)	2(0.5)
Thermal burn	熱傷	3(0.6)	1(0.2)
Limb injury	四肢損傷	2(0.4)	2(0.5)
Arteriovenous fistula site complication	動静脈瘻部位合併症	2(0.4)	1(0.2)
Rib fracture	肋骨骨折	1(0.2)	1(0.2)
Tooth fracture	歯牙破折	0(0.0)	2(0.5)
Ligament sprain	靭帯捻挫	0(0.0)	2(0.5)
Subcutaneous haematoma	皮下血腫	0(0.0)	2(0.5)
Joint injury	関節損傷	2(0.4)	0(0.0)
Shunt blood flow excessive	シャント血流過剰	1(0.2)	1(0.2)
Skin wound	皮膚創傷	1(0.2)	1(0.2)
Vascular access malfunction	血管アクセス機能不全	1(0.2)	1(0.2)
Dental restoration failure	歯科修復不成功	0(0.0)	2(0.5)
Fall	転倒	0(0.0)	1(0.2)
Head injury	頭部損傷	1(0.2)	0(0.0)
Injury	損傷	0(0.0)	1(0.2)
Seroma	漿液腫	0(0.0)	1(0.2)

表 2.7.4.9－18　発現時期別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 Baseline <= to <= Day84 n (%)	 >= Day85 n (%)
Sternal fracture	胸骨骨折	1(0.2)	0(0.0)
Tendon rupture	腱断裂	0(0.0)	1(0.2)
Skin laceration	皮膚裂傷	1(0.2)	0(0.0)
Nail injury	爪損傷	0(0.0)	1(0.2)
Eye contusion	眼挫傷	0(0.0)	1(0.2)
Animal bite	動物咬傷	0(0.0)	1(0.2)
Clavicle fracture	鎖骨骨折	1(0.2)	0(0.0)
Foot fracture	足骨折	0(0.0)	1(0.2)
Tooth injury	歯牙損傷	0(0.0)	1(0.2)
Arteriovenous graft site stenosis	動静脈グラフト部位狭窄	0(0.0)	1(0.2)
Arteriovenous fistula occlusion	動静脈瘻閉塞	1(0.2)	0(0.0)
Pelvic fracture	骨盤骨折	1(0.2)	0(0.0)
Vascular access complication	血管確保合併症	0(0.0)	1(0.2)
Procedural hypotension	処置による低血圧	0(0.0)	1(0.2)
Procedural hypertension	処置による高血圧	1(0.2)	0(0.0)
Heat illness	熱中症	0(0.0)	1(0.2)
Vascular access site inflammation	血管確保部位炎症	1(0.2)	0(0.0)
Soft tissue foreign body	軟部組織内異物	1(0.2)	0(0.0)
Heat stroke	熱射病	1(0.2)	0(0.0)
Peritoneal dialysis complication	腹膜透析合併症	0(0.0)	1(0.2)
Traumatic haemothorax	外傷性血胸	0(0.0)	1(0.2)
Surgical and medical procedures	外科および内科処置	2(0.4)	1(0.2)
Arteriovenous fistula operation	動静脈瘻手術	2(0.4)	1(0.2)

Note(s): MedDRA Version 21.1 and MedDRA/J Version 21.1.
Note(s): Percentages are based on the number of subjects in each period in each disease stage (N1).
Source: t_14_3_1_9_1.sas

5.3.5.3—2 Table 14.3.1.9.1 より引用

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）

	System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
NDD(N=202)	Total exposure period (months)		26.1	139.8	375.5	210.5	204.4
	Number of adverse events		25(95.7)	39(27.9)	160(42.6)	101(48.0)	83(40.6)
	Infections and infestations	感染症および寄生虫症	4(15.3)	8(5.7)	33(8.8)	19(9.0)	16(7.8)
	Nasopharyngitis	上咽頭炎	0(0.0)	2(1.4)	11(2.9)	10(4.8)	7(3.4)
	Gastroenteritis	胃腸炎	0(0.0)	1(0.7)	0(0.0)	1(0.5)	1(0.5)
	Conjunctivitis	結膜炎	0(0.0)	0(0.0)	1(0.3)	2(1.0)	0(0.0)
	Pneumonia	肺炎	0(0.0)	0(0.0)	1(0.3)	1(0.5)	1(0.5)
	Upper respiratory tract infection	上気道感染	1(3.8)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
	Cellulitis	蜂巣炎	1(3.8)	0(0.0)	3(0.8)	0(0.0)	1(0.5)
	Influenza	インフルエンザ	0(0.0)	2(1.4)	3(0.8)	0(0.0)	1(0.5)
	Cystitis	膀胱炎	0(0.0)	0(0.0)	3(0.8)	1(0.5)	0(0.0)
	Herpes zoster	帯状疱疹	0(0.0)	0(0.0)	0(0.0)	2(1.0)	0(0.0)
	Urinary tract infection	尿路感染	0(0.0)	0(0.0)	3(0.8)	1(0.5)	1(0.5)
	Periodontitis	歯周炎	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)
	Bronchitis	気管支炎	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
	Renal cyst infection	腎嚢胞感染	0(0.0)	0(0.0)	2(0.5)	0(0.0)	1(0.5)
	Otitis media	中耳炎	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
	Angular cheilitis	口角口唇炎	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)
	Paronychia	爪囲炎	1(3.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Sinusitis	副鼻腔炎	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Upper respiratory tract infection bacterial	細菌性上気道感染	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)
Body tinea	体部白癬	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Herpes simplex	単純ヘルペス	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
Osteomyelitis	骨髄炎	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Otitis externa	外耳炎	1(3.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Pneumonia chlamydial	クラミジア性肺炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
Pyelonephritis	腎盂腎炎	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Lung infection	肺感染	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
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）	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Oral papilloma	口腔乳頭腫	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Blood and lymphatic system disorders	血液およびリンパ系障害	0(0.0)	0(0.0)	0(0.0)	1(0.5)	1(0.5)
Iron deficiency anaemia	鉄欠乏性貧血	0(0.0)	0(0.0)	0(0.0)	1(0.5)	1(0.5)
Immune system disorders	免疫系障害	0(0.0)	0(0.0)	2(0.5)	0(0.0)	0(0.0)
Allergy to arthropod sting	節足動物刺傷アレルギー	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Allergy to arthropod bite	節足動物咬傷アレルギー	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Endocrine disorders	内分泌障害	1(3.8)	1(0.7)	0(0.0)	0(0.0)	0(0.0)
Hypothyroidism	甲状腺機能低下症	1(3.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Parathyroid gland enlargement	副甲状腺肥大	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Metabolism and nutrition disorders	代謝および栄養障害	1(3.8)	3(2.1)	10(2.7)	7(3.3)	3(1.5)
Decreased appetite	食欲減退	0(0.0)	0(0.0)	3(0.8)	0(0.0)	0(0.0)
Hyperkalaemia	高カリウム血症	0(0.0)	1(0.7)	1(0.3)	1(0.5)	1(0.5)
Dehydration	脱水	1(3.8)	0(0.0)	1(0.3)	1(0.5)	0(0.0)
Hyperphosphataemia	高リン酸塩血症	0(0.0)	1(0.7)	1(0.3)	0(0.0)	0(0.0)
Hypoglycaemia	低血糖	0(0.0)	1(0.7)	1(0.3)	0(0.0)	0(0.0)
Hyperuricaemia	高尿酸血症	0(0.0)	0(0.0)	1(0.3)	1(0.5)	0(0.0)
Metabolic acidosis	代謝性アシドーシス	0(0.0)	0(0.0)	1(0.3)	0(0.0)	1(0.5)
Diabetes mellitus	糖尿病	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Hyponatraemia	低ナトリウム血症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
Hypoproteinaemia	低蛋白血症	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Hyperlipidaemia	高脂血症	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Hyperamylasaemia	高アミラーゼ血症	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Type 2 diabetes mellitus	2型糖尿病	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Psychiatric disorders	精神障害	0(0.0)	1(0.7)	2(0.5)	2(1.0)	1(0.5)
Insomnia	不眠症	0(0.0)	0(0.0)	2(0.5)	1(0.5)	0(0.0)
Delirium	譫妄	0(0.0)	1(0.7)	0(0.0)	0(0.0)	1(0.5)
Anxiety	不安	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Nervous system disorders	神経系障害	0(0.0)	1(0.7)	1(0.3)	5(2.4)	2(1.0)
Headache	頭痛	0(0.0)	0(0.0)	0(0.0)	2(1.0)	2(1.0)
Dizziness	浮動性めまい	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Somnolence	傾眠	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Hypoaesthesia	感覚鈍麻	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)
Hypoglycaemic coma	低血糖昏睡	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Loss of consciousness	意識消失	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Eye disorders	眼障害	3(11.5)	1(0.7)	5(1.3)	3(1.4)	4(2.0)
Retinal haemorrhage	網膜出血	2(7.7)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Cataract	白内障	0(0.0)	1(0.7)	2(0.5)	0(0.0)	1(0.5)
Conjunctival haemorrhage	結膜出血	0(0.0)	0(0.0)	1(0.3)	1(0.5)	0(0.0)
Dry eye	ドライアイ	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Retinal vein occlusion	網膜静脈閉塞	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
Blepharitis	眼瞼炎	0(0.0)	0(0.0)	0(0.0)	1(0.5)	1(0.5)
Eczema eyelids	眼瞼湿疹	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Macular oedema	黄斑浮腫	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
Retinal exudates	網膜滲出物	1(3.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Age-related macular degeneration	加齢黄斑変性	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Ear and labyrinth disorders	耳および迷路障害	0(0.0)	0(0.0)	1(0.3)	1(0.5)	0(0.0)
Vertigo	回転性めまい	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Vertigo positional	頭位性回転性めまい	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Cardiac disorders	心臓障害	0(0.0)	1(0.7)	4(1.1)	2(1.0)	1(0.5)
Cardiac failure chronic	慢性心不全	0(0.0)	1(0.7)	1(0.3)	0(0.0)	1(0.5)
Palpitations	動悸	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Cardiac failure congestive	うっ血性心不全	0(0.0)	0(0.0)	1(0.3)	1(0.5)	0(0.0)
Atrial fibrillation	心房細動	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Bradycardia	徐脈	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Vascular disorders	血管障害	0(0.0)	1(0.7)	4(1.1)	2(1.0)	2(1.0)
Hypertension	高血圧	0(0.0)	0(0.0)	3(0.8)	2(1.0)	1(0.5)
Hypotension	低血圧	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
Orthostatic hypotension	起立性低血圧	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)
Vascular rupture	血管破裂	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	3(11.5)	0(0.0)	0(0.0)	4(1.9)	3(1.5)
Cough	咳嗽	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Haemoptysis	喀血	1(3.8)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Rhinitis allergic	アレルギー性鼻炎	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Asthma	喘息	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Interstitial lung disease	間質性肺疾患	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
Pleural effusion	胸水	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
Pulmonary congestion	肺うっ血	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
Pulmonary hypertension	肺高血圧症	1(3.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Reflux laryngitis	逆流性喉頭炎	1(3.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Gastrointestinal disorders	胃腸障害	6(23.0)	5(3.6)	32(8.5)	18(8.6)	16(7.8)
Diarrhoea	下痢	1(3.8)	0(0.0)	9(2.4)	6(2.9)	4(2.0)
Vomiting	嘔吐	1(3.8)	1(0.7)	5(1.3)	3(1.4)	1(0.5)
Nausea	悪心	0(0.0)	0(0.0)	3(0.8)	2(1.0)	2(1.0)
Constipation	便秘	2(7.7)	1(0.7)	4(1.1)	0(0.0)	4(2.0)
Dental caries	齲歯	0(0.0)	0(0.0)	1(0.3)	3(1.4)	0(0.0)
Abdominal discomfort	腹部不快感	0(0.0)	0(0.0)	1(0.3)	0(0.0)	1(0.5)
Abdominal pain	腹痛	0(0.0)	1(0.7)	2(0.5)	0(0.0)	0(0.0)
Stomatitis	口内炎	1(3.8)	0(0.0)	2(0.5)	0(0.0)	0(0.0)
Abdominal pain upper	上腹部痛	0(0.0)	0(0.0)	0(0.0)	1(0.5)	2(1.0)
Gastrooesophageal reflux disease	胃食道逆流性疾患	1(3.8)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Enterocolitis	腸炎	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)
Abdominal distension	腹部膨満	0(0.0)	1(0.7)	0(0.0)	1(0.5)	1(0.5)
Faeces soft	軟便	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Diverticulum intestinal	腸憩室	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Duodenal ulcer haemorrhage	出血性十二指腸潰瘍	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
Gastrointestinal disorder	胃腸障害	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Periodontal disease	歯周病	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Tooth loss	歯の脱落	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Gastrointestinal polyp haemorrhage	胃腸ポリープ出血	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Hepatobiliary disorders	肝胆道系障害	1(3.8)	0(0.0)	4(1.1)	1(0.5)	0(0.0)
Cholelithiasis	胆石症	1(3.8)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Hepatic function abnormal	肝機能異常	0(0.0)	0(0.0)	2(0.5)	0(0.0)	0(0.0)
Cholecystitis	胆嚢炎	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Hepatic cirrhosis	肝硬変	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	0(0.0)	1(0.7)	15(4.0)	4(1.9)	2(1.0)
Eczema	湿疹	0(0.0)	1(0.7)	2(0.5)	0(0.0)	0(0.0)
Dermatitis contact	接触皮膚炎	0(0.0)	0(0.0)	2(0.5)	0(0.0)	1(0.5)
Pruritus	そう痒症	0(0.0)	0(0.0)	2(0.5)	0(0.0)	0(0.0)
Haemorrhage subcutaneous	皮下出血	0(0.0)	0(0.0)	0(0.0)	2(1.0)	0(0.0)
Rash	発疹	0(0.0)	0(0.0)	2(0.5)	0(0.0)	0(0.0)
Drug eruption	薬疹	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Eczema asteatotic	皮脂欠乏性湿疹	0(0.0)	0(0.0)	2(0.5)	0(0.0)	0(0.0)
Urticaria	蕁麻疹	0(0.0)	0(0.0)	0(0.0)	1(0.5)	1(0.5)
Seborrhoeic dermatitis	脂漏性皮膚炎	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Decubitus ulcer	褥瘡性潰瘍	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Prurigo	痒疹	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Skin erosion	皮膚びらん	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Skin ulcer	皮膚潰瘍	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	1(3.8)	3(2.1)	9(2.4)	6(2.9)	3(1.5)
Back pain	背部痛	0(0.0)	1(0.7)	2(0.5)	2(1.0)	0(0.0)
Pain in extremity	四肢痛	0(0.0)	1(0.7)	2(0.5)	0(0.0)	0(0.0)
Musculoskeletal pain	筋骨格痛	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Muscle spasms	筋痙縮	0(0.0)	0(0.0)	1(0.3)	0(0.0)	2(1.0)
Arthralgia	関節痛	0(0.0)	0(0.0)	0(0.0)	2(1.0)	0(0.0)
Myalgia	筋肉痛	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Spinal osteoarthritis	変形性脊椎症	0(0.0)	0(0.0)	2(0.5)	0(0.0)	0(0.0)
Bursitis	滑液包炎	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Osteoporosis	骨粗鬆症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
Trigger finger	弾発指	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Arthritis	関節炎	1(3.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Synovial cyst	滑液嚢腫	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Renal and urinary disorders	腎および尿路障害	2(7.7)	4(2.9)	5(1.3)	9(4.3)	9(4.4)
Renal impairment	腎機能障害	1(3.8)	2(1.4)	2(0.5)	1(0.5)	2(1.0)
Chronic kidney disease	慢性腎臓病	0(0.0)	1(0.7)	2(0.5)	1(0.5)	3(1.5)
End stage renal disease	末期腎疾患	1(3.8)	0(0.0)	0(0.0)	2(1.0)	1(0.5)
Renal failure	腎不全	0(0.0)	0(0.0)	0(0.0)	2(1.0)	1(0.5)
Pollakiuria	頻尿	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)
Haematuria	血尿	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Hypertonic bladder	緊張性膀胱	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
Oliguria	乏尿	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Hypertensive nephropathy	高血圧性腎症	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Diabetic nephropathy	糖尿病性腎症	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Acute kidney injury	急性腎障害	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
Reproductive system and breast disorders	生殖系および乳房障害	0(0.0)	0(0.0)	1(0.3)	1(0.5)	1(0.5)
Benign prostatic hyperplasia	良性前立腺肥大症	0(0.0)	0(0.0)	0(0.0)	1(0.5)	1(0.5)
Nipple pain	乳頭痛	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	0(0.0)	3(2.1)	7(1.9)	9(4.3)	12(5.9)
Oedema peripheral	末梢性浮腫	0(0.0)	2(1.4)	2(0.5)	3(1.4)	5(2.4)
Pyrexia	発熱	0(0.0)	0(0.0)	1(0.3)	3(1.4)	3(1.5)
Malaise	倦怠感	0(0.0)	0(0.0)	2(0.5)	2(1.0)	1(0.5)
Oedema due to renal disease	腎疾患による浮腫	0(0.0)	1(0.7)	1(0.3)	1(0.5)	1(0.5)
Chest pain	胸痛	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Face oedema	顔面浮腫	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
Thirst	口渇	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
Investigations	臨床検査	1(3.8)	1(0.7)	9(2.4)	0(0.0)	1(0.5)
Blood pressure increased	血圧上昇	0(0.0)	0(0.0)	2(0.5)	0(0.0)	0(0.0)
Haemoglobin decreased	ヘモグロビン減少	1(3.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
C-reactive protein increased	C－反応性蛋白増加	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	0(0.0)	0(0.0)	2(0.5)	0(0.0)	0(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	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
Blood potassium decreased	血中カリウム減少	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Blood creatinine increased	血中クレアチニン増加	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)
Blood triglycerides increased	血中トリグリセリド増加	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Blood uric acid increased	血中尿酸増加	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	MT-6548 150mg Events(%)	MT-6548 300mg Events(%)	MT-6548 450mg Events(%)	MT-6548 600mg Events(%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	0(0.0)	4(2.9)	16(4.3)	6(2.9)	6(2.9)
Contusion	挫傷	0(0.0)	1(0.7)	9(2.4)	2(1.0)	0(0.0)
Shunt stenosis	シャント狭窄	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
Skin abrasion	皮膚擦過傷	0(0.0)	0(0.0)	1(0.3)	0(0.0)	1(0.5)
Wound	創傷	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Spinal compression fracture	脊椎圧迫骨折	0(0.0)	1(0.7)	2(0.5)	0(0.0)	1(0.5)
Thermal burn	熱傷	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Rib fracture	肋骨骨折	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Tooth fracture	歯牙破折	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Fall	転倒	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)
Head injury	頭部損傷	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Injury	損傷	0(0.0)	1(0.7)	0(0.0)	0(0.0)	0(0.0)
Seroma	漿液腫	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
Sternal fracture	胸骨骨折	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
Tendon rupture	腱断裂	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Skin laceration	皮膚裂傷	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Nail injury	爪損傷	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.5)
Eye contusion	眼挫傷	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Surgical and medical procedures	外科および内科処置	2(7.7)	1(0.7)	0(0.0)	0(0.0)	0(0.0)
Arteriovenous fistula operation	動静脈瘻手術	2(7.7)	1(0.7)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

	System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	MT-6548 150mg Events(%)	MT-6548 300mg Events(%)	MT-6548 450mg Events(%)	MT-6548 600mg Events(%)
HD(N=237)	Total exposure period (months)		35.9	194.7	399.0	196.3	261.2
	Number of adverse events		29(80.8)	95(48.8)	249(62.4)	134(68.3)	158(60.5)
	Infections and infestations	感染症および寄生虫症	4(11.1)	24(12.3)	58(14.5)	28(14.3)	25(9.6)
	Nasopharyngitis	上咽頭炎	3(8.4)	8(4.1)	26(6.5)	18(9.2)	13(5.0)
	Gastroenteritis	胃腸炎	0(0.0)	2(1.0)	5(1.3)	1(0.5)	2(0.8)
	Conjunctivitis	結膜炎	0(0.0)	1(0.5)	5(1.3)	2(1.0)	1(0.4)
	Pneumonia	肺炎	0(0.0)	2(1.0)	3(0.8)	1(0.5)	1(0.4)
	Upper respiratory tract infection	上気道感染	0(0.0)	0(0.0)	4(1.0)	1(0.5)	0(0.0)
	Cellulitis	蜂巣炎	1(2.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Cystitis	膀胱炎	0(0.0)	0(0.0)	0(0.0)	1(0.5)	1(0.4)
	Herpes zoster	帯状疱疹	0(0.0)	0(0.0)	2(0.5)	0(0.0)	2(0.8)
	Periodontitis	歯周炎	0(0.0)	1(0.5)	1(0.3)	1(0.5)	1(0.4)
	Bronchitis	気管支炎	0(0.0)	0(0.0)	2(0.5)	0(0.0)	0(0.0)
	Otitis media	中耳炎	0(0.0)	2(1.0)	0(0.0)	0(0.0)	0(0.0)
	Angular cheilitis	口角口唇炎	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
	Paronychia	爪囲炎	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
	Sinusitis	副鼻腔炎	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
	Upper respiratory tract infection bacterial	細菌性上気道感染	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
	Otitis media chronic	慢性中耳炎	0(0.0)	0(0.0)	1(0.3)	0(0.0)	1(0.4)
	Pharyngitis	咽頭炎	0(0.0)	1(0.5)	1(0.3)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	MT-6548 150mg Events(%)	MT-6548 300mg Events(%)	MT-6548 450mg Events(%)	MT-6548 600mg Events(%)
Tinea pedis	足部白癬	0(0.0)	1(0.5)	1(0.3)	0(0.0)	0(0.0)
Enteritis infectious	感染性腸炎	0(0.0)	1(0.5)	0(0.0)	0(0.0)	1(0.4)
Chronic sinusitis	慢性副鼻腔炎	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Epididymitis	精巣上体炎	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Furuncle	せつ	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Gastroenteritis viral	ウイルス性胃腸炎	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Gingivitis	歯肉炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Hordeolum	麦粒腫	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Skin infection	皮膚感染	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Tracheobronchitis	気管気管支炎	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Hepatic cyst infection	肝嚢胞感染	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Shunt infection	シャント感染	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Oral herpes	口腔ヘルペス	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Infected dermal cyst	感染性皮膚嚢腫	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Vascular device infection	血管デバイス感染	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	MT-6548 150mg Events(%)	MT-6548 300mg Events(%)	MT-6548 450mg Events(%)	MT-6548 600mg Events(%)
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）	0(0.0)	1(0.5)	2(0.5)	0(0.0)	2(0.8)
Breast cancer	乳癌	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Gastric cancer	胃癌	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Laryngeal papilloma	喉頭乳頭腫	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Seborrhoeic keratosis	脂漏性角化症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Skin papilloma	皮膚乳頭腫	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Blood and lymphatic system disorders	血液およびリンパ系障害	0(0.0)	0(0.0)	2(0.5)	0(0.0)	5(1.9)
Anaemia macrocytic	大球性貧血	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.8)
Anaemia	貧血	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Nephrogenic anaemia	腎性貧血	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Eosinophilia	好酸球増加症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Lymphadenitis	リンパ節炎	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Lymphadenopathy	リンパ節症	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Endocrine disorders	内分泌障害	0(0.0)	0(0.0)	2(0.5)	0(0.0)	0(0.0)
Hyperparathyroidism secondary	続発性副甲状腺機能亢進症	0(0.0)	0(0.0)	2(0.5)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Metabolism and nutrition disorders	代謝および栄養障害	1(2.8)	4(2.1)	6(1.5)	1(0.5)	0(0.0)
Decreased appetite	食欲減退	0(0.0)	1(0.5)	4(1.0)	1(0.5)	0(0.0)
Hyperkalaemia	高カリウム血症	1(2.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Hyperphosphataemia	高リン酸塩血症	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Hypoglycaemia	低血糖	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Hypocalcaemia	低カルシウム血症	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Dyslipidaemia	脂質異常症	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Hypocarnitinaemia	低カルニチン血症	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Psychiatric disorders	精神障害	0(0.0)	0(0.0)	3(0.8)	3(1.5)	2(0.8)
Insomnia	不眠症	0(0.0)	0(0.0)	2(0.5)	2(1.0)	2(0.8)
Anxiety	不安	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Abnormal behaviour	異常行動	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Nervous system disorders	神経系障害	2(5.6)	5(2.6)	10(2.5)	11(5.6)	10(3.8)
Headache	頭痛	1(2.8)	2(1.0)	5(1.3)	5(2.5)	3(1.1)
Dizziness	浮動性めまい	0(0.0)	1(0.5)	2(0.5)	1(0.5)	2(0.8)
Somnolence	傾眠	1(2.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Cerebral infarction	脳梗塞	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Carotid artery stenosis	頚動脈狭窄	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Cerebellar infarction	小脳梗塞	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Cerebral haemorrhage	脳出血	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Diabetic neuropathy	糖尿病性ニューロパチー	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Dizziness postural	体位性めまい	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Facial paralysis	顔面麻痺	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Myoclonus	ミオクローヌス	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Post herpetic neuralgia	ヘルペス後神経痛	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Sciatica	坐骨神経痛	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Toxic encephalopathy	中毒性脳症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Tremor	振戦	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Intercostal neuralgia	肋間神経痛	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Cervical radiculopathy	頚髄神経根障害	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Restless legs syndrome	下肢静止不能症候群	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	MT-6548 150mg Events(%)	MT-6548 300mg Events(%)	MT-6548 450mg Events(%)	MT-6548 600mg Events(%)
Eye disorders	眼障害	1(2.8)	3(1.5)	11(2.8)	4(2.0)	9(3.4)
Retinal haemorrhage	網膜出血	1(2.8)	1(0.5)	2(0.5)	1(0.5)	5(1.9)
Cataract	白内障	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.8)
Conjunctival haemorrhage	結膜出血	0(0.0)	0(0.0)	2(0.5)	0(0.0)	0(0.0)
Dry eye	ドライアイ	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Retinal vein occlusion	網膜静脈閉塞	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Diabetic retinopathy	糖尿病網膜症	0(0.0)	0(0.0)	1(0.3)	1(0.5)	1(0.4)
Ocular hyperaemia	眼充血	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Optic disc haemorrhage	視神経乳頭出血	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Punctate keratitis	点状角膜炎	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Retinal oedema	網膜浮腫	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Trichiasis	睫毛乱生	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Vitreous floaters	硝子体浮遊物	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Eye pruritus	眼そう痒症	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Cystoid macular oedema	嚢胞様黄斑浮腫	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Eyelid haematoma	眼瞼血腫	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Ear and labyrinth disorders	耳および迷路障害	0(0.0)	1(0.5)	2(0.5)	2(1.0)	1(0.4)
Vertigo	回転性めまい	0(0.0)	0(0.0)	1(0.3)	1(0.5)	1(0.4)
Deafness	難聴	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Sudden hearing loss	突発性難聴	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Eustachian tube stenosis	耳管狭窄	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Cardiac disorders	心臓障害	1(2.8)	0(0.0)	5(1.3)	4(2.0)	4(1.5)
Cardiac failure chronic	慢性心不全	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Palpitations	動悸	0(0.0)	0(0.0)	2(0.5)	2(1.0)	0(0.0)
Cardiac failure congestive	うっ血性心不全	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Myocardial ischaemia	心筋虚血	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.8)
Atrial fibrillation	心房細動	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Tachycardia paroxysmal	発作性頻脈	0(0.0)	0(0.0)	2(0.5)	0(0.0)	0(0.0)
Cardiac failure	心不全	1(2.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Pericarditis	心膜炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Cardiac dysfunction	心機能障害	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Vascular disorders	血管障害	2(5.6)	2(1.0)	7(1.8)	5(2.5)	3(1.1)
Hypertension	高血圧	0(0.0)	2(1.0)	1(0.3)	0(0.0)	0(0.0)
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	0(0.0)	0(0.0)	2(0.5)	1(0.5)	1(0.4)
Hypotension	低血圧	0(0.0)	0(0.0)	1(0.3)	0(0.0)	1(0.4)
Orthostatic hypotension	起立性低血圧	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Internal haemorrhage	内出血	1(2.8)	0(0.0)	1(0.3)	1(0.5)	0(0.0)
Aneurysm	動脈瘤	0(0.0)	0(0.0)	1(0.3)	1(0.5)	0(0.0)
Haemorrhage	出血	1(2.8)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Vascular pain	血管痛	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Vascular insufficiency	血行不全	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	0(0.0)	1(0.5)	8(2.0)	3(1.5)	5(1.9)
Cough	咳嗽	0(0.0)	1(0.5)	1(0.3)	0(0.0)	1(0.4)
Upper respiratory tract inflammation	上気道の炎症	0(0.0)	0(0.0)	2(0.5)	1(0.5)	0(0.0)
Haemoptysis	喀血	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Rhinitis allergic	アレルギー性鼻炎	0(0.0)	0(0.0)	1(0.3)	0(0.0)	1(0.4)
Epistaxis	鼻出血	0(0.0)	0(0.0)	2(0.5)	0(0.0)	1(0.4)
Asthma	喘息	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Sputum increased	喀痰増加	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.8)
Pulmonary oedema	肺水腫	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Sleep apnoea syndrome	睡眠時無呼吸症候群	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Gastrointestinal disorders	胃腸障害	3(5.6)	15(7.7)	44(11.0)	19(9.7)	21(8.0)
Diarrhoea	下痢	0(0.0)	6(3.1)	15(3.8)	5(2.5)	9(3.4)
Vomiting	嘔吐	0(0.0)	2(1.0)	7(1.8)	2(1.0)	1(0.4)
Nausea	悪心	0(0.0)	1(0.5)	3(0.8)	3(1.5)	1(0.4)
Constipation	便秘	0(0.0)	2(1.0)	3(0.8)	1(0.5)	0(0.0)
Dental caries	齲歯	0(0.0)	0(0.0)	2(0.5)	0(0.0)	0(0.0)
Abdominal discomfort	腹部不快感	0(0.0)	0(0.0)	2(0.5)	1(0.5)	0(0.0)
Abdominal pain	腹痛	0(0.0)	0(0.0)	2(0.5)	0(0.0)	1(0.4)
Stomatitis	口内炎	0(0.0)	0(0.0)	2(0.5)	1(0.5)	0(0.0)
Gastrooesophageal reflux disease	胃食道逆流性疾患	1(2.8)	0(0.0)	1(0.3)	1(0.5)	1(0.4)
Enterocolitis	腸炎	0(0.0)	1(0.5)	0(0.0)	1(0.5)	1(0.4)
Faeces soft	軟便	0(0.0)	1(0.5)	1(0.3)	0(0.0)	0(0.0)
Diverticulum intestinal	腸憩室	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Duodenal ulcer haemorrhage	出血性十二指腸潰瘍	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Toothache	歯痛	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.8)
Dry mouth	口内乾燥	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Duodenal ulcer	十二指腸潰瘍	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Dyspepsia	消化不良	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Gastric ulcer	胃潰瘍	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Gastric ulcer haemorrhage	出血性胃潰瘍	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Gastritis	胃炎	1(2.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Gastritis erosive	びらん性胃炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Glossitis	舌炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Haemorrhoids	痔核	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Melaena	メレナ	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Mouth haemorrhage	口腔内出血	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Pancreatitis	膵炎	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Large intestine polyp	大腸ポリープ	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Gastric disorder	胃障害	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Gastrointestinal motility disorder	消化管運動障害	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Loose tooth	弛緩歯	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Hepatobiliary disorders	肝胆道系障害	1(2.8)	0(0.0)	5(1.3)	0(0.0)	0(0.0)
Cholelithiasis	胆石症	0(0.0)	0(0.0)	3(0.8)	0(0.0)	0(0.0)
Cholecystitis	胆嚢炎	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Cholangitis	胆管炎	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Cholecystitis acute	急性胆嚢炎	1(2.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	MT-6548 150mg Events(%)	MT-6548 300mg Events(%)	MT-6548 450mg Events(%)	MT-6548 600mg Events(%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	1(2.8)	13(6.7)	20(5.0)	5(2.5)	15(5.7)
Eczema	湿疹	1(2.8)	2(1.0)	4(1.0)	1(0.5)	1(0.4)
Dermatitis contact	接触皮膚炎	0(0.0)	1(0.5)	2(0.5)	0(0.0)	2(0.8)
Pruritus	そう痒症	0(0.0)	1(0.5)	4(1.0)	0(0.0)	3(1.1)
Haemorrhage subcutaneous	皮下出血	0(0.0)	1(0.5)	0(0.0)	1(0.5)	3(1.1)
Rash	発疹	0(0.0)	0(0.0)	3(0.8)	0(0.0)	0(0.0)
Drug eruption	薬疹	0(0.0)	0(0.0)	2(0.5)	0(0.0)	2(0.8)
Ingrowing nail	嵌入爪	0(0.0)	1(0.5)	1(0.3)	1(0.5)	1(0.4)
Skin exfoliation	皮膚剥脱	0(0.0)	3(1.5)	0(0.0)	0(0.0)	0(0.0)
Seborrhoeic dermatitis	脂漏性皮膚炎	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Cold sweat	冷汗	0(0.0)	0(0.0)	2(0.5)	0(0.0)	0(0.0)
Dermal cyst	皮膚嚢腫	0(0.0)	1(0.5)	0(0.0)	0(0.0)	1(0.4)
Alopecia	脱毛症	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Dermatitis acneiform	ざ瘡様皮膚炎	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Hyperkeratosis	過角化	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Neurodermatitis	神経皮膚炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Rash pruritic	そう痒性皮疹	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Skin disorder	皮膚障害	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Xeroderma	乾皮症	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Skin mass	皮膚腫瘤	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	3(8.4)	11(5.7)	23(5.8)	12(6.1)	16(6.1)
Back pain	背部痛	1(2.8)	2(1.0)	3(0.8)	3(1.5)	1(0.4)
Pain in extremity	四肢痛	1(2.8)	2(1.0)	3(0.8)	1(0.5)	2(0.8)
Musculoskeletal pain	筋骨格痛	0(0.0)	1(0.5)	3(0.8)	3(1.5)	2(0.8)
Muscle spasms	筋痙縮	0(0.0)	1(0.5)	2(0.5)	1(0.5)	2(0.8)
Arthralgia	関節痛	0(0.0)	1(0.5)	1(0.3)	2(1.0)	1(0.4)
Myalgia	筋肉痛	0(0.0)	1(0.5)	3(0.8)	0(0.0)	2(0.8)
Spinal osteoarthritis	変形性脊椎症	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Neck pain	頸部痛	1(2.8)	1(0.5)	0(0.0)	0(0.0)	1(0.4)
Osteoarthritis	変形性関節症	0(0.0)	0(0.0)	1(0.3)	1(0.5)	1(0.4)
Bursitis	滑液包炎	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Osteoporosis	骨粗鬆症	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Trigger finger	弾発指	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Lumbar spinal stenosis	腰部脊柱管狭窄症	0(0.0)	0(0.0)	2(0.5)	0(0.0)	0(0.0)
Periarthritis	関節周囲炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.8)
Tenosynovitis	腱鞘炎	0(0.0)	0(0.0)	1(0.3)	1(0.5)	0(0.0)
Chondrocalcinosis pyrophosphate	ピロリン酸カルシウム結晶性軟骨石灰化症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Haemarthrosis	出血性関節症	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Musculoskeletal stiffness	筋骨格硬直	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Musculoskeletal discomfort	筋骨格不快感	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	 150mg Events(%)	 300mg Events(%)	 450mg Events(%)	 600mg Events(%)
Renal and urinary disorders	腎および尿路障害	0(0.0)	0(0.0)	1(0.3)	1(0.5)	0(0.0)
Pollakiuria	頻尿	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Ureterolithiasis	尿管結石症	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Reproductive system and breast disorders	生殖系および乳房障害	0(0.0)	0(0.0)	1(0.3)	3(1.5)	0(0.0)
Benign prostatic hyperplasia	良性前立腺肥大症	0(0.0)	0(0.0)	0(0.0)	2(1.0)	0(0.0)
Acquired hydrocele	後天性陰嚢水瘤	0(0.0)	0(0.0)	1(0.3)	1(0.5)	0(0.0)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	1(2.8)	1(0.5)	6(1.5)	2(1.0)	5(1.9)
Oedema peripheral	末梢性浮腫	1(2.8)	0(0.0)	1(0.3)	0(0.0)	3(1.1)
Pyrexia	発熱	0(0.0)	1(0.5)	2(0.5)	0(0.0)	2(0.8)
Chest discomfort	胸部不快感	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Feeling abnormal	異常感	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Injection site reaction	注射部位反応	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Peripheral swelling	末梢腫脹	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Puncture site haemorrhage	穿刺部位出血	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	MT-6548 150mg Events(%)	MT-6548 300mg Events(%)	MT-6548 450mg Events(%)	MT-6548 600mg Events(%)
Investigations	臨床検査	2(5.6)	1(0.5)	8(2.0)	2(1.0)	4(1.5)
Blood pressure increased	血圧上昇	0(0.0)	0(0.0)	1(0.3)	1(0.5)	0(0.0)
Haemoglobin decreased	ヘモグロビン減少	1(2.8)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
C-reactive protein increased	C－反応性蛋白増加	0(0.0)	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Blood pressure decreased	血圧低下	0(0.0)	0(0.0)	2(0.5)	0(0.0)	1(0.4)
Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Salmonella test positive	サルモネラ検査陽性	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.8)
Blood parathyroid hormone increased	血中副甲状腺ホルモン増加	1(2.8)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Blood uric acid decreased	血中尿酸減少	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Blood urine present	尿中血陽性	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Prostatic specific antigen increased	前立腺特異性抗原増加	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Serum ferritin decreased	血清フェリチン減少	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Transferrin saturation decreased	トランスフェリン飽和度低下	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	MT-6548 150mg Events(%)	MT-6548 300mg Events(%)	MT-6548 450mg Events(%)	MT-6548 600mg Events(%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	8(22.3)	13(6.7)	25(6.3)	29(14.8)	31(11.9)
Contusion	挫傷	2(5.6)	3(1.5)	4(1.0)	6(3.1)	4(1.5)
Shunt stenosis	シャント狭窄	1(2.8)	4(2.1)	9(2.3)	5(2.5)	7(2.7)
Skin abrasion	皮膚擦過傷	2(5.6)	1(0.5)	1(0.3)	2(1.0)	4(1.5)
Wound	創傷	0(0.0)	1(0.5)	1(0.3)	3(1.5)	0(0.0)
Shunt occlusion	シャント閉塞	0(0.0)	2(1.0)	0(0.0)	1(0.5)	2(0.8)
Limb injury	四肢損傷	2(5.6)	0(0.0)	2(0.5)	0(0.0)	1(0.4)
Thermal burn	熱傷	0(0.0)	0(0.0)	1(0.3)	1(0.5)	1(0.4)
Arteriovenous fistula site complication	動静脈瘻部位合併症	0(0.0)	0(0.0)	0(0.0)	1(0.5)	2(0.8)
Procedural hypotension	処置による低血圧	0(0.0)	0(0.0)	0(0.0)	2(1.0)	1(0.4)
Rib fracture	肋骨骨折	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Ligament sprain	靱帯捻挫	1(2.8)	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Subcutaneous haematoma	皮下血腫	0(0.0)	0(0.0)	1(0.3)	0(0.0)	1(0.4)
Joint injury	関節損傷	0(0.0)	0(0.0)	1(0.3)	1(0.5)	0(0.0)
Shunt blood flow excessive	シャント血流過剰	0(0.0)	0(0.0)	0(0.0)	1(0.5)	1(0.4)
Skin wound	皮膚創傷	0(0.0)	0(0.0)	1(0.3)	1(0.5)	0(0.0)
Vascular access malfunction	血管アクセス機能不全	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.8)
Dental restoration failure	歯科修復不成功	0(0.0)	1(0.5)	1(0.3)	0(0.0)	0(0.0)
Animal bite	動物咬傷	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Clavicle fracture	鎖骨骨折	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Foot fracture	足骨折	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Tooth injury	歯牙損傷	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Arteriovenous graft site stenosis	動静脈グラフト部位狭窄	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
Arteriovenous fistula occlusion	動静脈瘻閉塞	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Pelvic fracture	骨盤骨折	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Vascular access complication	血管確保合併症	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Procedural hypertension	処置による高血圧	0(0.0)	0(0.0)	0(0.0)	1(0.5)	0(0.0)
Heat illness	熱中症	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Vascular access site inflammation	血管確保部位炎症	0(0.0)	0(0.0)	1(0.3)	0(0.0)	0(0.0)
Soft tissue foreign body	軟部組織内異物	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.4)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

	System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	MT-6548 150mg Events(%)	MT-6548 300mg Events(%)	MT-6548 450mg Events(%)	MT-6548 600mg Events(%)
PD(N=42)	Total exposure period (months)		12.3	34.6	69.8	41.7	55.8
	Number of adverse events		10(81.4)	17(49.1)	47(67.3)	29(69.6)	35(62.7)
	Infections and infestations	感染症および寄生虫症	3(24.4)	4(11.6)	9(12.9)	9(21.6)	9(16.1)
	Nasopharyngitis	上咽頭炎	1(8.1)	3(8.7)	1(1.4)	1(2.4)	1(1.8)
	Conjunctivitis	結膜炎	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
	Pneumonia	肺炎	1(8.1)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Catheter site infection	カテーテル留置部位感染	0(0.0)	1(2.9)	2(2.9)	5(12.0)	3(5.4)
	Upper respiratory tract infection	上気道感染	0(0.0)	0(0.0)	2(2.9)	0(0.0)	0(0.0)
	Cellulitis	蜂巣炎	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
	Peritonitis	腹膜炎	1(8.1)	0(0.0)	1(1.4)	0(0.0)	3(5.4)
	Bronchitis	気管支炎	0(0.0)	0(0.0)	1(1.4)	0(0.0)	0(0.0)
	Body tinea	体部白癬	0(0.0)	0(0.0)	1(1.4)	0(0.0)	0(0.0)
	Diverticulitis	憩室炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
	Folliculitis	毛包炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
	Sepsis	敗血症	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
	Helicobacter infection	ヘリコバクター感染	0(0.0)	0(0.0)	1(1.4)	0(0.0)	0(0.0)
	Blood and lymphatic system disorders	血液およびリンパ系障害	1(8.1)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
	Anaemia	貧血	1(8.1)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
	Nephrogenic anaemia	腎性貧血	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	MT-6548 150mg Events(%)	MT-6548 300mg Events(%)	MT-6548 450mg Events(%)	MT-6548 600mg Events(%)
Metabolism and nutrition disorders	代謝および栄養障害	0(0.0)	1(2.9)	4(5.7)	3(7.2)	1(1.8)
Decreased appetite	食欲減退	0(0.0)	1(2.9)	2(2.9)	0(0.0)	0(0.0)
Dehydration	脱水	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
Hyperphosphataemia	高リン酸塩血症	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
Hypokalaemia	低カリウム血症	0(0.0)	0(0.0)	2(2.9)	0(0.0)	0(0.0)
Fluid overload	水分過負荷	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Hypoalbuminaemia	低アルブミン血症	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
Psychiatric disorders	精神障害	1(8.1)	0(0.0)	3(4.3)	0(0.0)	0(0.0)
Insomnia	不眠症	1(8.1)	0(0.0)	1(1.4)	0(0.0)	0(0.0)
Sleep disorder	睡眠障害	0(0.0)	0(0.0)	2(2.9)	0(0.0)	0(0.0)
Nervous system disorders	神経系障害	1(8.1)	0(0.0)	2(2.9)	1(2.4)	1(1.8)
Dizziness	浮動性めまい	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Cerebral infarction	脳梗塞	1(8.1)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Dizziness exertional	労作性めまい	0(0.0)	0(0.0)	1(1.4)	0(0.0)	0(0.0)
Dysgeusia	味覚異常	0(0.0)	0(0.0)	1(1.4)	0(0.0)	0(0.0)
Neuropathy peripheral	末梢性ニューロパチー	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	 150mg Events(%)	 300mg Events(%)	 450mg Events(%)	 600mg Events(%)
Eye disorders	眼障害	0(0.0)	0(0.0)	1(1.4)	2(4.8)	4(7.2)
Retinal haemorrhage	網膜出血	0(0.0)	0(0.0)	1(1.4)	0(0.0)	1(1.8)
Dry eye	ドライアイ	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
Retinal vein occlusion	網膜静脈閉塞	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Macular degeneration	黄斑変性	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Meibomian gland dysfunction	マイボーム腺機能不全	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
Macular fibrosis	黄斑線維症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Cardiac disorders	心臓障害	0(0.0)	0(0.0)	0(0.0)	1(2.4)	1(1.8)
Cardiac failure chronic	慢性心不全	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Myocardial ischaemia	心筋虚血	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
Vascular disorders	血管障害	1(8.1)	1(2.9)	3(4.3)	1(2.4)	1(1.8)
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	1(8.1)	0(0.0)	2(2.9)	0(0.0)	0(0.0)
Hypotension	低血圧	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Orthostatic hypotension	起立性低血圧	0(0.0)	1(2.9)	0(0.0)	0(0.0)	0(0.0)
Arteriosclerosis	動脈硬化症	0(0.0)	0(0.0)	1(1.4)	1(2.4)	0(0.0)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	0(0.0)	0(0.0)	1(1.4)	2(4.8)	0(0.0)
Cough	咳嗽	0(0.0)	0(0.0)	1(1.4)	1(2.4)	0(0.0)
Upper respiratory tract inflammation	上気道の炎症	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	MT-6548 150mg Events(%)	MT-6548 300mg Events(%)	MT-6548 450mg Events(%)	MT-6548 600mg Events(%)
Gastrointestinal disorders	胃腸障害	1(8.1)	5(14.5)	16(22.9)	2(4.8)	9(16.1)
Diarrhoea	下痢	1(8.1)	0(0.0)	5(7.2)	1(2.4)	2(3.6)
Vomiting	嘔吐	0(0.0)	0(0.0)	2(2.9)	0(0.0)	2(3.6)
Nausea	悪心	0(0.0)	0(0.0)	2(2.9)	0(0.0)	2(3.6)
Constipation	便秘	0(0.0)	0(0.0)	1(1.4)	0(0.0)	0(0.0)
Dental caries	齲歯	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Abdominal discomfort	腹部不快感	0(0.0)	1(2.9)	1(1.4)	0(0.0)	0(0.0)
Abdominal pain upper	上腹部痛	0(0.0)	1(2.9)	0(0.0)	1(2.4)	1(1.8)
Enterocolitis	腸炎	0(0.0)	0(0.0)	2(2.9)	0(0.0)	0(0.0)
Gastric polyps	胃ポリープ	0(0.0)	2(5.8)	1(1.4)	0(0.0)	0(0.0)
Gingival bleeding	歯肉出血	0(0.0)	0(0.0)	1(1.4)	0(0.0)	0(0.0)
Hiatus hernia	裂孔ヘルニア	0(0.0)	1(2.9)	0(0.0)	0(0.0)	0(0.0)
Inguinal hernia	鼠径ヘルニア	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Traumatic occlusion	外傷性咬合	0(0.0)	0(0.0)	1(1.4)	0(0.0)	0(0.0)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	0(0.0)	0(0.0)	2(2.9)	2(4.8)	1(1.8)
Dermatitis contact	接触皮膚炎	0(0.0)	0(0.0)	0(0.0)	1(2.4)	1(1.8)
Rash	発疹	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
Dermatitis	皮膚炎	0(0.0)	0(0.0)	1(1.4)	0(0.0)	0(0.0)
Hand dermatitis	手皮膚炎	0(0.0)	0(0.0)	1(1.4)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	0(0.0)	3(8.7)	0(0.0)	0(0.0)	2(3.6)
Back pain	背部痛	0(0.0)	1(2.9)	0(0.0)	0(0.0)	1(1.8)
Arthralgia	関節痛	0(0.0)	2(5.8)	0(0.0)	0(0.0)	0(0.0)
Arthritis	関節炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Renal and urinary disorders	腎および尿路障害	0(0.0)	1(2.9)	0(0.0)	1(2.4)	1(1.8)
Renal impairment	腎機能障害	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Haematuria	血尿	0(0.0)	1(2.9)	0(0.0)	0(0.0)	0(0.0)
Azotaemia	高窒素血症	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
Reproductive system and breast disorders	生殖系および乳房障害	1(8.1)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Acquired hydrocele	後天性陰嚢水瘤	1(8.1)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	0(0.0)	0(0.0)	4(5.7)	0(0.0)	3(5.4)
Pyrexia	発熱	0(0.0)	0(0.0)	2(2.9)	0(0.0)	0(0.0)
Oedema due to renal disease	腎疾患による浮腫	0(0.0)	0(0.0)	1(1.4)	0(0.0)	0(0.0)
Chest pain	胸痛	0(0.0)	0(0.0)	1(1.4)	0(0.0)	0(0.0)
Catheter site granuloma	カテーテル留置部位肉芽腫	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(3.6)
Catheter site haemorrhage	カテーテル留置部位出血	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Investigations	臨床検査	0(0.0)	2(5.8)	0(0.0)	1(2.4)	1(1.8)
C-reactive protein increased	C－反応性蛋白増加	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
Blood potassium decreased	血中カリウム減少	0(0.0)	1(2.9)	0(0.0)	0(0.0)	0(0.0)
Weight decreased	体重減少	0(0.0)	1(2.9)	0(0.0)	0(0.0)	0(0.0)
Optic nerve cup/disc ratio increased	視神経乳頭陥凹／乳頭比増加	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	1(8.1)	0(0.0)	2(2.9)	3(7.2)	1(1.8)
Contusion	挫傷	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
Shunt occlusion	シャント閉塞	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
Tooth fracture	歯牙破折	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(1.8)
Peritoneal dialysis complication	腹膜透析合併症	0(0.0)	0(0.0)	2(2.9)	0(0.0)	0(0.0)
Heat stroke	熱射病	0(0.0)	0(0.0)	0(0.0)	1(2.4)	0(0.0)
Traumatic haemothorax	外傷性血胸	1(8.1)	0(0.0)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

	System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	MT-6548 150mg Events(%)	MT-6548 300mg Events(%)	MT-6548 450mg Events(%)	MT-6548 600mg Events(%)
Total(N=481)	Total exposure period (months)		74.3	369.1	844.3	448.5	521.4
	Number of adverse events		64(86.2)	151(40.9)	456(54.0)	264(58.9)	276(52.9)
	Infections and infestations	感染症および寄生虫症	11(14.8)	36(9.8)	100(11.8)	56(12.5)	50(9.6)
	Nasopharyngitis	上咽頭炎	4(5.4)	13(3.5)	38(4.5)	29(6.5)	21(4.0)
	Gastroenteritis	胃腸炎	0(0.0)	3(0.8)	5(0.6)	2(0.4)	3(0.6)
	Conjunctivitis	結膜炎	0(0.0)	1(0.3)	6(0.7)	5(1.1)	1(0.2)
	Pneumonia	肺炎	1(1.3)	2(0.5)	4(0.5)	2(0.4)	2(0.4)
	Catheter site infection	カテーテル留置部位感染	0(0.0)	1(0.3)	2(0.2)	5(1.1)	3(0.6)
	Upper respiratory tract infection	上気道感染	1(1.3)	0(0.0)	6(0.7)	2(0.4)	0(0.0)
	Cellulitis	蜂巣炎	2(2.7)	0(0.0)	3(0.4)	1(0.2)	1(0.2)
	Influenza	インフルエンザ	0(0.0)	2(0.5)	3(0.4)	0(0.0)	1(0.2)
	Cystitis	膀胱炎	0(0.0)	0(0.0)	3(0.4)	2(0.4)	1(0.2)
	Herpes zoster	帯状疱疹	0(0.0)	0(0.0)	2(0.2)	2(0.4)	2(0.4)
	Urinary tract infection	尿路感染	0(0.0)	0(0.0)	3(0.4)	1(0.2)	1(0.2)
	Periodontitis	歯周炎	0(0.0)	2(0.5)	1(0.1)	1(0.2)	1(0.2)
	Peritonitis	腹膜炎	1(1.3)	0(0.0)	1(0.1)	0(0.0)	3(0.6)
	Bronchitis	気管支炎	0(0.0)	0(0.0)	4(0.5)	0(0.0)	0(0.0)
	Renal cyst infection	腎嚢胞感染	0(0.0)	0(0.0)	2(0.2)	0(0.0)	1(0.2)
	Otitis media	中耳炎	0(0.0)	2(0.5)	1(0.1)	0(0.0)	0(0.0)
	Angular cheilitis	口角口唇炎	0(0.0)	1(0.3)	0(0.0)	1(0.2)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Paronychia	爪囲炎	1(1.3)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Sinusitis	副鼻腔炎	0(0.0)	0(0.0)	1(0.1)	1(0.2)	0(0.0)
Upper respiratory tract infection bacterial	細菌性上気道感染	0(0.0)	1(0.3)	1(0.1)	0(0.0)	0(0.0)
Body tinea	体部白癬	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)
Otitis media chronic	慢性中耳炎	0(0.0)	0(0.0)	1(0.1)	0(0.0)	1(0.2)
Pharyngitis	咽頭炎	0(0.0)	1(0.3)	1(0.1)	0(0.0)	0(0.0)
Tinea pedis	足部白癬	0(0.0)	1(0.3)	1(0.1)	0(0.0)	0(0.0)
Enteritis infectious	感染性腸炎	0(0.0)	1(0.3)	0(0.0)	0(0.0)	1(0.2)
Herpes simplex	単純ヘルペス	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Osteomyelitis	骨髄炎	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Otitis externa	外耳炎	1(1.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Pneumonia chlamydial	クラミジア性肺炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Pyelonephritis	腎盂腎炎	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Lung infection	肺感染	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Chronic sinusitis	慢性副鼻腔炎	0(0.0)	1(0.3)	0(0.0)	0(0.0)	0(0.0)
Epididymitis	精巣上体炎	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Furuncle	せつ	0(0.0)	1(0.3)	0(0.0)	0(0.0)	0(0.0)
Gastroenteritis viral	ウイルス性胃腸炎	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Gingivitis	歯肉炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Hordeolum	麦粒腫	0(0.0)	1(0.3)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Skin infection	皮膚感染	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Tracheobronchitis	気管気管支炎	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Hepatic cyst infection	肝嚢胞感染	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Shunt infection	シャント感染	0(0.0)	1(0.3)	0(0.0)	0(0.0)	0(0.0)
Oral herpes	口腔ヘルペス	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Infected dermal cyst	感染性皮膚嚢腫	0(0.0)	1(0.3)	0(0.0)	0(0.0)	0(0.0)
Vascular device infection	血管デバイス感染	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Diverticulitis	憩室炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Folliculitis	毛包炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Sepsis	敗血症	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Helicobacter infection	ヘリコバクター感染	0(0.0)	0(0.0)	1(0.1)	0(0.0)	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）	0(0.0)	1(0.3)	2(0.2)	1(0.2)	2(0.4)
Oral papilloma	口腔乳頭腫	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Breast cancer	乳癌	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Gastric cancer	胃癌	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Laryngeal papilloma	喉頭乳頭腫	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Seborrhoeic keratosis	脂漏性角化症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Skin papilloma	皮膚乳頭腫	0(0.0)	1(0.3)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Blood and lymphatic system disorders	血液およびリンパ系障害	1(1.3)	0(0.0)	2(0.2)	2(0.4)	6(1.2)
Iron deficiency anaemia	鉄欠乏性貧血	0(0.0)	0(0.0)	0(0.0)	1(0.2)	1(0.2)
Anaemia macrocytic	大球性貧血	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.4)
Anaemia	貧血	1(1.3)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Nephrogenic anaemia	腎性貧血	0(0.0)	0(0.0)	0(0.0)	1(0.2)	1(0.2)
Eosinophilia	好酸球増加症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Lymphadenitis	リンパ節炎	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Lymphadenopathy	リンパ節症	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Immune system disorders	免疫系障害	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)
Allergy to arthropod sting	節足動物刺傷アレルギー	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Allergy to arthropod bite	節足動物咬傷アレルギー	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Endocrine disorders	内分泌障害	1(1.3)	1(0.3)	2(0.2)	0(0.0)	0(0.0)
Hyperparathyroidism secondary	続発性副甲状腺機能亢進症	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)
Hypothyroidism	甲状腺機能低下症	1(1.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Parathyroid gland enlargement	副甲状腺肥大	0(0.0)	1(0.3)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Metabolism and nutrition disorders	代謝および栄養障害	2(2.7)	8(2.2)	20(2.4)	11(2.5)	4(0.8)
Decreased appetite	食欲減退	0(0.0)	2(0.5)	9(1.1)	1(0.2)	0(0.0)
Hyperkalaemia	高カリウム血症	1(1.3)	1(0.3)	1(0.1)	1(0.2)	1(0.2)
Dehydration	脱水	1(1.3)	0(0.0)	1(0.1)	2(0.4)	0(0.0)
Hyperphosphataemia	高リン酸塩血症	0(0.0)	2(0.5)	1(0.1)	1(0.2)	0(0.0)
Hypoglycaemia	低血糖	0(0.0)	2(0.5)	1(0.1)	0(0.0)	0(0.0)
Hyperuricaemia	高尿酸血症	0(0.0)	0(0.0)	1(0.1)	1(0.2)	0(0.0)
Metabolic acidosis	代謝性アシドーシス	0(0.0)	0(0.0)	1(0.1)	0(0.0)	1(0.2)
Hypokalaemia	低カリウム血症	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)
Diabetes mellitus	糖尿病	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Hyponatraemia	低ナトリウム血症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Hypoproteinaemia	低蛋白血症	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Hyperlipidaemia	高脂血症	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Hyperamylasaemia	高アミラーゼ血症	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Type 2 diabetes mellitus	2型糖尿病	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Hypocalcaemia	低カルシウム血症	0(0.0)	1(0.3)	0(0.0)	0(0.0)	0(0.0)
Dyslipidaemia	脂質異常症	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Hypocarnitinaemia	低カルニチン血症	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Fluid overload	水分過負荷	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Hypoalbuminaemia	低アルブミン血症	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Psychiatric disorders	精神障害	1(1.3)	1(0.3)	8(0.9)	5(1.1)	3(0.6)
Insomnia	不眠症	1(1.3)	0(0.0)	5(0.6)	3(0.7)	2(0.4)
Delirium	譫妄	0(0.0)	1(0.3)	0(0.0)	0(0.0)	1(0.2)
Anxiety	不安	0(0.0)	0(0.0)	0(0.0)	2(0.4)	0(0.0)
Sleep disorder	睡眠障害	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)
Abnormal behaviour	異常行動	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Nervous system disorders	神経系障害	3(4.0)	6(1.6)	13(1.5)	17(3.8)	13(2.5)
Headache	頭痛	1(1.3)	2(0.5)	5(0.6)	7(1.6)	5(1.0)
Dizziness	浮動性めまい	0(0.0)	1(0.3)	2(0.2)	2(0.4)	3(0.6)
Somnolence	傾眠	1(1.3)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Cerebral infarction	脳梗塞	1(1.3)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Hypoaesthesia	感覚鈍麻	0(0.0)	1(0.3)	0(0.0)	0(0.0)	0(0.0)
Hypoglycaemic coma	低血糖昏睡	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Loss of consciousness	意識消失	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Carotid artery stenosis	頸動脈狭窄	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Cerebellar infarction	小脳梗塞	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Cerebral haemorrhage	脳出血	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Diabetic neuropathy	糖尿病性ニューロパチー	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Dizziness postural	体位性めまい	0(0.0)	1(0.3)	0(0.0)	0(0.0)	0(0.0)
Facial paralysis	顔面麻痺	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Myoclonus	ミオクローヌス	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Post herpetic neuralgia	ヘルペス後神経痛	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Sciatica	坐骨神経痛	0(0.0)	1(0.3)	0(0.0)	0(0.0)	0(0.0)
Toxic encephalopathy	中毒性脳症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Tremor	振戦	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Intercostal neuralgia	肋間神経痛	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Cervical radiculopathy	頸髄神経根障害	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Restless legs syndrome	下肢静止不能症候群	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Dizziness exertional	労作性めまい	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Dysgeusia	味覚異常	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Neuropathy peripheral	末梢性ニューロパチー	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Eye disorders	眼障害	4(5.4)	4(1.1)	17(2.0)	9(2.0)	17(3.3)
Retinal haemorrhage	網膜出血	3(4.0)	1(0.3)	3(0.4)	1(0.2)	6(1.2)
Cataract	白内障	0(0.0)	1(0.3)	2(0.2)	0(0.0)	3(0.6)
Conjunctival haemorrhage	結膜出血	0(0.0)	0(0.0)	3(0.4)	1(0.2)	0(0.0)
Dry eye	ドライアイ	0(0.0)	0(0.0)	1(0.1)	2(0.4)	0(0.0)
Retinal vein occlusion	網膜静脈閉塞	0(0.0)	0(0.0)	1(0.1)	0(0.0)	2(0.4)
Diabetic retinopathy	糖尿病網膜症	0(0.0)	0(0.0)	1(0.1)	1(0.2)	1(0.2)
Blepharitis	眼瞼炎	0(0.0)	0(0.0)	0(0.0)	1(0.2)	1(0.2)
Eczema eyelids	眼瞼湿疹	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Macular oedema	黄斑浮腫	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Retinal exudates	網膜滲出物	1(1.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Age-related macular degeneration	加齢黄斑変性	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Ocular hyperaemia	眼充血	0(0.0)	1(0.3)	0(0.0)	0(0.0)	0(0.0)
Optic disc haemorrhage	視神経乳頭出血	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Punctate keratitis	点状角膜炎	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Retinal oedema	網膜浮腫	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Trichiasis	睫毛乱生	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Vitreous floaters	硝子体浮遊物	0(0.0)	1(0.3)	0(0.0)	0(0.0)	0(0.0)
Eye pruritus	眼そう痒症	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Cystoid macular oedema	嚢胞様黄斑浮腫	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Eyelid haematoma	眼瞼血腫	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Macular degeneration	黄斑変性	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Meibomian gland dysfunction	マイボーム腺機能不全	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Macular fibrosis	黄斑線維症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Ear and labyrinth disorders	耳および迷路障害	0(0.0)	1(0.3)	3(0.4)	3(0.7)	1(0.2)
Vertigo	回転性めまい	0(0.0)	0(0.0)	2(0.2)	1(0.2)	1(0.2)
Vertigo positional	頭位性回転性めまい	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Deafness	難聴	0(0.0)	1(0.3)	0(0.0)	0(0.0)	0(0.0)
Sudden hearing loss	突発性難聴	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Eustachian tube stenosis	耳管狭窄	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Cardiac disorders	心臓障害	1(1.3)	1(0.3)	9(1.1)	7(1.6)	6(1.2)
Cardiac failure chronic	慢性心不全	0(0.0)	1(0.3)	1(0.1)	0(0.0)	3(0.6)
Palpitations	動悸	0(0.0)	0(0.0)	3(0.4)	2(0.4)	0(0.0)
Cardiac failure congestive	うっ血性心不全	0(0.0)	0(0.0)	1(0.1)	2(0.4)	0(0.0)
Myocardial ischaemia	心筋虚血	0(0.0)	0(0.0)	0(0.0)	1(0.2)	2(0.4)
Atrial fibrillation	心房細動	0(0.0)	0(0.0)	0(0.0)	2(0.4)	0(0.0)
Tachycardia paroxysmal	発作性頻脈	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)
Bradycardia	徐脈	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Cardiac failure	心不全	1(1.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Pericarditis	心膜炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Cardiac dysfunction	心機能障害	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Vascular disorders	血管障害	3(4.0)	4(1.1)	14(1.7)	8(1.8)	6(1.2)
Hypertension	高血圧	0(0.0)	2(0.5)	4(0.5)	2(0.4)	1(0.2)
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	1(1.3)	0(0.0)	4(0.5)	1(0.2)	1(0.2)
Hypotension	低血圧	0(0.0)	0(0.0)	1(0.1)	0(0.0)	3(0.6)
Orthostatic hypotension	起立性低血圧	0(0.0)	2(0.5)	0(0.0)	1(0.2)	0(0.0)
Internal haemorrhage	内出血	1(1.3)	0(0.0)	1(0.1)	1(0.2)	0(0.0)
Aneurysm	動脈瘤	0(0.0)	0(0.0)	1(0.1)	1(0.2)	0(0.0)
Haemorrhage	出血	1(1.3)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Arteriosclerosis	動脈硬化症	0(0.0)	0(0.0)	1(0.1)	1(0.2)	0(0.0)
Vascular rupture	血管破裂	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Vascular pain	血管痛	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Vascular insufficiency	血行不全	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	3(4.0)	1(0.3)	9(1.1)	9(2.0)	8(1.5)
Cough	咳嗽	0(0.0)	1(0.3)	2(0.2)	2(0.4)	1(0.2)
Upper respiratory tract inflammation	上気道の炎症	0(0.0)	0(0.0)	2(0.2)	2(0.4)	0(0.0)
Haemoptysis	喀血	1(1.3)	0(0.0)	1(0.1)	1(0.2)	0(0.0)
Rhinitis allergic	アレルギー性鼻炎	0(0.0)	0(0.0)	1(0.1)	1(0.2)	1(0.2)
Epistaxis	鼻出血	0(0.0)	0(0.0)	2(0.2)	0(0.0)	1(0.2)
Asthma	喘息	0(0.0)	0(0.0)	0(0.0)	2(0.4)	0(0.0)
Sputum increased	喀痰増加	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.4)
Interstitial lung disease	間質性肺疾患	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Pleural effusion	胸水	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Pulmonary congestion	肺うっ血	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Pulmonary hypertension	肺高血圧症	1(1.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Reflux laryngitis	逆流性喉頭炎	1(1.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Pulmonary oedema	肺水腫	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Sleep apnoea syndrome	睡眠時無呼吸症候群	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Gastrointestinal disorders	胃腸障害	9(12.1)	25(6.8)	92(10.9)	39(8.7)	46(8.8)
Diarrhoea	下痢	2(2.7)	6(1.6)	29(3.4)	12(2.7)	15(2.9)
Vomiting	嘔吐	1(1.3)	3(0.8)	14(1.7)	5(1.1)	4(0.8)
Nausea	悪心	0(0.0)	1(0.3)	8(0.9)	5(1.1)	5(1.0)
Constipation	便秘	2(2.7)	3(0.8)	8(0.9)	1(0.2)	4(0.8)
Dental caries	齲歯	0(0.0)	0(0.0)	3(0.4)	3(0.7)	1(0.2)
Abdominal discomfort	腹部不快感	0(0.0)	1(0.3)	4(0.5)	1(0.2)	1(0.2)
Abdominal pain	腹痛	0(0.0)	1(0.3)	4(0.5)	0(0.0)	1(0.2)
Stomatitis	口内炎	1(1.3)	0(0.0)	4(0.5)	1(0.2)	0(0.0)
Abdominal pain upper	上腹部痛	0(0.0)	1(0.3)	0(0.0)	2(0.4)	3(0.6)
Gastrooesophageal reflux disease	胃食道逆流性疾患	2(2.7)	0(0.0)	2(0.2)	1(0.2)	1(0.2)
Enterocolitis	腸炎	0(0.0)	2(0.5)	2(0.2)	1(0.2)	1(0.2)
Abdominal distension	腹部膨満	0(0.0)	1(0.3)	0(0.0)	1(0.2)	1(0.2)
Faeces soft	軟便	0(0.0)	1(0.3)	2(0.2)	0(0.0)	0(0.0)
Gastric polyps	胃ポリープ	0(0.0)	2(0.5)	1(0.1)	0(0.0)	0(0.0)
Diverticulum intestinal	腸憩室	0(0.0)	0(0.0)	1(0.1)	1(0.2)	0(0.0)
Duodenal ulcer haemorrhage	出血性十二指腸潰瘍	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.4)
Toothache	歯痛	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.4)
Gastrointestinal disorder	胃腸障害	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Periodontal disease	歯周病	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Tooth loss	歯の脱落	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Gastrointestinal polyp haemorrhage	胃腸ポリープ出血	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Dry mouth	口内乾燥	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Duodenal ulcer	十二指腸潰瘍	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Dyspepsia	消化不良	0(0.0)	1(0.3)	0(0.0)	0(0.0)	0(0.0)
Gastric ulcer	胃潰瘍	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Gastric ulcer haemorrhage	出血性胃潰瘍	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Gastritis	胃炎	1(1.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Gastritis erosive	びらん性胃炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Glossitis	舌炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Haemorrhoids	痔核	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Melaena	メレナ	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Mouth haemorrhage	口腔内出血	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Pancreatitis	膵炎	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Large intestine polyp	大腸ポリープ	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Gastric disorder	胃障害	0(0.0)	1(0.3)	0(0.0)	0(0.0)	0(0.0)
Gastrointestinal motility disorder	消化管運動障害	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Loose tooth	弛緩歯	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Gingival bleeding	歯肉出血	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Hiatus hernia	裂孔ヘルニア	0(0.0)	1(0.3)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	MT-6548 150mg Events(%)	MT-6548 300mg Events(%)	MT-6548 450mg Events(%)	MT-6548 600mg Events(%)
Inguinal hernia	鼠径ヘルニア	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Traumatic occlusion	外傷性咬合	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Hepatobiliary disorders	肝胆道系障害	2(2.7)	0(0.0)	9(1.1)	1(0.2)	0(0.0)
Cholelithiasis	胆石症	1(1.3)	0(0.0)	3(0.4)	1(0.2)	0(0.0)
Hepatic function abnormal	肝機能異常	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)
Cholecystitis	胆嚢炎	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)
Hepatic cirrhosis	肝硬変	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Cholangitis	胆管炎	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Cholecystitis acute	急性胆嚢炎	1(1.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	MT-6548 150mg Events(%)	MT-6548 300mg Events(%)	MT-6548 450mg Events(%)	MT-6548 600mg Events(%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	1(1.3)	14(3.8)	37(4.4)	11(2.5)	18(3.5)
Eczema	湿疹	1(1.3)	3(0.8)	6(0.7)	1(0.2)	1(0.2)
Dermatitis contact	接触皮膚炎	0(0.0)	1(0.3)	4(0.5)	1(0.2)	4(0.8)
Pruritus	そう痒症	0(0.0)	1(0.3)	6(0.7)	0(0.0)	3(0.6)
Haemorrhage subcutaneous	皮下出血	0(0.0)	1(0.3)	0(0.0)	3(0.7)	3(0.6)
Rash	発疹	0(0.0)	0(0.0)	5(0.6)	1(0.2)	0(0.0)
Drug eruption	薬疹	0(0.0)	0(0.0)	3(0.4)	0(0.0)	2(0.4)
Ingrowing nail	嵌入爪	0(0.0)	1(0.3)	1(0.1)	1(0.2)	1(0.2)
Skin exfoliation	皮膚剥脱	0(0.0)	3(0.8)	0(0.0)	0(0.0)	0(0.0)
Eczema asteatotic	皮脂欠乏性湿疹	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)
Urticaria	蕁麻疹	0(0.0)	0(0.0)	0(0.0)	1(0.2)	1(0.2)
Seborrhoeic dermatitis	脂漏性皮膚炎	0(0.0)	1(0.3)	1(0.1)	0(0.0)	0(0.0)
Cold sweat	冷汗	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)
Dermal cyst	皮膚嚢腫	0(0.0)	1(0.3)	0(0.0)	0(0.0)	1(0.2)
Decubitus ulcer	褥瘡性潰瘍	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Prurigo	痒疹	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Skin erosion	皮膚びらん	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Skin ulcer	皮膚潰瘍	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Alopecia	脱毛症	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Dermatitis acneiform	ざ瘡様皮膚炎	0(0.0)	1(0.3)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Hyperkeratosis	過角化	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Neurodermatitis	神経皮膚炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Rash pruritic	そう痒性皮疹	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Skin disorder	皮膚障害	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Xeroderma	乾皮症	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Skin mass	皮膚腫瘤	0(0.0)	1(0.3)	0(0.0)	0(0.0)	0(0.0)
Dermatitis	皮膚炎	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Hand dermatitis	手皮膚炎	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	4(5.4)	17(4.6)	32(3.8)	18(4.0)	21(4.0)
Back pain	背部痛	1(1.3)	4(1.1)	5(0.6)	5(1.1)	2(0.4)
Pain in extremity	四肢痛	1(1.3)	3(0.8)	5(0.6)	1(0.2)	2(0.4)
Musculoskeletal pain	筋骨格痛	0(0.0)	1(0.3)	4(0.5)	3(0.7)	2(0.4)
Muscle spasms	筋痙縮	0(0.0)	1(0.3)	3(0.4)	1(0.2)	4(0.8)
Arthralgia	関節痛	0(0.0)	3(0.8)	1(0.1)	4(0.9)	1(0.2)
Myalgia	筋肉痛	0(0.0)	1(0.3)	4(0.5)	0(0.0)	2(0.4)
Spinal osteoarthritis	変形性脊椎症	0(0.0)	0(0.0)	3(0.4)	0(0.0)	0(0.0)
Neck pain	頚部痛	1(1.3)	1(0.3)	0(0.0)	0(0.0)	1(0.2)
Osteoarthritis	変形性関節症	0(0.0)	0(0.0)	1(0.1)	1(0.2)	1(0.2)
Bursitis	滑液包炎	0(0.0)	1(0.3)	0(0.0)	1(0.2)	0(0.0)
Osteoporosis	骨粗鬆症	0(0.0)	0(0.0)	1(0.1)	0(0.0)	1(0.2)
Trigger finger	弾発指	0(0.0)	0(0.0)	0(0.0)	1(0.2)	1(0.2)
Arthritis	関節炎	1(1.3)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Lumbar spinal stenosis	腰部脊柱管狭窄症	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)
Periarthritis	関節周囲炎	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.4)
Tenosynovitis	腱鞘炎	0(0.0)	0(0.0)	1(0.1)	1(0.2)	0(0.0)
Synovial cyst	滑液嚢腫	0(0.0)	1(0.3)	0(0.0)	0(0.0)	0(0.0)
Chondrocalcinosis pyrophosphate	ピロリン酸カルシウム結晶性軟骨石灰化症	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Haemarthrosis	出血性関節症	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Musculoskeletal stiffness	筋骨格硬直	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Musculoskeletal discomfort	筋骨格不快感	0(0.0)	1(0.3)	0(0.0)	0(0.0)	0(0.0)
Renal and urinary disorders	腎および尿路障害	2(2.7)	5(1.4)	6(0.7)	11(3.5)	10(1.9)
Renal impairment	腎機能障害	1(1.3)	2(0.5)	2(0.2)	1(0.2)	3(0.6)
Chronic kidney disease	慢性腎臓病	0(0.0)	1(0.3)	2(0.2)	1(0.2)	3(0.6)
End stage renal disease	末期腎疾患	1(1.3)	0(0.0)	0(0.0)	2(0.4)	1(0.2)
Renal failure	腎不全	0(0.0)	0(0.0)	0(0.0)	2(0.4)	1(0.2)
Pollakiuria	頻尿	0(0.0)	1(0.3)	1(0.1)	0(0.0)	0(0.0)
Haematuria	血尿	0(0.0)	1(0.3)	0(0.0)	1(0.2)	0(0.0)
Hypertonic bladder	緊張性膀胱	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Oliguria	乏尿	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Hypertensive nephropathy	高血圧性腎症	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Diabetic nephropathy	糖尿病性腎症	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Acute kidney injury	急性腎障害	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Ureterolithiasis	尿管結石症	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Azotaemia	高窒素血症	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Reproductive system and breast disorders	生殖系および乳房障害	1(1.3)	0(0.0)	2(0.2)	4(0.9)	1(0.2)
Benign prostatic hyperplasia	良性前立腺肥大症	0(0.0)	0(0.0)	0(0.0)	3(0.7)	1(0.2)
Acquired hydrocele	後天性陰嚢水瘤	1(1.3)	0(0.0)	1(0.1)	1(0.2)	0(0.0)
Nipple pain	乳頭痛	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	MT-6548 150mg Events(%)	MT-6548 300mg Events(%)	MT-6548 450mg Events(%)	MT-6548 600mg Events(%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	1(1.3)	4(1.1)	17(2.0)	11(2.5)	20(3.8)
Oedema peripheral	末梢性浮腫	1(1.3)	2(0.5)	3(0.4)	3(0.7)	8(1.5)
Pyrexia	発熱	0(0.0)	1(0.3)	5(0.6)	3(0.7)	5(1.0)
Malaise	倦怠感	0(0.0)	0(0.0)	2(0.2)	2(0.4)	1(0.2)
Oedema due to renal disease	腎疾患による浮腫	0(0.0)	1(0.3)	2(0.2)	1(0.2)	1(0.2)
Chest pain	胸痛	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)
Catheter site granuloma	カテーテル留置部位肉芽腫	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.4)
Face oedema	顔面浮腫	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Thirst	口渇	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Chest discomfort	胸部不快感	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Feeling abnormal	異常感	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Injection site reaction	注射部位反応	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Peripheral swelling	末梢腫脹	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Puncture site haemorrhage	穿刺部位出血	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Catheter site haemorrhage	カテーテル留置部位出血	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Investigations	臨床検査	3(4.0)	4(1.1)	17(2.0)	3(0.7)	6(1.2)
Blood pressure increased	血圧上昇	0(0.0)	0(0.0)	3(0.4)	1(0.2)	0(0.0)
Haemoglobin decreased	ヘモグロビン減少	2(2.7)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
C-reactive protein increased	Ｃ－反応性蛋白増加	0(0.0)	1(0.3)	1(0.1)	1(0.2)	0(0.0)
Blood pressure decreased	血圧低下	0(0.0)	0(0.0)	2(0.2)	0(0.0)	1(0.2)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(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	0(0.0)	0(0.0)	1(0.1)	0(0.0)	1(0.2)
Blood potassium decreased	血中カリウム減少	0(0.0)	1(0.3)	1(0.1)	0(0.0)	0(0.0)
Salmonella test positive	サルモネラ検査陽性	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.4)
Blood creatinine increased	血中クレアチニン増加	0(0.0)	1(0.3)	0(0.0)	0(0.0)	0(0.0)
Blood triglycerides increased	血中トリグリセリド増加	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Blood uric acid increased	血中尿酸増加	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Blood parathyroid hormone increased	血中副甲状腺ホルモン増加	1(1.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Blood uric acid decreased	血中尿酸減少	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Blood urine present	尿中血陽性	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Prostatic specific antigen increased	前立腺特異性抗原増加	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Serum ferritin decreased	血清フェリチン減少	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Transferrin saturation decreased	トランスフェリン飽和度低下	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Weight decreased	体重減少	0(0.0)	1(0.3)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Optic nerve cup/disc ratio increased	視神経乳頭陥凹／乳頭比増加	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	MT-6548 150mg Events(%)	MT-6548 300mg Events(%)	MT-6548 450mg Events(%)	MT-6548 600mg Events(%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	9(12.1)	17(4.6)	43(5.1)	38(8.5)	38(7.3)
Contusion	挫傷	2(2.7)	4(1.1)	13(1.5)	9(2.0)	4(0.8)
Shunt stenosis	シャント狭窄	1(1.3)	4(1.1)	9(1.1)	5(1.1)	8(1.5)
Skin abrasion	皮膚擦過傷	2(2.7)	1(0.3)	2(0.2)	2(0.4)	5(1.0)
Wound	創傷	0(0.0)	1(0.3)	2(0.2)	3(0.7)	0(0.0)
Shunt occlusion	シャント閉塞	0(0.0)	2(0.5)	0(0.0)	2(0.4)	2(0.4)
Limb injury	四肢損傷	2(2.7)	0(0.0)	2(0.2)	0(0.0)	1(0.2)
Spinal compression fracture	脊椎圧迫骨折	0(0.0)	1(0.3)	2(0.2)	0(0.0)	1(0.2)
Thermal burn	熱傷	0(0.0)	0(0.0)	1(0.1)	2(0.4)	1(0.2)
Arteriovenous fistula site complication	動静脈瘻部位合併症	0(0.0)	0(0.0)	0(0.0)	1(0.2)	2(0.4)
Procedural hypotension	処置による低血圧	0(0.0)	0(0.0)	0(0.0)	2(0.4)	1(0.2)
Rib fracture	肋骨骨折	0(0.0)	0(0.0)	0(0.0)	1(0.2)	1(0.2)
Tooth fracture	歯牙破折	0(0.0)	0(0.0)	1(0.1)	0(0.0)	1(0.2)
Ligament sprain	靱帯捻挫	1(1.3)	1(0.3)	0(0.0)	0(0.0)	0(0.0)
Subcutaneous haematoma	皮下血腫	0(0.0)	0(0.0)	1(0.1)	0(0.0)	1(0.2)
Joint injury	関節損傷	0(0.0)	0(0.0)	1(0.1)	1(0.2)	0(0.0)
Shunt blood flow excessive	シャント血流過剰	0(0.0)	0(0.0)	0(0.0)	1(0.2)	1(0.2)
Skin wound	皮膚創傷	0(0.0)	0(0.0)	1(0.1)	1(0.2)	0(0.0)
Vascular access malfunction	血管アクセス機能不全	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2(0.4)
Dental restoration failure	歯科修復不成功	0(0.0)	1(0.3)	1(0.1)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Peritoneal dialysis complication	腹膜透析合併症	0(0.0)	0(0.0)	2(0.2)	0(0.0)	0(0.0)
Fall	転倒	0(0.0)	1(0.3)	0(0.0)	0(0.0)	0(0.0)
Head injury	頭部損傷	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Injury	損傷	0(0.0)	1(0.3)	0(0.0)	0(0.0)	0(0.0)
Seroma	漿液腫	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Sternal fracture	胸骨骨折	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Tendon rupture	腱断裂	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Skin laceration	皮膚裂傷	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Nail injury	爪損傷	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Eye contusion	眼挫傷	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Animal bite	動物咬傷	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Clavicle fracture	鎖骨骨折	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Foot fracture	足骨折	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Tooth injury	歯牙損傷	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Arteriovenous graft site stenosis	動静脈グラフト部位狭窄	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Arteriovenous fistula occlusion	動静脈瘻閉塞	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Pelvic fracture	骨盤骨折	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Vascular access complication	血管確保合併症	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Procedural hypertension	処置による高血圧	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Heat illness	熱中症	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)

表 2.7.4.9－19　直前の投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0mg Events(%)	150mg Events(%)	300mg Events(%)	450mg Events(%)	600mg Events(%)
Vascular access site inflammation	血管確保部位炎症	0(0.0)	0(0.0)	1(0.1)	0(0.0)	0(0.0)
Soft tissue foreign body	軟部組織内異物	0(0.0)	0(0.0)	0(0.0)	0(0.0)	1(0.2)
Heat stroke	熱射病	0(0.0)	0(0.0)	0(0.0)	1(0.2)	0(0.0)
Traumatic haemothorax	外傷性血胸	1(1.3)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Surgical and medical procedures	外科および内科処置	2(2.7)	1(0.3)	0(0.0)	0(0.0)	0(0.0)
Arteriovenous fistula operation	動静脈瘻手術	2(2.7)	1(0.3)	0(0.0)	0(0.0)	0(0.0)

Note(s): MedDRA Version 21.1 and MedDRA/J Version 21.1.
Note(s): The dose at onset may not be the same as the randomized dose.
Note(s): Percentages are based on the total exposure period.
Source: t_14_3_1_10_2.sas

5.3.5.3—2 Table 14.3.1.10.2 より引用

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）

	System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	 1/4 * MCD <= to < 2/4 * MCD n (%)	 2/4 * MCD <= to < 3/4 * MCD n (%)	 >= 3/4 * MCD n (%)
NDD	N1		202	182	120	68
MCD=88500	Average exposure days		68.4	117.4	148.7	165.7
	Subjects with at least one adverse event		103(51.0)	76(41.8)	32(26.7)	17(25.0)
	Infections and infestations	感染症および寄生虫症	36(17.8)	26(14.3)	5(4.2)	3(4.4)
	Nasopharyngitis	上咽頭炎	14(6.9)	12(6.6)	1(0.8)	3(4.4)
	Conjunctivitis	結膜炎	0(0.0)	3(1.6)	0(0.0)	0(0.0)
	Gastroenteritis	胃腸炎	2(1.0)	0(0.0)	1(0.8)	0(0.0)
	Pneumonia	肺炎	0(0.0)	1(0.5)	2(1.7)	0(0.0)
	Upper respiratory tract infection	上気道感染	1(0.5)	1(0.5)	0(0.0)	0(0.0)
	Influenza	インフルエンザ	6(3.0)	0(0.0)	0(0.0)	0(0.0)
	Cystitis	膀胱炎	3(1.5)	1(0.5)	0(0.0)	0(0.0)
	Cellulitis	蜂巣炎	2(1.0)	2(1.1)	0(0.0)	0(0.0)
	Herpes zoster	帯状疱疹	0(0.0)	2(1.1)	0(0.0)	0(0.0)
	Urinary tract infection	尿路感染	4(2.0)	1(0.5)	0(0.0)	0(0.0)
	Periodontitis	歯周炎	1(0.5)	0(0.0)	0(0.0)	0(0.0)
	Bronchitis	気管支炎	1(0.5)	0(0.0)	0(0.0)	0(0.0)
	Renal cyst infection	腎嚢胞感染	1(0.5)	2(1.1)	0(0.0)	0(0.0)
	Otitis media	中耳炎	1(0.5)	0(0.0)	0(0.0)	0(0.0)
	Angular cheilitis	口角口唇炎	1(0.5)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Paronychia	爪囲炎	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Sinusitis	副鼻腔炎	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Upper respiratory tract infection bacterial	細菌性上気道感染	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Body tinea	体部白癬	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Herpes simplex	単純ヘルペス	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Osteomyelitis	骨髄炎	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Otitis externa	外耳炎	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Pneumonia chlamydial	クラミジア性肺炎	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
Pyelonephritis	腎盂腎炎	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)
Lung infection	肺感染	0 (0.0)	1 (0.5)	0 (0.0)	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）	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)
Oral papilloma	口腔乳頭腫	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)
Blood and lymphatic system disorders	血液およびリンパ系障害	1 (0.5)	0 (0.0)	0 (0.0)	1 (1.5)
Iron deficiency anaemia	鉄欠乏性貧血	1 (0.5)	0 (0.0)	0 (0.0)	1 (1.5)
Immune system disorders	免疫系障害	2 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)
Allergy to arthropod sting	節足動物刺傷アレルギー	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Allergy to arthropod bite	節足動物咬傷アレルギー	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Endocrine disorders	内分泌障害	1(0.5)	1(0.5)	0(0.0)	0(0.0)
Hypothyroidism	甲状腺機能低下症	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Parathyroid gland enlargement	副甲状腺肥大	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Metabolism and nutrition disorders	代謝および栄養障害	12(5.9)	6(3.3)	3(2.5)	0(0.0)
Decreased appetite	食欲減退	2(1.0)	1(0.5)	0(0.0)	0(0.0)
Hyperkalaemia	高カリウム血症	2(1.0)	1(0.5)	1(0.8)	0(0.0)
Dehydration	脱水	1(0.5)	2(1.1)	0(0.0)	0(0.0)
Hyperphosphataemia	高リン酸塩血症	1(0.5)	1(0.5)	0(0.0)	0(0.0)
Hypoglycaemia	低血糖	2(1.0)	0(0.0)	0(0.0)	0(0.0)
Hyperuricaemia	高尿酸血症	2(1.0)	0(0.0)	0(0.0)	0(0.0)
Metabolic acidosis	代謝性アシドーシス	1(0.5)	0(0.0)	1(0.8)	0(0.0)
Diabetes mellitus	糖尿病	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Hyponatraemia	低ナトリウム血症	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Hypoproteinaemia	低蛋白血症	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Hyperlipidaemia	高脂血症	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Hyperamylasaemia	高アミラーゼ血症	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Type 2 diabetes mellitus	２型糖尿病	1(0.5)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Psychiatric disorders	精神障害	3(1.5)	2(1.1)	1(0.8)	0(0.0)
Insomnia	不眠症	1(0.5)	1(0.5)	1(0.8)	0(0.0)
Delirium	譫妄	1(0.5)	1(0.5)	0(0.0)	0(0.0)
Anxiety	不安	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Nervous system disorders	神経系障害	4(2.0)	3(1.6)	1(0.8)	0(0.0)
Headache	頭痛	1(0.5)	3(1.6)	0(0.0)	0(0.0)
Dizziness	浮動性めまい	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Somnolence	傾眠	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Hypoaesthesia	感覚鈍麻	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Hypoglycaemic coma	低血糖昏睡	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Loss of consciousness	意識消失	1(0.5)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Eye disorders	眼障害	3(1.5)	7(3.8)	3(2.5)	2(2.9)
Retinal haemorrhage	網膜出血	0(0.0)	1(0.5)	1(0.8)	0(0.0)
Cataract	白内障	2(1.0)	2(1.1)	0(0.0)	0(0.0)
Conjunctival haemorrhage	結膜出血	1(0.5)	1(0.5)	0(0.0)	0(0.0)
Dry eye	ドライアイ	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Retinal vein occlusion	網膜静脈閉塞	0(0.0)	0(0.0)	0(0.0)	1(1.5)
Blepharitis	眼瞼炎	0(0.0)	1(0.5)	1(0.8)	0(0.0)
Eczema eyelids	眼瞼湿疹	0(0.0)	0(0.0)	0(0.0)	1(1.5)
Macular oedema	黄斑浮腫	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Retinal exudates	網膜滲出物	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Age-related macular degeneration	加齢黄斑変性	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Ear and labyrinth disorders	耳および迷路障害	1(0.5)	0(0.0)	1(0.8)	0(0.0)
Vertigo	回転性めまい	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Vertigo positional	頭位性回転性めまい	0(0.0)	0(0.0)	1(0.8)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Cardiac disorders	心臓障害	3(1.5)	3(1.6)	2(1.7)	0(0.0)
Cardiac failure chronic	慢性心不全	1(0.5)	2(1.1)	0(0.0)	0(0.0)
Cardiac failure congestive	うっ血性心不全	0(0.0)	1(0.5)	1(0.8)	0(0.0)
Palpitations	動悸	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Atrial fibrillation	心房細動	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Bradycardia	徐脈	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Vascular disorders	血管障害	6(3.0)	2(1.1)	1(0.8)	0(0.0)
Hypertension	高血圧	5(2.5)	1(0.5)	0(0.0)	0(0.0)
Hypotension	低血圧	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Orthostatic hypotension	起立性低血圧	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Vascular rupture	血管破裂	0(0.0)	0(0.0)	1(0.8)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	2(1.0)	3(1.6)	1(0.8)	2(2.9)
Cough	咳嗽	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Rhinitis allergic	アレルギー性鼻炎	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Asthma	喘息	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Haemoptysis	喀血	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Interstitial lung disease	間質性肺疾患	0(0.0)	0(0.0)	0(0.0)	1(1.5)
Pleural effusion	胸水	0(0.0)	0(0.0)	0(0.0)	1(1.5)
Pulmonary congestion	肺うっ血	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Pulmonary hypertension	肺高血圧症	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Reflux laryngitis	逆流性喉頭炎	1(0.5)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Gastrointestinal disorders	胃腸障害	32(15.8)	18(9.9)	10(8.3)	2(2.9)
Diarrhoea	下痢	10(5.0)	7(3.8)	2(1.7)	0(0.0)
Vomiting	嘔吐	4(2.0)	1(0.5)	3(2.5)	0(0.0)
Nausea	悪心	5(2.5)	2(1.1)	0(0.0)	0(0.0)
Constipation	便秘	2(1.0)	5(2.7)	4(3.3)	0(0.0)
Dental caries	齲歯	2(1.0)	1(0.5)	0(0.0)	1(1.5)
Gastrooesophageal reflux disease	胃食道逆流性疾患	2(1.0)	1(0.5)	0(0.0)	0(0.0)
Abdominal discomfort	腹部不快感	1(0.5)	1(0.5)	0(0.0)	0(0.0)
Stomatitis	口内炎	2(1.0)	1(0.5)	0(0.0)	0(0.0)
Abdominal pain upper	上腹部痛	0(0.0)	3(1.6)	0(0.0)	0(0.0)
Enterocolitis	腸炎	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Abdominal pain	腹痛	1(0.5)	1(0.5)	0(0.0)	0(0.0)
Abdominal distension	腹部膨満	2(1.0)	0(0.0)	1(0.8)	0(0.0)
Faeces soft	軟便	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Diverticulum intestinal	腸憩室	0(0.0)	0(0.0)	0(0.0)	1(1.5)
Duodenal ulcer haemorrhage	出血性十二指腸潰瘍	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Gastritis	胃炎	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Gastrointestinal disorder	胃腸障害	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Periodontal disease	歯周病	1(0.5)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Tooth loss	歯の脱落	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Gastrointestinal polyp haemorrhage	胃腸ポリープ出血	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatobiliary disorders	肝胆道系障害	1 (0.5)	4 (2.2)	1 (0.8)	0 (0.0)
Cholelithiasis	胆石症	0 (0.0)	1 (0.5)	1 (0.8)	0 (0.0)
Hepatic function abnormal	肝機能異常	1 (0.5)	1 (0.5)	0 (0.0)	0 (0.0)
Cholecystitis	胆嚢炎	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)
Hepatic cirrhosis	肝硬変	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	12(5.9)	6(3.3)	2(1.7)	1(1.5)
Eczema	湿疹	3(1.5)	0(0.0)	0(0.0)	0(0.0)
Dermatitis contact	接触皮膚炎	2(1.0)	1(0.5)	0(0.0)	0(0.0)
Pruritus	そう痒症	1(0.5)	1(0.5)	0(0.0)	0(0.0)
Haemorrhage subcutaneous	皮下出血	1(0.5)	0(0.0)	1(0.8)	0(0.0)
Rash	発疹	1(0.5)	1(0.5)	0(0.0)	0(0.0)
Drug eruption	薬疹	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Eczema asteatotic	皮脂欠乏性湿疹	2(1.0)	0(0.0)	0(0.0)	0(0.0)
Urticaria	蕁麻疹	0(0.0)	1(0.5)	0(0.0)	1(1.5)
Seborrhoeic dermatitis	脂漏性皮膚炎	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Decubitus ulcer	褥瘡性潰瘍	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Prurigo	痒疹	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Skin erosion	皮膚びらん	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Skin ulcer	皮膚潰瘍	1(0.5)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	5(2.5)	7(3.8)	4(3.3)	1(1.5)
Back pain	背部痛	2(1.0)	3(1.6)	0(0.0)	0(0.0)
Pain in extremity	四肢痛	1(0.5)	2(1.1)	0(0.0)	0(0.0)
Musculoskeletal pain	筋骨格痛	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Muscle spasms	筋痙縮	0(0.0)	1(0.5)	1(0.8)	1(1.5)
Arthralgia	関節痛	0(0.0)	1(0.5)	1(0.8)	0(0.0)
Myalgia	筋肉痛	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Spinal osteoarthritis	変形性脊椎症	1(0.5)	1(0.5)	0(0.0)	0(0.0)
Bursitis	滑液包炎	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Osteoporosis	骨粗鬆症	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Trigger finger	弾発指	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Arthritis	関節炎	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Synovial cyst	滑液嚢腫	1(0.5)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Renal and urinary disorders	腎および尿路障害	8(4.0)	10(5.5)	2(1.7)	5(7.4)
Renal impairment	腎機能障害	3(1.5)	2(1.1)	2(1.7)	0(0.0)
Chronic kidney disease	慢性腎臓病	1(0.5)	3(1.6)	0(0.0)	2(2.9)
End stage renal disease	末期腎疾患	0(0.0)	2(1.1)	0(0.0)	1(1.5)
Renal failure	腎不全	0(0.0)	1(0.5)	0(0.0)	1(1.5)
Pollakiuria	頻尿	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Haematuria	血尿	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Hypertonic bladder	緊張性膀胱	0(0.0)	0(0.0)	0(0.0)	1(1.5)
Oliguria	乏尿	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Hypertensive nephropathy	高血圧性腎症	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Diabetic nephropathy	糖尿病性腎症	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Acute kidney injury	急性腎障害	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Reproductive system and breast disorders	生殖系および乳房障害	2(1.0)	0(0.0)	0(0.0)	1(1.5)
Benign prostatic hyperplasia	良性前立腺肥大症	1(0.5)	0(0.0)	0(0.0)	1(1.5)
Nipple pain	乳頭痛	1(0.5)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	1/4 * MCD <= to < 2/4 * MCD n (%)	2/4 * MCD <= to < 3/4 * MCD n (%)	>= 3/4 * MCD n (%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	12(5.9)	6(3.3)	5(4.2)	4(5.9)
Oedema peripheral	末梢性浮腫	5(2.5)	2(1.1)	1(0.8)	3(4.4)
Pyrexia	発熱	1(0.5)	2(1.1)	4(3.3)	0(0.0)
Malaise	倦怠感	3(1.5)	2(1.1)	0(0.0)	0(0.0)
Oedema due to renal disease	腎疾患による浮腫	4(2.0)	0(0.0)	0(0.0)	0(0.0)
Chest pain	胸痛	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Face oedema	顔面浮腫	0(0.0)	0(0.0)	0(0.0)	1(1.5)
Thirst	口渇	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Investigations	臨床検査	7(3.5)	2(1.1)	2(1.7)	0(0.0)
Blood pressure increased	血圧上昇	1(0.5)	0(0.0)	1(0.8)	0(0.0)
Haemoglobin decreased	ヘモグロビン減少	1(0.5)	0(0.0)	0(0.0)	0(0.0)
C-reactive protein increased	C－反応性蛋白増加	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	1(0.5)	1(0.5)	0(0.0)	0(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	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Blood potassium decreased	血中カリウム減少	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Blood creatinine increased	血中クレアチニン増加	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Blood triglycerides increased	血中トリグリセリド増加	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Blood uric acid increased	血中尿酸増加	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1(0.5)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	10(5.0)	9(4.9)	3(2.5)	2(2.9)
Contusion	挫傷	4(2.0)	7(3.8)	0(0.0)	0(0.0)
Shunt stenosis	シャント狭窄	0(0.0)	0(0.0)	0(0.0)	1(1.5)
Skin abrasion	皮膚擦過傷	0(0.0)	0(0.0)	1(0.8)	1(1.5)
Wound	創傷	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Spinal compression fracture	脊椎圧迫骨折	2(1.0)	1(0.5)	1(0.8)	0(0.0)
Thermal burn	熱傷	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Rib fracture	肋骨骨折	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Tooth fracture	歯牙破折	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Fall	転倒	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Head injury	頭部損傷	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Injury	損傷	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Seroma	漿液腫	0(0.0)	0(0.0)	0(0.0)	1(1.5)
Sternal fracture	胸骨骨折	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Tendon rupture	腱断裂	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Skin laceration	皮膚裂傷	1(0.5)	0(0.0)	0(0.0)	0(0.0)
Nail injury	爪損傷	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Eye contusion	眼挫傷	0(0.0)	1(0.5)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

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Surgical and medical procedures	外科および内科処置	2(1.0)	1(0.5)	0(0.0)	0(0.0)
Arteriovenous fistula operation	動静脈瘻手術	2(1.0)	1(0.5)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

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HD	N1		237	206	130	71
MCD=90000	Average exposure days		70.8	121.6	145.7	165.3
	Subjects with at least one adverse event		156(65.8)	114(55.3)	61(46.9)	27(38.0)
	Infections and infestations	感染症および寄生虫症	62(26.2)	30(14.6)	18(13.8)	4(5.6)
	Nasopharyngitis	上咽頭炎	32(13.5)	16(7.8)	9(6.9)	3(4.2)
	Conjunctivitis	結膜炎	3(1.3)	3(1.5)	3(2.3)	0(0.0)
	Gastroenteritis	胃腸炎	5(2.1)	1(0.5)	2(1.5)	1(1.4)
	Pneumonia	肺炎	3(1.3)	2(1.0)	2(1.5)	0(0.0)
	Upper respiratory tract infection	上気道感染	3(1.3)	1(0.5)	1(0.8)	0(0.0)
	Cystitis	膀胱炎	0(0.0)	2(1.0)	0(0.0)	0(0.0)
	Cellulitis	蜂巣炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)
	Herpes zoster	帯状疱疹	3(1.3)	1(0.5)	0(0.0)	0(0.0)
	Periodontitis	歯周炎	1(0.4)	3(1.5)	0(0.0)	0(0.0)
	Bronchitis	気管支炎	1(0.4)	1(0.5)	0(0.0)	0(0.0)
	Otitis media	中耳炎	0(0.0)	2(1.0)	0(0.0)	0(0.0)
	Angular cheilitis	口角口唇炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)
	Paronychia	爪囲炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)
	Sinusitis	副鼻腔炎	0(0.0)	0(0.0)	1(0.8)	0(0.0)
	Upper respiratory tract infection bacterial	細菌性上気道感染	1(0.4)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

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Otitis media chronic	慢性中耳炎	1(0.4)	0(0.0)	1(0.8)	0(0.0)
Pharyngitis	咽頭炎	2(0.8)	0(0.0)	0(0.0)	0(0.0)
Tinea pedis	足部白癬	2(0.8)	0(0.0)	0(0.0)	0(0.0)
Enteritis infectious	感染性腸炎	1(0.4)	1(0.5)	0(0.0)	0(0.0)
Chronic sinusitis	慢性副鼻腔炎	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Epididymitis	精巣上体炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Furuncle	せつ	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Gastroenteritis viral	ウイルス性胃腸炎	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Gingivitis	歯肉炎	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Hordeolum	麦粒腫	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Skin infection	皮膚感染	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Tracheobronchitis	気管気管支炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Hepatic cyst infection	肝嚢胞感染	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Shunt infection	シャント感染	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Oral herpes	口腔ヘルペス	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Infected dermal cyst	感染性皮膚嚢腫	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Vascular device infection	血管デバイス感染	1(0.4)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

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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）	2(0.8)	1(0.5)	1(0.8)	1(1.4)
Breast cancer	乳癌	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Gastric cancer	胃癌	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Laryngeal papilloma	喉頭乳頭腫	0(0.0)	0(0.0)	0(0.0)	1(1.4)
Seborrhoeic keratosis	脂漏性角化症	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Skin papilloma	皮膚乳頭腫	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Blood and lymphatic system disorders	血液およびリンパ系障害	2(0.8)	3(1.5)	1(0.8)	1(1.4)
Anaemia macrocytic	大球性貧血	0(0.0)	1(0.5)	1(0.8)	0(0.0)
Anaemia	貧血	0(0.0)	0(0.0)	0(0.0)	1(1.4)
Nephrogenic anaemia	腎性貧血	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Eosinophilia	好酸球増加症	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Lymphadenitis	リンパ節炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Lymphadenopathy	リンパ節症	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Endocrine disorders	内分泌障害	2(0.8)	0(0.0)	0(0.0)	0(0.0)
Hyperparathyroidism secondary	続発性副甲状腺機能亢進症	2(0.8)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

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Metabolism and nutrition disorders	代謝および栄養障害	7(3.0)	3(1.5)	1(0.8)	0(0.0)
Decreased appetite	食欲減退	4(1.7)	1(0.5)	1(0.8)	0(0.0)
Hyperkalaemia	高カリウム血症	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Hyperphosphataemia	高リン酸塩血症	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Hypoglycaemia	低血糖	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Hypocalcaemia	低カルシウム血症	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Dyslipidaemia	脂質異常症	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Hypocarnitinaemia	低カルニチン血症	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Psychiatric disorders	精神障害	2(0.8)	4(1.9)	2(1.5)	0(0.0)
Insomnia	不眠症	1(0.4)	3(1.5)	2(1.5)	0(0.0)
Anxiety	不安	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Abnormal behaviour	異常行動	1(0.4)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

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Nervous system disorders	神経系障害	21(8.9)	10(4.9)	6(4.6)	1(1.4)
Headache	頭痛	10(4.2)	2(1.0)	4(3.1)	0(0.0)
Dizziness	浮動性めまい	3(1.3)	2(1.0)	0(0.0)	1(1.4)
Somnolence	傾眠	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Cerebral infarction	脳梗塞	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Carotid artery stenosis	頚動脈狭窄	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Cerebellar infarction	小脳梗塞	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Cerebral haemorrhage	脳出血	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Diabetic neuropathy	糖尿病性ニューロパチー	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Dizziness postural	体位性めまい	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Facial paralysis	顔面麻痺	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Myoclonus	ミオクローヌス	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Post herpetic neuralgia	ヘルペス後神経痛	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Sciatica	坐骨神経痛	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Toxic encephalopathy	中毒性脳症	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Tremor	振戦	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Intercostal neuralgia	肋間神経痛	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Cervical radiculopathy	頚髄神経根障害	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Restless legs syndrome	下肢静止不能症候群	0(0.0)	1(0.5)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Eye disorders	眼障害	4(1.7)	6(2.9)	7(5.4)	9(12.7)
Retinal haemorrhage	網膜出血	0(0.0)	2(1.0)	3(2.3)	5(7.0)
Cataract	白内障	0(0.0)	0(0.0)	0(0.0)	2(2.8)
Conjunctival haemorrhage	結膜出血	2(0.8)	0(0.0)	0(0.0)	0(0.0)
Dry eye	ドライアイ	0(0.0)	0(0.0)	0(0.0)	1(1.4)
Retinal vein occlusion	網膜静脈閉塞	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Diabetic retinopathy	糖尿病網膜症	0(0.0)	1(0.5)	1(0.8)	1(1.4)
Ocular hyperaemia	眼充血	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Optic disc haemorrhage	視神経乳頭出血	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Punctate keratitis	点状角膜炎	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Retinal oedema	網膜浮腫	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Trichiasis	睫毛乱生	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Vitreous floaters	硝子体浮遊物	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Eye pruritus	眼そう痒症	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Cystoid macular oedema	嚢胞様黄斑浮腫	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Eyelid haematoma	眼瞼血腫	0(0.0)	0(0.0)	1(0.8)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

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Ear and labyrinth disorders	耳および迷路障害	2(0.8)	4(1.9)	0(0.0)	0(0.0)
Vertigo	回転性めまい	1(0.4)	2(1.0)	0(0.0)	0(0.0)
Deafness	難聴	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Sudden hearing loss	突発性難聴	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Eustachian tube stenosis	耳管狭窄	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Cardiac disorders	心臓障害	5(2.1)	2(1.0)	4(3.1)	0(0.0)
Cardiac failure chronic	慢性心不全	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Cardiac failure congestive	うっ血性心不全	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Palpitations	動悸	1(0.4)	0(0.0)	1(0.8)	0(0.0)
Atrial fibrillation	心房細動	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Tachycardia paroxysmal	発作性頻脈	2(0.8)	0(0.0)	0(0.0)	0(0.0)
Myocardial ischaemia	心筋虚血	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Cardiac failure	心不全	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Pericarditis	心膜炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Cardiac dysfunction	心機能障害	0(0.0)	0(0.0)	1(0.8)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Vascular disorders	血管障害	9(3.8)	8(3.9)	0(0.0)	1(1.4)
Hypertension	高血圧	2(0.8)	1(0.5)	0(0.0)	0(0.0)
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	1(0.4)	3(1.5)	0(0.0)	0(0.0)
Hypotension	低血圧	1(0.4)	1(0.5)	0(0.0)	0(0.0)
Orthostatic hypotension	起立性低血圧	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Internal haemorrhage	内出血	3(1.3)	0(0.0)	0(0.0)	0(0.0)
Haemorrhage	出血	0(0.0)	2(1.0)	0(0.0)	0(0.0)
Aneurysm	動脈瘤	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Vascular pain	血管痛	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Vascular insufficiency	血行不全	0(0.0)	0(0.0)	0(0.0)	1(1.4)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	7(3.0)	5(2.4)	4(3.1)	1(1.4)
Cough	咳嗽	2(0.8)	0(0.0)	1(0.8)	0(0.0)
Upper respiratory tract inflammation	上気道の炎症	1(0.4)	2(1.0)	0(0.0)	0(0.0)
Rhinitis allergic	アレルギー性鼻炎	1(0.4)	1(0.5)	0(0.0)	0(0.0)
Epistaxis	鼻出血	1(0.4)	1(0.5)	1(0.8)	0(0.0)
Asthma	喘息	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Haemoptysis	喀血	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Sputum increased	喀痰増加	0(0.0)	0(0.0)	1(0.8)	1(1.4)
Pulmonary oedema	肺水腫	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Sleep apnoea syndrome	睡眠時無呼吸症候群	1(0.4)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Gastrointestinal disorders	胃腸障害	46(19.4)	21(10.2)	11(8.5)	1(1.4)
Diarrhoea	下痢	20(8.4)	7(3.4)	3(2.3)	0(0.0)
Vomiting	嘔吐	6(2.5)	5(2.4)	0(0.0)	0(0.0)
Nausea	悪心	5(2.1)	2(1.0)	1(0.8)	0(0.0)
Constipation	便秘	5(2.1)	1(0.5)	0(0.0)	0(0.0)
Dental caries	齲歯	2(0.8)	0(0.0)	0(0.0)	0(0.0)
Gastrooesophageal reflux disease	胃食道逆流性疾患	3(1.3)	0(0.0)	1(0.8)	0(0.0)
Abdominal discomfort	腹部不快感	3(1.3)	0(0.0)	0(0.0)	0(0.0)
Stomatitis	口内炎	3(1.3)	0(0.0)	0(0.0)	0(0.0)
Enterocolitis	腸炎	1(0.4)	0(0.0)	2(1.5)	0(0.0)
Abdominal pain	腹痛	3(1.3)	0(0.0)	0(0.0)	0(0.0)
Faeces soft	軟便	1(0.4)	1(0.5)	0(0.0)	0(0.0)
Diverticulum intestinal	腸憩室	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Duodenal ulcer haemorrhage	出血性十二指腸潰瘍	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Gastritis	胃炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Toothache	歯痛	0(0.0)	0(0.0)	1(0.8)	1(1.4)
Dry mouth	口内乾燥	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Duodenal ulcer	十二指腸潰瘍	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Dyspepsia	消化不良	1(0.4)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Gastric ulcer	胃潰瘍	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Gastric ulcer haemorrhage	出血性胃潰瘍	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Gastritis erosive	びらん性胃炎	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Glossitis	舌炎	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Haemorrhoids	痔核	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Melaena	メレナ	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Mouth haemorrhage	口腔内出血	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Pancreatitis	膵炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Large intestine polyp	大腸ポリープ	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Gastric disorder	胃障害	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Gastrointestinal motility disorder	消化管運動障害	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Loose tooth	弛緩歯	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Hepatobiliary disorders	肝胆道系障害	2(0.8)	2(1.0)	0(0.0)	0(0.0)
Cholelithiasis	胆石症	1(0.4)	2(1.0)	0(0.0)	0(0.0)
Cholecystitis	胆嚢炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Cholangitis	胆管炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Cholecystitis acute	急性胆嚢炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

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Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	22(9.3)	20(9.7)	7(5.4)	3(4.2)
Eczema	湿疹	2(0.8)	6(2.9)	1(0.8)	0(0.0)
Dermatitis contact	接触皮膚炎	2(0.8)	1(0.5)	2(1.5)	0(0.0)
Pruritus	そう痒症	4(1.7)	3(1.5)	0(0.0)	1(1.4)
Haemorrhage subcutaneous	皮下出血	1(0.4)	1(0.5)	2(1.5)	1(1.4)
Rash	発疹	3(1.3)	0(0.0)	0(0.0)	0(0.0)
Drug eruption	薬疹	1(0.4)	2(1.0)	1(0.8)	0(0.0)
Ingrowing nail	嵌入爪	2(0.8)	1(0.5)	0(0.0)	1(1.4)
Skin exfoliation	皮膚剥脱	1(0.4)	2(1.0)	0(0.0)	0(0.0)
Seborrhoeic dermatitis	脂漏性皮膚炎	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Cold sweat	冷汗	2(0.8)	0(0.0)	0(0.0)	0(0.0)
Dermal cyst	皮膚嚢腫	1(0.4)	0(0.0)	1(0.8)	0(0.0)
Alopecia	脱毛症	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Dermatitis acneiform	ざ瘡様皮膚炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Hyperkeratosis	過角化	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Neurodermatitis	神経皮膚炎	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Rash pruritic	そう痒性皮疹	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Skin disorder	皮膚障害	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Xeroderma	乾皮症	0(0.0)	0(0.0)	1(0.8)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

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Skin mass	皮膚腫瘤	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

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Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	24(10.1)	20(9.7)	9(6.9)	4(5.6)
Back pain	背部痛	3(1.3)	5(2.4)	1(0.8)	1(1.4)
Pain in extremity	四肢痛	5(2.1)	3(1.5)	1(0.8)	0(0.0)
Musculoskeletal pain	筋骨格痛	2(0.8)	4(1.9)	3(2.3)	0(0.0)
Muscle spasms	筋痙縮	2(0.8)	4(1.9)	0(0.0)	0(0.0)
Arthralgia	関節痛	3(1.3)	1(0.5)	1(0.8)	0(0.0)
Myalgia	筋肉痛	3(1.3)	2(1.0)	1(0.8)	0(0.0)
Spinal osteoarthritis	変形性脊椎症	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Neck pain	頸部痛	2(0.8)	0(0.0)	1(0.8)	0(0.0)
Osteoarthritis	変形性関節症	1(0.4)	1(0.5)	1(0.8)	0(0.0)
Bursitis	滑液包炎	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Osteoporosis	骨粗鬆症	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Trigger finger	弾発指	0(0.0)	0(0.0)	0(0.0)	1(1.4)
Lumbar spinal stenosis	腰部脊柱管狭窄症	2(0.8)	0(0.0)	0(0.0)	0(0.0)
Periarthritis	関節周囲炎	0(0.0)	0(0.0)	1(0.8)	1(1.4)
Tenosynovitis	腱鞘炎	0(0.0)	2(1.0)	0(0.0)	0(0.0)
Chondrocalcinosis pyrophosphate	ピロリン酸カルシウム結晶性軟骨石灰化症	0(0.0)	0(0.0)	0(0.0)	1(1.4)
Haemarthrosis	出血性関節症	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Musculoskeletal stiffness	筋骨格硬直	1(0.4)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

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Musculoskeletal discomfort	筋骨格不快感	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Renal and urinary disorders	腎および尿路障害	1(0.4)	0(0.0)	1(0.8)	0(0.0)
Pollakiuria	頻尿	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Ureterolithiasis	尿管結石症	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Reproductive system and breast disorders	生殖系および乳房障害	2(0.8)	1(0.5)	1(0.8)	0(0.0)
Benign prostatic hyperplasia	良性前立腺肥大症	1(0.4)	1(0.5)	0(0.0)	0(0.0)
Acquired hydrocele	後天性陰嚢水瘤	1(0.4)	0(0.0)	1(0.8)	0(0.0)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	9(3.8)	1(0.5)	4(3.1)	0(0.0)
Oedema peripheral	末梢性浮腫	2(0.8)	1(0.5)	2(1.5)	0(0.0)
Pyrexia	発熱	3(1.3)	1(0.5)	1(0.8)	0(0.0)
Chest discomfort	胸部不快感	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Feeling abnormal	異常感	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Injection site reaction	注射部位反応	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Peripheral swelling	末梢腫脹	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Puncture site haemorrhage	穿刺部位出血	1(0.4)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Investigations	臨床検査	9(3.8)	3(1.5)	2(1.5)	1(1.4)
Blood pressure increased	血圧上昇	1(0.4)	1(0.5)	0(0.0)	0(0.0)
Haemoglobin decreased	ヘモグロビン減少	2(0.8)	0(0.0)	0(0.0)	0(0.0)
C-reactive protein increased	C－反応性蛋白増加	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Blood pressure decreased	血圧低下	2(0.8)	0(0.0)	0(0.0)	1(1.4)
Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Blood parathyroid hormone increased	血中副甲状腺ホルモン増加	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Blood uric acid decreased	血中尿酸減少	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Blood urine present	尿中血陽性	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Prostatic specific antigen increased	前立腺特異性抗原増加	0(0.0)	0(0.0)	1(0.8)	0(0.0)
Serum ferritin decreased	血清フェリチン減少	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Transferrin saturation decreased	トランスフェリン飽和度低下	1(0.4)	0(0.0)	0(0.0)	0(0.0)
Salmonella test positive	サルモネラ検査陽性	0(0.0)	1(0.5)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	 1/4 * MCD <= to < 2/4 * MCD n (%)	 2/4 * MCD <= to < 3/4 * MCD n (%)	 >= 3/4 * MCD n (%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	37(15.6)	30(14.6)	13(10.0)	6(8.5)
Contusion	挫傷	8(3.4)	4(1.9)	4(3.1)	2(2.8)
Shunt stenosis	シャント狭窄	14(5.9)	9(4.4)	1(0.8)	1(1.4)
Skin abrasion	皮膚擦過傷	4(1.7)	3(1.5)	1(0.8)	2(2.8)
Wound	創傷	3(1.3)	1(0.5)	1(0.8)	0(0.0)
Shunt occlusion	シャント閉塞	1(0.4)	2(1.0)	1(0.8)	0(0.0)
Thermal burn	熱傷	1(0.4)	1(0.5)	0(0.0)	1(1.4)
Arteriovenous fistula site complication	動静脈瘻部位合併症	2(0.8)	1(0.5)	0(0.0)	0(0.0)
Limb injury	四肢損傷	2(0.8)	0(0.0)	1(0.8)	0(0.0)
Rib fracture	肋骨骨折	0(0.0)	1(0.5)	0(0.0)	0(0.0)
Ligament sprain	靭帯捻挫	0(0.0)	1(0.5)	1(0.8)	0(0.0)
Subcutaneous haematoma	皮下血腫	0(0.0)	0(0.0)	2(1.5)	0(0.0)
Joint injury	関節損傷	1(0.4)	1(0.5)	0(0.0)	0(0.0)
Procedural hypotension	処置による低血圧	0(0.0)	1(0.5)	1(0.8)	0(0.0)
Shunt blood flow excessive	シャント血流過剰	1(0.4)	0(0.0)	1(0.8)	0(0.0)
Skin wound	皮膚創傷	1(0.4)	1(0.5)	0(0.0)	0(0.0)
Vascular access malfunction	血管アクセス機能不全	1(0.4)	0(0.0)	1(0.8)	0(0.0)
Dental restoration failure	歯科修復不成功	0(0.0)	1(0.5)	1(0.8)	0(0.0)
Animal bite	動物咬傷	0(0.0)	1(0.5)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Clavicle fracture	鎖骨骨折	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)
Foot fracture	足骨折	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)
Tooth injury	歯牙損傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)
Arteriovenous graft site stenosis	動静脈グラフト部位狭窄	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
Arteriovenous fistula occlusion	動静脈瘻閉塞	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Pelvic fracture	骨盤骨折	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)
Vascular access complication	血管確保合併症	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)
Procedural hypertension	処置による高血圧	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Heat illness	熱中症	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)
Vascular access site inflammation	血管確保部位炎症	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Soft tissue foreign body	軟部組織内異物	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

	System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
PD	N1		42	36	27	16
MCD=90300	Average exposure days		76.7	120.8	151.8	169.2
	Subjects with at least one adverse event		33(78.6)	20(55.6)	18(66.7)	7(43.8)
	Infections and infestations	感染症および寄生虫症	13(31.0)	10(27.8)	5(18.5)	1(6.3)
	Nasopharyngitis	上咽頭炎	5(11.9)	2(5.6)	0(0.0)	0(0.0)
	Conjunctivitis	結膜炎	1(2.4)	0(0.0)	0(0.0)	0(0.0)
	Pneumonia	肺炎	0(0.0)	0(0.0)	1(3.7)	0(0.0)
	Catheter site infection	カテーテル留置部位感染	3(7.1)	5(13.9)	3(11.1)	0(0.0)
	Upper respiratory tract infection	上気道感染	2(4.8)	0(0.0)	0(0.0)	0(0.0)
	Cellulitis	蜂巣炎	1(2.4)	0(0.0)	0(0.0)	0(0.0)
	Peritonitis	腹膜炎	1(2.4)	3(8.3)	0(0.0)	1(6.3)
	Bronchitis	気管支炎	0(0.0)	0(0.0)	1(3.7)	0(0.0)
	Body tinea	体部白癬	1(2.4)	0(0.0)	0(0.0)	0(0.0)
	Diverticulitis	憩室炎	0(0.0)	1(2.8)	0(0.0)	0(0.0)
	Folliculitis	毛包炎	0(0.0)	1(2.8)	0(0.0)	0(0.0)
	Sepsis	敗血症	1(2.4)	0(0.0)	0(0.0)	0(0.0)
	Helicobacter infection	ヘリコバクター感染	1(2.4)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Blood and lymphatic system disorders	血液およびリンパ系障害	2(4.8)	0(0.0)	0(0.0)	0(0.0)
Anaemia	貧血	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Nephrogenic anaemia	腎性貧血	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Metabolism and nutrition disorders	代謝および栄養障害	2(4.8)	1(2.8)	3(11.1)	0(0.0)
Decreased appetite	食欲減退	2(4.8)	0(0.0)	1(3.7)	0(0.0)
Dehydration	脱水	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Hyperphosphataemia	高リン酸塩血症	0(0.0)	1(2.8)	0(0.0)	0(0.0)
Fluid overload	水分過負荷	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Hypoalbuminaemia	低アルブミン血症	0(0.0)	1(2.8)	0(0.0)	0(0.0)
Hypokalaemia	低カリウム血症	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Psychiatric disorders	精神障害	2(4.8)	0(0.0)	2(7.4)	0(0.0)
Insomnia	不眠症	1(2.4)	0(0.0)	1(3.7)	0(0.0)
Sleep disorder	睡眠障害	1(2.4)	0(0.0)	1(3.7)	0(0.0)
Nervous system disorders	神経系障害	3(7.1)	0(0.0)	1(3.7)	1(6.3)
Dizziness	浮動性めまい	0(0.0)	0(0.0)	0(0.0)	1(6.3)
Cerebral infarction	脳梗塞	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Dizziness exertional	労作性めまい	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Dysgeusia	味覚異常	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Neuropathy peripheral	末梢性ニューロパチー	0(0.0)	0(0.0)	1(3.7)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Eye disorders	眼障害	1(2.4)	0(0.0)	3(11.1)	2(12.5)
Retinal haemorrhage	網膜出血	0(0.0)	0(0.0)	1(3.7)	1(6.3)
Dry eye	ドライアイ	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Retinal vein occlusion	網膜静脈閉塞	0(0.0)	0(0.0)	0(0.0)	1(6.3)
Macular degeneration	黄斑変性	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Meibomian gland dysfunction	マイボーム腺機能不全	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Macular fibrosis	黄斑線維症	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Cardiac disorders	心臓障害	1(2.4)	0(0.0)	1(3.7)	0(0.0)
Cardiac failure chronic	慢性心不全	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Myocardial ischaemia	心筋虚血	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Vascular disorders	血管障害	3(7.1)	1(2.8)	1(3.7)	1(6.3)
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	2(4.8)	0(0.0)	0(0.0)	0(0.0)
Hypotension	低血圧	0(0.0)	0(0.0)	0(0.0)	1(6.3)
Orthostatic hypotension	起立性低血圧	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Arteriosclerosis	動脈硬化症	0(0.0)	1(2.8)	1(3.7)	0(0.0)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	2(4.8)	0(0.0)	1(3.7)	0(0.0)
Cough	咳嗽	2(4.8)	0(0.0)	0(0.0)	0(0.0)
Upper respiratory tract inflammation	上気道の炎症	0(0.0)	0(0.0)	1(3.7)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Gastrointestinal disorders	胃腸障害	11(26.2)	6(22.2)	4(14.8)	2(12.5)
Diarrhoea	下痢	3(7.1)	3(8.3)	3(11.1)	0(0.0)
Vomiting	嘔吐	2(4.8)	2(5.6)	0(0.0)	0(0.0)
Nausea	悪心	2(4.8)	0(0.0)	1(3.7)	1(6.3)
Constipation	便秘	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Dental caries	齲歯	0(0.0)	0(0.0)	0(0.0)	1(6.3)
Abdominal discomfort	腹部不快感	2(4.8)	0(0.0)	0(0.0)	0(0.0)
Abdominal pain upper	上腹部痛	0(0.0)	3(8.3)	0(0.0)	0(0.0)
Enterocolitis	腸炎	1(2.4)	1(2.8)	0(0.0)	0(0.0)
Gastric polyps	胃ポリープ	2(4.8)	0(0.0)	0(0.0)	0(0.0)
Gingival bleeding	歯肉出血	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Hiatus hernia	裂孔ヘルニア	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Inguinal hernia	鼠径ヘルニア	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Traumatic occlusion	外傷性咬合	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	4(9.5)	0(0.0)	1(3.7)	0(0.0)
Dermatitis contact	接触皮膚炎	1(2.4)	0(0.0)	1(3.7)	0(0.0)
Rash	発疹	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Dermatitis	皮膚炎	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Hand dermatitis	手皮膚炎	1(2.4)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	1(2.4)	1(2.8)	0(0.0)	2(12.5)
Back pain	背部痛	0(0.0)	1(2.8)	0(0.0)	1(6.3)
Arthralgia	関節痛	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Arthritis	関節炎	0(0.0)	0(0.0)	0(0.0)	1(6.3)
Renal and urinary disorders	腎および尿路障害	1(2.4)	2(5.6)	0(0.0)	0(0.0)
Renal impairment	腎機能障害	0(0.0)	1(2.8)	0(0.0)	0(0.0)
Haematuria	血尿	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Azotaemia	高窒素血症	0(0.0)	1(2.8)	0(0.0)	0(0.0)
Reproductive system and breast disorders	生殖系および乳房障害	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Acquired hydrocele	後天性陰嚢水瘤	0(0.0)	0(0.0)	1(3.7)	0(0.0)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	3(7.1)	2(5.6)	2(7.4)	0(0.0)
Pyrexia	発熱	1(2.4)	1(2.8)	0(0.0)	0(0.0)
Oedema due to renal disease	腎疾患による浮腫	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Chest pain	胸痛	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Catheter site granuloma	カテーテル留置部位肉芽腫	1(2.4)	1(2.8)	0(0.0)	0(0.0)
Catheter site haemorrhage	カテーテル留置部位出血	0(0.0)	0(0.0)	1(3.7)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	1/4 * MCD <= to < 2/4 * MCD n (%)	2/4 * MCD <= to < 3/4 * MCD n (%)	>= 3/4 * MCD n (%)
Investigations	臨床検査	1(2.4)	2(5.6)	1(3.7)	0(0.0)
C-reactive protein increased	C－反応性蛋白増加	0(0.0)	1(2.8)	0(0.0)	0(0.0)
Blood potassium decreased	血中カリウム減少	0(0.0)	1(2.8)	0(0.0)	0(0.0)
Weight decreased	体重減少	1(2.4)	0(0.0)	0(0.0)	0(0.0)
Optic nerve cup/disc ratio increased	視神経乳頭陥凹／乳頭比増加	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	0(0.0)	2(5.6)	4(14.8)	0(0.0)
Contusion	挫傷	0(0.0)	1(2.8)	0(0.0)	0(0.0)
Shunt occlusion	シャント閉塞	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Tooth fracture	歯牙破折	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Heat stroke	熱射病	0(0.0)	1(2.8)	0(0.0)	0(0.0)
Peritoneal dialysis complication	腹膜透析合併症	0(0.0)	0(0.0)	1(3.7)	0(0.0)
Traumatic haemothorax	外傷性血胸	0(0.0)	0(0.0)	1(3.7)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

	System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Total	N1		481	423	276	153
MCD=90300	Average exposure days		71.1	120.5	148.4	165.8
	Subjects with at least one adverse event		294(61.1)	210(49.6)	110(39.9)	48(31.4)
	Infections and infestations	感染症および寄生虫症	112(23.3)	66(15.6)	28(10.1)	7(4.6)
	Nasopharyngitis	上咽頭炎	52(10.8)	29(6.9)	11(4.0)	5(3.3)
	Conjunctivitis	結膜炎	4(0.8)	7(1.7)	2(0.7)	0(0.0)
	Gastroenteritis	胃腸炎	7(1.5)	1(0.2)	3(1.1)	1(0.7)
	Pneumonia	肺炎	3(0.6)	3(0.7)	5(1.8)	0(0.0)
	Catheter site infection	カテーテル留置部位感染	3(0.6)	5(1.2)	3(1.1)	0(0.0)
	Upper respiratory tract infection	上気道感染	6(1.2)	2(0.5)	1(0.4)	0(0.0)
	Influenza	インフルエンザ	6(1.2)	0(0.0)	0(0.0)	0(0.0)
	Cystitis	膀胱炎	3(0.6)	3(0.7)	0(0.0)	0(0.0)
	Cellulitis	蜂巣炎	4(0.8)	2(0.5)	0(0.0)	0(0.0)
	Herpes zoster	帯状疱疹	3(0.6)	3(0.7)	0(0.0)	0(0.0)
	Urinary tract infection	尿路感染	4(0.8)	1(0.2)	0(0.0)	0(0.0)
	Periodontitis	歯周炎	2(0.4)	3(0.7)	0(0.0)	0(0.0)
	Peritonitis	腹膜炎	1(0.2)	3(0.7)	0(0.0)	1(0.7)
	Bronchitis	気管支炎	2(0.4)	1(0.2)	1(0.4)	0(0.0)
	Renal cyst infection	腎嚢胞感染	1(0.2)	2(0.5)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Otitis media	中耳炎	1(0.2)	2(0.5)	0(0.0)	0(0.0)
Angular cheilitis	口角口唇炎	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Paronychia	爪囲炎	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Sinusitis	副鼻腔炎	1(0.2)	0(0.0)	1(0.4)	0(0.0)
Upper respiratory tract infection bacterial	細菌性上気道感染	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Body tinea	体部白癬	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Otitis media chronic	慢性中耳炎	1(0.2)	0(0.0)	1(0.4)	0(0.0)
Pharyngitis	咽頭炎	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Tinea pedis	足部白癬	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Enteritis infectious	感染性腸炎	1(0.2)	1(0.2)	0(0.0)	0(0.0)
Herpes simplex	単純ヘルペス	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Osteomyelitis	骨髄炎	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Otitis externa	外耳炎	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Pneumonia chlamydial	クラミジア性肺炎	0(0.0)	0(0.0)	1(0.4)	0(0.0)
Pyelonephritis	腎盂腎炎	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Lung infection	肺感染	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Chronic sinusitis	慢性副鼻腔炎	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Epididymitis	精巣上体炎	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Furuncle	せつ	1(0.2)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Gastroenteritis viral	ウイルス性胃腸炎	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
Gingivitis	歯肉炎	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
Hordeolum	麦粒腫	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Skin infection	皮膚感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Tracheobronchitis	気管気管支炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatic cyst infection	肝嚢胞感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Shunt infection	シャント感染	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
Oral herpes	口腔ヘルペス	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Infected dermal cyst	感染性皮膚嚢腫	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
Vascular device infection	血管デバイス感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Diverticulitis	憩室炎	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
Folliculitis	毛包炎	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
Sepsis	敗血症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Helicobacter infection	ヘリコバクター感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
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）	2(0.4)	2(0.5)	1(0.4)	1(0.7)
Oral papilloma	口腔乳頭腫	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Breast cancer	乳癌	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Gastric cancer	胃癌	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Laryngeal papilloma	喉頭乳頭腫	0(0.0)	0(0.0)	0(0.0)	1(0.7)
Seborrhoeic keratosis	脂漏性角化症	0(0.0)	0(0.0)	1(0.4)	0(0.0)
Skin papilloma	皮膚乳頭腫	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Blood and lymphatic system disorders	血液およびリンパ系障害	5(1.0)	3(0.7)	1(0.4)	2(1.3)
Iron deficiency anaemia	鉄欠乏性貧血	1(0.2)	0(0.0)	0(0.0)	1(0.7)
Anaemia macrocytic	大球性貧血	0(0.0)	1(0.2)	1(0.4)	0(0.0)
Anaemia	貧血	1(0.2)	0(0.0)	0(0.0)	1(0.7)
Nephrogenic anaemia	腎性貧血	1(0.2)	1(0.2)	0(0.0)	0(0.0)
Eosinophilia	好酸球増加症	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Lymphadenitis	リンパ節炎	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Lymphadenopathy	リンパ節症	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Immune system disorders	免疫系障害	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Allergy to arthropod sting	節足動物刺傷アレルギー	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Allergy to arthropod bite	節足動物咬傷アレルギー	1(0.2)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Endocrine disorders	内分泌障害	3(0.6)	1(0.2)	0(0.0)	0(0.0)
Hyperparathyroidism secondary	続発性副甲状腺機能亢進症	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Hypothyroidism	甲状腺機能低下症	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Parathyroid gland enlargement	副甲状腺肥大	1(0.2)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Metabolism and nutrition disorders	代謝および栄養障害	21(4.4)	11(2.6)	6(2.2)	0(0.0)
Decreased appetite	食欲減退	8(1.7)	3(0.7)	1(0.4)	0(0.0)
Hyperkalaemia	高カリウム血症	3(0.6)	1(0.2)	1(0.4)	0(0.0)
Dehydration	脱水	1(0.2)	2(0.5)	1(0.4)	0(0.0)
Hyperphosphataemia	高リン酸塩血症	2(0.4)	2(0.5)	0(0.0)	0(0.0)
Hypoglycaemia	低血糖	3(0.6)	0(0.0)	0(0.0)	0(0.0)
Hyperuricaemia	高尿酸血症	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Metabolic acidosis	代謝性アシドーシス	1(0.2)	0(0.0)	1(0.4)	0(0.0)
Diabetes mellitus	糖尿病	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Hyponatraemia	低ナトリウム血症	0(0.0)	0(0.0)	1(0.4)	0(0.0)
Hypoproteinaemia	低蛋白血症	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Hyperlipidaemia	高脂血症	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Hyperamylasaemia	高アミラーゼ血症	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Type 2 diabetes mellitus	２型糖尿病	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Hypocalcaemia	低カルシウム血症	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Dyslipidaemia	脂質異常症	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Hypocarnitinaemia	低カルニチン血症	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Fluid overload	水分過負荷	0(0.0)	0(0.0)	1(0.4)	0(0.0)
Hypoalbuminaemia	低アルブミン血症	0(0.0)	1(0.2)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Hypokalaemia	低カリウム血症	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
Psychiatric disorders	精神障害	7 (1.5)	7 (1.7)	4 (1.4)	0 (0.0)
Insomnia	不眠症	3 (0.6)	5 (1.2)	3 (1.1)	0 (0.0)
Delirium	譫妄	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)
Anxiety	不安	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)
Sleep disorder	睡眠障害	1 (0.2)	0 (0.0)	1 (0.4)	0 (0.0)
Abnormal behaviour	異常行動	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Nervous system disorders	神経系障害	28(5.8)	13(3.1)	8(2.9)	2(1.3)
Headache	頭痛	11(2.3)	5(1.2)	4(1.4)	0(0.0)
Dizziness	浮動性めまい	4(0.8)	2(0.5)	0(0.0)	2(1.3)
Somnolence	傾眠	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Cerebral infarction	脳梗塞	1(0.2)	1(0.2)	0(0.0)	0(0.0)
Hypoaesthesia	感覚鈍麻	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Hypoglycaemic coma	低血糖昏睡	0(0.0)	0(0.0)	1(0.4)	0(0.0)
Loss of consciousness	意識消失	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Carotid artery stenosis	頚動脈狭窄	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Cerebellar infarction	小脳梗塞	0(0.0)	0(0.0)	1(0.4)	0(0.0)
Cerebral haemorrhage	脳出血	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Diabetic neuropathy	糖尿病性ニューロパチー	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Dizziness postural	体位性めまい	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Facial paralysis	顔面麻痺	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Myoclonus	ミオクローヌス	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Post herpetic neuralgia	ヘルペス後神経痛	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Sciatica	坐骨神経痛	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Toxic encephalopathy	中毒性脳症	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Tremor	振戦	1(0.2)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Intercostal neuralgia	肋間神経痛	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
Cervical radiculopathy	頸髄神経根障害	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Restless legs syndrome	下肢静止不能症候群	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
Dizziness exertional	労作性めまい	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Dysgeusia	味覚異常	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Neuropathy peripheral	末梢性ニューロパチー	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Eye disorders	眼障害	8(1.7)	13(3.1)	14(5.1)	12(7.8)
Retinal haemorrhage	網膜出血	0(0.0)	3(0.7)	5(1.8)	6(3.9)
Cataract	白内障	2(0.4)	2(0.5)	0(0.0)	2(1.3)
Conjunctival haemorrhage	結膜出血	3(0.6)	1(0.2)	0(0.0)	0(0.0)
Dry eye	ドライアイ	0(0.0)	0(0.0)	2(0.7)	1(0.7)
Retinal vein occlusion	網膜静脈閉塞	0(0.0)	0(0.0)	1(0.4)	2(1.3)
Diabetic retinopathy	糖尿病網膜症	0(0.0)	1(0.2)	1(0.4)	1(0.7)
Blepharitis	眼瞼炎	0(0.0)	1(0.2)	1(0.4)	0(0.0)
Eczema eyelids	眼瞼湿疹	0(0.0)	0(0.0)	1(0.4)	0(0.0)
Macular oedema	黄斑浮腫	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Retinal exudates	網膜滲出物	0(0.0)	0(0.0)	1(0.4)	0(0.0)
Age-related macular degeneration	加齢黄斑変性	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Ocular hyperaemia	眼充血	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Optic disc haemorrhage	視神経乳頭出血	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Punctate keratitis	点状角膜炎	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Retinal oedema	網膜浮腫	0(0.0)	0(0.0)	1(0.4)	0(0.0)
Trichiasis	睫毛乱生	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Vitreous floaters	硝子体浮遊物	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Eye pruritus	眼そう痒症	1(0.2)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Cystoid macular oedema	嚢胞様黄斑浮腫	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
Eyelid haematoma	眼瞼血腫	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
Macular degeneration	黄斑変性	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
Meibomian gland dysfunction	マイボーム腺機能不全	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Macular fibrosis	黄斑線維症	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
Ear and labyrinth disorders	耳および迷路障害	3 (0.6)	4 (0.9)	1 (0.4)	0 (0.0)
Vertigo	回転性めまい	2 (0.4)	2 (0.5)	0 (0.0)	0 (0.0)
Vertigo positional	頭位性回転性めまい	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
Deafness	難聴	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
Sudden hearing loss	突発性難聴	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Eustachian tube stenosis	耳管狭窄	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6546 0 <= to < 1/4 * MCD n (%)	MT-6546 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6546 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6546 >= 3/4 * MCD n (%)
Cardiac disorders	心臓障害	10(2.1)	4(0.9)	7(2.5)	0(0.0)
Cardiac failure chronic	慢性心不全	2(0.4)	1(0.2)	2(0.7)	0(0.0)
Cardiac failure congestive	うっ血性心不全	0(0.0)	2(0.5)	1(0.4)	0(0.0)
Palpitations	動悸	2(0.4)	0(0.0)	1(0.4)	0(0.0)
Atrial fibrillation	心房細動	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Tachycardia paroxysmal	発作性頻脈	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Myocardial ischaemia	心筋虚血	1(0.2)	1(0.2)	0(0.0)	0(0.0)
Bradycardia	徐脈	0(0.0)	0(0.0)	1(0.4)	0(0.0)
Cardiac failure	心不全	0(0.0)	0(0.0)	1(0.4)	0(0.0)
Pericarditis	心膜炎	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Cardiac dysfunction	心機能障害	0(0.0)	0(0.0)	1(0.4)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Vascular disorders	血管障害	18(3.7)	11(2.6)	2(0.7)	2(1.3)
Hypertension	高血圧	7(1.5)	2(0.5)	0(0.0)	0(0.0)
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	3(0.6)	3(0.7)	0(0.0)	0(0.0)
Hypotension	低血圧	1(0.2)	2(0.5)	0(0.0)	1(0.7)
Orthostatic hypotension	起立性低血圧	3(0.6)	0(0.0)	0(0.0)	0(0.0)
Internal haemorrhage	内出血	3(0.6)	0(0.0)	0(0.0)	0(0.0)
Haemorrhage	出血	0(0.0)	2(0.5)	0(0.0)	0(0.0)
Arteriosclerosis	動脈硬化症	0(0.0)	1(0.2)	1(0.4)	0(0.0)
Vascular rupture	血管破裂	0(0.0)	0(0.0)	1(0.4)	0(0.0)
Aneurysm	動脈瘤	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Vascular pain	血管痛	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Vascular insufficiency	血行不全	0(0.0)	0(0.0)	0(0.0)	1(0.7)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	11(2.3)	8(1.9)	7(2.5)	2(1.3)
Cough	咳嗽	4(0.8)	1(0.2)	1(0.4)	0(0.0)
Upper respiratory tract inflammation	上気道の炎症	1(0.2)	2(0.5)	1(0.4)	0(0.0)
Rhinitis allergic	アレルギー性鼻炎	1(0.2)	2(0.5)	0(0.0)	0(0.0)
Epistaxis	鼻出血	1(0.2)	1(0.2)	1(0.4)	0(0.0)
Asthma	喘息	1(0.2)	0(0.0)	1(0.4)	0(0.0)
Haemoptysis	喀血	1(0.2)	1(0.2)	0(0.0)	0(0.0)
Sputum increased	喀痰増加	0(0.0)	0(0.0)	1(0.4)	1(0.7)
Interstitial lung disease	間質性肺疾患	0(0.0)	0(0.0)	1(0.4)	0(0.0)
Pleural effusion	胸水	0(0.0)	0(0.0)	0(0.0)	1(0.7)
Pulmonary congestion	肺うっ血	0(0.0)	0(0.0)	1(0.4)	0(0.0)
Pulmonary hypertension	肺高血圧症	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Reflux laryngitis	逆流性喉頭炎	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Pulmonary oedema	肺水腫	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Sleep apnoea syndrome	睡眠時無呼吸症候群	1(0.2)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Gastrointestinal disorders	胃腸障害	92(19.1)	46(10.9)	24(8.7)	5(3.3)
Diarrhoea	下痢	34(7.1)	16(3.8)	8(2.9)	0(0.0)
Vomiting	嘔吐	12(2.5)	8(1.9)	3(1.1)	0(0.0)
Nausea	悪心	14(2.9)	2(0.5)	2(0.7)	1(0.7)
Constipation	便秘	8(1.7)	7(1.7)	3(1.1)	0(0.0)
Dental caries	齲歯	4(0.8)	1(0.2)	0(0.0)	2(1.3)
Gastrooesophageal reflux disease	胃食道逆流性疾患	5(1.0)	1(0.2)	1(0.4)	0(0.0)
Abdominal discomfort	腹部不快感	6(1.2)	1(0.2)	0(0.0)	0(0.0)
Stomatitis	口内炎	5(1.0)	1(0.2)	0(0.0)	0(0.0)
Abdominal pain upper	上腹部痛	0(0.0)	6(1.4)	0(0.0)	0(0.0)
Enterocolitis	腸炎	3(0.6)	1(0.2)	2(0.7)	0(0.0)
Abdominal pain	腹痛	4(0.8)	1(0.2)	0(0.0)	0(0.0)
Abdominal distension	腹部膨満	2(0.4)	0(0.0)	1(0.4)	0(0.0)
Faeces soft	軟便	2(0.4)	1(0.2)	0(0.0)	0(0.0)
Diverticulum intestinal	腸憩室	1(0.2)	0(0.0)	0(0.0)	1(0.7)
Duodenal ulcer haemorrhage	出血性十二指腸潰瘍	0(0.0)	2(0.5)	0(0.0)	0(0.0)
Gastritis	胃炎	1(0.2)	1(0.2)	0(0.0)	0(0.0)
Toothache	歯痛	0(0.0)	0(0.0)	1(0.4)	1(0.7)
Gastric polyps	胃ポリープ	2(0.4)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Gastrointestinal disorder	胃腸障害	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Periodontal disease	歯周病	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Tooth loss	歯の脱落	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Gastrointestinal polyp haemorrhage	胃腸ポリープ出血	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Dry mouth	口内乾燥	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Duodenal ulcer	十二指腸潰瘍	0(0.0)	0(0.0)	1(0.4)	0(0.0)
Dyspepsia	消化不良	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Gastric ulcer	胃潰瘍	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Gastric ulcer haemorrhage	出血性胃潰瘍	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Gastritis erosive	びらん性胃炎	0(0.0)	0(0.0)	1(0.4)	0(0.0)
Glossitis	舌炎	0(0.0)	0(0.0)	1(0.4)	0(0.0)
Haemorrhoids	痔核	0(0.0)	0(0.0)	1(0.4)	0(0.0)
Melaena	メレナ	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Mouth haemorrhage	口腔内出血	0(0.0)	0(0.0)	1(0.4)	0(0.0)
Pancreatitis	膵炎	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Large intestine polyp	大腸ポリープ	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Gastric disorder	胃障害	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Gastrointestinal motility disorder	消化管運動障害	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Loose tooth	弛緩歯	1(0.2)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Gingival bleeding	歯肉出血	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Hiatus hernia	裂孔ヘルニア	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Inguinal hernia	鼠径ヘルニア	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
Traumatic occlusion	外傷性咬合	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatobiliary disorders	肝胆道系障害	3 (0.6)	6 (1.4)	1 (0.4)	0 (0.0)
Cholelithiasis	胆石症	1 (0.2)	3 (0.7)	1 (0.4)	0 (0.0)
Hepatic function abnormal	肝機能異常	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)
Cholecystitis	胆嚢炎	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)
Hepatic cirrhosis	肝硬変	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
Cholangitis	胆管炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Cholecystitis acute	急性胆嚢炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	38(7.9)	28(6.6)	8(2.9)	4(2.6)
Eczema	湿疹	5(1.0)	6(1.4)	1(0.4)	0(0.0)
Dermatitis contact	接触皮膚炎	5(1.0)	2(0.5)	3(1.1)	0(0.0)
Pruritus	そう痒症	5(1.0)	4(0.9)	0(0.0)	1(0.7)
Haemorrhage subcutaneous	皮下出血	2(0.4)	2(0.5)	2(0.7)	1(0.7)
Rash	発疹	5(1.0)	1(0.2)	0(0.0)	0(0.0)
Drug eruption	薬疹	1(0.2)	3(0.7)	1(0.4)	0(0.0)
Ingrowing nail	嵌入爪	2(0.4)	1(0.2)	0(0.0)	1(0.7)
Skin exfoliation	皮膚剥脱	1(0.2)	2(0.5)	0(0.0)	0(0.0)
Eczema asteatotic	皮脂欠乏性湿疹	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Urticaria	蕁麻疹	0(0.0)	1(0.2)	0(0.0)	1(0.7)
Seborrhoeic dermatitis	脂漏性皮膚炎	1(0.2)	1(0.2)	0(0.0)	0(0.0)
Cold sweat	冷汗	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Dermal cyst	皮膚嚢腫	1(0.2)	0(0.0)	1(0.4)	0(0.0)
Decubitus ulcer	褥瘡性潰瘍	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Prurigo	痒疹	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Skin erosion	皮膚びらん	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Skin ulcer	皮膚潰瘍	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Alopecia	脱毛症	1(0.2)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Dermatitis acneiform	ざ瘡様皮膚炎	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Hyperkeratosis	過角化	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Neurodermatitis	神経皮膚炎	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Rash pruritic	そう痒性皮疹	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Skin disorder	皮膚障害	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Xeroderma	乾皮症	0(0.0)	0(0.0)	1(0.4)	0(0.0)
Skin mass	皮膚腫瘤	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Dermatitis	皮膚炎	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Hand dermatitis	手皮膚炎	1(0.2)	0(0.0)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	30(6.2)	28(6.6)	13(4.7)	7(4.6)
Back pain	背部痛	5(1.0)	9(2.1)	1(0.4)	2(1.3)
Pain in extremity	四肢痛	6(1.2)	5(1.2)	1(0.4)	0(0.0)
Musculoskeletal pain	筋骨格痛	2(0.4)	5(1.2)	3(1.1)	0(0.0)
Muscle spasms	筋痙縮	2(0.4)	5(1.2)	1(0.4)	1(0.7)
Arthralgia	関節痛	4(0.8)	2(0.5)	2(0.7)	0(0.0)
Myalgia	筋肉痛	3(0.6)	2(0.5)	2(0.7)	0(0.0)
Spinal osteoarthritis	変形性脊椎症	1(0.2)	2(0.5)	0(0.0)	0(0.0)
Neck pain	頸部痛	2(0.4)	0(0.0)	1(0.4)	0(0.0)
Osteoarthritis	変形性関節症	1(0.2)	1(0.2)	1(0.4)	0(0.0)
Bursitis	滑液包炎	0(0.0)	1(0.2)	1(0.4)	0(0.0)
Osteoporosis	骨粗鬆症	1(0.2)	0(0.0)	1(0.4)	0(0.0)
Trigger finger	弾発指	1(0.2)	0(0.0)	0(0.0)	1(0.7)
Arthritis	関節炎	1(0.2)	0(0.0)	0(0.0)	1(0.7)
Lumbar spinal stenosis	腰部脊柱管狭窄症	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Periarthritis	関節周囲炎	0(0.0)	0(0.0)	1(0.4)	1(0.7)
Tenosynovitis	腱鞘炎	0(0.0)	2(0.5)	0(0.0)	0(0.0)
Synovial cyst	滑液嚢腫	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Chondrocalcinosis pyrophosphate	ピロリン酸カルシウム結晶性軟骨石灰化症	0(0.0)	0(0.0)	0(0.0)	1(0.7)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Haemarthrosis	出血性関節症	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Musculoskeletal stiffness	筋骨格硬直	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Musculoskeletal discomfort	筋骨格不快感	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Renal and urinary disorders	腎および尿路障害	10(2.1)	12(2.8)	3(1.1)	5(3.3)
Renal impairment	腎機能障害	3(0.6)	3(0.7)	2(0.7)	0(0.0)
Chronic kidney disease	慢性腎臓病	1(0.2)	3(0.7)	0(0.0)	2(1.3)
End stage renal disease	末期腎疾患	0(0.0)	2(0.5)	0(0.0)	1(0.7)
Renal failure	腎不全	0(0.0)	1(0.2)	0(0.0)	1(0.7)
Pollakiuria	頻尿	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Haematuria	血尿	2(0.4)	0(0.0)	0(0.0)	0(0.0)
Hypertonic bladder	緊張性膀胱	0(0.0)	0(0.0)	0(0.0)	1(0.7)
Oliguria	乏尿	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Hypertensive nephropathy	高血圧性腎症	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Diabetic nephropathy	糖尿病性腎症	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Acute kidney injury	急性腎障害	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Ureterolithiasis	尿管結石症	0(0.0)	0(0.0)	1(0.4)	0(0.0)
Azotaemia	高窒素血症	0(0.0)	1(0.2)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Reproductive system and breast disorders	生殖系および乳房障害	4 (0.8)	1 (0.2)	2 (0.7)	1 (0.7)
Benign prostatic hyperplasia	良性前立腺肥大症	2 (0.4)	1 (0.2)	0 (0.0)	1 (0.7)
Acquired hydrocele	後天性陰嚢水瘤	1 (0.2)	0 (0.0)	2 (0.7)	0 (0.0)
Nipple pain	乳頭痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	24 (5.0)	9 (2.1)	11 (4.0)	3 (2.0)
Oedema peripheral	末梢性浮腫	7 (1.5)	3 (0.7)	3 (1.1)	3 (2.0)
Pyrexia	発熱	5 (1.0)	4 (0.9)	5 (1.8)	0 (0.0)
Malaise	倦怠感	3 (0.6)	2 (0.5)	0 (0.0)	0 (0.0)
Oedema due to renal disease	腎疾患による浮腫	4 (0.8)	0 (0.0)	1 (0.4)	0 (0.0)
Chest pain	胸痛	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Catheter site granuloma	カテーテル留置部位肉芽腫	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)
Face oedema	顔面浮腫	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
Thirst	口渇	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
Chest discomfort	胸部不快感	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Feeling abnormal	異常感	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Injection site reaction	注射部位反応	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Peripheral swelling	末梢腫脹	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
Puncture site haemorrhage	穿刺部位出血	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Catheter site haemorrhage	カテーテル留置部位出血	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Investigations	臨床検査	17(3.5)	8(1.9)	4(1.4)	1(0.7)
Blood pressure increased	血圧上昇	2(0.4)	1(0.2)	1(0.4)	0(0.0)
Haemoglobin decreased	ヘモグロビン減少	3(0.6)	0(0.0)	0(0.0)	0(0.0)
C-reactive protein increased	Ｃ－反応性蛋白増加	1(0.2)	1(0.2)	1(0.4)	0(0.0)
Blood pressure decreased	血圧低下	2(0.4)	0(0.0)	0(0.0)	1(0.7)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	1(0.2)	1(0.2)	0(0.0)	0(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	1(0.2)	1(0.2)	0(0.0)	0(0.0)
Blood potassium decreased	血中カリウム減少	0(0.0)	2(0.5)	0(0.0)	0(0.0)
Blood creatinine increased	血中クレアチニン増加	0(0.0)	1(0.2)	0(0.0)	0(0.0)
Blood triglycerides increased	血中トリグリセリド増加	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Blood uric acid increased	血中尿酸増加	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Blood parathyroid hormone increased	血中副甲状腺ホルモン増加	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Blood uric acid decreased	血中尿酸減少	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Blood urine present	尿中血陽性	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Prostatic specific antigen increased	前立腺特異性抗原増加	0(0.0)	0(0.0)	1(0.4)	0(0.0)
Serum ferritin decreased	血清フェリチン減少	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Transferrin saturation decreased	トランスフェリン飽和度低下	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Salmonella test positive	サルモネラ検査陽性	0(0.0)	1(0.2)	0(0.0)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Weight decreased	体重減少	1(0.2)	0(0.0)	0(0.0)	0(0.0)
Optic nerve cup/disc ratio increased	視神経乳頭陥凹／乳頭比増加	0(0.0)	0(0.0)	1(0.4)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	47(9.8)	41(9.7)	20(7.2)	8(5.2)
Contusion	挫傷	12(2.5)	12(2.8)	4(1.4)	2(1.3)
Shunt stenosis	シャント狭窄	14(2.9)	9(2.1)	1(0.4)	2(1.3)
Skin abrasion	皮膚擦過傷	4(0.8)	3(0.7)	2(0.7)	3(2.0)
Wound	創傷	4(0.8)	2(0.5)	0(0.0)	0(0.0)
Shunt occlusion	シャント閉塞	1(0.2)	2(0.5)	2(0.7)	0(0.0)
Spinal compression fracture	脊椎圧迫骨折	2(0.4)	1(0.2)	1(0.4)	0(0.0)
Thermal burn	熱傷	2(0.4)	1(0.2)	0(0.0)	1(0.7)
Arteriovenous fistula site complication	動静脈瘻部位合併症	2(0.4)	1(0.2)	0(0.0)	0(0.0)
Limb injury	四肢損傷	2(0.4)	0(0.0)	1(0.4)	0(0.0)
Rib fracture	肋骨骨折	0(0.0)	2(0.5)	0(0.0)	0(0.0)
Tooth fracture	歯牙破折	0(0.0)	1(0.2)	1(0.4)	0(0.0)
Ligament sprain	靭帯捻挫	0(0.0)	1(0.2)	1(0.4)	0(0.0)
Subcutaneous haematoma	皮下血腫	0(0.0)	0(0.0)	2(0.7)	0(0.0)
Joint injury	関節損傷	1(0.2)	1(0.2)	0(0.0)	0(0.0)
Procedural hypotension	処置による低血圧	0(0.0)	1(0.2)	1(0.4)	0(0.0)
Shunt blood flow excessive	シャント血流過剰	1(0.2)	0(0.0)	1(0.4)	0(0.0)
Skin wound	皮膚創傷	1(0.2)	1(0.2)	0(0.0)	0(0.0)
Vascular access malfunction	血管アクセス機能不全	1(0.2)	0(0.0)	1(0.4)	0(0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Dental restoration failure	歯科修復不成功	0 (0.0)	1 (0.2)	1 (0.4)	0 (0.0)
Fall	転倒	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Head injury	頭部損傷	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Injury	損傷	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Seroma	漿液腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Sternal fracture	胸骨骨折	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
Tendon rupture	腱断裂	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Skin laceration	皮膚裂傷	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Nail injury	爪損傷	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
Eye contusion	眼挫傷	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
Animal bite	動物咬傷	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
Clavicle fracture	鎖骨骨折	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
Foot fracture	足骨折	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Tooth injury	歯牙損傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Arteriovenous graft site stenosis	動静脈グラフト部位狭窄	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
Arteriovenous fistula occlusion	動静脈瘻閉塞	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Pelvic fracture	骨盤骨折	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
Vascular access complication	血管確保合併症	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
Procedural hypertension	処置による高血圧	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4.9－20　累積投与量別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 0 <= to < 1/4 * MCD n (%)	MT-6548 1/4 * MCD <= to < 2/4 * MCD n (%)	MT-6548 2/4 * MCD <= to < 3/4 * MCD n (%)	MT-6548 >= 3/4 * MCD n (%)
Heat illness	熱中症	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
Vascular access site inflammation	血管確保部位炎症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Soft tissue foreign body	軟部組織内異物	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
Heat stroke	熱射病	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
Peritoneal dialysis complication	腹膜透析合併症	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
Traumatic haemothorax	外傷性血胸	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
Surgical and medical procedures	外科および内科処置	2 (0.4)	1 (0.2)	0 (0.0)	0 (0.0)
Arteriovenous fistula operation	動静脈瘻手術	2 (0.4)	1 (0.2)	0 (0.0)	0 (0.0)

Note(s): MedDRA Version 21.1 and MedDRA/J Version 21.1.
Note(s): MCD Maximum cumulative dose.
Note(s): Percentages are based on the number of subjects in each category (N1).
Source: t_14_3_1_11_1.sas

5.3.5.3—2 Table 14.3.1.11.1 より引用

表 2.7.4.9－21　休薬前後別の有害事象の内訳（MT-6548-J01 試験）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N*=21) 4 weeks before drug interruption n (%)	MT-6548(N*=21) 4 weeks after drug interruption n (%)	darbepoetin(N*=38) 4 weeks before drug interruption n (%)	darbepoetin(N*=38) 4 weeks after drug interruption n (%)
Subjects with at least one adverse event		3(14.3)	2(9.5)	10(26.3)	11(28.9)
Infections and infestations	感染症および寄生虫症	1(4.8)	1(4.8)	3(7.9)	4(10.5)
Nasopharyngitis	上咽頭炎	1(4.8)	0(0.0)	1(2.6)	1(2.6)
Cellulitis	蜂巣炎	0(0.0)	1(4.8)	0(0.0)	0(0.0)
Conjunctivitis	結膜炎	0(0.0)	0(0.0)	1(2.6)	1(2.6)
Dermatophytosis of nail	爪の皮膚糸状菌症	0(0.0)	0(0.0)	1(2.6)	0(0.0)
Herpes zoster	帯状疱疹	0(0.0)	0(0.0)	0(0.0)	1(2.6)
Otitis media	中耳炎	0(0.0)	0(0.0)	0(0.0)	1(2.6)
Metabolism and nutrition disorders	代謝および栄養障害	0(0.0)	1(4.8)	1(2.6)	1(2.6)
Dehydration	脱水	0(0.0)	1(4.8)	0(0.0)	0(0.0)
Hyponatraemia	低ナトリウム血症	0(0.0)	0(0.0)	1(2.6)	1(2.6)
Nervous system disorders	神経系障害	0(0.0)	0(0.0)	1(2.6)	0(0.0)
Sciatica	坐骨神経痛	0(0.0)	0(0.0)	1(2.6)	0(0.0)
Eye disorders	眼障害	0(0.0)	1(4.8)	2(5.3)	1(2.6)
Retinal haemorrhage	網膜出血	0(0.0)	1(4.8)	1(2.6)	1(2.6)
Cataract	白内障	0(0.0)	0(0.0)	1(2.6)	1(2.6)
Asthenopia	眼精疲労	0(0.0)	0(0.0)	1(2.6)	0(0.0)
Vascular disorders	血管障害	0(0.0)	0(0.0)	1(2.6)	0(0.0)
Hot flush	ほてり	0(0.0)	0(0.0)	1(2.6)	0(0.0)

表 2.7.4.9－21　休薬前後別の有害事象の内訳（MT-6548-J01 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N*=21) 4 weeks before drug interruption n (%)	MT-6548(N*=21) 4 weeks after drug interruption n (%)	darbepoetin(N*=38) 4 weeks before drug interruption n (%)	darbepoetin(N*=38) 4 weeks after drug interruption n (%)
Gastrointestinal disorders	胃腸障害	1(4.8)	0(0.0)	2(5.3)	3(7.9)
Nausea	悪心	1(4.8)	0(0.0)	1(2.6)	0(0.0)
Gastrooesophageal reflux disease	胃食道逆流性疾患	0(0.0)	0(0.0)	1(2.6)	1(2.6)
Abdominal pain upper	上腹部痛	0(0.0)	0(0.0)	0(0.0)	1(2.6)
Aphthous ulcer	アフタ性潰瘍	0(0.0)	0(0.0)	0(0.0)	1(2.6)
Hepatobiliary disorders	肝胆道系障害	0(0.0)	0(0.0)	0(0.0)	1(2.6)
Hepatic function abnormal	肝機能異常	0(0.0)	0(0.0)	0(0.0)	1(2.6)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	1(4.8)	1(4.8)	1(2.6)	2(5.3)
Arthritis	関節炎	0(0.0)	1(4.8)	0(0.0)	0(0.0)
Synovial cyst	滑液嚢腫	1(4.8)	0(0.0)	0(0.0)	0(0.0)
Back pain	背部痛	0(0.0)	0(0.0)	0(0.0)	1(2.6)
Lumbar spinal stenosis	腰部脊柱管狭窄症	0(0.0)	0(0.0)	0(0.0)	1(2.6)
Intervertebral disc protrusion	椎間板突出	0(0.0)	0(0.0)	1(2.6)	0(0.0)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	0(0.0)	0(0.0)	0(0.0)	1(2.6)
Radius fracture	橈骨骨折	0(0.0)	0(0.0)	0(0.0)	1(2.6)

Note(s): MedDRA Version 20.1 and MedDRA/J Version 20.1.
Note(s): N*: number of subjects interrupted the study drug.
Data Source: Listing 16.2.5.1
Source: t_14_3_1_18.sas

5.3.5.1—6 表 14.3.1.18 より引用

表 2.7.4.9－22　休薬前後別の有害事象の内訳（MT-6548-J03 試験）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N*=25) 4 weeks before drug interruption n (%)	MT-6548(N*=25) 4 weeks after drug interruption n (%)	darbepoetin(N*=16) 4 weeks before drug interruption n (%)	darbepoetin(N*=16) 4 weeks after drug interruption n (%)
Subjects with at least one adverse event		2(8.0)	2(8.0)	1(6.3)	3(18.8)
Infections and infestations	感染症および寄生虫症	0(0.0)	1(4.0)	1(6.3)	0(0.0)
Cellulitis	蜂巣炎	0(0.0)	1(4.0)	0(0.0)	0(0.0)
Pharyngitis	咽頭炎	0(0.0)	0(0.0)	1(6.3)	0(0.0)
Metabolism and nutrition disorders	代謝および栄養障害	0(0.0)	1(4.0)	0(0.0)	0(0.0)
Hyperphosphataemia	高リン酸塩血症	0(0.0)	1(4.0)	0(0.0)	0(0.0)
Hypoglycaemia	低血糖	0(0.0)	1(4.0)	0(0.0)	0(0.0)
Cardiac disorders	心臓障害	0(0.0)	0(0.0)	0(0.0)	1(6.3)
Coronary artery stenosis	冠動脈狭窄	0(0.0)	0(0.0)	0(0.0)	1(6.3)
Vascular disorders	血管障害	0(0.0)	0(0.0)	0(0.0)	1(6.3)
Peripheral artery occlusion	末梢動脈閉塞	0(0.0)	0(0.0)	0(0.0)	1(6.3)
Gastrointestinal disorders	胃腸障害	1(4.0)	1(4.0)	0(0.0)	1(6.3)
Diarrhoea	下痢	1(4.0)	0(0.0)	0(0.0)	0(0.0)
Nausea	悪心	0(0.0)	1(4.0)	0(0.0)	0(0.0)
Abdominal pain	腹痛	0(0.0)	0(0.0)	0(0.0)	1(6.3)
Investigations	臨床検査	0(0.0)	0(0.0)	1(6.3)	1(6.3)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	0(0.0)	0(0.0)	1(6.3)	1(6.3)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	0(0.0)	0(0.0)	1(6.3)	1(6.3)

表 2.7.4.9－22　休薬前後別の有害事象の内訳（MT-6548-J03 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548(N*=25) 4 weeks before drug interruption n (%)	MT-6548(N*=25) 4 weeks after drug interruption n (%)	darbepoetin(N*=16) 4 weeks before drug interruption n (%)	darbepoetin(N*=16) 4 weeks after drug interruption n (%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	1(4.0)	0(0.0)	0(0.0)	1(6.3)
Shunt occlusion	シャント閉塞	1(4.0)	0(0.0)	0(0.0)	0(0.0)
Dialysis related complication	透析関連合併症	0(0.0)	0(0.0)	0(0.0)	1(6.3)

Note(s): MedDRA Version 20.1 and MedDRA/J Version 20.1.
Note(s): N*: number of subjects interrupted the study drug.
Data Source: Listing 16.2.5.1
Source: t_14_3_1_18.sas

5.3.5.1―7 表 14.3.1.18 より引用

表 2.7.4.9－23　休薬前後別の有害事象の内訳（ISS-1）

	System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 4 weeks before drug interruption n (%)	MT-6548 4 weeks after drug interruption n (%)
NDD(N1=47)	Subjects with at least one adverse event		15(31.9)	13(27.7)
	Infections and infestations	感染症および寄生虫症	2(4.3)	3(6.4)
	Nasopharyngitis	上咽頭炎	1(2.1)	0(0.0)
	Cellulitis	蜂巣炎	0(0.0)	1(2.1)
	Upper respiratory tract infection	上気道感染	0(0.0)	1(2.1)
	Influenza	インフルエンザ	1(2.1)	0(0.0)
	Otitis externa	外耳炎	0(0.0)	1(2.1)
	Upper respiratory tract infection bacterial	細菌性上気道感染	1(2.1)	0(0.0)
	Endocrine disorders	内分泌障害	1(2.1)	1(2.1)
	Hypothyroidism	甲状腺機能低下症	1(2.1)	1(2.1)
	Metabolism and nutrition disorders	代謝および栄養障害	2(4.3)	2(4.3)
	Dehydration	脱水	0(0.0)	2(4.3)
	Hyperphosphataemia	高リン酸塩血症	1(2.1)	0(0.0)
	Hyperkalaemia	高カリウム血症	1(2.1)	0(0.0)
	Eye disorders	眼障害	0(0.0)	1(2.1)
	Retinal haemorrhage	網膜出血	0(0.0)	1(2.1)
	Vascular disorders	血管障害	2(4.3)	0(0.0)
	Hypertension	高血圧	2(4.3)	0(0.0)
	Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	1(2.1)	2(4.3)
	Haemoptysis	喀血	1(2.1)	1(2.1)
	Pulmonary hypertension	肺高血圧症	0(0.0)	1(2.1)
	Reflux laryngitis	逆流性喉頭炎	0(0.0)	1(2.1)

表 2.7.4.9－23　休薬前後別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 4 weeks before drug interruption n (%)	MT-6548 4 weeks after drug interruption n (%)
Gastrointestinal disorders	胃腸障害	4(8.5)	3(6.4)
Diarrhoea	下痢	1(2.1)	1(2.1)
Constipation	便秘	0(0.0)	2(4.3)
Nausea	悪心	1(2.1)	0(0.0)
Dental caries	齲歯	1(2.1)	0(0.0)
Gastrooesophageal reflux disease	胃食道逆流性疾患	0(0.0)	1(2.1)
Vomiting	嘔吐	1(2.1)	0(0.0)
Hepatobiliary disorders	肝胆道系障害	1(2.1)	0(0.0)
Hepatic function abnormal	肝機能異常	1(2.1)	0(0.0)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	1(2.1)	2(4.3)
Eczema asteatotic	皮脂欠乏性湿疹	1(2.1)	1(2.1)
Eczema	湿疹	0(0.0)	1(2.1)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	1(2.1)	1(2.1)
Arthritis	関節炎	0(0.0)	1(2.1)
Synovial cyst	滑液嚢腫	1(2.1)	0(0.0)
Renal and urinary disorders	腎および尿路障害	4(8.5)	2(4.3)
Diabetic nephropathy	糖尿病性腎症	1(2.1)	1(2.1)
End stage renal disease	末期腎疾患	1(2.1)	1(2.1)
Hypertensive nephropathy	高血圧性腎症	1(2.1)	0(0.0)
Renal impairment	腎機能障害	1(2.1)	0(0.0)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	0(0.0)	1(2.1)
Oedema due to renal disease	腎疾患による浮腫	0(0.0)	1(2.1)

表 2.7.4.9－23　休薬前後別の有害事象の内訳（ISS-1）（続き）

	System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 4 weeks before drug interruption n (%)	MT-6548 4 weeks after drug interruption n (%)
	Injury, poisoning and procedural complications	傷害、中毒および処置合併症	1(2.1)	2(4.3)
	Wound	創傷	1(2.1)	1(2.1)
	Contusion	挫傷	0(0.0)	1(2.1)
	Spinal compression fracture	脊椎圧迫骨折	0(0.0)	1(2.1)
	Surgical and medical procedures	外科および内科処置	0(0.0)	2(4.3)
	Arteriovenous fistula operation	動静脈瘻手術	0(0.0)	2(4.3)
HD(N1=57)	Subjects with at least one adverse event		15(26.3)	23(40.4)
	Infections and infestations	感染症および寄生虫症	6(10.5)	6(10.5)
	Nasopharyngitis	上咽頭炎	3(5.3)	2(3.5)
	Cellulitis	蜂巣炎	0(0.0)	1(1.8)
	Upper respiratory tract infection	上気道感染	0(0.0)	1(1.8)
	Enteritis infectious	感染性腸炎	1(1.8)	1(1.8)
	Bronchitis	気管支炎	0(0.0)	1(1.8)
	Gingivitis	歯肉炎	0(0.0)	1(1.8)
	Herpes zoster	帯状疱疹	1(1.8)	0(0.0)
	Periodontitis	歯周炎	0(0.0)	1(1.8)
	Shunt infection	シャント感染	1(1.8)	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）	0(0.0)	1(1.8)
	Skin papilloma	皮膚乳頭腫	0(0.0)	1(1.8)
	Blood and lymphatic system disorders	血液およびリンパ系障害	0(0.0)	1(1.8)
	Anaemia macrocytic	大球性貧血	0(0.0)	1(1.8)

表 2.7.4.9－23　休薬前後別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 4 weeks before drug interruption n (%)	MT-6548 4 weeks after drug interruption n (%)
Metabolism and nutrition disorders	代謝および栄養障害	1(1.8)	2(3.5)
Hyperphosphataemia	高リン酸塩血症	0(0.0)	1(1.8)
Hypocalcaemia	低カルシウム血症	1(1.8)	1(1.8)
Hypoglycaemia	低血糖	0(0.0)	1(1.8)
Nervous system disorders	神経系障害	2(3.5)	4(7.0)
Headache	頭痛	1(1.8)	2(3.5)
Post herpetic neuralgia	ヘルペス後神経痛	0(0.0)	1(1.8)
Toxic encephalopathy	中毒性脳症	1(1.8)	0(0.0)
Restless legs syndrome	下肢静止不能症候群	0(0.0)	1(1.8)
Cardiac disorders	心臓障害	0(0.0)	1(1.8)
Pericarditis	心膜炎	0(0.0)	1(1.8)
Vascular disorders	血管障害	0(0.0)	1(1.8)
Haemorrhage	出血	0(0.0)	1(1.8)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	1(1.8)	1(1.8)
Upper respiratory tract inflammation	上気道の炎症	1(1.8)	1(1.8)
Gastrointestinal disorders	胃腸障害	3(5.3)	5(8.8)
Diarrhoea	下痢	2(3.5)	4(7.0)
Constipation	便秘	1(1.8)	0(0.0)
Nausea	悪心	1(1.8)	1(1.8)
Abdominal pain	腹痛	0(0.0)	1(1.8)

表 2.7.4.9－23　休薬前後別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 4 weeks before drug interruption n (%)	MT-6548 4 weeks after drug interruption n (%)
Hepatobiliary disorders	肝胆道系障害	2(3.5)	1(1.8)
Cholecystitis acute	急性胆嚢炎	1(1.8)	1(1.8)
Cholelithiasis	胆石症	1(1.8)	0(0.0)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	1(1.8)	2(3.5)
Eczema	湿疹	0(0.0)	1(1.8)
Dermal cyst	皮膚嚢腫	1(1.8)	0(0.0)
Rash pruritic	そう痒性皮疹	0(0.0)	1(1.8)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	1(1.8)	2(3.5)
Arthralgia	関節痛	1(1.8)	0(0.0)
Back pain	背部痛	0(0.0)	1(1.8)
Tenosynovitis	腱鞘炎	0(0.0)	1(1.8)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	1(1.8)	1(1.8)
Pyrexia	発熱	1(1.8)	1(1.8)
Investigations	臨床検査	1(1.8)	2(3.5)
Blood parathyroid hormone increased	血中副甲状腺ホルモン増加	1(1.8)	1(1.8)
Blood pressure increased	血圧上昇	0(0.0)	1(1.8)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	5(8.8)	7(12.3)
Arteriovenous fistula site complication	動静脈瘻部位合併症	3(5.3)	2(3.5)
Shunt stenosis	シャント狭窄	1(1.8)	4(7.0)
Contusion	挫傷	0(0.0)	1(1.8)
Ligament sprain	靱帯捻挫	0(0.0)	1(1.8)
Shunt occlusion	シャント閉塞	1(1.8)	0(0.0)

表 2.7.4.9－23　休薬前後別の有害事象の内訳（ISS-1）（続き）

	System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 4 weeks before drug interruption n (%)	MT-6548 4 weeks after drug interruption n (%)
PD(N1=10)	Subjects with at least one adverse event		3(30.0)	5(50.0)
	Infections and infestations	感染症および寄生虫症	1(10.0)	1(10.0)
	Nasopharyngitis	上咽頭炎	0(0.0)	1(10.0)
	Catheter site infection	カテーテル留置部位感染	1(10.0)	0(0.0)
	Psychiatric disorders	精神障害	0(0.0)	1(10.0)
	Insomnia	不眠症	0(0.0)	1(10.0)
	Nervous system disorders	神経系障害	1(10.0)	1(10.0)
	Cerebral infarction	脳梗塞	1(10.0)	1(10.0)
	Eye disorders	眼障害	1(10.0)	0(0.0)
	Dry eye	ドライアイ	1(10.0)	0(0.0)
	Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	1(10.0)	0(0.0)
	Upper respiratory tract inflammation	上気道の炎症	1(10.0)	0(0.0)
	Gastrointestinal disorders	胃腸障害	0(0.0)	1(10.0)
	Diarrhoea	下痢	0(0.0)	1(10.0)
	Reproductive system and breast disorders	生殖系および乳房障害	0(0.0)	1(10.0)
	Acquired hydrocele	後天性陰嚢水瘤	0(0.0)	1(10.0)
	Injury, poisoning and procedural complications	傷害、中毒および処置合併症	0(0.0)	1(10.0)
	Traumatic haemothorax	外傷性血胸	0(0.0)	1(10.0)

表 2.7.4.9－23　休薬前後別の有害事象の内訳（ISS-1）（続き）

	System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 4 weeks before drug interruption n (%)	MT-6548 4 weeks after drug interruption n (%)
Total(N1=114)	Subjects with at least one adverse event		33(28.9)	41(36.0)
	Infections and infestations	感染症および寄生虫症	9(7.9)	10(8.8)
	Nasopharyngitis	上咽頭炎	4(3.5)	3(2.6)
	Cellulitis	蜂巣炎	0(0.0)	2(1.8)
	Upper respiratory tract infection	上気道感染	0(0.0)	2(1.8)
	Enteritis infectious	感染性腸炎	1(0.9)	1(0.9)
	Influenza	インフルエンザ	1(0.9)	0(0.0)
	Otitis externa	外耳炎	0(0.0)	1(0.9)
	Upper respiratory tract infection bacterial	細菌性上気道感染	1(0.9)	0(0.0)
	Bronchitis	気管支炎	0(0.0)	1(0.9)
	Gingivitis	歯肉炎	0(0.0)	1(0.9)
	Herpes zoster	帯状疱疹	1(0.9)	0(0.0)
	Periodontitis	歯周炎	0(0.0)	1(0.9)
	Shunt infection	シャント感染	1(0.9)	0(0.0)
	Catheter site infection	カテーテル留置部位感染	1(0.9)	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）	0(0.0)	1(0.9)
	Skin papilloma	皮膚乳頭腫	0(0.0)	1(0.9)
	Blood and lymphatic system disorders	血液およびリンパ系障害	0(0.0)	1(0.9)
	Anaemia macrocytic	大球性貧血	0(0.0)	1(0.9)
	Endocrine disorders	内分泌障害	1(0.9)	1(0.9)
	Hypothyroidism	甲状腺機能低下症	1(0.9)	1(0.9)

表 2.7.4.9－23　休薬前後別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 4 weeks before drug interruption n (%)	MT-6548 4 weeks after drug interruption n (%)
Metabolism and nutrition disorders	代謝および栄養障害	3(2.6)	4(3.5)
Dehydration	脱水	0(0.0)	2(1.8)
Hyperphosphataemia	高リン酸塩血症	1(0.9)	1(0.9)
Hypocalcaemia	低カルシウム血症	1(0.9)	1(0.9)
Hyperkalaemia	高カリウム血症	1(0.9)	0(0.0)
Hypoglycaemia	低血糖	0(0.0)	1(0.9)
Psychiatric disorders	精神障害	0(0.0)	1(0.9)
Insomnia	不眠症	0(0.0)	1(0.9)
Nervous system disorders	神経系障害	3(2.6)	5(4.4)
Headache	頭痛	1(0.9)	2(1.8)
Cerebral infarction	脳梗塞	1(0.9)	1(0.9)
Post herpetic neuralgia	ヘルペス後神経痛	0(0.0)	1(0.9)
Toxic encephalopathy	中毒性脳症	1(0.9)	0(0.0)
Restless legs syndrome	下肢静止不能症候群	0(0.0)	1(0.9)
Eye disorders	眼障害	1(0.9)	1(0.9)
Retinal haemorrhage	網膜出血	0(0.0)	1(0.9)
Dry eye	ドライアイ	1(0.9)	0(0.0)
Cardiac disorders	心臓障害	0(0.0)	1(0.9)
Pericarditis	心膜炎	0(0.0)	1(0.9)
Vascular disorders	血管障害	2(1.8)	1(0.9)
Hypertension	高血圧	2(1.8)	0(0.0)
Haemorrhage	出血	0(0.0)	1(0.9)

表 2.7.4.9－23　休薬前後別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 4 weeks before drug interruption n (%)	MT-6548 4 weeks after drug interruption n (%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	3(2.6)	3(2.6)
Upper respiratory tract inflammation	上気道の炎症	2(1.8)	1(0.9)
Haemoptysis	喀血	1(0.9)	1(0.9)
Pulmonary hypertension	肺高血圧症	0(0.0)	1(0.9)
Reflux laryngitis	逆流性喉頭炎	0(0.0)	1(0.9)
Gastrointestinal disorders	胃腸障害	7(6.1)	9(7.9)
Diarrhoea	下痢	3(2.6)	6(5.3)
Constipation	便秘	1(0.9)	2(1.8)
Nausea	悪心	2(1.8)	1(0.9)
Dental caries	齲歯	1(0.9)	0(0.0)
Gastrooesophageal reflux disease	胃食道逆流性疾患	0(0.0)	1(0.9)
Vomiting	嘔吐	1(0.9)	0(0.0)
Abdominal pain	腹痛	0(0.0)	1(0.9)
Hepatobiliary disorders	肝胆道系障害	3(2.6)	1(0.9)
Cholecystitis acute	急性胆嚢炎	1(0.9)	1(0.9)
Hepatic function abnormal	肝機能異常	1(0.9)	0(0.0)
Cholelithiasis	胆石症	1(0.9)	0(0.0)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	2(1.8)	4(3.5)
Eczema asteatotic	皮脂欠乏性湿疹	1(0.9)	1(0.9)
Eczema	湿疹	0(0.0)	2(1.8)
Dermal cyst	皮膚嚢腫	1(0.9)	0(0.0)
Rash pruritic	そう痒性皮疹	0(0.0)	1(0.9)

表 2.7.4.9－23　休薬前後別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 4 weeks before drug interruption n (%)	MT-6548 4 weeks after drug interruption n (%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	2(1.8)	3(2.6)
Arthritis	関節炎	0(0.0)	1(0.9)
Synovial cyst	滑液嚢腫	1(0.9)	0(0.0)
Arthralgia	関節痛	1(0.9)	0(0.0)
Back pain	背部痛	0(0.0)	1(0.9)
Tenosynovitis	腱鞘炎	0(0.0)	1(0.9)
Renal and urinary disorders	腎および尿路障害	4(3.5)	2(1.8)
Diabetic nephropathy	糖尿病性腎症	1(0.9)	1(0.9)
End stage renal disease	末期腎疾患	1(0.9)	1(0.9)
Hypertensive nephropathy	高血圧性腎症	1(0.9)	0(0.0)
Renal impairment	腎機能障害	1(0.9)	0(0.0)
Reproductive system and breast disorders	生殖系および乳房障害	0(0.0)	1(0.9)
Acquired hydrocele	後天性陰嚢水瘤	0(0.0)	1(0.9)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	1(0.9)	2(1.8)
Pyrexia	発熱	1(0.9)	1(0.9)
Oedema due to renal disease	腎疾患による浮腫	0(0.0)	1(0.9)
Investigations	臨床検査	1(0.9)	2(1.8)
Blood parathyroid hormone increased	血中副甲状腺ホルモン増加	1(0.9)	1(0.9)
Blood pressure increased	血圧上昇	0(0.0)	1(0.9)

表 2.7.4.9－23　休薬前後別の有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 4 weeks before drug interruption n (%)	MT-6548 4 weeks after drug interruption n (%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	6(5.3)	10(8.8)
Arteriovenous fistula site complication	動静脈瘻部位合併症	3(2.6)	2(1.8)
Shunt stenosis	シャント狭窄	1(0.9)	4(3.5)
Wound	創傷	1(0.9)	1(0.9)
Contusion	挫傷	0(0.0)	2(1.8)
Spinal compression fracture	脊椎圧迫骨折	0(0.0)	1(0.9)
Ligament sprain	靱帯捻挫	0(0.0)	1(0.9)
Shunt occlusion	シャント閉塞	1(0.9)	0(0.0)
Traumatic haemothorax	外傷性血胸	0(0.0)	1(0.9)
Surgical and medical procedures	外科および内科処置	0(0.0)	2(1.8)
Arteriovenous fistula operation	動静脈瘻手術	0(0.0)	2(1.8)

Note(s): MedDRA Version 21.1 and MedDRA/J Version 21.1.
Note(s): N1: number of subjects interrupted the study drug.
Source: t_14_3_1_12_1.sas

5.3.5.3—2 Table 14.3.1.12.1 より引用

表 2.7.4.9－24　MT-6548 群で 2%以上発現した有害事象の内訳（MT-6548-J01 試験）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 (N=151) n(%)	darbepoetin (N=153) n(%)
Subjects with at least one adverse event		109(72.2)	112(73.2)
Infections and infestations	感染症および寄生虫症	46(30.5)	42(27.5)
Nasopharyngitis	上咽頭炎	22(14.6)	19(12.4)
Cystitis	膀胱炎	3(2.0)	5(3.3)
Urinary tract infection	尿路感染	3(2.0)	4(2.6)
Pneumonia	肺炎	3(2.0)	3(2.0)
Conjunctivitis	結膜炎	3(2.0)	2(1.3)
Cellulitis	蜂巣炎	3(2.0)	0(0.0)
Gastroenteritis	胃腸炎	3(2.0)	0(0.0)
Dermatophytosis of nail	爪の皮膚糸状菌症	0(0.0)	3(2.0)
Blood and lymphatic system disorders	血液およびリンパ系障害	2(1.3)	6(3.9)
Iron deficiency anaemia	鉄欠乏性貧血	2(1.3)	5(3.3)
Metabolism and nutrition disorders	代謝および栄養障害	14(9.3)	19(12.4)
Decreased appetite	食欲減退	3(2.0)	1(0.7)
Dehydration	脱水	2(1.3)	3(2.0)
Metabolic acidosis	代謝性アシドーシス	1(0.7)	4(2.6)
Hyperkalaemia	高カリウム血症	0(0.0)	5(3.3)
Psychiatric disorders	精神障害	4(2.6)	1(0.7)
Insomnia	不眠症	3(2.0)	0(0.0)
Nervous system disorders	神経系障害	6(4.0)	8(5.2)
Headache	頭痛	3(2.0)	3(2.0)

表 2.7.4.9－24　MT-6548 群で 2%以上発現した有害事象の内訳（MT-6548-J01 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 (N=151) n(%)	darbepoetin (N=153) n(%)
Eye disorders	眼障害	12(7.9)	14(9.2)
Cataract	白内障	3(2.0)	1(0.7)
Retinal haemorrhage	網膜出血	2(1.3)	3(2.0)
Diabetic retinopathy	糖尿病網膜症	0(0.0)	3(2.0)
Cardiac disorders	心臓障害	8(5.3)	3(2.0)
Cardiac failure chronic	慢性心不全	3(2.0)	0(0.0)
Vascular disorders	血管障害	3(2.0)	8(5.2)
Hypertension	高血圧	1(0.7)	4(2.6)
Gastrointestinal disorders	胃腸障害	43(28.5)	37(24.2)
Diarrhoea	下痢	16(10.6)	5(3.3)
Constipation	便秘	8(5.3)	6(3.9)
Vomiting	嘔吐	7(4.6)	1(0.7)
Nausea	悪心	4(2.6)	3(2.0)
Abdominal pain upper	上腹部痛	3(2.0)	2(1.3)
Abdominal discomfort	腹部不快感	2(1.3)	3(2.0)
Dental caries	齲歯	2(1.3)	3(2.0)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	16(10.6)	15(9.8)
Eczema	湿疹	2(1.3)	3(2.0)
Haemorrhage subcutaneous	皮下出血	2(1.3)	3(2.0)
Renal and urinary disorders	腎および尿路障害	16(10.6)	15(9.8)
Chronic kidney disease	慢性腎臓病	5(3.3)	6(3.9)
Renal impairment	腎機能障害	4(2.6)	3(2.0)

表 2.7.4.9－24　MT-6548 群で 2%以上発現した有害事象の内訳（MT-6548-J01 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 (N=151) n(%)	darbepoetin (N=153) n(%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	16(10.6)	6(3.9)
Oedema peripheral	末梢性浮腫	7(4.6)	3(2.0)
Malaise	倦怠感	5(3.3)	1(0.7)
Pyrexia	発熱	5(3.3)	0(0.0)
Investigations	臨床検査	10(6.6)	11(7.2)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	2(1.3)	3(2.0)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	17(11.3)	14(9.2)
Contusion	挫傷	8(5.3)	2(1.3)
Heat illness	熱中症	0(0.0)	3(2.0)

Note(s): MedDRA Version 21.1 and MedDRA/J Version 21.1.
Source: t_14_3_1_3_1_1.sas

5.3.5.3—2 Table 14.3.1.3.1.1 より引用

表 2.7.4.9－25　MT-6548 群で 2%以上発現した有害事象の内訳（MT-6548-J03 試験）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 (N=162) n(%)	darbepoetin (N=161) n(%)
Subjects with at least one adverse event		145(89.5)	142(88.2)
Infections and infestations	感染症および寄生虫症	65(40.1)	77(47.8)
Nasopharyngitis	上咽頭炎	32(19.8)	46(28.6)
Conjunctivitis	結膜炎	8(4.9)	1(0.6)
Gastroenteritis	胃腸炎	8(4.9)	0(0.0)
Upper respiratory tract infection	上気道感染	4(2.5)	5(3.1)
Pneumonia	肺炎	4(2.5)	0(0.0)
Pharyngitis	咽頭炎	2(1.2)	5(3.1)
Tinea pedis	足部白癬	2(1.2)	4(2.5)
Shunt infection	シャント感染	0(0.0)	5(3.1)
Metabolism and nutrition disorders	代謝および栄養障害	10(6.2)	7(4.3)
Decreased appetite	食欲減退	6(3.7)	2(1.2)
Psychiatric disorders	精神障害	5(3.1)	3(1.9)
Insomnia	不眠症	4(2.5)	3(1.9)
Nervous system disorders	神経系障害	24(14.8)	11(6.8)
Headache	頭痛	9(5.6)	3(1.9)
Dizziness	浮動性めまい	6(3.7)	3(1.9)
Eye disorders	眼障害	23(14.2)	17(10.6)
Retinal haemorrhage	網膜出血	10(6.2)	5(3.1)

表 2.7.4.9－25　MT-6548 群で 2%以上発現した有害事象の内訳（MT-6548-J03 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 (N=162) n(%)	darbepoetin (N=161) n(%)
Gastrointestinal disorders	胃腸障害	46(28.4)	48(29.8)
Diarrhoea	下痢	17(10.5)	16(9.9)
Vomiting	嘔吐	8(4.9)	9(5.6)
Nausea	悪心	6(3.7)	1(0.6)
Constipation	便秘	4(2.5)	5(3.1)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	38(23.5)	21(13.0)
Eczema	湿疹	8(4.9)	5(3.1)
Pruritus	そう痒症	6(3.7)	4(2.5)
Haemorrhage subcutaneous	皮下出血	5(3.1)	2(1.2)
Dermatitis contact	接触皮膚炎	4(2.5)	0(0.0)
Drug eruption	薬疹	4(2.5)	0(0.0)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	40(24.7)	32(19.9)
Back pain	背部痛	8(4.9)	3(1.9)
Pain in extremity	四肢痛	8(4.9)	2(1.2)
Musculoskeletal pain	筋骨格痛	7(4.3)	5(3.1)
Myalgia	筋肉痛	5(3.1)	3(1.9)
Arthralgia	関節痛	3(1.9)	6(3.7)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	12(7.4)	8(5.0)
Oedema peripheral	末梢性浮腫	5(3.1)	0(0.0)

表 2.7.4.9－25　MT-6548 群で 2%以上発現した有害事象の内訳（MT-6548-J03 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 (N=162) n(%)	darbepoetin (N=161) n(%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	42(25.9)	52(32.3)
Shunt stenosis	シャント狭窄	13(8.0)	20(12.4)
Contusion	挫傷	11(6.8)	10(6.2)
Skin abrasion	皮膚擦過傷	4(2.5)	7(4.3)
Wound	創傷	4(2.5)	3(1.9)

Note(s): MedDRA Version 21.1 and MedDRA/J Version 21.1.
Source: t_14_3_1_3_1_2.sas

5.3.5.3—2 Table 14.3.1.3.1.2 より引用

表 2.7.4.9－26　いずれかの病期で 2%以上発現した有害事象の内訳（ISS-1）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	Total (N=481) n(%)
Subjects with at least one adverse event		150(74.3)	209(88.2)	38(90.5)	397(82.5)
Infections and infestations	感染症および寄生虫症	62(30.7)	96(40.5)	22(52.4)	180(37.4)
Nasopharyngitis	上咽頭炎	27(13.4)	49(20.7)	6(14.3)	82(17.0)
Conjunctivitis	結膜炎	3(1.5)	9(3.8)	1(2.4)	13(2.7)
Gastroenteritis	胃腸炎	3(1.5)	9(3.8)	0(0.0)	12(2.5)
Pneumonia	肺炎	3(1.5)	7(3.0)	1(2.4)	11(2.3)
Catheter site infection	カテーテル留置部位感染	0(0.0)	0(0.0)	10(23.8)	10(2.1)
Upper respiratory tract infection	上気道感染	2(1.0)	5(2.1)	2(4.8)	9(1.9)
Influenza	インフルエンザ	6(3.0)	0(0.0)	0(0.0)	6(1.2)
Cystitis	膀胱炎	4(2.0)	2(0.8)	0(0.0)	6(1.2)
Cellulitis	蜂巣炎	3(1.5)	1(0.4)	1(2.4)	5(1.0)
Peritonitis	腹膜炎	0(0.0)	0(0.0)	5(11.9)	5(1.0)
Urinary tract infection	尿路感染	4(2.0)	0(0.0)	0(0.0)	4(0.8)
Bronchitis	気管支炎	1(0.5)	2(0.8)	1(2.4)	4(0.8)
Body tinea	体部白癬	1(0.5)	0(0.0)	1(2.4)	2(0.4)
Diverticulitis	憩室炎	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Folliculitis	毛包炎	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Sepsis	敗血症	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Helicobacter infection	ヘリコバクター感染	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Blood and lymphatic system disorders	血液およびリンパ系障害	2(1.0)	7(3.0)	2(4.8)	11(2.3)
Anaemia	貧血	0(0.0)	1(0.4)	1(2.4)	2(0.4)
Nephrogenic anaemia	腎性貧血	0(0.0)	1(0.4)	1(2.4)	2(0.4)

表 2.7.4.9－26　いずれかの病期で 2%以上発現した有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Metabolism and nutrition disorders	代謝および栄養障害	21(10.4)	11(4.6)	5(11.9)	37(7.7)
Decreased appetite	食欲減退	3(1.5)	6(2.5)	3(7.1)	12(2.5)
Hyperkalaemia	高カリウム血症	4(2.0)	1(0.4)	0(0.0)	5(1.0)
Dehydration	脱水	3(1.5)	0(0.0)	1(2.4)	4(0.8)
Hyperphosphataemia	高リン酸塩血症	2(1.0)	1(0.4)	1(2.4)	4(0.8)
Fluid overload	水分過負荷	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Hypoalbuminaemia	低アルブミン血症	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Hypokalaemia	低カリウム血症	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Psychiatric disorders	精神障害	6(3.0)	8(3.4)	3(7.1)	17(3.5)
Insomnia	不眠症	3(1.5)	6(2.5)	2(4.8)	11(2.3)
Sleep disorder	睡眠障害	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Nervous system disorders	神経系障害	8(4.0)	35(14.8)	5(11.9)	48(10.0)
Headache	頭痛	4(2.0)	16(6.8)	0(0.0)	20(4.2)
Dizziness	浮動性めまい	1(0.5)	6(2.5)	1(2.4)	8(1.7)
Cerebral infarction	脳梗塞	0(0.0)	1(0.4)	1(2.4)	2(0.4)
Dizziness exertional	労作性めまい	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Dysgeusia	味覚異常	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Neuropathy peripheral	末梢性ニューロパチー	0(0.0)	0(0.0)	1(2.4)	1(0.2)

表 2.7.4.9－26　いずれかの病期で 2%以上発現した有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Eye disorders	眼障害	13(6.4)	25(10.5)	6(14.3)	44(9.1)
Retinal haemorrhage	網膜出血	2(1.0)	10(4.2)	2(4.8)	14(2.9)
Dry eye	ドライアイ	1(0.5)	1(0.4)	1(2.4)	3(0.6)
Retinal vein occlusion	網膜静脈閉塞	1(0.5)	1(0.4)	1(2.4)	3(0.6)
Macular degeneration	黄斑変性	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Meibomian gland dysfunction	マイボーム腺機能不全	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Macular fibrosis	黄斑線維症	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Cardiac disorders	心臓障害	8(4.0)	10(4.2)	2(4.8)	20(4.2)
Cardiac failure chronic	慢性心不全	3(1.5)	1(0.4)	1(2.4)	5(1.0)
Myocardial ischaemia	心筋虚血	0(0.0)	1(0.4)	1(2.4)	2(0.4)
Vascular disorders	血管障害	9(4.5)	17(7.2)	6(14.3)	32(6.7)
Hypertension	高血圧	6(3.0)	3(1.3)	0(0.0)	9(1.9)
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	0(0.0)	3(1.3)	2(4.8)	5(1.0)
Hypotension	低血圧	1(0.5)	2(0.8)	1(2.4)	4(0.8)
Orthostatic hypotension	起立性低血圧	1(0.5)	1(0.4)	1(2.4)	3(0.6)
Arteriosclerosis	動脈硬化症	0(0.0)	0(0.0)	2(4.8)	2(0.4)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	8(4.0)	13(5.5)	3(7.1)	24(5.0)
Cough	咳嗽	1(0.5)	3(1.3)	2(4.8)	6(1.2)
Upper respiratory tract inflammation	上気道の炎症	0(0.0)	3(1.3)	1(2.4)	4(0.8)

表 2.7.4.9－26　いずれかの病期で 2%以上発現した有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Gastrointestinal disorders	胃腸障害	58(28.7)	68(28.7)	18(42.9)	144(29.9)
Diarrhoea	下痢	19(9.4)	28(11.8)	8(19.0)	55(11.4)
Vomiting	嘔吐	8(4.0)	11(4.6)	4(9.5)	23(4.8)
Constipation	便秘	11(5.4)	6(2.5)	1(2.4)	18(3.7)
Nausea	悪心	7(3.5)	8(3.4)	3(7.1)	18(3.7)
Dental caries	齲歯	4(2.0)	2(0.8)	1(2.4)	7(1.5)
Abdominal discomfort	腹部不快感	2(1.0)	3(1.3)	2(4.8)	7(1.5)
Abdominal pain upper	上腹部痛	3(1.5)	0(0.0)	3(7.1)	6(1.2)
Enterocolitis	腸炎	1(0.5)	3(1.3)	2(4.8)	6(1.2)
Gastric polyps	胃ポリープ	0(0.0)	0(0.0)	2(4.8)	2(0.4)
Gingival bleeding	歯肉出血	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Hiatus hernia	裂孔ヘルニア	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Inguinal hernia	鼠径ヘルニア	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Traumatic occlusion	外傷性咬合	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	18(8.9)	47(19.8)	5(11.9)	70(14.6)
Eczema	湿疹	3(1.5)	9(3.8)	0(0.0)	12(2.5)
Pruritus	そう痒症	2(1.0)	8(3.4)	0(0.0)	10(2.1)
Dermatitis contact	接触皮膚炎	2(1.0)	4(1.7)	2(4.8)	8(1.7)
Haemorrhage subcutaneous	皮下出血	2(1.0)	5(2.1)	0(0.0)	7(1.5)
Rash	発疹	2(1.0)	3(1.3)	1(2.4)	6(1.2)
Dermatitis	皮膚炎	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Hand dermatitis	手皮膚炎	0(0.0)	0(0.0)	1(2.4)	1(0.2)

表 2.7.4.9－26　いずれかの病期で 2%以上発現した有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	17(8.4)	51(21.5)	4(9.5)	72(15.0)
Back pain	背部痛	5(2.5)	10(4.2)	2(4.8)	17(3.5)
Pain in extremity	四肢痛	3(1.5)	9(3.8)	0(0.0)	12(2.5)
Muscle spasms	筋痙縮	3(1.5)	6(2.5)	0(0.0)	9(1.9)
Musculoskeletal pain	筋骨格痛	1(0.5)	8(3.4)	0(0.0)	9(1.9)
Arthralgia	関節痛	2(1.0)	5(2.1)	1(2.4)	8(1.7)
Myalgia	筋肉痛	1(0.5)	6(2.5)	0(0.0)	7(1.5)
Arthritis	関節炎	1(0.5)	0(0.0)	1(2.4)	2(0.4)
Renal and urinary disorders	腎および尿路障害	25(12.4)	2(0.8)	3(7.1)	30(6.2)
Renal impairment	腎機能障害	7(3.5)	0(0.0)	1(2.4)	8(1.7)
Chronic kidney disease	慢性腎臓病	6(3.0)	0(0.0)	0(0.0)	6(1.2)
Haematuria	血尿	1(0.5)	0(0.0)	1(2.4)	2(0.4)
Azotaemia	高窒素血症	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Reproductive system and breast disorders	生殖系および乳房障害	3(1.5)	3(1.3)	1(2.4)	7(1.5)
Acquired hydrocele	後天性陰嚢水瘤	0(0.0)	1(0.4)	1(2.4)	2(0.4)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	20(9.9)	14(5.9)	6(14.3)	40(8.3)
Oedema peripheral	末梢性浮腫	9(4.5)	5(2.1)	0(0.0)	14(2.9)
Pyrexia	発熱	5(2.5)	5(2.1)	2(4.8)	12(2.5)
Malaise	倦怠感	5(2.5)	0(0.0)	0(0.0)	5(1.0)
Oedema due to renal disease	腎疾患による浮腫	4(2.0)	0(0.0)	1(2.4)	5(1.0)
Chest pain	胸痛	1(0.5)	0(0.0)	1(2.4)	2(0.4)
Catheter site haemorrhage	カテーテル留置部位出血	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Catheter site granuloma	カテーテル留置部位肉芽腫	0(0.0)	0(0.0)	1(2.4)	1(0.2)

表 2.7.4.9－26　いずれかの病期で 2%以上発現した有害事象の内訳（ISS-1）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA/J)	MT-6548 NDD (N=202) n(%)	MT-6548 HD (N=237) n(%)	MT-6548 PD (N=42) n(%)	MT-6548 Total (N=481) n(%)
Investigations	臨床検査	11(5.4)	14(5.9)	3(7.1)	28(5.8)
C-reactive protein increased	C－反応性蛋白増加	1(0.5)	1(0.4)	1(2.4)	3(0.6)
Blood potassium decreased	血中カリウム減少	1(0.5)	0(0.0)	1(2.4)	2(0.4)
Weight decreased	体重減少	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Optic nerve cup/disc ratio increased	視神経乳頭陥凹／乳頭比増加	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	23(11.4)	66(27.8)	6(14.3)	95(19.8)
Contusion	挫傷	11(5.4)	15(6.3)	1(2.4)	27(5.6)
Shunt stenosis	シャント狭窄	1(0.5)	22(9.3)	0(0.0)	23(4.8)
Skin abrasion	皮膚擦過傷	2(1.0)	9(3.8)	0(0.0)	11(2.3)
Wound	創傷	1(0.5)	5(2.1)	0(0.0)	6(1.2)
Spinal compression fracture	脊椎圧迫骨折	4(2.0)	0(0.0)	0(0.0)	4(0.8)
Shunt occlusion	シャント閉塞	0(0.0)	3(1.3)	1(2.4)	4(0.8)
Tooth fracture	歯牙破折	1(0.5)	0(0.0)	1(2.4)	2(0.4)
Heat stroke	熱射病	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Peritoneal dialysis complication	腹膜透析合併症	0(0.0)	0(0.0)	1(2.4)	1(0.2)
Traumatic haemothorax	外傷性血胸	0(0.0)	0(0.0)	1(2.4)	1(0.2)

Note(s): MedDRA Version 21.1 and MedDRA/J Version 21.1.
Source: t_14_3_1_3_2.sas

5.3.5.3—2 Table 14.3.1.3.2 より引用

表 2.7.4.9－27　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver21.1）

AESI	PT Code	PT Name	SOC
Hypersensitivity	10061035	Acquired C1 inhibitor deficiency	
Hypersensitivity	10048799	Acute generalised exanthematous pustulosis	
Hypersensitivity	10059773	Administration related reaction	
Hypersensitivity	10075096	Administration site dermatitis	
Hypersensitivity	10075099	Administration site eczema	
Hypersensitivity	10075102	Administration site hypersensitivity	
Hypersensitivity	10071156	Administration site rash	
Hypersensitivity	10075954	Administration site recall reaction	
Hypersensitivity	10075109	Administration site urticaria	
Hypersensitivity	10075959	Administration site vasculitis	
Hypersensitivity	10052613	Allergic bronchitis	
Hypersensitivity	10059447	Allergic colitis	
Hypersensitivity	10053779	Allergic cough	
Hypersensitivity	10051394	Allergic cystitis	
Hypersensitivity	10075185	Allergic eosinophilia	
Hypersensitivity	10075308	Allergic gastroenteritis	
Hypersensitivity	10071198	Allergic hepatitis	
Hypersensitivity	10057380	Allergic keratitis	
Hypersensitivity	10060924	Allergic oedema	
Hypersensitivity	10075072	Allergic otitis externa	
Hypersensitivity	10061557	Allergic otitis media	
Hypersensitivity	10050639	Allergic pharyngitis	
Hypersensitivity	10078853	Allergic reaction to excipient	
Hypersensitivity	10063532	Allergic respiratory disease	
Hypersensitivity	10063527	Allergic respiratory symptom	
Hypersensitivity	10048153	Allergic sinusitis	
Hypersensitivity	10079554	Allergic stomatitis	
Hypersensitivity	10066173	Allergic transfusion reaction	
Hypersensitivity	10075479	Allergy alert test positive	
Hypersensitivity	10056352	Allergy test positive	
Hypersensitivity	10074079	Allergy to immunoglobulin therapy	
Hypersensitivity	10077279	Allergy to surgical sutures	
Hypersensitivity	10055048	Allergy to vaccine	
Hypersensitivity	10001890	Alveolitis allergic	
Hypersensitivity	10002198	Anaphylactic reaction	
Hypersensitivity	10002199	Anaphylactic shock	
Hypersensitivity	10067113	Anaphylactic transfusion reaction	
Hypersensitivity	10002216	Anaphylactoid reaction	
Hypersensitivity	10063119	Anaphylactoid shock	
Hypersensitivity	10002222	Anaphylaxis treatment	
Hypersensitivity	10002424	Angioedema	
Hypersensitivity	10064059	Antiallergic therapy	
Hypersensitivity	10065514	Antiendomysial antibody positive	
Hypersensitivity	10050894	Anti-neutrophil cytoplasmic antibody positive vasculitis	
Hypersensitivity	10003036	Application site dermatitis	
Hypersensitivity	10050099	Application site eczema	
Hypersensitivity	10063583	Application site hypersensitivity	
Hypersensitivity	10003054	Application site rash	
Hypersensitivity	10076024	Application site recall reaction	
Hypersensitivity	10050104	Application site urticaria	
Hypersensitivity	10076027	Application site vasculitis	
Hypersensitivity	10061430	Arthritis allergic	
Hypersensitivity	10075084	Aspirin-exacerbated respiratory disease	
Hypersensitivity	10081492	Atopic cough	
Hypersensitivity	10003645	Atopy	
Hypersensitivity	10005149	Blepharitis allergic	
Hypersensitivity	10005589	Blood immunoglobulin E abnormal	
Hypersensitivity	10005591	Blood immunoglobulin E increased	
Hypersensitivity	10005404	Bromoderma	
Hypersensitivity	10006482	Bronchospasm	
Hypersensitivity	10073992	Catheter site dermatitis	
Hypersensitivity	10073995	Catheter site eczema	
Hypersensitivity	10073998	Catheter site hypersensitivity	
Hypersensitivity	10052271	Catheter site rash	
Hypersensitivity	10052272	Catheter site urticaria	
Hypersensitivity	10074014	Catheter site vasculitis	
Hypersensitivity	10071389	Chronic eosinophilic rhinosinusitis	
Hypersensitivity	10071380	Chronic hyperplastic eosinophilic sinusitis	
Hypersensitivity	10009192	Circulatory collapse	
Hypersensitivity	10052250	Circumoral oedema	
Hypersensitivity	10081703	Circumoral swelling	
Hypersensitivity	10010726	Conjunctival oedema	
Hypersensitivity	10010744	Conjunctivitis allergic	
Hypersensitivity	10067510	Contact stomatitis	
Hypersensitivity	10058973	Contrast media allergy	
Hypersensitivity	10010836	Contrast media reaction	
Hypersensitivity	10011033	Corneal oedema	
Hypersensitivity	10011596	Cutaneous vasculitis	
Hypersensitivity	10062918	Dennie-Morgan fold	
Hypersensitivity	10012431	Dermatitis	
Hypersensitivity	10012432	Dermatitis acneiform	
Hypersensitivity	10012434	Dermatitis allergic	
Hypersensitivity	10012438	Dermatitis atopic	
Hypersensitivity	10012441	Dermatitis bullous	
Hypersensitivity	10012442	Dermatitis contact	
Hypersensitivity	10012455	Dermatitis exfoliative	
Hypersensitivity	10012456	Dermatitis exfoliative generalised	
Hypersensitivity	10012468	Dermatitis herpetiformis	
Hypersensitivity	10012470	Dermatitis infected	
Hypersensitivity	10058675	Dermatitis psoriasiform	
Hypersensitivity	10072867	Device allergy	
Hypersensitivity	10076885	Dialysis membrane reaction	
Hypersensitivity	10070559	Distributive shock	
Hypersensitivity	10076470	Documented hypersensitivity to administered product	

表 2.7.4.9－27　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver21.1）（続き）

AESI	PT Code	PT Name	SOC
Hypersensitivity	10013687	Drug eruption	
Hypersensitivity	10013700	Drug hypersensitivity	
Hypersensitivity	10074350	Drug provocation test	
Hypersensitivity	10073508	Drug reaction with eosinophilia and systemic symptoms	
Hypersensitivity	10014184	Eczema	
Hypersensitivity	10014198	Eczema infantile	
Hypersensitivity	10014201	Eczema nummular	
Hypersensitivity	10068042	Eczema vaccinatum	
Hypersensitivity	10058681	Eczema vesicular	
Hypersensitivity	10055182	Eczema weeping	
Hypersensitivity	10056387	Encephalitis allergic	
Hypersensitivity	10014627	Encephalopathy allergic	
Hypersensitivity	10078117	Eosinophilic granulomatosis with polyangiitis	
Hypersensitivity	10059284	Epidermal necrosis	
Hypersensitivity	10053177	Epidermolysis	
Hypersensitivity	10014893	Epidermolysis bullosa	
Hypersensitivity	10015029	Epiglottic oedema	
Hypersensitivity	10015218	Erythema multiforme	
Hypersensitivity	10015225	Erythema nodosum	
Hypersensitivity	10064579	Exfoliative rash	
Hypersensitivity	10015907	Eye allergy	
Hypersensitivity	10052139	Eye oedema	
Hypersensitivity	10015967	Eye swelling	
Hypersensitivity	10015993	Eyelid oedema	
Hypersensitivity	10016029	Face oedema	
Hypersensitivity	10016741	Fixed eruption	
Hypersensitivity	10018258	Giant papillary conjunctivitis	
Hypersensitivity	10048305	Gingival oedema	
Hypersensitivity	10018291	Gingival swelling	
Hypersensitivity	10066837	Gleich's syndrome	
Hypersensitivity	10058499	Haemorrhagic urticaria	
Hypersensitivity	10058888	Hand dermatitis	
Hypersensitivity	10019617	Henoch-Schonlein purpura	
Hypersensitivity	10059440	Henoch-Schonlein purpura nephritis	
Hypersensitivity	10062506	Heparin-induced thrombocytopenia	
Hypersensitivity	10019860	Hereditary angioedema	
Hypersensitivity	10080955	Hereditary angioedema with C1 esterase inhibitor deficiency	
Hypersensitivity	10020751	Hypersensitivity	
Hypersensitivity	10081004	Hypersensitivity myocarditis	
Hypersensitivity	10020764	Hypersensitivity vasculitis	
Hypersensitivity	10021247	Idiopathic urticaria	
Hypersensitivity	10067142	Immediate post-injection reaction	
Hypersensitivity	10074887	Immune thrombocytopenic purpura	
Hypersensitivity	10070581	Immune tolerance induction	
Hypersensitivity	10077665	Immune-mediated adverse reaction	
Hypersensitivity	10063855	Implant site dermatitis	
Hypersensitivity	10063858	Implant site hypersensitivity	
Hypersensitivity	10063786	Implant site rash	
Hypersensitivity	10063787	Implant site urticaria	
Hypersensitivity	10073168	Incision site dermatitis	
Hypersensitivity	10073411	Incision site rash	
Hypersensitivity	10051792	Infusion related reaction	
Hypersensitivity	10065458	Infusion site dermatitis	
Hypersensitivity	10074850	Infusion site eczema	
Hypersensitivity	10065471	Infusion site hypersensitivity	
Hypersensitivity	10058830	Infusion site rash	
Hypersensitivity	10076085	Infusion site recall reaction	
Hypersensitivity	10065480	Infusion site urticaria	
Hypersensitivity	10074851	Infusion site vasculitis	
Hypersensitivity	10071152	Injection related reaction	
Hypersensitivity	10022056	Injection site dermatitis	
Hypersensitivity	10066221	Injection site eczema	
Hypersensitivity	10022071	Injection site hypersensitivity	
Hypersensitivity	10022094	Injection site rash	
Hypersensitivity	10066797	Injection site recall reaction	
Hypersensitivity	10022107	Injection site urticaria	
Hypersensitivity	10067985	Injection site vasculitis	
Hypersensitivity	10073612	Instillation site hypersensitivity	
Hypersensitivity	10073622	Instillation site rash	
Hypersensitivity	10073627	Instillation site urticaria	
Hypersensitivity	10067972	Interstitial granulomatous dermatitis	
Hypersensitivity	10076229	Intestinal angioedema	
Hypersensitivity	10052088	Iodine allergy	
Hypersensitivity	10051891	Kaposi's varicelliform eruption	
Hypersensitivity	10069187	Kounis syndrome	
Hypersensitivity	10023845	Laryngeal oedema	
Hypersensitivity	10064866	Laryngitis allergic	
Hypersensitivity	10023891	Laryngospasm	
Hypersensitivity	10023893	Laryngotracheal oedema	
Hypersensitivity	10070482	Limbal swelling	
Hypersensitivity	10024558	Lip oedema	
Hypersensitivity	10024570	Lip swelling	
Hypersensitivity	10076806	Mast cell degranulation present	
Hypersensitivity	10075572	Medical device site dermatitis	
Hypersensitivity	10075575	Medical device site eczema	
Hypersensitivity	10075578	Medical device site hypersensitivity	
Hypersensitivity	10075585	Medical device site rash	
Hypersensitivity	10076140	Medical device site recall reaction	
Hypersensitivity	10075588	Medical device site urticaria	
Hypersensitivity	10075203	Mouth swelling	
Hypersensitivity	10056671	Mucocutaneous rash	
Hypersensitivity	10028164	Multiple allergies	
Hypersensitivity	10029120	Nephritis allergic	
Hypersensitivity	10029415	Nikolsky's sign	

表 2.7.4.9－27　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver21.1）（続き）

AESI	PT Code	PT Name	SOC
Hypersensitivity	10075807	Nodular rash	
Hypersensitivity	10030081	Oculomucocutaneous syndrome	
Hypersensitivity	10067317	Oculorespiratory syndrome	
Hypersensitivity	10030110	Oedema mouth	
Hypersensitivity	10068355	Oral allergy syndrome	
Hypersensitivity	10067950	Oropharyngeal blistering	
Hypersensitivity	10078783	Oropharyngeal oedema	
Hypersensitivity	10031111	Oropharyngeal spasm	
Hypersensitivity	10031118	Oropharyngeal swelling	
Hypersensitivity	10056998	Palatal oedema	
Hypersensitivity	10074403	Palatal swelling	
Hypersensitivity	10068809	Palisaded neutrophilic granulomatous dermatitis	
Hypersensitivity	10056872	Palpable purpura	
Hypersensitivity	10074332	Pathergy reaction	
Hypersensitivity	10034541	Perioral dermatitis	
Hypersensitivity	10034545	Periorbital oedema	
Hypersensitivity	10056547	Periorbital swelling	
Hypersensitivity	10034829	Pharyngeal oedema	
Hypersensitivity	10080894	Procedural shock	
Hypersensitivity	10063438	Pruritus allergic	
Hypersensitivity	10037789	Radioallergosorbent test positive	
Hypersensitivity	10037844	Rash	
Hypersensitivity	10037855	Rash erythematous	
Hypersensitivity	10037857	Rash follicular	
Hypersensitivity	10037858	Rash generalised	
Hypersensitivity	10037867	Rash macular	
Hypersensitivity	10037868	Rash maculo-papular	
Hypersensitivity	10050004	Rash maculovesicular	
Hypersensitivity	10037870	Rash morbilliform	
Hypersensitivity	10037871	Rash neonatal	
Hypersensitivity	10037879	Rash papulosquamous	
Hypersensitivity	10037884	Rash pruritic	
Hypersensitivity	10037888	Rash pustular	
Hypersensitivity	10057864	Rash rubeliform	
Hypersensitivity	10037890	Rash scarlatiniform	
Hypersensitivity	10037898	Rash vesicular	
Hypersensitivity	10037973	Reaction to azo-dyes	
Hypersensitivity	10037974	Reaction to colouring	
Hypersensitivity	10079925	Reaction to excipient	
Hypersensitivity	10064788	Reaction to preservatives	
Hypersensitivity	10038192	Red man syndrome	
Hypersensitivity	10039085	Rhinitis allergic	
Hypersensitivity	10057431	Scleral oedema	
Hypersensitivity	10051126	Scleritis allergic	
Hypersensitivity	10039755	Scrotal oedema	
Hypersensitivity	10040400	Serum sickness	
Hypersensitivity	10040402	Serum sickness-like reaction	
Hypersensitivity	10040560	Shock	
Hypersensitivity	10040581	Shock symptom	
Hypersensitivity	10040883	Skin necrosis	
Hypersensitivity	10040914	Skin reaction	
Hypersensitivity	10040934	Skin test positive	
Hypersensitivity	10041307	Solar urticaria	
Hypersensitivity	10041316	Solvent sensitivity	
Hypersensitivity	10042033	Stevens-Johnson syndrome	
Hypersensitivity	10074509	Stoma site hypersensitivity	
Hypersensitivity	10059071	Stoma site rash	
Hypersensitivity	10042682	Swelling face	
Hypersensitivity	10042690	Swelling of eyelid	
Hypersensitivity	10042727	Swollen tongue	
Hypersensitivity	10078325	Symmetrical drug-related intertriginous and flexural exanthema	
Hypersensitivity	10078645	Therapeutic product cross-reactivity	
Hypersensitivity	10043967	Tongue oedema	
Hypersensitivity	10044223	Toxic epidermal necrolysis	
Hypersensitivity	10057970	Toxic skin eruption	
Hypersensitivity	10044296	Tracheal oedema	
Hypersensitivity	10045240	Type I hypersensitivity	
Hypersensitivity	10054000	Type II hypersensitivity	
Hypersensitivity	10053614	Type III immune complex mediated reaction	
Hypersensitivity	10053613	Type IV hypersensitivity reaction	
Hypersensitivity	10046735	Urticaria	
Hypersensitivity	10046740	Urticaria cholinergic	
Hypersensitivity	10052568	Urticaria chronic	
Hypersensitivity	10046742	Urticaria contact	
Hypersensitivity	10046750	Urticaria papular	
Hypersensitivity	10046751	Urticaria physical	
Hypersensitivity	10046752	Urticaria pigmentosa	
Hypersensitivity	10046755	Urticaria vesiculosa	
Hypersensitivity	10048520	Urticarial vasculitis	
Hypersensitivity	10069477	Vaccination site dermatitis	
Hypersensitivity	10076161	Vaccination site eczema	
Hypersensitivity	10069489	Vaccination site exfoliation	
Hypersensitivity	10058880	Vaccination site hypersensitivity	
Hypersensitivity	10069482	Vaccination site rash	
Hypersensitivity	10076188	Vaccination site recall reaction	
Hypersensitivity	10058622	Vaccination site urticaria	
Hypersensitivity	10076191	Vaccination site vasculitis	
Hypersensitivity	10059623	Vaccination site vesicles	
Hypersensitivity	10064483	Vaginal exfoliation	
Hypersensitivity	10048943	Vaginal ulceration	
Hypersensitivity	10047111	Vasculitic rash	
Hypersensitivity	10081000	Vernal keratoconjunctivitis	
Hypersensitivity	10077117	Vessel puncture site rash	
Hypersensitivity	10077813	Vessel puncture site vesicles	

表 2.7.4.9－27　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver21.1）（続き）

AESI	PT Code	PT Name	SOC
Hypersensitivity	10047768	Vulval ulceration	
Hypersensitivity	10071588	Vulvovaginal rash	
Hypersensitivity	10050181	Vulvovaginal ulceration	
Hypersensitivity	10080783	Vulvovaginitis allergic	
Hypertension	10000358	Accelerated hypertension	
Hypertension	10005732	Blood pressure ambulatory increased	
Hypertension	10005739	Blood pressure diastolic increased	
Hypertension	10051128	Blood pressure inadequately controlled	
Hypertension	10005750	Blood pressure increased	
Hypertension	10063926	Blood pressure management	
Hypertension	10053355	Blood pressure orthostatic increased	
Hypertension	10005760	Blood pressure systolic increased	
Hypertension	10081751	Catecholamine crisis	
Hypertension	10012758	Diastolic hypertension	
Hypertension	10014129	Eclampsia	
Hypertension	10057615	Endocrine hypertension	
Hypertension	10015488	Essential hypertension	
Hypertension	10070538	Gestational hypertension	
Hypertension	10049058	HELLP syndrome	
Hypertension	10020571	Hyperaldosteronism	
Hypertension	10020772	Hypertension	
Hypertension	10048781	Hypertension neonatal	
Hypertension	10059238	Hypertensive angiopathy	
Hypertension	10020801	Hypertensive cardiomegaly	
Hypertension	10058222	Hypertensive cardiomyopathy	
Hypertension	10077000	Hypertensive cerebrovascular disease	
Hypertension	10020802	Hypertensive crisis	
Hypertension	10058179	Hypertensive emergency	
Hypertension	10020803	Hypertensive encephalopathy	
Hypertension	10079496	Hypertensive end-organ damage	
Hypertension	10020823	Hypertensive heart disease	
Hypertension	10055171	Hypertensive nephropathy	
Hypertension	10049079	Labile hypertension	
Hypertension	10025600	Malignant hypertension	
Hypertension	10025603	Malignant hypertensive heart disease	
Hypertension	10026674	Malignant renal hypertension	
Hypertension	10028824	Maternal hypertension affecting foetus	
Hypertension	10028885	Mean arterial pressure increased	
Hypertension	10052066	Metabolic syndrome	
Hypertension	10057598	Neurogenic hypertension	
Hypertension	10065508	Orthostatic hypertension	
Hypertension	10076704	Page kidney	
Hypertension	10036485	Pre-eclampsia	
Hypertension	10065918	Prehypertension	
Hypertension	10062886	Procedural hypertension	
Hypertension	10038464	Renal hypertension	
Hypertension	10074864	Renal sympathetic nerve ablation	
Hypertension	10038562	Renovascular hypertension	
Hypertension	10038926	Retinopathy hypertensive	
Hypertension	10039808	Secondary aldosteronism	
Hypertension	10039834	Secondary hypertension	
Hypertension	10078932	Supine hypertension	
Hypertension	10042957	Systolic hypertension	
Hypertension	10048007	Withdrawal hypertension	
Retinal disorder	10054881	Acquired segmented retinopathy	
Retinal disorder	10079357	Acute macular outer retinopathy	
Retinal disorder	10074444	Acute zonal occult outer retinopathy	
Retinal disorder	10064930	Age-related macular degeneration	
Retinal disorder	10053227	AIDS retinopathy	
Retinal disorder	10001903	Amaurosis fugax	
Retinal disorder	10002444	Angiogram retina abnormal	
Retinal disorder	10063452	Arteriosclerotic retinopathy	
Retinal disorder	10071578	Autoimmune retinopathy	
Retinal disorder	10004390	Benign neoplasm of retina	
Retinal disorder	10004863	Biopsy retina abnormal	
Retinal disorder	10072959	Birdshot chorioretinopathy	
Retinal disorder	10074331	Cholesterolosis bulbi	
Retinal disorder	10008762	Chorioretinal atrophy	
Retinal disorder	10061763	Chorioretinal disorder	
Retinal disorder	10008766	Chorioretinal scar	
Retinal disorder	10008769	Chorioretinitis	
Retinal disorder	10063118	Chorioretinopathy	
Retinal disorder	10010050	Colour blindness	
Retinal disorder	10010051	Colour blindness acquired	
Retinal disorder	10010056	Colour vision tests abnormal	
Retinal disorder	10010057	Colour vision tests abnormal blue-yellow	
Retinal disorder	10010058	Colour vision tests abnormal red-green	
Retinal disorder	10071321	Commotio retinae	
Retinal disorder	10058202	Cystoid macular oedema	
Retinal disorder	10078905	Delayed light adaptation	
Retinal disorder	10071004	Detachment of macular retinal pigment epithelium	
Retinal disorder	10052501	Detachment of retinal pigment epithelium	
Retinal disorder	10012668	Diabetic retinal oedema	
Retinal disorder	10012689	Diabetic retinopathy	
Retinal disorder	10078228	Diffuse uveal melanocytic proliferation	
Retinal disorder	10075567	Dry age-related macular degeneration	
Retinal disorder	10015831	Extraocular retinoblastoma	
Retinal disorder	10015901	Exudative retinopathy	
Retinal disorder	10051045	Eye naevus	
Retinal disorder	10017520	Fundoscopy abnormal	
Retinal disorder	10077392	Immune recovery uveitis	
Retinal disorder	10073499	Internal limiting membrane peeling	
Retinal disorder	10079929	IRVAN syndrome	
Retinal disorder	10059239	Leukaemic retinopathy	

表 2.7.4.9－27　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver21.1）（続き）

AESI	PT Code	PT Name	SOC
Retinal disorder	10048935	Ischaemia retinalis	
Retinal disorder	10025407	Macular cyst	
Retinal disorder	10025409	Macular degeneration	
Retinal disorder	10075873	Macular detachment	
Retinal disorder	10071392	Macular fibrosis	
Retinal disorder	10051058	Macular hole	
Retinal disorder	10065534	Macular ischaemia	
Retinal disorder	10025415	Macular oedema	
Retinal disorder	10025416	Macular opacity	
Retinal disorder	10071041	Macular pigmentation	
Retinal disorder	10060815	Macular pseudohole	
Retinal disorder	10025419	Macular reflex abnormal	
Retinal disorder	10065318	Macular rupture	
Retinal disorder	10063185	Macular scar	
Retinal disorder	10025425	Maculopathy	
Retinal disorder	10026432	Malignant neoplasm of retina	
Retinal disorder	10078376	MEK inhibitor-associated serous retinopathy	
Retinal disorder	10063341	Metamorphopsia	
Retinal disorder	10078958	Myopic chorioretinal degeneration	
Retinal disorder	10084997	Neoplasm retinitis	
Retinal disorder	10071129	Neovascular age-related macular degeneration	
Retinal disorder	10062940	Neuropathy, ataxia, retinitis pigmentosa syndrome	
Retinal disorder	10074696	Noninfective chorioretinitis	
Retinal disorder	10074699	Noninfective retinitis	
Retinal disorder	10081568	Non-proliferative retinopathy	
Retinal disorder	10065311	Paraneoplastic retinopathy	
Retinal disorder	10034962	Photopsia	
Retinal disorder	10037525	Pupillary light reflex tests abnormal	
Retinal disorder	10075189	Purtscher retinopathy	
Retinal disorder	10084714	Radiation retinopathy	
Retinal disorder	10064145	Retinal aneurysm	
Retinal disorder	10079121	Retinal aneurysm rupture	
Retinal disorder	10038824	Retinal arteriovenous malformation	
Retinal disorder	10038826	Retinal artery embolism	
Retinal disorder	10038827	Retinal artery occlusion	
Retinal disorder	10038829	Retinal artery spasm	
Retinal disorder	10038830	Retinal artery stenosis	
Retinal disorder	10038831	Retinal artery thrombosis	
Retinal disorder	10077911	Retinal collateral vessels	
Retinal disorder	10052643	Retinal coloboma	
Retinal disorder	10074808	Retinal cryoablation	
Retinal disorder	10038839	Retinal cyst	
Retinal disorder	10038840	Retinal cyst excision	
Retinal disorder	10038845	Retinal degeneration	
Retinal disorder	10038846	Retinal depigmentation	
Retinal disorder	10038847	Retinal deposits	
Retinal disorder	10038848	Retinal detachment	
Retinal disorder	10038853	Retinal disorder	
Retinal disorder	10062776	Retinal drusen	
Retinal disorder	10038857	Retinal dystrophy	
Retinal disorder	10038862	Retinal exudates	
Retinal disorder	10071391	Retinal fibrosis	
Retinal disorder	10038886	Retinal function test abnormal	
Retinal disorder	10038887	Retinal haemorrhage	
Retinal disorder	10067848	Retinal implant	
Retinal disorder	10051742	Retinal infarction	
Retinal disorder	10064833	Retinal infiltrates	
Retinal disorder	10057430	Retinal injury	
Retinal disorder	10038871	Retinal ischaemia	
Retinal disorder	10038873	Retinal laser coagulation	
Retinal disorder	10057428	Retinal melanocytoma	
Retinal disorder	10038878	Retinal melanoma	
Retinal disorder	10052784	Retinal migraine	
Retinal disorder	10057407	Retinal neoplasm	
Retinal disorder	10055666	Retinal neovascularisation	
Retinal disorder	10038895	Retinal oedema	
Retinal disorder	10062107	Retinal operation	
Retinal disorder	10038881	Retinal pallor	
Retinal disorder	10071246	Retinal perivascular sheathing	
Retinal disorder	10069652	Retinal phototoxicity	
Retinal disorder	10062971	Retinal pigment epithelial tear	
Retinal disorder	10038893	Retinal pigment epitheliopathy	
Retinal disorder	10038894	Retinal pigmentation	
Retinal disorder	10038895	Retinal scar	
Retinal disorder	10038897	Retinal tear	
Retinal disorder	10038899	Retinal telangiectasia	
Retinal disorder	10077890	Retinal thickening	
Retinal disorder	10048955	Retinal toxicity	
Retinal disorder	10067870	Retinal transplant	
Retinal disorder	10038900	Retinal tumour excision	
Retinal disorder	10038901	Retinal vascular disorder	
Retinal disorder	10038903	Retinal vascular occlusion	
Retinal disorder	10062108	Retinal vascular thrombosis	
Retinal disorder	10038905	Retinal vasculitis	
Retinal disorder	10038907	Retinal vein occlusion	
Retinal disorder	10038908	Retinal vein thrombosis	
Retinal disorder	10081463	Retinal vein varices	
Retinal disorder	10073562	Retinal vessel avulsion	
Retinal disorder	10079569	Retinal white without pressure	
Retinal disorder	10038910	Retinitis	
Retinal disorder	10038914	Retinitis pigmentosa	
Retinal disorder	10038916	Retinoblastoma	
Retinal disorder	10059663	Retinogram abnormal	
Retinal disorder	10038923	Retinopathy	

表 2.7.4.9－27　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver21.1）（続き）

AESI	PT Code	PT Name	SOC
Retinal disorder	10051447	Retinopathy haemorrhagic	
Retinal disorder	10038926	Retinopathy hypertensive	
Retinal disorder	10038930	Retinopathy hyperviscosity	
Retinal disorder	10038933	Retinopathy of prematurity	
Retinal disorder	10038934	Retinopathy proliferative	
Retinal disorder	10038935	Retinopathy sickle cell	
Retinal disorder	10038936	Retinopathy solar	
Retinal disorder	10068985	Retinopexy	
Retinal disorder	10061492	Retinoschisis	
Retinal disorder	10065569	Rhegmatogenous retinal detachment	
Retinal disorder	10039677	Scintillating scotoma	
Retinal disorder	10066785	Scleral buckling surgery	
Retinal disorder	10040114	Serous retinal detachment	
Retinal disorder	10081652	Serpiginous choroiditis	
Retinal disorder	10062958	Subretinal fibrosis	
Retinal disorder	10068356	Subretinal fluid	
Retinal disorder	10071935	Subretinal haematoma	
Retinal disorder	10080316	Tractional retinal detachment	
Retinal disorder	10045178	Tunnel vision	
Retinal disorder	10065622	Venous stasis retinopathy	
Retinal disorder	10047567	Visual field tests abnormal	
Retinal disorder	10066421	Vitreal cells	
Retinal disorder	10047644	Vitrectomy	
Retinal disorder	10071035	Vitreomacular interface abnormal	
Retinal disorder	10057435	Vitreous adhesions	
Retinal disorder	10047650	Vitreous detachment	
Retinal disorder	10047651	Vitreous disorder	
Retinal disorder	10047654	Vitreous floaters	
Retinal disorder	10071936	Vitreous haematoma	
Retinal disorder	10047655	Vitreous haemorrhage	
Retinal disorder	10077514	Vitreous haze	
Retinal disorder	10047663	Vitritis	
Cardiovascular event	10081099	Acute cardiac event	
Cardiovascular event	10051592	Acute coronary syndrome	
Cardiovascular event	10000891	Acute myocardial infarction	
Cardiovascular event	10002388	Angina unstable	
Cardiovascular event	10005472	Blood creatine phosphokinase MB abnormal	
Cardiovascular event	10005474	Blood creatine phosphokinase MB increased	
Cardiovascular event	10011084	Coronary artery embolism	
Cardiovascular event	10011086	Coronary artery occlusion	
Cardiovascular event	10053261	Coronary artery reocclusion	
Cardiovascular event	10011091	Coronary artery thrombosis	
Cardiovascular event	10056025	Coronary bypass thrombosis	
Cardiovascular event	10075182	Coronary vascular graft occlusion	
Cardiovascular event	10068187	Kounis syndrome	
Cardiovascular event	10028596	Myocardial infarction	
Cardiovascular event	10028602	Myocardial necrosis	
Cardiovascular event	10051624	Myocardial reperfusion injury	
Cardiovascular event	10072186	Myocardial stunning	
Cardiovascular event	10033697	Papillary muscle infarction	
Cardiovascular event	10078319	Periprocedural myocardial infarction	
Cardiovascular event	10066592	Post procedural myocardial infarction	
Cardiovascular event	10058144	Postinfarction angina	
Cardiovascular event	10049768	Silent myocardial infarction	
Cardiovascular event	10058288	Troponin I increased	
Cardiovascular event	10058287	Troponin increased	
Cardiovascular event	10058289	Troponin T increased	
Cardiovascular event	10005468	Blood creatine phosphokinase abnormal	
Cardiovascular event	10005470	Blood creatine phosphokinase increased	
Cardiovascular event	10076898	Cardiac ventricular scarring	
Cardiovascular event	10072252	ECG electrically inactive area	
Cardiovascular event	10075298	ECG signs of myocardial infarction	
Cardiovascular event	10051177	Electrocardiogram Q wave abnormal	
Cardiovascular event	10014390	Electrocardiogram ST segment abnormal	
Cardiovascular event	10014392	Electrocardiogram ST segment elevation	
Cardiovascular event	10049225	Electrocardiogram ST-T segment elevation	
Cardiovascular event	10062314	Electrocardiogram U wave inversion	
Cardiovascular event	10061216	Infarction	
Cardiovascular event	10075211	Myocardial necrosis marker increased	
Cardiovascular event	10061501	Scan myocardial perfusion abnormal	
Cardiovascular event	10049060	Vascular graft occlusion	
Cardiovascular event	10077143	Vascular stent occlusion	
Cardiovascular event	10063634	Vascular stent thrombosis	
Cardiovascular event	10081099	Acute cardiac event	
Cardiovascular event	10002383	Angina pectoris	
Cardiovascular event	10002388	Angina unstable	
Cardiovascular event	10076419	Anginal equivalent	
Cardiovascular event	10003211	Arteriosclerosis coronary artery	
Cardiovascular event	10003225	Arteriospasm coronary	
Cardiovascular event	10050329	Coronary angioplasty	
Cardiovascular event	10052085	Coronary arterial stent insertion	
Cardiovascular event	10011077	Coronary artery bypass	
Cardiovascular event	10079589	Coronary artery compression	
Cardiovascular event	10011078	Coronary artery disease	
Cardiovascular event	10049531	Coronary artery dissection	
Cardiovascular event	10052895	Coronary artery insufficiency	
Cardiovascular event	10056489	Coronary artery restenosis	
Cardiovascular event	10011089	Coronary artery stenosis	
Cardiovascular event	10011090	Coronary artery surgery	
Cardiovascular event	10076527	Coronary brachytherapy	
Cardiovascular event	10077824	Coronary bypass stenosis	
Cardiovascular event	10011101	Coronary endarterectomy	
Cardiovascular event	10068534	Coronary no-reflow phenomenon	
Cardiovascular event	10011105	Coronary ostial stenosis	

表 2.7.4.9－27　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver21.1）（続き）

AESI	PT Code	PT Name	SOC
Cardiovascular event	10048887	Coronary revascularisation	
Cardiovascular event	10077334	Coronary vascular graft stenosis	
Cardiovascular event	10080788	Diabetic coronary microangiopathy	
Cardiovascular event	10013428	Dissecting coronary artery aneurysm	
Cardiovascular event	10058317	ECG signs of myocardial ischaemia	
Cardiovascular event	10067876	External counterpulsation	
Cardiovascular event	10055803	Haemorrhage coronary artery	
Cardiovascular event	10048858	Ischaemic cardiomyopathy	
Cardiovascular event	10077864	Ischaemic mitral regurgitation	
Cardiovascular event	10072685	Microvascular coronary artery disease	
Cardiovascular event	10078880	Myocardial hypoxia	
Cardiovascular event	10028600	Myocardial ischaemia	
Cardiovascular event	10065608	Percutaneous coronary intervention	
Cardiovascular event	10034759	Prinzmetal angina	
Cardiovascular event	10066286	Stress cardiomyopathy	
Cardiovascular event	10064994	Subclavian coronary steal syndrome	
Cardiovascular event	10058145	Subendocardial ischaemia	
Cardiovascular event	10080787	Wellens' syndrome	
Cardiovascular event	10003201	Arteriogram coronary abnormal	
Cardiovascular event	10055014	Cardiac stress test abnormal	
Cardiovascular event	10074359	Cardiopulmonary exercise test abnormal	
Cardiovascular event	10064939	Cardiovascular event prophylaxis	
Cardiovascular event	10060806	Computerised tomogram coronary artery abnormal	
Cardiovascular event	10081493	Electrocardiogram PR segment depression	
Cardiovascular event	10014391	Electrocardiogram ST segment depression	
Cardiovascular event	10052333	Electrocardiogram ST-T segment abnormal	
Cardiovascular event	10049224	Electrocardiogram ST-T segment depression	
Cardiovascular event	10050380	Electrocardiogram T wave abnormal	
Cardiovascular event	10014395	Electrocardiogram T wave inversion	
Cardiovascular event	10062314	Electrocardiogram U wave inversion	
Cardiovascular event	10015645	Exercise electrocardiogram abnormal	
Cardiovascular event	10015653	Exercise test abnormal	
Cardiovascular event	10077146	Post angioplasty restenosis	
Cardiovascular event	10070748	Stress echocardiogram abnormal	
Cardiovascular event	10077144	Vascular stent stenosis	
Cardiovascular event	10079016	Wall motion score index abnormal	
Cardiovascular event	10057375	Balint's syndrome	
Cardiovascular event	10077607	Basilar artery aneurysm	
Cardiovascular event	10007686	Carotid artery aneurysm	
Cardiovascular event	10050403	Carotid artery dissection	
Cardiovascular event	10077079	Cerebral endovascular aneurysm repair	
Cardiovascular event	10075401	Cerebral reperfusion injury	
Cardiovascular event	10075249	Cerebral ventricular rupture	
Cardiovascular event	10048165	Cerebrovascular accident prophylaxis	
Cardiovascular event	10054749	Charcot-Bouchard microaneurysms	
Cardiovascular event	10071359	Congenital hemiparesis	
Cardiovascular event	10071326	CSF bilirubin positive	
Cardiovascular event	10078388	Delayed ischaemic neurological deficit	
Cardiovascular event	10077170	Hemianaesthesia	
Cardiovascular event	10077171	Hemiasomatognosia	
Cardiovascular event	10080713	Hemihyperaesthesia	
Cardiovascular event	10078746	Hemiparaesthesia	
Cardiovascular event	10019465	Hemiparesis	
Cardiovascular event	10019468	Hemiplegia	
Cardiovascular event	10022736	Intra-cerebral aneurysm operation	
Cardiovascular event	10022758	Intracranial aneurysm	
Cardiovascular event	10081515	Lateropulsion	
Cardiovascular event	10070606	Post stroke depression	
Cardiovascular event	10079859	Posthaemorrhagic hydrocephalus	
Cardiovascular event	10077889	Vein of Galen aneurysmal malformation	
Cardiovascular event	10077498	Vertebral artery aneurysm	
Cardiovascular event	10071716	Vertebral artery dissection	
Cardiovascular event	10049663	Agnosia	
Cardiovascular event	10052906	Angiogram cerebral abnormal	
Cardiovascular event	10002948	Aphasia	
Cardiovascular event	10057967	Brain injury	
Cardiovascular event	10064012	Central pain syndrome	
Cardiovascular event	10070728	Cerebral haemosiderin deposition	
Cardiovascular event	10075562	CSF red blood cell count positive	
Cardiovascular event	10013033	Diplegia	
Cardiovascular event	10013887	Dysarthria	
Cardiovascular event	10071355	Internal carotid artery kinking	
Cardiovascular event	10073565	Intracranial artery dissection	
Cardiovascular event	10072882	Modified Rankin score decreased	
Cardiovascular event	10072881	Modified Rankin score increased	
Cardiovascular event	10027925	Monoparesis	
Cardiovascular event	10027926	Monoplegia	
Cardiovascular event	10065531	NIH stroke scale abnormal	
Cardiovascular event	10065529	NIH stroke scale score decreased	
Cardiovascular event	10065528	NIH stroke scale score increased	
Cardiovascular event	10033799	Paralysis	
Cardiovascular event	10033885	Paraparesis	
Cardiovascular event	10033892	Paraplegia	
Cardiovascular event	10033985	Paresis	
Cardiovascular event	10049680	Quadriparesis	
Cardiovascular event	10037714	Quadriplegia	
Cardiovascular event	10075037	Right hemisphere deficit syndrome	
Cardiovascular event	10070564	Superficial siderosis of central nervous system	
Cardiovascular event	10077168	Visual agnosia	
Cardiovascular event	10066856	Visual midline shift syndrome	
Cardiovascular event	10077031	Basal ganglia haematoma	
Cardiovascular event	10067057	Basal ganglia haemorrhage	
Cardiovascular event	10071043	Basal ganglia stroke	
Cardiovascular event	10075736	Basilar artery perforation	

表 2.7.4.9－27　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver21.1）（続き）

AESI	PT Code	PT Name	SOC
Cardiovascular event	10073330	Brain stem haematoma	
Cardiovascular event	10006145	Brain stem haemorrhage	
Cardiovascular event	10071205	Brain stem microhaemorrhage	
Cardiovascular event	10058644	Brain stem stroke	
Cardiovascular event	10051328	Carotid aneurysm rupture	
Cardiovascular event	10075728	Carotid artery perforation	
Cardiovascular event	10072043	Central nervous system haemorrhage	
Cardiovascular event	10061038	Cerebellar haematoma	
Cardiovascular event	10008030	Cerebellar haemorrhage	
Cardiovascular event	10071206	Cerebellar microhaemorrhage	
Cardiovascular event	10079062	Cerebellar stroke	
Cardiovascular event	10075394	Cerebral aneurysm perforation	
Cardiovascular event	10008076	Cerebral aneurysm ruptured syphilitic	
Cardiovascular event	10008086	Cerebral arteriovenous malformation haemorrhagic	
Cardiovascular event	10075734	Cerebral artery perforation	
Cardiovascular event	10053942	Cerebral haematoma	
Cardiovascular event	10008111	Cerebral haemorrhage	
Cardiovascular event	10050157	Cerebral haemorrhage foetal	
Cardiovascular event	10008112	Cerebral haemorrhage neonatal	
Cardiovascular event	10067277	Cerebral microhaemorrhage	
Cardiovascular event	10008180	Cerebrovascular accident	
Cardiovascular event	10008186	Cerebrovascular disorder	
Cardiovascular event	10073681	Epidural haemorrhage	
Cardiovascular event	10078254	Extra-axial haemorrhage	
Cardiovascular event	10015769	Extradural haematoma	
Cardiovascular event	10080347	Extraischaemic cerebral haematoma	
Cardiovascular event	10018985	Haemorrhage intracranial	
Cardiovascular event	10019005	Haemorrhagic cerebral infarction	
Cardiovascular event	10019015	Haemorrhagic stroke	
Cardiovascular event	10055677	Haemorrhagic transformation stroke	
Cardiovascular event	10062025	Intracerebral haematoma evacuation	
Cardiovascular event	10058481	Intracranial haematoma	
Cardiovascular event	10022775	Intracranial tumour haemorrhage	
Cardiovascular event	10022840	Intraventricular haemorrhage	
Cardiovascular event	10022841	Intraventricular haemorrhage neonatal	
Cardiovascular event	10052593	Meningorrhagia	
Cardiovascular event	10073845	Perinatal stroke	
Cardiovascular event	10076706	Periventricular haemorrhage neonatal	
Cardiovascular event	10049760	Pituitary haemorrhage	
Cardiovascular event	10058940	Putamen haemorrhage	
Cardiovascular event	10039330	Ruptured cerebral aneurysm	
Cardiovascular event	10076051	Spinal cord haematoma	
Cardiovascular event	10048992	Spinal cord haemorrhage	
Cardiovascular event	10050162	Spinal epidural haematoma	
Cardiovascular event	10049236	Spinal epidural haemorrhage	
Cardiovascular event	10073564	Spinal subarachnoid haemorrhage	
Cardiovascular event	10050164	Spinal subdural haematoma	
Cardiovascular event	10073563	Spinal subdural haemorrhage	
Cardiovascular event	10058613	Stroke in evolution	
Cardiovascular event	10075701	Subarachnoid haematoma	
Cardiovascular event	10042318	Subarachnoid haemorrhage	
Cardiovascular event	10042317	Subarachnoid haemorrhage neonatal	
Cardiovascular event	10042381	Subdural haematoma	
Cardiovascular event	10042383	Subdural haematoma evacuation	
Cardiovascular event	10042384	Subdural haemorrhage	
Cardiovascular event	10042385	Subdural haemorrhage neonatal	
Cardiovascular event	10058939	Thalamus haemorrhage	
Cardiovascular event	10075735	Vertebral artery perforation	
Cardiovascular event	10001903	Amaurosis fugax	
Cardiovascular event	10059020	Basal ganglia infarction	
Cardiovascular event	10071043	Basal ganglia stroke	
Cardiovascular event	10048953	Basilar artery occlusion	
Cardiovascular event	10004163	Basilar artery stenosis	
Cardiovascular event	10053093	Basilar artery thrombosis	
Cardiovascular event	10075448	Brachiocephalic arteriosclerosis	
Cardiovascular event	10069694	Brachiocephalic artery occlusion	
Cardiovascular event	10075450	Brachiocephalic artery stenosis	
Cardiovascular event	10006127	Brain hypoxia	
Cardiovascular event	10074422	Brain stem embolism	
Cardiovascular event	10006147	Brain stem infarction	
Cardiovascular event	10006148	Brain stem ischaemia	
Cardiovascular event	10058644	Brain stem stroke	
Cardiovascular event	10052573	Brain stem thrombosis	
Cardiovascular event	10080887	Brain stent insertion	
Cardiovascular event	10065555	CADASIL	
Cardiovascular event	10067744	Capsular warning syndrome	
Cardiovascular event	10081315	CARASIL syndrome	
Cardiovascular event	10071260	Carotid angioplasty	
Cardiovascular event	10007684	Carotid arterial embolus	
Cardiovascular event	10067116	Carotid arteriosclerosis	
Cardiovascular event	10053003	Carotid artery bypass	
Cardiovascular event	10061744	Carotid artery disease	
Cardiovascular event	10064949	Carotid artery insufficiency	
Cardiovascular event	10048964	Carotid artery occlusion	
Cardiovascular event	10072558	Carotid artery restenosis	
Cardiovascular event	10007687	Carotid artery stenosis	
Cardiovascular event	10056102	Carotid artery stent insertion	
Cardiovascular event	10069952	Carotid artery stent removal	
Cardiovascular event	10007688	Carotid artery thrombosis	
Cardiovascular event	10007692	Carotid endarterectomy	
Cardiovascular event	10072559	Carotid revascularisation	
Cardiovascular event	10053633	Cerebellar artery occlusion	
Cardiovascular event	10008023	Cerebellar artery thrombosis	
Cardiovascular event	10067187	Cerebellar embolism	

表 2.7.4.9－27　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver21.1）（続き）

AESI	PT Code	PT Name	SOC
Cardiovascular event	10008034	Cerebellar infarction	
Cardiovascular event	10008521	Cerebellar ischaemia	
Cardiovascular event	10079052	Cerebellar stroke	
Cardiovascular event	10065559	Cerebral arteriosclerosis	
Cardiovascular event	10008088	Cerebral artery embolism	
Cardiovascular event	10008089	Cerebral artery occlusion	
Cardiovascular event	10075423	Cerebral artery restenosis	
Cardiovascular event	10063648	Cerebral artery stenosis	
Cardiovascular event	10008092	Cerebral artery thrombosis	
Cardiovascular event	10070813	Cerebral gas embolism	
Cardiovascular event	10008118	Cerebral infarction	
Cardiovascular event	10008119	Cerebral infarction foetal	
Cardiovascular event	10008120	Cerebral ischaemia	
Cardiovascular event	10078311	Cerebral microembolism	
Cardiovascular event	10071508	Cerebral revascularisation	
Cardiovascular event	10070671	Cerebral septic infarct	
Cardiovascular event	10070878	Cerebral small vessel ischaemic disease	
Cardiovascular event	10008132	Cerebral thrombosis	
Cardiovascular event	10076885	Cerebral vascular occlusion	
Cardiovascular event	10058109	Cerebral vasoconstriction	
Cardiovascular event	10008138	Cerebral venous thrombosis	
Cardiovascular event	10008190	Cerebrovascular accident	
Cardiovascular event	10008195	Cerebrovascular disorder	
Cardiovascular event	10058842	Cerebrovascular insufficiency	
Cardiovascular event	10061751	Cerebrovascular stenosis	
Cardiovascular event	10076388	Delayed ischaemic neurological deficit	
Cardiovascular event	10060839	Embolic cerebral infarction	
Cardiovascular event	10014498	Embolic stroke	
Cardiovascular event	10070511	Hypoxic-ischaemic encephalopathy	
Cardiovascular event	10070754	Inner ear infarction	
Cardiovascular event	10060840	Ischaemic cerebral infarction	
Cardiovascular event	10061256	Ischaemic stroke	
Cardiovascular event	10051078	Lacunar infarction	
Cardiovascular event	10076994	Lacunar stroke	
Cardiovascular event	10024033	Lateral medullary syndrome	
Cardiovascular event	10056237	Migrainous infarction	
Cardiovascular event	10057462	Millard-Gubler syndrome	
Cardiovascular event	10028047	Moyamoya disease	
Cardiovascular event	10073945	Perinatal stroke	
Cardiovascular event	10078202	Post cardiac arrest syndrome	
Cardiovascular event	10066591	Post procedural stroke	
Cardiovascular event	10077033	Precerebral arteriosclerosis	
Cardiovascular event	10036511	Precerebral artery occlusion	
Cardiovascular event	10073240	Reversible cerebral vasoconstriction syndrome	
Cardiovascular event	10050496	Reversible ischaemic neurological deficit	
Cardiovascular event	10049440	Spinal artery embolism	
Cardiovascular event	10071316	Spinal artery thrombosis	
Cardiovascular event	10058571	Spinal cord infarction	
Cardiovascular event	10050209	Spinal cord ischaemia	
Cardiovascular event	10059513	Stroke in evolution	
Cardiovascular event	10042335	Subclavian steal syndrome	
Cardiovascular event	10064961	Thalamic infarction	
Cardiovascular event	10067347	Thrombotic cerebral infarction	
Cardiovascular event	10043647	Thrombotic stroke	
Cardiovascular event	10044390	Transient ischaemic attack	
Cardiovascular event	10063851	Vascular encephalopathy	
Cardiovascular event	10077143	Vascular stent occlusion	
Cardiovascular event	10077144	Vascular stent stenosis	
Cardiovascular event	10048965	Vertebral artery occlusion	
Cardiovascular event	10047330	Vertebral artery stenosis	
Cardiovascular event	10057777	Vertebral artery thrombosis	
Cardiovascular event	10047334	Vertebrobasilar insufficiency	
Hepatotoxicity	10061009	Bilirubin excretion disorder	
Hepatotoxicity	10048611	Cholaemia	
Hepatotoxicity	10008635	Cholestasis	
Hepatotoxicity	10067969	Cholestatic liver injury	
Hepatotoxicity	10064180	Cholestatic pruritus	
Hepatotoxicity	10072268	Drug-induced liver injury	
Hepatotoxicity	10019754	Hepatitis cholestatic	
Hepatotoxicity	10020578	Hyperbilirubinaemia	
Hepatotoxicity	10021209	Icterus index increased	
Hepatotoxicity	10023126	Jaundice	
Hepatotoxicity	10023129	Jaundice cholestatic	
Hepatotoxicity	10023136	Jaundice hepatocellular	
Hepatotoxicity	10068758	Mixed liver injury	
Hepatotoxicity	10058117	Ocular icterus	
Hepatotoxicity	10074151	Parenteral nutrition associated liver disease	
Hepatotoxicity	10071634	Deficiency of bile secretion	
Hepatotoxicity	10048245	Yellow skin	
Hepatotoxicity	10003680	Acquired hepatocerebral degeneration	
Hepatotoxicity	10000804	Acute hepatic failure	
Hepatotoxicity	10077305	Acute on chronic liver failure	
Hepatotoxicity	10070815	Acute yellow liver atrophy	
Hepatotoxicity	10003445	Ascites	
Hepatotoxicity	10003547	Asterixis	
Hepatotoxicity	10068547	Bacterascites	
Hepatotoxicity	10004659	Biliary cirrhosis	
Hepatotoxicity	10004664	Biliary fibrosis	
Hepatotoxicity	10067969	Cholestatic liver injury	
Hepatotoxicity	10057573	Chronic hepatic failure	
Hepatotoxicity	10010075	Coma hepatic	
Hepatotoxicity	10063075	Cryptogenic cirrhosis	
Hepatotoxicity	10071265	Diabetic hepatopathy	
Hepatotoxicity	10072268	Drug-induced liver injury	

表 2.7.4.9－27　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver21.1）（続き）

AESI	PT Code	PT Name	SOC
Hepatotoxicity	10051010	Duodenal varices	
Hepatotoxicity	10072319	Gallbladder varices	
Hepatotoxicity	10076237	Gastric variceal injection	
Hepatotoxicity	10076238	Gastric variceal ligation	
Hepatotoxicity	10051012	Gastric varices	
Hepatotoxicity	10057572	Gastric varices haemorrhage	
Hepatotoxicity	10061997	Hepatectomy	
Hepatotoxicity	10019637	Hepatic atrophy	
Hepatotoxicity	10065274	Hepatic calcification	
Hepatotoxicity	10019641	Hepatic cirrhosis	
Hepatotoxicity	10019660	Hepatic encephalopathy	
Hepatotoxicity	10066599	Hepatic encephalopathy prophylaxis	
Hepatotoxicity	10019663	Hepatic failure	
Hepatotoxicity	10019668	Hepatic fibrosis	
Hepatotoxicity	10067365	Hepatic hydrothorax	
Hepatotoxicity	10064568	Hepatic infiltration eosinophilic	
Hepatotoxicity	10061998	Hepatic lesion	
Hepatotoxicity	10019682	Hepatic necrosis	
Hepatotoxicity	10077215	Hepatic steato-fibrosis	
Hepatotoxicity	10019708	Hepatic steatosis	
Hepatotoxicity	10019772	Hepatitis fulminant	
Hepatotoxicity	10062000	Hepatobiliary disease	
Hepatotoxicity	10053244	Hepatocellular foamy cell syndrome	
Hepatotoxicity	10019837	Hepatocellular injury	
Hepatotoxicity	10052274	Hepatopulmonary syndrome	
Hepatotoxicity	10019845	Hepatorenal failure	
Hepatotoxicity	10019846	Hepatorenal syndrome	
Hepatotoxicity	10019851	Hepatotoxicity	
Hepatotoxicity	10071502	Intestinal varices	
Hepatotoxicity	10078058	Intestinal varices haemorrhage	
Hepatotoxicity	10052280	Liver and small intestine transplant	
Hepatotoxicity	10076840	Liver dialysis	
Hepatotoxicity	10024670	Liver disorder	
Hepatotoxicity	10067125	Liver injury	
Hepatotoxicity	10062040	Liver operation	
Hepatotoxicity	10024714	Liver transplant	
Hepatotoxicity	10025129	Lupoid hepatic cirrhosis	
Hepatotoxicity	10076204	Minimal hepatic encephalopathy	
Hepatotoxicity	10066758	Mixed liver injury	
Hepatotoxicity	10051081	Nodular regenerative hyperplasia	
Hepatotoxicity	10029530	Non-alcoholic fatty liver	
Hepatotoxicity	10053219	Non-alcoholic steatohepatitis	
Hepatotoxicity	10077259	Non-cirrhotic portal hypertension	
Hepatotoxicity	10049631	Oedema due to hepatic disease	
Hepatotoxicity	10030210	Oesophageal varices haemorrhage	
Hepatotoxicity	10073215	Peripancreatic varices	
Hepatotoxicity	10074726	Portal fibrosis	
Hepatotoxicity	10036200	Portal hypertension	
Hepatotoxicity	10079448	Portal hypertensive colopathy	
Hepatotoxicity	10068923	Portal hypertensive enteropathy	
Hepatotoxicity	10050897	Portal hypertensive gastropathy	
Hepatotoxicity	10073979	Portal vein cavernous transformation	
Hepatotoxicity	10073209	Portal vein dilatation	
Hepatotoxicity	10067281	Portopulmonary hypertension	
Hepatotoxicity	10080429	Primary biliary cholangitis	
Hepatotoxicity	10080679	Regenerative siderotic hepatic nodule	
Hepatotoxicity	10052279	Renal and liver transplant	
Hepatotoxicity	10067338	Retrograde portal vein flow	
Hepatotoxicity	10039012	Reye's syndrome	
Hepatotoxicity	10070953	Reynold's syndrome	
Hepatotoxicity	10057823	Splenic varices	
Hepatotoxicity	10068662	Splenic varices haemorrhage	
Hepatotoxicity	10076331	Steatohepatitis	
Hepatotoxicity	10056956	Subacute hepatic failure	
Hepatotoxicity	10056091	Varices oesophageal	
Hepatotoxicity	10072284	Varicose veins of abdominal wall	
Hepatotoxicity	10078438	White nipple sign	
Hepatotoxicity	10068924	Anorectal varices	
Hepatotoxicity	10068925	Anorectal varices haemorrhage	
Hepatotoxicity	10072629	Intrahepatic portal hepatic venous fistula	
Hepatotoxicity	10052716	Peritoneovenous shunt	
Hepatotoxicity	10036204	Portal shunt	
Hepatotoxicity	10077479	Portal shunt procedure	
Hepatotoxicity	10069380	Small-for-size liver syndrome	
Hepatotoxicity	10041519	Spider naevus	
Hepatotoxicity	10041661	Splenorenal shunt	
Hepatotoxicity	10077281	Splenorenal shunt procedure	
Hepatotoxicity	10076239	Spontaneous intrahepatic portosystemic venous shunt	
Hepatotoxicity	10075186	Stomal varices	
Hepatotoxicity	10068253	Acute graft versus host disease in liver	
Hepatotoxicity	10071188	Allergic hepatitis	
Hepatotoxicity	10080576	Alloimmune hepatitis	
Hepatotoxicity	10003827	Autoimmune hepatitis	
Hepatotoxicity	10072160	Chronic graft versus host disease in liver	
Hepatotoxicity	10008508	Chronic hepatitis	
Hepatotoxicity	10064676	Graft versus host disease in liver	
Hepatotoxicity	10019717	Hepatitis	
Hepatotoxicity	10019727	Hepatitis acute	
Hepatotoxicity	10019754	Hepatitis cholestatic	
Hepatotoxicity	10019755	Hepatitis chronic active	
Hepatotoxicity	10019758	Hepatitis chronic persistent	
Hepatotoxicity	10019772	Hepatitis fulminant	
Hepatotoxicity	10019795	Hepatitis toxic	
Hepatotoxicity	10078462	Immune-mediated hepatitis	

表 2.7.4.9－27　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver21.1）（続き）

AESI	PT Code	PT Name	SOC
Hepatotoxicity	10020025	Ischaemic hepatitis	
Hepatotoxicity	10067737	Lupus hepatitis	
Hepatotoxicity	10053219	Non-alcoholic steatohepatitis	
Hepatotoxicity	10051015	Radiation hepatitis	
Hepatotoxicity	10078331	Steatohepatitis	
Hepatotoxicity	10018704	Granulomatous liver disease	
Hepatotoxicity	10068554	Liver sarcoidosis	
Hepatotoxicity	10075331	Portal tract inflammation	
Hepatotoxicity	10004269	Benign hepatic neoplasm	
Hepatotoxicity	10077922	Benign hepatobiliary neoplasm	
Hepatotoxicity	10052285	Focal nodular hyperplasia	
Hepatotoxicity	10018821	Haemangioma of liver	
Hepatotoxicity	10067796	Haemorrhagic hepatic cyst	
Hepatotoxicity	10018629	Hepatic adenoma	
Hepatotoxicity	10019646	Hepatic cyst	
Hepatotoxicity	10053973	Hepatic cyst ruptured	
Hepatotoxicity	10054885	Hepatic haemangioma rupture	
Hepatotoxicity	10079685	Hepatic hamartoma	
Hepatotoxicity	10079889	Hepatobiliary cyst	
Hepatotoxicity	10077851	Cholangiosarcoma	
Hepatotoxicity	10067388	Hepatic angiosarcoma	
Hepatotoxicity	10073069	Hepatic cancer	
Hepatotoxicity	10055110	Hepatic cancer metastatic	
Hepatotoxicity	10073070	Hepatic cancer recurrent	
Hepatotoxicity	10058318	Hepatic cancer stage I	
Hepatotoxicity	10058319	Hepatic cancer stage II	
Hepatotoxicity	10058324	Hepatic cancer stage III	
Hepatotoxicity	10058325	Hepatic cancer stage IV	
Hepatotoxicity	10073073	Hepatobiliary cancer	
Hepatotoxicity	10073074	Hepatobiliary cancer in situ	
Hepatotoxicity	10062001	Hepatoblastoma	
Hepatotoxicity	10018823	Hepatoblastoma recurrent	
Hepatotoxicity	10073071	Hepatocellular carcinoma	
Hepatotoxicity	10050842	Liver carcinoma ruptured	
Hepatotoxicity	10027761	Mixed hepatocellular cholangiocarcinoma	
Hepatotoxicity	10074766	Liver ablation	
Hepatotoxicity	10019685	Hepatic neoplasm	
Hepatotoxicity	10061203	Hepatobiliary neoplasm	
Hepatotoxicity	10001547	Alanine aminotransferase abnormal	
Hepatotoxicity	10001551	Alanine aminotransferase increased	
Hepatotoxicity	10001942	Ammonia abnormal	
Hepatotoxicity	10001946	Ammonia increased	
Hepatotoxicity	10003445	Ascites	
Hepatotoxicity	10003477	Aspartate aminotransferase abnormal	
Hepatotoxicity	10003481	Aspartate aminotransferase increased	
Hepatotoxicity	10068547	Bacterascites	
Hepatotoxicity	10051344	Bile output abnormal	
Hepatotoxicity	10051343	Bile output decreased	
Hepatotoxicity	10074150	Biliary ascites	
Hepatotoxicity	10067718	Bilirubin conjugated abnormal	
Hepatotoxicity	10004685	Bilirubin conjugated increased	
Hepatotoxicity	10077356	Bilirubin urine present	
Hepatotoxicity	10004792	Biopsy liver abnormal	
Hepatotoxicity	10058477	Blood bilirubin abnormal	
Hepatotoxicity	10005364	Blood bilirubin increased	
Hepatotoxicity	10005370	Blood bilirubin unconjugated increased	
Hepatotoxicity	10006408	Bromosulphthalein test abnormal	
Hepatotoxicity	10077020	Child-Pugh-Turcotte score abnormal	
Hepatotoxicity	10068287	Child-Pugh-Turcotte score increased	
Hepatotoxicity	10076215	Computerised tomogram liver	
Hepatotoxicity	10078380	Computerised tomogram liver abnormal	
Hepatotoxicity	10052554	Fostor hepaticus	
Hepatotoxicity	10059710	Galactose elimination capacity test abnormal	
Hepatotoxicity	10059712	Galactose elimination capacity test decreased	
Hepatotoxicity	10017688	Gamma-glutamyltransferase abnormal	
Hepatotoxicity	10017693	Gamma-glutamyltransferase increased	
Hepatotoxicity	10051333	Guanase increased	
Hepatotoxicity	10018621	Hepaplastin abnormal	
Hepatotoxicity	10018622	Hepaplastin decreased	
Hepatotoxicity	10068987	Hepatic artery flow decreased	
Hepatotoxicity	10019645	Hepatic congestion	
Hepatotoxicity	10052585	Hepatic enzyme abnormal	
Hepatotoxicity	10060784	Hepatic enzyme decreased	
Hepatotoxicity	10060795	Hepatic enzyme increased	
Hepatotoxicity	10019670	Hepatic function abnormal	
Hepatotoxicity	10067365	Hepatic hydrothorax	
Hepatotoxicity	10076254	Hepatic hypertrophy	
Hepatotoxicity	10057110	Hepatic mass	
Hepatotoxicity	10019705	Hepatic pain	
Hepatotoxicity	10068244	Hepatic sequestration	
Hepatotoxicity	10068358	Hepatic vascular resistance increased	
Hepatotoxicity	10068195	Hepatobiliary scan abnormal	
Hepatotoxicity	10019842	Hepatomegaly	
Hepatotoxicity	10019847	Hepatosplenomegaly	
Hepatotoxicity	10020575	Hyperammonaemia	
Hepatotoxicity	10020578	Hyperbilirubinaemia	
Hepatotoxicity	10051824	Hypercholia	
Hepatotoxicity	10068237	Hypertransaminasaemia	
Hepatotoxicity	10023321	Kayser-Fleischer ring	
Hepatotoxicity	10024690	Liver function test abnormal	
Hepatotoxicity	10077677	Liver function test decreased	
Hepatotoxicity	10077692	Liver function test increased	
Hepatotoxicity	10052550	Liver induration	
Hepatotoxicity	10075985	Liver palpable	

表 2.7.4.9－27　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver21.1）（続き）

AESI	PT Code	PT Name	SOC
Hepatotoxicity	10061947	Liver scan abnormal	
Hepatotoxicity	10024712	Liver tenderness	
Hepatotoxicity	10064712	Mitochondrial aspartate aminotransferase increased	
Hepatotoxicity	10066969	Molar ratio of total branched-chain amino acid to tyrosine	
Hepatotoxicity	10080035	Nuclear magnetic resonance imaging liver abnormal	
Hepatotoxicity	10049531	Oedema due to hepatic disease	
Hepatotoxicity	10054125	Perihepatic discomfort	
Hepatotoxicity	10067338	Retrograde portal vein flow	
Hepatotoxicity	10054558	Total bile acids increased	
Hepatotoxicity	10062688	Transaminases abnormal	
Hepatotoxicity	10054889	Transaminases increased	
Hepatotoxicity	10045428	Ultrasound liver abnormal	
Hepatotoxicity	10050792	Urine bilirubin increased	
Hepatotoxicity	10078438	White nipple sign	
Hepatotoxicity	10056535	X-ray hepatobiliary abnormal	
Hepatotoxicity	10000028	5'-nucleotidase increased	
Hepatotoxicity	10059571	Blood alkaline phosphatase abnormal	
Hepatotoxicity	10059570	Blood alkaline phosphatase increased	
Hepatotoxicity	10005429	Blood cholinesterase abnormal	
Hepatotoxicity	10005430	Blood cholinesterase decreased	
Hepatotoxicity	10071634	Deficiency of bile secretion	
Hepatotoxicity	10049483	Glutamate dehydrogenase increased	
Hepatotoxicity	10080824	Glycocholic acid increased	
Hepatotoxicity	10059766	Haemorrhagic ascites	
Hepatotoxicity	10074084	Hepatic fibrosis marker abnormal	
Hepatotoxicity	10074413	Hepatic fibrosis marker increased	
Hepatotoxicity	10079586	Hepatic lymphocytic infiltration	
Hepatotoxicity	10020942	Hypoalbuminaemia	
Hepatotoxicity	10024275	Leucine aminopeptidase increased	
Hepatotoxicity	10074352	Liver iron concentration abnormal	
Hepatotoxicity	10074354	Liver iron concentration increased	
Hepatotoxicity	10077291	Model for end stage liver disease score abnormal	
Hepatotoxicity	10077292	Model for end stage liver disease score increased	
Hepatotoxicity	10068821	Periportal oedema	
Hepatotoxicity	10069000	Peritoneal fluid protein abnormal	
Hepatotoxicity	10068999	Peritoneal fluid protein decreased	
Hepatotoxicity	10068998	Peritoneal fluid protein increased	
Hepatotoxicity	10066004	Pneumobilia	
Hepatotoxicity	10067337	Portal vein flow decreased	
Hepatotoxicity	10064936	Portal vein pressure increased	
Hepatotoxicity	10048473	Retinol binding protein decreased	
Hepatotoxicity	10070480	Urobilinogen urine decreased	
Hepatotoxicity	10070478	Urobilinogen urine increased	
Hepatotoxicity	10074561	Acquired antithrombin III deficiency	
Hepatotoxicity	10068370	Acquired protein S deficiency	
Hepatotoxicity	10077670	Anti factor X activity abnormal	
Hepatotoxicity	10077674	Anti factor X activity decreased	
Hepatotoxicity	10077671	Anti factor X activity increased	
Hepatotoxicity	10049547	Antithrombin III decreased	
Hepatotoxicity	10005518	Blood fibrinogen abnormal	
Hepatotoxicity	10005520	Blood fibrinogen decreased	
Hepatotoxicity	10005818	Blood thrombin abnormal	
Hepatotoxicity	10005820	Blood thrombin decreased	
Hepatotoxicity	10005824	Blood thromboplastin abnormal	
Hepatotoxicity	10005826	Blood thromboplastin decreased	
Hepatotoxicity	10009736	Coagulation factor decreased	
Hepatotoxicity	10061770	Coagulation factor IX level abnormal	
Hepatotoxicity	10009746	Coagulation factor IX level decreased	
Hepatotoxicity	10061771	Coagulation factor V level abnormal	
Hepatotoxicity	10009754	Coagulation factor V level decreased	
Hepatotoxicity	10061772	Coagulation factor VII level abnormal	
Hepatotoxicity	10009761	Coagulation factor VII level decreased	
Hepatotoxicity	10061774	Coagulation factor X level abnormal	
Hepatotoxicity	10009775	Coagulation factor X level decreased	
Hepatotoxicity	10074737	Hyperfibrinolysis	
Hepatotoxicity	10020973	Hypocoagulable state	
Hepatotoxicity	10051125	Hypofibrinogenaemia	
Hepatotoxicity	10021085	Hypoprothrombinaemia	
Hepatotoxicity	10058517	Hypothrombinaemia	
Hepatotoxicity	10058518	Hypothromboplastinaemia	
Hepatotoxicity	10022592	International normalised ratio abnormal	
Hepatotoxicity	10022595	International normalised ratio increased	
Hepatotoxicity	10037005	Protein C decreased	
Hepatotoxicity	10051736	Protein S abnormal	
Hepatotoxicity	10051120	Protein S decreased	
Hepatotoxicity	10037048	Prothrombin level abnormal	
Hepatotoxicity	10037050	Prothrombin level decreased	
Hepatotoxicity	10037057	Prothrombin time abnormal	
Hepatotoxicity	10037063	Prothrombin time prolonged	
Hepatotoxicity	10061818	Prothrombin time ratio abnormal	
Hepatotoxicity	10037068	Prothrombin time ratio increased	
Hepatotoxicity	10051319	Thrombin time abnormal	
Hepatotoxicity	10051390	Thrombin time prolonged	
Thrombotic events	10074337	Acute aortic syndrome	
Thrombotic events	10000881	Acute myocardial infarction	
Thrombotic events	10001902	Amaurosis	
Thrombotic events	10001903	Amaurosis fugax	
Thrombotic events	10002475	Angioplasty	
Thrombotic events	10057617	Aortic bypass	
Thrombotic events	10002897	Aortic embolus	
Thrombotic events	10061651	Aortic surgery	
Thrombotic events	10002910	Aortic thrombosis	
Thrombotic events	10057794	Aortogram abnormal	
Thrombotic events	10071026	Arteriectomy	

表 2.7.4.9－27　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver21.1）（続き）

AESI	PT Code	PT Name	SOC
Thrombotic events	10003140	Arterectomy with graft replacement	
Thrombotic events	10081731	Arterial angioplasty	
Thrombotic events	10077766	Arterial bypass occlusion	
Thrombotic events	10056418	Arterial bypass operation	
Thrombotic events	10077765	Arterial bypass thrombosis	
Thrombotic events	10061655	Arterial graft	
Thrombotic events	10062589	Arterial occlusive disease	
Thrombotic events	10061657	Arterial stent insertion	
Thrombotic events	10052949	Arterial therapeutic procedure	
Thrombotic events	10003178	Arterial thrombosis	
Thrombotic events	10061659	Arteriogram abnormal	
Thrombotic events	10003195	Arteriogram carotid abnormal	
Thrombotic events	10078636	Arteriotomy	
Thrombotic events	10063075	Atherectomy	
Thrombotic events	10076804	Atherosclerotic plaque rupture	
Thrombotic events	10079735	Atrial appendage closure	
Thrombotic events	10080843	Atrial appendage resection	
Thrombotic events	10069020	Basal ganglia infarction	
Thrombotic events	10048863	Basilar artery occlusion	
Thrombotic events	10063093	Basilar artery thrombosis	
Thrombotic events	10005184	Blindness transient	
Thrombotic events	10069684	Brachiocephalic artery occlusion	
Thrombotic events	10067744	Capsular warning syndrome	
Thrombotic events	10071260	Carotid angioplasty	
Thrombotic events	10007684	Carotid arterial embolus	
Thrombotic events	10053003	Carotid artery bypass	
Thrombotic events	10048964	Carotid artery occlusion	
Thrombotic events	10066102	Carotid artery stent insertion	
Thrombotic events	10007688	Carotid artery thrombosis	
Thrombotic events	10007692	Carotid endarterectomy	
Thrombotic events	10053633	Cerebellar artery occlusion	
Thrombotic events	10008023	Cerebellar artery thrombosis	
Thrombotic events	10008088	Cerebral artery embolism	
Thrombotic events	10008089	Cerebral artery occlusion	
Thrombotic events	10008092	Cerebral artery thrombosis	
Thrombotic events	10065384	Cerebral hypoperfusion	
Thrombotic events	10058842	Cerebrovascular insufficiency	
Thrombotic events	10061751	Cerebrovascular stenosis	
Thrombotic events	10069696	Coeliac artery occlusion	
Thrombotic events	10050329	Coronary angioplasty	
Thrombotic events	10052086	Coronary arterial stent insertion	
Thrombotic events	10011077	Coronary artery bypass	
Thrombotic events	10011084	Coronary artery embolism	
Thrombotic events	10011086	Coronary artery occlusion	
Thrombotic events	10053251	Coronary artery reocclusion	
Thrombotic events	10011090	Coronary artery surgery	
Thrombotic events	10011091	Coronary artery thrombosis	
Thrombotic events	10011101	Coronary endarterectomy	
Thrombotic events	10048887	Coronary revascularisation	
Thrombotic events	10075152	Coronary vascular graft occlusion	
Thrombotic events	10058729	Embolia cutis medicamentosa	
Thrombotic events	10014513	Embolism arterial	
Thrombotic events	10014648	Endarterectomy	
Thrombotic events	10068365	Femoral artery embolism	
Thrombotic events	10018635	Hepatic artery embolism	
Thrombotic events	10051991	Hepatic artery occlusion	
Thrombotic events	10019636	Hepatic artery thrombosis	
Thrombotic events	10063518	Hypothenar hammer syndrome	
Thrombotic events	10021338	Iliac artery embolism	
Thrombotic events	10064901	Iliac artery occlusion	
Thrombotic events	10052989	Intra-aortic balloon placement	
Thrombotic events	10056382	Intraoperative cerebral artery occlusion	
Thrombotic events	10060840	Ischaemic cerebral infarction	
Thrombotic events	10061256	Ischaemic stroke	
Thrombotic events	10051078	Lacunar infarction	
Thrombotic events	10024242	Leriche syndrome	
Thrombotic events	10027394	Mesenteric arterial occlusion	
Thrombotic events	10065580	Mesenteric arteriosclerosis	
Thrombotic events	10027395	Mesenteric artery embolism	
Thrombotic events	10027396	Mesenteric artery stenosis	
Thrombotic events	10071261	Mesenteric artery stent insertion	
Thrombotic events	10027397	Mesenteric artery thrombosis	
Thrombotic events	10028596	Myocardial infarction	
Thrombotic events	10028602	Myocardial necrosis	
Thrombotic events	10081144	Ophthalmic artery thrombosis	
Thrombotic events	10033697	Papillary muscle infarction	
Thrombotic events	10069035	Penile artery occlusion	
Thrombotic events	10065608	Percutaneous coronary intervention	
Thrombotic events	10062585	Peripheral arterial occlusive disease	
Thrombotic events	10063379	Peripheral arterial reocclusion	
Thrombotic events	10057518	Peripheral artery angioplasty	
Thrombotic events	10072561	Peripheral artery bypass	
Thrombotic events	10057525	Peripheral artery occlusion	
Thrombotic events	10072562	Peripheral artery stent insertion	
Thrombotic events	10072564	Peripheral artery thrombosis	
Thrombotic events	10061340	Peripheral embolism	
Thrombotic events	10072560	Peripheral endarterectomy	
Thrombotic events	10071642	Popliteal artery entrapment syndrome	
Thrombotic events	10066592	Post procedural myocardial infarction	
Thrombotic events	10058144	Postinfarction angina	
Thrombotic events	10036511	Precerebral artery occlusion	
Thrombotic events	10074717	Precerebral artery thrombosis	
Thrombotic events	10078857	Profundaplasty	
Thrombotic events	10078201	Pulmonary artery occlusion	

表 2.7.4.9－27　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver21.1）（続き）

AESI	PT Code	PT Name	SOC
Thrombotic events	10053731	Pulmonary artery therapeutic procedure	
Thrombotic events	10037340	Pulmonary artery thrombosis	
Thrombotic events	10072883	Pulmonary endarterectomy	
Thrombotic events	10079988	Pulmonary tumour thrombotic microangiopathy	
Thrombotic events	10057493	Renal artery angioplasty	
Thrombotic events	10048868	Renal artery occlusion	
Thrombotic events	10038380	Renal artery thrombosis	
Thrombotic events	10063544	Renal embolism	
Thrombotic events	10038826	Retinal artery embolism	
Thrombotic events	10038827	Retinal artery occlusion	
Thrombotic events	10038831	Retinal artery thrombosis	
Thrombotic events	10049768	Silent myocardial infarction	
Thrombotic events	10048440	Spinal artery embolism	
Thrombotic events	10071316	Spinal artery thrombosis	
Thrombotic events	10074600	Splenic artery thrombosis	
Thrombotic events	10068577	Splenic embolism	
Thrombotic events	10065286	Stress cardiomyopathy	
Thrombotic events	10042332	Subclavian artery embolism	
Thrombotic events	10065585	Subclavian artery occlusion	
Thrombotic events	10042334	Subclavian artery thrombosis	
Thrombotic events	10064958	Thromboembolectomy	
Thrombotic events	10043645	Thrombotic microangiopathy	
Thrombotic events	10043648	Thrombotic thrombocytopenic purpura	
Thrombotic events	10044390	Transient ischaemic attack	
Thrombotic events	10062353	Truncus coeliacus thrombosis	
Thrombotic events	10078269	Vascular pseudoaneurysm thrombosis	
Thrombotic events	10048965	Vertebral artery occlusion	
Thrombotic events	10057777	Vertebral artery thrombosis	
Thrombotic events	10047532	Visual acuity reduced transiently	
Thrombotic events	10003880	Axillary vein thrombosis	
Thrombotic events	10076837	Brachiocephalic vein occlusion	
Thrombotic events	10063383	Brachiocephalic vein thrombosis	
Thrombotic events	10006537	Budd-Chiari syndrome	
Thrombotic events	10052688	Catheterisation venous	
Thrombotic events	10007830	Cavernous sinus thrombosis	
Thrombotic events	10053377	Central venous catheterisation	
Thrombotic events	10008138	Cerebral venous thrombosis	
Thrombotic events	10079209	Compression garment application	
Thrombotic events	10051055	Deep vein thrombosis	
Thrombotic events	10066881	Deep vein thrombosis postoperative	
Thrombotic events	10014522	Embolism venous	
Thrombotic events	10078810	Hepatic vein embolism	
Thrombotic events	10058991	Hepatic vein occlusion	
Thrombotic events	10019713	Hepatic vein thrombosis	
Thrombotic events	10051031	Homans' sign positive	
Thrombotic events	10058992	Iliac vein occlusion	
Thrombotic events	10070911	Inferior vena cava syndrome	
Thrombotic events	10058987	Inferior vena caval occlusion	
Thrombotic events	10061251	Intracranial venous sinus thrombosis	
Thrombotic events	10076835	Jugular vein occlusion	
Thrombotic events	10023237	Jugular vein thrombosis	
Thrombotic events	10075428	Mahler sign	
Thrombotic events	10069727	May-Thurner syndrome	
Thrombotic events	10027402	Mesenteric vein thrombosis	
Thrombotic events	10027403	Mesenteric venous occlusion	
Thrombotic events	10023925	Obstetrical pulmonary embolism	
Thrombotic events	10073708	Obstructive shock	
Thrombotic events	10074348	Ophthalmic vein thrombosis	
Thrombotic events	10072059	Ovarian vein thrombosis	
Thrombotic events	10050216	Paget-Schroetter syndrome	
Thrombotic events	10034272	Pelvic venous thrombosis	
Thrombotic events	10034324	Penile vein thrombosis	
Thrombotic events	10048874	Phlebectomy	
Thrombotic events	10073979	Portal vein cavernous transformation	
Thrombotic events	10058989	Portal vein occlusion	
Thrombotic events	10036206	Portal vein thrombosis	
Thrombotic events	10077623	Portosplenomesenteric venous thrombosis	
Thrombotic events	10053909	Post procedural pulmonary embolism	
Thrombotic events	10048591	Post thrombotic syndrome	
Thrombotic events	10050902	Postoperative thrombosis	
Thrombotic events	10036300	Postpartum venous thrombosis	
Thrombotic events	10037377	Pulmonary embolism	
Thrombotic events	10037410	Pulmonary infarction	
Thrombotic events	10037421	Pulmonary microemboli	
Thrombotic events	10037437	Pulmonary thrombosis	
Thrombotic events	10068690	Pulmonary vein occlusion	
Thrombotic events	10037458	Pulmonary veno-occlusive disease	
Thrombotic events	10037459	Pulmonary venous thrombosis	
Thrombotic events	10038547	Renal vein embolism	
Thrombotic events	10056293	Renal vein occlusion	
Thrombotic events	10038548	Renal vein thrombosis	
Thrombotic events	10038907	Retinal vein occlusion	
Thrombotic events	10038908	Retinal vein thrombosis	
Thrombotic events	10068479	S1 Q3 T3 pattern	
Thrombotic events	10068122	Splenic vein occlusion	
Thrombotic events	10041558	Splenic vein thrombosis	
Thrombotic events	10079164	Subclavian vein occlusion	
Thrombotic events	10049446	Subclavian vein thrombosis	
Thrombotic events	10042567	Superior sagittal sinus thrombosis	
Thrombotic events	10058988	Superior vena cava occlusion	
Thrombotic events	10042569	Superior vena cava syndrome	
Thrombotic events	10043570	Thrombophlebitis	
Thrombotic events	10043581	Thrombophlebitis migrans	
Thrombotic events	10043586	Thrombophlebitis neonatal	

表 2.7.4.9－27　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver21.1）（続き）

AESI	PT Code	PT Name	SOC
Thrombotic events	10043595	Thrombophlebitis superficial	
Thrombotic events	10043605	Thrombosed varicose vein	
Thrombotic events	10067270	Thrombosis corpora cavernosa	
Thrombotic events	10044457	Transverse sinus thrombosis	
Thrombotic events	10047193	Vena cava embolism	
Thrombotic events	10048932	Vena cava filter insertion	
Thrombotic events	10074397	Vena cava filter removal	
Thrombotic events	10047195	Vena cava thrombosis	
Thrombotic events	10047206	Venogram abnormal	
Thrombotic events	10062173	Venoocclusive disease	
Thrombotic events	10047216	Venoocclusive liver disease	
Thrombotic events	10077826	Venous angioplasty	
Thrombotic events	10058990	Venous occlusion	
Thrombotic events	10062175	Venous operation	
Thrombotic events	10068605	Venous recanalisation	
Thrombotic events	10052964	Venous repair	
Thrombotic events	10063389	Venous stent insertion	
Thrombotic events	10047249	Venous thrombosis	
Thrombotic events	10067030	Venous thrombosis in pregnancy	
Thrombotic events	10051408	Venous thrombosis limb	
Thrombotic events	10064602	Venous thrombosis neonatal	
Thrombotic events	10077829	Visceral venous thrombosis	
Thrombotic events	10075968	Administration site thrombosis	
Thrombotic events	10075178	Adrenal thrombosis	
Thrombotic events	10080956	Angiogram abnormal	
Thrombotic events	10052906	Angiogram cerebral abnormal	
Thrombotic events	10057517	Angiogram peripheral abnormal	
Thrombotic events	10076026	Application site thrombosis	
Thrombotic events	10058562	Arteriovenous fistula occlusion	
Thrombotic events	10003192	Arteriovenous fistula thrombosis	
Thrombotic events	10053182	Arteriovenous graft thrombosis	
Thrombotic events	10078895	Artificial blood vessel occlusion	
Thrombotic events	10048532	Atrial thrombosis	
Thrombotic events	10071043	Basal ganglia stroke	
Thrombotic events	10049824	Bone infarction	
Thrombotic events	10074422	Brain stem embolism	
Thrombotic events	10006147	Brain stem infarction	
Thrombotic events	10068644	Brain stem stroke	
Thrombotic events	10062573	Brain stem thrombosis	
Thrombotic events	10053994	Cardiac ventricular thrombosis	
Thrombotic events	10079523	Catheter site thrombosis	
Thrombotic events	10067167	Cerebellar embolism	
Thrombotic events	10008034	Cerebellar infarction	
Thrombotic events	10076929	Cerebral congestion	
Thrombotic events	10008118	Cerebral infarction	
Thrombotic events	10008119	Cerebral infarction foetal	
Thrombotic events	10008120	Cerebral ischaemia	
Thrombotic events	10078311	Cerebral microembolism	
Thrombotic events	10070871	Cerebral septic infarct	
Thrombotic events	10008132	Cerebral thrombosis	
Thrombotic events	10078895	Cerebral vascular occlusion	
Thrombotic events	10052173	Cerebrospinal thrombotic tamponade	
Thrombotic events	10008190	Cerebrovascular accident	
Thrombotic events	10049185	Cerebrovascular accident prophylaxis	
Thrombotic events	10008196	Cerebrovascular disorder	
Thrombotic events	10051802	Cerebrovascular operation	
Thrombotic events	10057403	Choroidal infarction	
Thrombotic events	10069729	Collateral circulation	
Thrombotic events	10059025	Coronary bypass thrombosis	
Thrombotic events	10074896	Device embolisation	
Thrombotic events	10084585	Device occlusion	
Thrombotic events	10077455	Device related thrombosis	
Thrombotic events	10013033	Diplegia	
Thrombotic events	10013048	Directional Doppler flow tests abnormal	
Thrombotic events	10013442	Disseminated intravascular coagulation	
Thrombotic events	10013443	Disseminated intravascular coagulation in newborn	
Thrombotic events	10090839	Embolic cerebral infarction	
Thrombotic events	10065680	Embolic pneumonia	
Thrombotic events	10014498	Embolic stroke	
Thrombotic events	10061169	Embolism	
Thrombotic events	10053601	Foetal cerebrovascular disorder	
Thrombotic events	10051259	Graft thrombosis	
Thrombotic events	10079902	Haemorrhagic adrenal infarction	
Thrombotic events	10019005	Haemorrhagic cerebral infarction	
Thrombotic events	10019013	Haemorrhagic infarction	
Thrombotic events	10019016	Haemorrhagic stroke	
Thrombotic events	10055677	Haemorrhagic transformation stroke	
Thrombotic events	10019023	Haemorrhoids thrombosed	
Thrombotic events	10019465	Hemiparesis	
Thrombotic events	10019468	Hemiplegia	
Thrombotic events	10062506	Heparin-induced thrombocytopenia	
Thrombotic events	10019680	Hepatic infarction	
Thrombotic events	10074494	Hepatic vascular thrombosis	
Thrombotic events	10063868	Implant site thrombosis	
Thrombotic events	10076839	Incision site vessel occlusion	
Thrombotic events	10061216	Infarction	
Thrombotic events	10065489	Infusion site thrombosis	
Thrombotic events	10022104	Injection site thrombosis	
Thrombotic events	10070754	Inner ear infarction	
Thrombotic events	10073625	Instillation site thrombosis	
Thrombotic events	10022657	Intestinal infarction	
Thrombotic events	10068087	Intracardiac mass	
Thrombotic events	10048520	Intracardiac thrombus	
Thrombotic events	10076145	Medical device site thrombosis	

表 2.7.4.9－27　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver21.1）（続き）

AESI	PT Code	PT Name	SOC
Thrombotic events	10027401	Mesenteric vascular insufficiency	
Thrombotic events	10074583	Mesenteric vascular occlusion	
Thrombotic events	10073734	Microembolism	
Thrombotic events	10027925	Monoparesis	
Thrombotic events	10027926	Monoplegia	
Thrombotic events	10030936	Optic nerve infarction	
Thrombotic events	10068239	Pancreatic infarction	
Thrombotic events	10060059	Paradoxical embolism	
Thrombotic events	10078251	Paraneoplastic thrombosis	
Thrombotic events	10033885	Paraparesis	
Thrombotic events	10033892	Paraplegia	
Thrombotic events	10033985	Paresis	
Thrombotic events	10053351	Peripheral revascularisation	
Thrombotic events	10035092	Pituitary infarction	
Thrombotic events	10064620	Placental infarction	
Thrombotic events	10059829	Pneumatic compression therapy	
Thrombotic events	10077479	Portal shunt procedure	
Thrombotic events	10066581	Post procedural stroke	
Thrombotic events	10077022	Postpartum thrombosis	
Thrombotic events	10063176	Prosthetic cardiac valve thrombosis	
Thrombotic events	10068628	Prosthetic vessel implantation	
Thrombotic events	10049690	Quadriparesis	
Thrombotic events	10037714	Quadriplegia	
Thrombotic events	10038470	Renal infarct	
Thrombotic events	10072226	Renal vascular thrombosis	
Thrombotic events	10051742	Retinal infarction	
Thrombotic events	10062108	Retinal vascular thrombosis	
Thrombotic events	10040621	Shunt occlusion	
Thrombotic events	10058054	Shunt thrombosis	
Thrombotic events	10058571	Spinal cord infarction	
Thrombotic events	10041648	Splenic infarction	
Thrombotic events	10074601	Splenic thrombosis	
Thrombotic events	10074515	Stoma site thrombosis	
Thrombotic events	10059613	Stroke in evolution	
Thrombotic events	10058408	Surgical vascular shunt	
Thrombotic events	10043337	Testicular infarction	
Thrombotic events	10064961	Thalamic infarction	
Thrombotic events	10043530	Thrombectomy	
Thrombotic events	10043540	Thromboangiitis obliterans	
Thrombotic events	10043568	Thrombolysis	
Thrombotic events	10043607	Thrombosis	
Thrombotic events	10062546	Thrombosis in device	
Thrombotic events	10043626	Thrombosis mesenteric vessel	
Thrombotic events	10043634	Thrombosis prophylaxis	
Thrombotic events	10067347	Thrombotic cerebral infarction	
Thrombotic events	10043647	Thrombotic stroke	
Thrombotic events	10043742	Thyroid infarction	
Thrombotic events	10045168	Tumour embolism	
Thrombotic events	10068067	Tumour thrombosis	
Thrombotic events	10061504	Ultrasonic angiogram abnormal	
Thrombotic events	10045413	Ultrasound Doppler abnormal	
Thrombotic events	10076714	Umbilical cord occlusion	
Thrombotic events	10071652	Umbilical cord thrombosis	
Thrombotic events	10078190	Vaccination site thrombosis	
Thrombotic events	10078875	Vascular access site thrombosis	
Thrombotic events	10080803	Vascular device occlusion	
Thrombotic events	10067740	Vascular graft	
Thrombotic events	10049080	Vascular graft occlusion	
Thrombotic events	10089922	Vascular graft thrombosis	
Thrombotic events	10049071	Vascular operation	
Thrombotic events	10063382	Vascular stent insertion	
Thrombotic events	10077143	Vascular stent occlusion	
Thrombotic events	10063934	Vascular stent thrombosis	
Thrombotic events	10058794	Vasodilation procedure	
Thrombotic events	10076838	Vessel puncture site occlusion	
Thrombotic events	10070649	Vessel puncture site thrombosis	
Thrombotic events	10066856	Visual midline shift syndrome	
Gastrointestinal disorders	10047700	Vomiting	
Gastrointestinal disorders	10012735	Diarrhoea	
Gastrointestinal disorders	10028813	Nausea	
Gastrointestinal disorders	10000081	Abdominal pain	
Headache	10018211	Headache	
Blood uric acid increased	10005851	Blood uric acid increased	
Hyperkalaemia	10020646	Hyperkalaemia	
Hyperkalaemia	10005722	Blood potassium abnormal	
Hyperkalaemia	10005725	Blood potassium increased	
Malignancy			Neoplasms benign, malignant and unspecified (incl cysts and polyps)
QT prolongation	10053748	Electrocardiogram QT interval abnormal	
QT prolongation	10014387	Electrocardiogram QT prolonged	
QT prolongation	10024803	Long QT syndrome	
QT prolongation	10057826	Long QT syndrome congenital	
QT prolongation	10044066	Torsade de pointes	
QT prolongation	10047302	Ventricular tachycardia	
QT prolongation	10007515	Cardiac arrest	
QT prolongation	10049993	Cardiac death	
QT prolongation	10061592	Cardiac fibrillation	
QT prolongation	10007617	Cardio-respiratory arrest	
QT prolongation	10052464	Electrocardiogram repolarisation abnormality	
QT prolongation	10062314	Electrocardiogram U wave inversion	
QT prolongation	10057813	Electrocardiogram U wave present	
QT prolongation	10055032	Electrocardiogram U-wave abnormality	
QT prolongation	10024855	Loss of consciousness	
QT prolongation	10077361	Multiple organ dysfunction syndrome	

表 2.7.4.9－27　注目すべき有害事象及び QT 延長に関する基本語リスト（MedDRA/J ver21.1）（続き）

AESI	PT Code	PT Name	SOC
QT prolongation	10048418	Sudden cardiac death	
QT prolongation	10042434	Sudden death	
QT prolongation	10042772	Syncope	
QT prolongation	10047281	Ventricular arrhythmia	
QT prolongation	10047290	Ventricular fibrillation	
QT prolongation	10047294	Ventricular flutter	
QT prolongation	10065341	Ventricular tachyarrhythmia	

5.3.5.3—1 統計解析計画書 別添より引用

表 2.7.4.9－28　規定した基準一覧

項目	規定した基準
尿酸	いずれかの時点で，ベースラインと比較して 25%以上上昇し，かつ 7.0 mg/dL 超を示した被験者
血清 K	いずれかの時点で，6.0 mmol/L 超 7.0 mmol/L を示した被験者
	いずれかの時点で，7.0 mmol/L 超を示した被験者
VEGF	いずれかの時点で，ベースラインの 2 倍，かつ 200 pg/mL 以上を示した被験者
Hb	NDD-CKD，PD-CKD：いずれかの時点で，13.0 g/dL 超を示した被験者
	HD-CKD：いずれかの時点で，12.0 g/dL 超を示した被験者
	NDD-CKD，PD-CKD：いずれかの時点で，14.0 g/dL 超を示した被験者
	HD-CKD：いずれかの時点で，13.0 g/dL 超を示した被験者
	（ISS-1 のみ）NDD-CKD，PD-CKD：いずれかの時点で，ベースラインからの変化量が 2.0 g/dL 超かつ 13.0 g/dL 超を示した被験者
	（ISS-1 のみ）HD-CKD：いずれかの時点で，ベースラインからの変化量が 2.0 g/dL 超かつ 12.0 g/dL 超を示した被験者
	（ISS-1 のみ）NDD-CKD，PD-CKD：いずれかの時点で，ベースラインからの変化量が 2.0 g/dL 超かつ 14.0 g/dL 超を示した被験者
	（ISS-1 のみ）HD-CKD：いずれかの時点で，ベースラインからの変化量が 2.0 g/dL 超かつ 13.0 g/dL 超を示した被験者
eGFR	（NDD-CKD のみ）いずれかの時点で，ベースラインと比較して 30%以上減少した被験者
AST，ALT	いずれかの時点で，AST が ULN の 3 倍超を示した被験者
	いずれかの時点で，AST が ULN の 5 倍超を示した被験者
	いずれかの時点で，ALT が ULN の 3 倍超を示した被験者
	いずれかの時点で，ALT が ULN の 5 倍超を示した被験者
	いずれかの時点で，AST が ULN の 3 倍超かつ総ビリルビンが ULN の 2 倍超を示した被験者
	いずれかの時点で，ALT が ULN の 3 倍超かつ総ビリルビンが ULN の 2 倍超を示した被験者
	いずれかの時点で，AST 又は ALT が ULN の 3 倍超かつ ALP が ULN の 2 倍未満かつ総ビリルビンが ULN の 2 倍超を示した被験者

表 2.7.4.9－28　規定した基準一覧（続き）

項目	規定した基準
収縮期血圧	NDD-CKD，PD-CKD：いずれかの時点で，ベースラインからの変化量が 20 mmHg 超かつ 180 mmHg 超を示した被験者
	HD-CKD：いずれかの時点で，ベースラインからの変化量が 20 mmHg 超かつ 190 mmHg 超を示した被験者
拡張期血圧	いずれかの時点で，ベースラインからの変化量が 15 mmHg 超かつ 110 mmHg 超を示した被験者

NDD-CKD：保存期慢性腎臓病；PD-CKD：腹膜透析を実施中の慢性腎臓病；HD-CKD：血液透析を実施中の慢性腎臓病；ULN：基準値上限

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）

Parameter:Ery. Mean Corpuscular Volume (fL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	93.6	5.2	93.0	(82, 119)						
	Week 2	151	94.2	5.3	94.0	(82, 118)	151	93.6 (5.2)	0.6	1.2	1.0	(-2, 4)
	Week 4	149	94.6	5.3	94.0	(83, 120)	149	93.5 (5.3)	1.0	1.6	1.0	(-3, 6)
	Week 6	148	95.2	5.6	95.0	(82, 122)	148	93.5 (5.3)	1.7	1.9	1.0	(-3, 10)
	Week 8	145	95.5	5.4	96.0	(83, 122)	145	93.5 (5.2)	2.0	2.1	2.0	(-3, 9)
	Week 10	145	95.7	5.4	96.0	(82, 124)	145	93.4 (5.2)	2.3	2.2	2.0	(-3, 11)
	Week 12	145	95.9	5.5	96.0	(83, 123)	145	93.5 (5.2)	2.4	2.4	2.0	(-2, 14)
	Week 16	143	95.9	5.8	96.0	(82, 124)	143	93.5 (5.3)	2.4	2.7	2.0	(-4, 17)
	Week 20	140	95.9	6.0	95.0	(82, 128)	140	93.5 (5.2)	2.4	2.9	2.0	(-4, 16)
	Week 24	132	95.8	6.3	95.0	(82, 132)	132	93.6 (5.3)	2.2	3.1	2.0	(-4, 17)
darbepoetin	Baseline	153	93.5	5.6	93.0	(79, 110)						
	Week 2	153	94.0	6.3	94.0	(77, 131)	153	93.5 (5.6)	0.5	2.4	0.0	(-3, 27)
	Week 4	153	93.8	5.5	94.0	(78, 109)	153	93.5 (5.6)	0.3	1.5	0.0	(-7, 3)
	Week 6	152	94.0	5.6	94.0	(77, 109)	152	93.5 (5.6)	0.5	2.0	1.0	(-10, 6)
	Week 8	151	93.6	5.7	93.0	(76, 109)	151	93.5 (5.7)	0.0	2.5	0.0	(-12, 7)
	Week 10	150	93.7	5.9	94.0	(76, 112)	150	93.6 (5.6)	0.0	2.7	0.0	(-13, 7)
	Week 12	148	93.3	5.7	93.0	(75, 113)	148	93.7 (5.6)	-0.4	3.2	0.0	(-16, 6)
	Week 16	148	92.9	6.0	92.5	(75, 112)	148	93.6 (5.6)	-0.8	3.6	-1.0	(-18, 7)
	Week 20	144	92.6	5.8	92.5	(76, 112)	144	93.8 (5.5)	-1.2	3.9	-1.0	(-19, 8)
	Week 24	140	92.9	5.5	93.0	(75, 108)	140	93.6 (5.4)	-0.7	3.7	-1.0	(-17, 9)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Ery. Mean Corpuscular Hemoglobin (pg)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	31.07	1.89	31.00	(26.2, 39.7)						
	Week 2	151	31.21	1.94	31.10	(26.7, 40.3)	151	31.07 (1.89)	0.14	0.50	0.20	(-1.1, 1.3)
	Week 4	149	31.41	1.90	31.30	(27.1, 40.3)	149	31.05 (1.89)	0.36	0.59	0.30	(-1.7, 1.9)
	Week 6	148	31.56	1.96	31.40	(27.1, 41.0)	148	31.05 (1.90)	0.51	0.75	0.50	(-1.2, 3.2)
	Week 8	145	31.57	1.89	31.60	(27.1, 40.7)	145	31.03 (1.88)	0.54	0.81	0.40	(-1.3, 3.9)
	Week 10	145	31.68	1.98	31.80	(27.1, 42.3)	145	31.02 (1.88)	0.66	0.94	0.60	(-1.8, 4.9)
	Week 12	145	31.71	1.98	31.80	(26.8, 42.1)	145	31.03 (1.88)	0.67	0.97	0.60	(-1.3, 4.8)
	Week 16	143	31.73	2.06	31.70	(27.0, 42.5)	143	31.02 (1.89)	0.71	1.18	0.60	(-1.7, 7.0)
	Week 20	140	31.80	2.16	31.95	(26.8, 43.6)	140	31.07 (1.89)	0.74	1.30	0.50	(-1.8, 6.2)
	Week 24	132	31.84	2.25	31.60	(27.2, 45.2)	132	31.08 (1.91)	0.75	1.36	0.60	(-1.9, 7.0)
darbepoetin	Baseline	153	31.10	2.11	31.00	(25.7, 36.9)						
	Week 2	153	31.17	2.38	31.10	(24.9, 46.2)	153	31.10 (2.11)	0.06	0.95	0.00	(-1.9, 9.3)
	Week 4	153	31.01	1.99	31.00	(25.4, 36.8)	153	31.10 (2.11)	-0.09	0.67	-0.10	(-2.7, 1.8)
	Week 6	152	30.97	2.00	30.90	(24.7, 36.2)	152	31.11 (2.11)	-0.14	0.79	-0.10	(-3.8, 1.7)
	Week 8	151	30.87	2.06	30.80	(24.5, 37.8)	151	31.11 (2.12)	-0.25	1.09	-0.20	(-5.5, 2.1)
	Week 10	150	30.75	2.13	30.85	(24.8, 37.1)	150	31.15 (2.10)	-0.40	1.16	-0.30	(-4.8, 2.3)
	Week 12	148	30.65	2.10	30.55	(24.3, 36.9)	148	31.16 (2.11)	-0.51	1.46	-0.40	(-6.6, 3.0)
	Week 16	148	30.55	2.22	30.50	(23.7, 36.9)	148	31.15 (2.10)	-0.61	1.51	-0.55	(-6.2, 3.7)
	Week 20	144	30.56	2.10	30.55	(23.6, 36.8)	144	31.19 (2.07)	-0.63	1.68	-0.60	(-6.9, 4.0)
	Week 24	140	30.77	2.15	30.80	(23.1, 37.9)	140	31.17 (2.04)	-0.40	1.57	-0.40	(-7.0, 4.6)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Ery. Mean Corpuscular HGB Concentration (%)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	33.18	0.63	33.20	(31.5, 34.5)						
	Week 2	151	33.13	0.65	33.10	(31.3, 34.8)	151	33.18 (0.63)	-0.05	0.53	0.00	(-1.5, 1.2)
	Week 4	149	33.19	0.59	33.20	(31.5, 34.8)	149	33.18 (0.63)	0.01	0.52	-0.10	(-1.6, 1.4)
	Week 6	148	33.13	0.55	33.15	(31.4, 34.6)	148	33.18 (0.63)	-0.05	0.55	0.00	(-1.5, 1.1)
	Week 8	145	33.07	0.50	33.00	(32.0, 34.6)	145	33.19 (0.63)	-0.12	0.58	-0.20	(-1.3, 1.5)
	Week 10	145	33.08	0.51	33.10	(31.7, 34.3)	145	33.18 (0.63)	-0.11	0.56	-0.10	(-1.3, 1.4)
	Week 12	145	33.05	0.52	33.10	(31.8, 34.7)	145	33.19 (0.63)	-0.14	0.55	-0.20	(-1.4, 1.5)
	Week 16	143	33.08	0.50	33.00	(32.0, 34.8)	143	33.18 (0.63)	-0.10	0.63	-0.20	(-1.8, 2.2)
	Week 20	140	33.17	0.48	33.10	(31.9, 34.6)	140	33.20 (0.63)	-0.03	0.69	-0.10	(-1.5, 1.9)
	Week 24	132	33.22	0.52	33.20	(31.7, 34.7)	132	33.20 (0.62)	0.01	0.73	0.00	(-1.5, 3.2)
darbepoetin	Baseline	153	33.25	0.72	33.20	(30.5, 35.6)						
	Week 2	153	33.14	0.68	33.20	(31.3, 35.3)	153	33.25 (0.72)	-0.11	0.53	-0.10	(-1.5, 1.1)
	Week 4	153	33.04	0.56	33.10	(31.8, 35.1)	153	33.25 (0.72)	-0.21	0.54	-0.20	(-1.8, 1.4)
	Week 6	152	32.93	0.55	32.90	(31.5, 34.6)	152	33.25 (0.72)	-0.32	0.56	-0.40	(-1.8, 1.8)
	Week 8	151	32.96	0.59	33.00	(31.4, 35.8)	151	33.26 (0.72)	-0.30	0.62	-0.40	(-1.8, 1.1)
	Week 10	150	32.81	0.57	32.90	(31.2, 34.9)	150	33.25 (0.72)	-0.45	0.64	-0.40	(-2.3, 1.5)
	Week 12	148	32.84	0.55	32.90	(31.4, 34.3)	148	33.25 (0.72)	-0.42	0.72	-0.40	(-2.3, 1.4)
	Week 16	148	32.86	0.68	32.80	(31.0, 36.0)	148	33.26 (0.72)	-0.40	0.69	-0.40	(-2.0, 1.7)
	Week 20	144	32.98	0.60	33.05	(30.8, 35.0)	144	33.27 (0.73)	-0.29	0.72	-0.30	(-2.2, 1.6)
	Week 24	140	33.09	0.66	33.20	(30.9, 35.1)	140	33.30 (0.72)	-0.21	0.73	-0.20	(-2.3, 2.0)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Erythrocytes Distribution Width (%)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	14.48	1.56	14.20	(12.4, 22.8)						
	Week 2	151	14.94	1.66	14.60	(12.1, 23.5)	151	14.48 (1.56)	0.46	0.65	0.40	(-0.9, 3.3)
	Week 4	149	15.17	1.79	14.80	(12.0, 23.7)	149	14.49 (1.56)	0.68	0.95	0.60	(-1.5, 5.3)
	Week 6	148	15.26	1.92	14.80	(12.3, 23.7)	148	14.48 (1.56)	0.77	1.15	0.70	(-1.9, 9.1)
	Week 8	145	15.04	1.70	14.60	(12.3, 21.8)	145	14.48 (1.57)	0.55	0.99	0.50	(-2.2, 3.8)
	Week 10	145	14.88	1.61	14.70	(12.4, 20.4)	145	14.49 (1.57)	0.39	1.19	0.30	(-3.3, 4.2)
	Week 12	145	14.62	1.56	14.40	(11.9, 21.3)	145	14.47 (1.57)	0.15	1.27	0.10	(-3.2, 4.1)
	Week 16	143	14.20	1.29	14.00	(11.9, 19.4)	143	14.48 (1.58)	-0.28	1.36	-0.10	(-4.9, 3.1)
	Week 20	140	14.20	1.35	13.90	(11.4, 20.4)	140	14.44 (1.57)	-0.24	1.48	-0.20	(-5.6, 5.9)
	Week 24	132	14.36	1.47	14.10	(11.8, 21.8)	132	14.40 (1.59)	-0.04	1.47	0.00	(-5.4, 4.7)
darbepoetin	Baseline	153	14.56	1.73	14.20	(11.9, 22.7)						
	Week 2	153	14.84	1.69	14.40	(12.4, 22.7)	153	14.56 (1.73)	0.28	0.58	0.30	(-1.5, 2.1)
	Week 4	153	14.84	1.66	14.50	(12.5, 22.2)	153	14.56 (1.73)	0.28	0.78	0.20	(-2.4, 3.2)
	Week 6	152	15.03	1.70	14.70	(12.1, 22.7)	152	14.55 (1.73)	0.47	0.92	0.50	(-2.8, 2.7)
	Week 8	151	14.85	1.62	14.50	(12.0, 22.9)	151	14.55 (1.74)	0.30	0.98	0.30	(-3.5, 3.3)
	Week 10	150	15.00	1.75	14.70	(12.1, 23.4)	150	14.55 (1.73)	0.45	1.18	0.40	(-3.3, 6.7)
	Week 12	148	14.94	1.76	14.60	(12.2, 24.7)	148	14.54 (1.73)	0.40	1.29	0.40	(-4.0, 5.7)
	Week 16	148	15.02	1.84	14.40	(12.4, 24.8)	148	14.52 (1.72)	0.49	1.58	0.30	(-4.3, 5.8)
	Week 20	144	15.26	1.87	14.90	(12.2, 24.9)	144	14.50 (1.72)	0.76	1.75	0.60	(-4.1, 6.7)
	Week 24	140	15.32	1.90	15.00	(12.5, 23.8)	140	14.44 (1.71)	0.88	1.89	0.80	(-4.9, 8.6)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Leukocytes (/uL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	5709.3	1836.8	5300.0	(2400, 18700)						
	Week 2	151	5823.2	2127.9	5400.0	(2500, 19700)	151	5709.3 (1836.8)	113.9	1424.7	100.0	(-3100, 11500)
	Week 4	149	5586.6	1757.6	5200.0	(2400, 12000)	149	5739.6 (1826.1)	-153.0	1051.6	-100.0	(-3700, 2900)
	Week 6	148	5753.4	1589.9	5500.0	(2800, 10900)	148	5745.3 (1831.0)	8.1	1266.9	100.0	(-7000, 3600)
	Week 8	145	5912.4	1766.9	5500.0	(2600, 11600)	145	5730.3 (1787.7)	182.1	1166.1	200.0	(-2900, 6300)
	Week 10	145	5952.4	1852.0	5600.0	(2800, 17600)	145	5725.5 (1790.1)	226.9	1400.9	200.0	(-3700, 11400)
	Week 12	145	5569.0	1480.7	5500.0	(2800, 10400)	145	5726.9 (1789.6)	-157.9	1128.0	0.0	(-4900, 2700)
	Week 16	143	5839.2	1735.7	5500.0	(2800, 14500)	143	5722.4 (1801.7)	116.8	1356.7	100.0	(-3400, 7400)
	Week 20	140	5862.9	1767.5	5600.0	(3100, 12700)	140	5701.4 (1775.7)	161.4	1624.4	100.0	(-5100, 8000)
	Week 24	132	5845.5	1856.7	5550.0	(2500, 14900)	132	5725.0 (1810.8)	120.5	1428.9	50.0	(-3600, 7800)
darbepoetin	Baseline	153	5578.4	1591.2	5400.0	(2800, 11400)						
	Week 2	153	5515.7	1633.1	5200.0	(2800, 12400)	153	5578.4 (1591.2)	-62.7	1165.3	-100.0	(-4300, 6900)
	Week 4	153	5520.3	1611.2	5400.0	(2700, 13000)	153	5578.4 (1591.2)	-58.2	1187.1	0.0	(-3600, 6500)
	Week 6	152	5474.3	1668.6	5300.0	(2500, 13800)	152	5578.3 (1596.5)	-103.9	1121.8	0.0	(-5200, 5100)
	Week 8	151	5414.6	1422.9	5200.0	(2300, 9300)	151	5577.5 (1601.8)	-162.9	994.0	-100.0	(-4200, 2500)
	Week 10	150	5545.3	1575.3	5300.0	(2800, 10700)	150	5560.7 (1597.1)	-15.3	1146.0	-100.0	(-4700, 5500)
	Week 12	148	5600.0	1641.3	5400.0	(2700, 10500)	148	5581.8 (1614.9)	18.2	1174.6	0.0	(-3100, 4700)
	Week 16	148	5538.5	1532.3	5500.0	(3100, 10800)	148	5558.1 (1602.9)	-19.6	1143.1	0.0	(-4800, 3000)
	Week 20	144	5685.4	1487.4	5600.0	(3300, 10000)	144	5550.0 (1590.5)	135.4	1178.7	100.0	(-4400, 4200)
	Week 24	140	5630.7	1633.0	5300.0	(2900, 11300)	140	5555.7 (1615.3)	75.0	1319.4	0.0	(-4900, 5600)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Neutrophils/Leukocytes (%)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	150	64.05	9.51	63.90	(35.5, 89.0)						
	Week 2	150	63.64	9.48	63.40	(37.0, 91.5)	150	64.05 (9.51)	-0.42	6.90	0.25	(-22.9, 20.0)
	Week 4	148	63.21	9.44	63.15	(36.8, 91.1)	148	64.10 (9.53)	-0.89	6.90	-0.25	(-21.0, 20.4)
	Week 6	148	64.34	8.92	64.45	(41.0, 88.5)	147	64.10 (9.56)	0.29	6.69	0.90	(-16.7, 20.4)
	Week 8	144	64.10	9.34	64.25	(38.5, 91.0)	144	63.96 (9.59)	0.13	7.23	-0.30	(-18.6, 22.1)
	Week 10	145	64.29	8.92	64.10	(39.9, 87.5)	144	64.02 (9.58)	0.29	7.74	0.55	(-28.6, 17.3)
	Week 12	144	64.15	9.42	64.15	(37.2, 89.0)	144	63.98 (9.59)	0.16	6.75	0.20	(-21.1, 18.0)
	Week 16	141	64.64	9.03	64.90	(43.1, 88.0)	141	64.04 (9.69)	0.60	6.97	0.70	(-15.9, 24.5)
	Week 20	139	65.62	9.93	65.50	(36.3, 90.0)	139	63.85 (9.70)	1.77	8.05	1.90	(-19.0, 27.6)
	Week 24	131	65.47	9.16	64.90	(35.9, 92.5)	131	63.74 (9.73)	1.73	8.01	1.30	(-18.6, 28.0)
darbepoetin	Baseline	153	64.30	8.16	64.00	(42.9, 92.0)						
	Week 2	153	63.55	8.72	64.00	(39.5, 87.5)	153	64.30 (8.16)	-0.75	7.68	0.20	(-33.5, 31.5)
	Week 4	153	63.64	8.92	64.00	(42.0, 93.5)	153	64.30 (8.16)	-0.67	7.24	-0.60	(-28.0, 28.2)
	Week 6	152	64.34	8.15	65.45	(43.1, 83.0)	152	64.31 (8.19)	0.03	6.56	0.35	(-22.0, 15.4)
	Week 8	151	63.28	8.77	64.00	(35.6, 84.5)	151	64.26 (8.19)	-0.98	7.61	-0.40	(-31.0, 25.5)
	Week 10	150	64.78	8.34	65.60	(40.0, 82.5)	150	64.21 (8.19)	0.57	7.21	0.95	(-23.5, 25.0)
	Week 12	148	63.67	9.45	63.95	(32.7, 96.0)	148	64.15 (8.24)	-0.48	7.58	0.30	(-25.5, 18.5)
	Week 16	148	63.63	8.94	65.00	(32.1, 82.0)	148	64.14 (8.16)	-0.51	7.52	-0.40	(-36.4, 20.1)
	Week 20	144	64.50	8.97	65.35	(41.3, 89.0)	144	63.96 (8.19)	0.54	7.85	0.80	(-26.5, 21.2)
	Week 24	140	64.75	9.11	65.45	(39.7, 91.5)	140	64.17 (8.19)	0.58	7.72	0.65	(-23.5, 22.2)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Eosinophils/Leukocytes (%)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	150	3.72	2.94	3.00	(0.0, 23.0)						
	Week 2	150	3.98	3.05	3.50	(0.0, 19.2)	150	3.72 (2.94)	0.25	1.85	0.10	(-3.9, 13.0)
	Week 4	148	3.94	3.16	3.05	(0.0, 23.5)	148	3.73 (2.96)	0.21	2.46	0.10	(-6.8, 17.5)
	Week 6	148	3.85	2.68	3.40	(0.1, 19.1)	147	3.74 (2.96)	0.13	2.01	0.10	(-6.4, 9.8)
	Week 8	144	3.92	2.93	3.05	(0.0, 18.5)	144	3.76 (2.99)	0.16	2.12	0.00	(-5.1, 7.5)
	Week 10	145	4.01	3.41	3.00	(0.0, 22.0)	144	3.76 (2.99)	0.28	2.72	-0.05	(-7.0, 16.0)
	Week 12	144	3.97	2.94	3.35	(0.0, 17.2)	144	3.78 (2.98)	0.19	2.19	0.10	(-5.8, 8.1)
	Week 16	141	3.62	2.68	2.90	(0.0, 15.2)	141	3.68 (2.89)	-0.05	2.04	0.00	(-7.8, 7.0)
	Week 20	139	3.63	2.98	3.00	(0.0, 23.0)	139	3.76 (3.02)	-0.13	2.36	-0.10	(-7.5, 17.0)
	Week 24	131	3.69	3.21	3.00	(0.0, 25.0)	131	3.73 (2.98)	-0.04	2.90	0.10	(-9.5, 18.7)
darbepoetin	Baseline	153	3.72	2.81	3.00	(0.0, 15.2)						
	Week 2	153	3.74	3.04	2.90	(0.0, 20.5)	153	3.72 (2.81)	0.02	2.21	0.00	(-8.1, 15.5)
	Week 4	153	3.63	3.11	3.00	(0.0, 26.0)	153	3.72 (2.81)	-0.09	2.20	0.00	(-7.7, 10.8)
	Week 6	152	3.46	2.41	2.85	(0.0, 13.7)	152	3.70 (2.80)	-0.24	2.06	0.00	(-9.1, 6.9)
	Week 8	151	3.59	2.85	3.00	(0.0, 20.0)	151	3.69 (2.81)	-0.10	2.06	0.00	(-10.5, 5.8)
	Week 10	150	3.48	2.68	2.95	(0.5, 16.4)	150	3.72 (2.82)	-0.24	2.19	-0.20	(-10.8, 8.7)
	Week 12	148	3.64	2.85	3.05	(0.0, 18.8)	148	3.72 (2.83)	-0.08	2.08	-0.10	(-10.5, 6.2)
	Week 16	148	3.70	3.06	3.00	(0.0, 23.0)	148	3.74 (2.83)	-0.04	2.30	0.00	(-9.8, 9.5)
	Week 20	144	3.65	3.11	3.00	(0.0, 18.8)	144	3.74 (2.83)	-0.09	2.45	0.00	(-10.8, 9.4)
	Week 24	140	3.55	2.89	3.00	(0.0, 19.6)	140	3.67 (2.74)	-0.12	2.39	-0.20	(-11.1, 7.5)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Monocytes/Leukocytes (%)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	150	6.31	2.13	6.25	(0.9, 12.5)						
	Week 2	150	6.95	1.99	7.00	(3.0, 12.8)	150	6.31 (2.13)	0.63	1.86	0.45	(-4.4, 6.8)
	Week 4	148	7.10	2.27	7.00	(2.0, 12.5)	148	6.30 (2.10)	0.80	1.97	0.70	(-6.0, 6.0)
	Week 6	148	6.86	2.10	6.85	(1.1, 12.1)	147	6.30 (2.10)	0.55	2.08	0.50	(-5.8, 5.6)
	Week 8	144	7.07	2.15	7.00	(3.0, 12.6)	144	6.30 (2.12)	0.76	1.96	0.60	(-5.9, 10.4)
	Week 10	145	6.87	2.05	6.60	(2.5, 11.9)	144	6.29 (2.12)	0.57	1.87	0.60	(-7.1, 5.5)
	Week 12	144	6.87	2.25	7.00	(1.5, 13.0)	144	6.29 (2.12)	0.58	2.12	0.80	(-5.4, 4.7)
	Week 16	141	7.27	2.22	7.00	(1.5, 15.0)	141	6.28 (2.13)	0.99	1.96	0.90	(-6.2, 6.5)
	Week 20	139	7.00	2.26	7.00	(2.0, 15.0)	139	6.36 (2.12)	0.64	2.13	0.70	(-4.9, 5.3)
	Week 24	131	6.97	2.18	6.90	(2.5, 14.5)	131	6.40 (2.10)	0.56	2.37	0.60	(-8.5, 5.7)
darbepoetin	Baseline	153	6.47	2.04	6.20	(2.5, 13.5)						
	Week 2	153	6.82	2.11	6.50	(2.0, 14.0)	153	6.47 (2.04)	0.34	2.09	0.30	(-7.5, 7.5)
	Week 4	153	6.70	1.98	6.50	(1.0, 12.9)	153	6.47 (2.04)	0.23	2.02	0.20	(-5.0, 7.4)
	Week 6	152	6.74	2.14	6.60	(2.1, 13.5)	152	6.48 (2.04)	0.26	1.98	0.30	(-6.0, 5.4)
	Week 8	151	6.82	2.01	6.70	(2.0, 12.3)	151	6.48 (2.05)	0.34	2.15	0.40	(-7.0, 6.5)
	Week 10	150	6.80	1.94	6.70	(3.0, 14.5)	150	6.49 (2.04)	0.30	2.14	0.55	(-8.5, 6.6)
	Week 12	148	6.78	2.12	6.55	(1.0, 15.0)	148	6.52 (2.03)	0.26	2.11	0.25	(-5.7, 6.6)
	Week 16	148	6.49	1.97	6.45	(2.0, 12.9)	148	6.50 (2.04)	-0.02	2.12	0.00	(-4.8, 7.5)
	Week 20	144	6.45	1.97	6.30	(2.1, 12.5)	144	6.52 (2.06)	-0.07	1.95	-0.05	(-5.1, 5.2)
	Week 24	140	6.59	2.14	6.35	(0.7, 12.8)	140	6.45 (1.97)	0.15	2.00	0.20	(-6.3, 6.0)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Lymphocytes/Leukocytes (%)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	150	25.54	8.20	24.90	(7.5, 51.2)						
	Week 2	150	25.06	8.28	24.65	(5.0, 54.5)	150	25.54 (8.20)	-0.48	5.47	-0.95	(-19.9, 13.7)
	Week 4	148	25.39	8.50	24.50	(5.7, 51.4)	148	25.49 (8.22)	-0.10	5.31	0.00	(-13.3, 16.2)
	Week 6	148	24.55	8.00	24.10	(7.5, 48.0)	147	25.49 (8.25)	-1.01	5.15	-0.60	(-20.0, 12.7)
	Week 8	144	24.51	8.28	24.05	(4.0, 49.4)	144	25.60 (8.29)	-1.09	5.91	-0.65	(-17.4, 14.1)
	Week 10	145	24.47	7.86	24.00	(7.0, 46.8)	144	25.56 (8.28)	-1.13	5.90	-1.00	(-15.6, 22.8)
	Week 12	144	24.62	8.56	23.65	(7.0, 53.1)	144	25.57 (8.29)	-0.95	5.35	-1.00	(-15.4, 19.9)
	Week 16	141	24.09	7.99	23.00	(6.5, 47.0)	141	25.63 (8.35)	-1.55	5.90	-1.70	(-25.4, 12.3)
	Week 20	139	23.45	8.69	22.60	(6.0, 56.5)	139	25.67 (8.37)	-2.22	6.71	-1.50	(-24.5, 11.7)
	Week 24	131	23.52	8.20	22.50	(2.0, 59.3)	131	25.76 (8.43)	-2.24	6.66	-1.50	(-20.4, 15.2)
darbepoetin	Baseline	153	25.14	6.91	25.00	(4.0, 44.7)						
	Week 2	153	25.53	7.54	25.10	(7.5, 43.1)	153	25.14 (6.91)	0.39	5.89	0.80	(-22.0, 28.0)
	Week 4	153	25.70	7.90	25.00	(5.5, 47.2)	153	25.14 (6.91)	0.55	5.72	0.80	(-25.1, 23.0)
	Week 6	152	25.15	7.41	24.70	(10.1, 44.9)	152	25.15 (6.93)	-0.01	5.03	-0.35	(-13.2, 16.5)
	Week 8	151	25.96	7.82	24.90	(8.4, 50.9)	151	25.21 (6.92)	0.75	5.88	0.80	(-16.0, 23.4)
	Week 10	150	24.58	7.37	23.50	(9.9, 44.5)	150	25.22 (6.94)	-0.64	5.72	-0.25	(-22.5, 15.4)
	Week 12	148	25.53	8.27	24.40	(3.0, 53.5)	148	25.25 (6.97)	0.28	5.95	0.00	(-14.0, 20.0)
	Week 16	148	25.83	8.12	25.00	(9.0, 56.7)	148	25.26 (6.90)	0.57	6.05	0.30	(-17.3, 23.2)
	Week 20	144	25.04	8.09	24.25	(8.0, 48.0)	144	25.42 (6.90)	-0.38	6.20	-0.65	(-17.8, 20.5)
	Week 24	140	24.73	7.77	23.40	(3.5, 45.4)	140	25.36 (6.90)	-0.63	5.86	-0.65	(-16.6, 14.1)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Basophils/Leukocytes (%)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	150	0.37	0.31	0.30	(0.0, 2.0)						
	Week 2	150	0.38	0.33	0.30	(0.0, 1.2)	150	0.37 (0.31)	0.01	0.44	0.00	(-2.0, 1.2)
	Week 4	148	0.36	0.30	0.30	(0.0, 1.4)	148	0.37 (0.32)	-0.01	0.42	0.00	(-1.3, 1.2)
	Week 6	148	0.40	0.37	0.40	(0.0, 2.2)	147	0.37 (0.32)	0.03	0.48	0.00	(-1.7, 2.0)
	Week 8	144	0.40	0.33	0.40	(0.0, 1.7)	144	0.37 (0.32)	0.03	0.45	0.00	(-2.0, 1.7)
	Week 10	145	0.36	0.34	0.30	(0.0, 2.0)	144	0.37 (0.32)	-0.01	0.43	0.00	(-1.9, 1.7)
	Week 12	144	0.39	0.31	0.40	(0.0, 1.6)	144	0.37 (0.31)	0.02	0.37	0.00	(-1.5, 0.9)
	Week 16	141	0.38	0.38	0.30	(0.0, 2.5)	141	0.37 (0.31)	0.01	0.49	0.00	(-2.0, 2.3)
	Week 20	139	0.30	0.27	0.30	(0.0, 1.1)	139	0.36 (0.28)	-0.06	0.34	0.00	(-1.4, 0.9)
	Week 24	131	0.34	0.35	0.30	(0.0, 1.8)	131	0.37 (0.29)	-0.02	0.43	0.00	(-1.3, 1.4)
darbepoetin	Baseline	153	0.36	0.32	0.30	(0.0, 2.0)						
	Week 2	153	0.36	0.34	0.30	(0.0, 2.0)	153	0.36 (0.32)	0.00	0.49	0.00	(-2.0, 2.0)
	Week 4	153	0.33	0.30	0.30	(0.0, 1.5)	153	0.36 (0.32)	-0.03	0.38	0.00	(-1.7, 1.3)
	Week 6	152	0.31	0.27	0.30	(0.0, 1.1)	152	0.36 (0.32)	-0.05	0.37	0.00	(-1.7, 1.0)
	Week 8	151	0.35	0.32	0.30	(0.0, 1.5)	151	0.36 (0.32)	-0.01	0.45	0.00	(-1.7, 1.4)
	Week 10	150	0.37	0.33	0.30	(0.0, 1.6)	150	0.36 (0.32)	0.01	0.43	0.00	(-1.5, 1.3)
	Week 12	148	0.39	0.31	0.40	(0.0, 1.5)	148	0.37 (0.32)	0.02	0.43	0.00	(-1.7, 1.2)
	Week 16	148	0.35	0.34	0.30	(0.0, 2.0)	148	0.36 (0.32)	-0.01	0.43	0.00	(-1.5, 2.0)
	Week 20	144	0.36	0.33	0.30	(0.0, 2.0)	144	0.36 (0.32)	0.00	0.47	0.00	(-1.8, 2.0)
	Week 24	140	0.38	0.34	0.30	(0.0, 2.0)	140	0.36 (0.29)	0.02	0.42	0.00	(-1.0, 1.7)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Platelets (10^4/uL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	19.74	6.32	18.60	(7.4, 41.5)						
	Week 2	151	20.39	6.46	19.50	(6.9, 39.4)	151	19.74 (6.32)	0.65	3.00	0.80	(-13.9, 9.5)
	Week 4	148	20.01	6.84	18.80	(8.1, 59.1)	148	19.77 (6.38)	0.23	3.62	0.00	(-10.7, 32.6)
	Week 6	147	20.16	6.28	19.10	(7.9, 38.7)	147	19.83 (6.37)	0.33	3.05	0.60	(-12.7, 12.2)
	Week 8	144	20.16	6.20	19.40	(6.9, 46.4)	144	19.84 (6.40)	0.32	2.95	0.15	(-8.6, 15.9)
	Week 10	145	19.97	6.18	19.10	(4.7, 40.4)	145	19.81 (6.40)	0.15	3.29	0.20	(-12.9, 11.7)
	Week 12	144	20.08	6.10	19.00	(9.0, 38.1)	144	19.72 (6.38)	0.36	3.20	0.50	(-13.4, 8.4)
	Week 16	143	19.93	5.80	19.20	(6.6, 39.5)	143	19.74 (6.39)	0.19	3.31	0.30	(-13.0, 8.7)
	Week 20	138	20.08	5.91	19.50	(8.2, 40.8)	138	19.83 (6.39)	0.25	3.56	0.30	(-16.5, 9.8)
	Week 24	131	20.37	6.30	19.30	(5.2, 42.1)	131	20.05 (6.38)	0.32	3.71	0.30	(-14.5, 13.5)
darbepoetin	Baseline	152	19.72	5.37	18.85	(6.6, 35.7)						
	Week 2	150	20.05	5.49	19.60	(9.1, 38.9)	150	19.65 (5.37)	0.40	2.73	0.55	(-10.1, 12.1)
	Week 4	149	20.83	6.60	20.00	(7.0, 55.1)	149	19.75 (5.36)	1.08	3.68	0.50	(-8.5, 29.5)
	Week 6	149	20.73	5.98	20.30	(7.6, 43.8)	149	19.74 (5.36)	0.99	3.41	0.90	(-7.7, 18.2)
	Week 8	147	20.71	5.66	20.50	(8.5, 46.1)	147	19.81 (5.37)	0.90	3.32	0.60	(-6.4, 10.4)
	Week 10	147	20.93	5.94	20.60	(7.6, 40.4)	147	19.71 (5.39)	1.23	3.40	1.00	(-7.0, 13.8)
	Week 12	146	20.12	5.72	19.80	(7.8, 37.3)	146	19.72 (5.44)	0.41	3.16	0.15	(-8.1, 10.6)
	Week 16	146	19.09	5.57	19.20	(2.5, 46.3)	146	19.63 (5.39)	-0.54	3.37	-0.60	(-10.6, 16.2)
	Week 20	141	19.36	5.16	19.80	(7.4, 38.9)	141	19.61 (5.41)	-0.25	3.15	-0.20	(-10.2, 9.5)
	Week 24	138	19.37	5.39	18.95	(4.1, 36.5)	138	19.70 (5.34)	-0.33	3.15	-0.30	(-9.0, 9.6)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Protein (g/dL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	6.79	0.56	6.80	(5.1, 8.4)						
	Week 2	151	6.81	0.55	6.80	(5.3, 8.8)	151	6.79 (0.56)	0.01	0.31	0.00	(-0.8, 0.8)
	Week 4	149	6.76	0.59	6.80	(5.4, 8.8)	149	6.79 (0.57)	-0.03	0.32	-0.10	(-1.1, 0.7)
	Week 6	148	6.75	0.60	6.80	(5.0, 8.7)	148	6.79 (0.57)	-0.03	0.33	0.00	(-1.2, 0.8)
	Week 8	145	6.77	0.60	6.80	(5.2, 8.4)	145	6.78 (0.57)	-0.01	0.33	0.00	(-1.1, 0.8)
	Week 10	145	6.77	0.60	6.80	(5.3, 9.1)	145	6.78 (0.57)	-0.01	0.36	0.00	(-1.2, 0.9)
	Week 12	145	6.82	0.59	6.80	(5.1, 8.5)	145	6.78 (0.57)	0.04	0.39	0.00	(-1.2, 0.9)
	Week 16	143	6.76	0.65	6.80	(4.8, 9.1)	143	6.79 (0.56)	-0.04	0.44	0.00	(-1.6, 0.9)
	Week 20	140	6.78	0.62	6.85	(4.9, 9.0)	140	6.78 (0.57)	-0.01	0.41	0.00	(-1.3, 1.0)
	Week 24	132	6.84	0.64	6.90	(5.0, 9.2)	132	6.81 (0.57)	0.03	0.44	0.00	(-1.1, 1.7)
darbepoetin	Baseline	153	6.74	0.60	6.80	(4.1, 8.2)						
	Week 2	153	6.71	0.58	6.80	(4.1, 7.8)	153	6.74 (0.60)	-0.02	0.31	0.00	(-0.9, 0.9)
	Week 4	153	6.71	0.63	6.80	(4.2, 8.3)	153	6.74 (0.60)	-0.02	0.35	0.00	(-1.4, 1.1)
	Week 6	152	6.68	0.62	6.70	(4.2, 8.2)	152	6.73 (0.60)	-0.05	0.35	-0.10	(-1.2, 0.8)
	Week 8	151	6.71	0.60	6.80	(4.4, 8.1)	151	6.73 (0.60)	-0.03	0.33	0.00	(-1.1, 0.9)
	Week 10	150	6.70	0.56	6.70	(4.3, 7.9)	150	6.73 (0.60)	-0.03	0.37	0.00	(-1.0, 1.0)
	Week 12	148	6.75	0.61	6.75	(4.2, 8.0)	148	6.72 (0.60)	0.03	0.34	0.00	(-1.1, 0.8)
	Week 16	148	6.73	0.63	6.80	(4.3, 8.6)	148	6.74 (0.60)	-0.01	0.43	0.00	(-1.0, 1.3)
	Week 20	144	6.74	0.63	6.80	(3.9, 7.9)	144	6.74 (0.61)	0.00	0.39	0.00	(-1.0, 1.2)
	Week 24	140	6.80	0.66	6.85	(3.9, 8.4)	140	6.75 (0.61)	0.05	0.48	0.05	(-1.5, 1.6)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Albumin (g/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	3.77	0.42	3.80	(2.4, 4.7)						
	Week 2	151	3.73	0.38	3.80	(2.4, 4.5)	151	3.77 (0.42)	-0.04	0.20	0.00	(-0.8, 0.4)
	Week 4	149	3.70	0.41	3.70	(1.7, 4.5)	149	3.77 (0.42)	-0.07	0.27	-0.10	(-2.1, 0.5)
	Week 6	148	3.68	0.40	3.70	(2.0, 4.5)	148	3.76 (0.42)	-0.08	0.24	-0.10	(-1.1, 0.8)
	Week 8	145	3.70	0.38	3.70	(2.4, 4.6)	145	3.76 (0.43)	-0.06	0.23	0.00	(-1.0, 0.8)
	Week 10	145	3.67	0.37	3.70	(2.4, 4.4)	145	3.76 (0.43)	-0.09	0.25	-0.10	(-1.0, 0.8)
	Week 12	145	3.68	0.38	3.70	(2.1, 4.4)	145	3.76 (0.43)	-0.08	0.27	-0.10	(-1.0, 0.9)
	Week 16	143	3.66	0.43	3.70	(2.0, 4.6)	143	3.76 (0.43)	-0.10	0.31	-0.10	(-1.2, 0.9)
	Week 20	140	3.67	0.45	3.80	(1.7, 4.5)	140	3.75 (0.43)	-0.09	0.32	-0.10	(-1.2, 0.9)
	Week 24	132	3.75	0.39	3.80	(2.5, 4.7)	132	3.78 (0.42)	-0.03	0.33	0.00	(-1.1, 1.2)
darbepoetin	Baseline	153	3.79	0.44	3.80	(1.8, 4.6)						
	Week 2	153	3.76	0.44	3.80	(1.7, 5.0)	153	3.79 (0.44)	-0.03	0.21	0.00	(-1.0, 0.5)
	Week 4	153	3.73	0.46	3.80	(1.7, 5.3)	153	3.79 (0.44)	-0.05	0.27	0.00	(-1.7, 0.7)
	Week 6	152	3.75	0.45	3.80	(1.9, 4.8)	152	3.78 (0.44)	-0.03	0.24	0.00	(-1.2, 0.6)
	Week 8	151	3.75	0.44	3.80	(1.8, 4.5)	151	3.78 (0.44)	-0.04	0.23	0.00	(-0.9, 0.7)
	Week 10	150	3.72	0.43	3.80	(1.9, 4.7)	150	3.78 (0.44)	-0.06	0.27	0.00	(-1.0, 0.7)
	Week 12	148	3.74	0.46	3.80	(1.7, 4.6)	148	3.77 (0.44)	-0.03	0.25	0.00	(-1.1, 0.8)
	Week 16	148	3.70	0.46	3.80	(1.9, 4.8)	148	3.78 (0.44)	-0.08	0.30	-0.10	(-1.3, 0.7)
	Week 20	144	3.72	0.50	3.80	(1.6, 4.9)	144	3.78 (0.44)	-0.06	0.29	0.00	(-0.9, 0.7)
	Week 24	140	3.79	0.49	3.90	(1.7, 4.8)	140	3.79 (0.45)	0.00	0.32	0.00	(-0.8, 0.9)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Glucose (mg/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	120.2	38.9	108.0	(72, 308)						
	Week 2	151	116.8	40.6	105.0	(64, 377)	151	120.2 (38.9)	-3.4	40.3	-2.0	(-197, 201)
	Week 4	149	119.1	38.6	106.0	(53, 278)	149	120.3 (39.1)	-1.2	33.3	-1.0	(-136, 104)
	Week 6	148	119.3	37.4	107.5	(54, 262)	148	120.5 (39.2)	-1.2	31.1	-2.0	(-139, 118)
	Week 8	145	119.3	40.0	107.0	(64, 312)	145	120.2 (39.1)	-0.9	34.9	1.0	(-135, 121)
	Week 10	145	119.6	37.1	107.0	(66, 228)	145	120.3 (39.2)	-0.7	32.4	-3.0	(-148, 116)
	Week 12	145	122.4	45.0	109.0	(73, 426)	145	120.8 (39.4)	1.6	36.6	-1.0	(-122, 250)
	Week 16	143	120.1	40.1	106.0	(71, 313)	143	121.0 (39.5)	-0.9	39.6	-1.0	(-213, 104)
	Week 20	140	121.2	41.9	105.0	(57, 284)	140	121.0 (40.0)	0.2	40.0	-1.5	(-115, 198)
	Week 24	132	110.9	31.2	102.0	(38, 275)	132	119.0 (38.0)	-8.0	36.8	-5.5	(-210, 198)
darbepoetin	Baseline	153	122.0	33.2	114.0	(68, 230)						
	Week 2	153	121.3	34.5	111.0	(73, 291)	153	122.0 (33.2)	-0.8	26.7	-1.0	(-72, 87)
	Week 4	153	125.6	44.2	112.0	(66, 294)	153	122.0 (33.2)	3.5	36.4	2.0	(-106, 122)
	Week 6	152	124.9	42.3	114.0	(57, 371)	152	121.9 (33.3)	3.0	36.3	-2.0	(-105, 159)
	Week 8	151	129.0	41.0	116.0	(64, 329)	151	122.0 (33.4)	6.9	30.6	5.0	(-95, 117)
	Week 10	150	126.3	42.7	115.0	(70, 313)	150	122.0 (33.5)	4.3	33.6	0.0	(-111, 163)
	Week 12	148	125.4	44.5	113.0	(67, 390)	148	121.4 (32.8)	4.0	35.7	-1.0	(-109, 178)
	Week 16	148	126.3	46.0	109.5	(70, 422)	148	121.0 (32.3)	5.3	36.6	-2.0	(-104, 192)
	Week 20	144	123.7	45.0	111.5	(63, 395)	144	121.5 (32.5)	2.1	34.6	-0.5	(-104, 165)
	Week 24	140	115.9	38.3	105.0	(73, 283)	140	121.5 (32.9)	-5.6	33.1	-5.0	(-114, 138)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Urea Nitrogen (mg/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	44.08	19.99	39.80	(14.5, 162.4)						
	Week 2	151	43.66	17.78	40.90	(16.9, 122.7)	151	44.08 (19.99)	-0.42	7.96	0.20	(-39.7, 21.9)
	Week 4	149	42.19	17.85	40.00	(7.9, 114.4)	149	44.18 (20.08)	-1.99	8.89	-1.50	(-48.0, 16.8)
	Week 6	148	41.51	16.65	39.05	(12.7, 107.4)	148	43.95 (19.95)	-2.44	8.86	-1.90	(-55.0, 15.9)
	Week 8	145	41.32	16.13	40.00	(15.3, 109.9)	145	43.63 (19.34)	-2.31	9.11	-1.80	(-52.5, 18.6)
	Week 10	145	42.08	16.76	39.30	(15.3, 127.3)	145	43.83 (19.36)	-1.74	8.56	-0.80	(-35.1, 12.5)
	Week 12	145	41.71	16.71	38.20	(13.1, 126.6)	145	43.83 (19.36)	-2.12	8.66	-2.00	(-35.8, 20.5)
	Week 16	143	43.14	17.82	40.60	(15.9, 132.2)	143	43.65 (19.44)	-0.51	9.75	0.40	(-30.2, 40.4)
	Week 20	140	43.36	17.61	40.95	(11.2, 121.9)	140	43.09 (18.93)	0.27	9.91	0.35	(-40.5, 39.9)
	Week 24	132	42.43	18.55	39.85	(12.0, 112.2)	132	42.29 (16.29)	0.14	9.60	0.00	(-20.6, 56.0)
darbepoetin	Baseline	153	40.95	17.40	38.40	(10.0, 98.0)						
	Week 2	153	40.12	16.34	38.60	(9.9, 88.7)	153	40.95 (17.40)	-0.84	7.67	-0.10	(-22.1, 30.5)
	Week 4	153	39.93	16.54	37.90	(9.8, 90.6)	153	40.95 (17.40)	-1.02	7.90	-0.40	(-29.0, 22.4)
	Week 6	152	39.46	16.39	36.45	(10.9, 89.9)	152	40.78 (17.33)	-1.32	7.71	-0.75	(-25.7, 16.3)
	Week 8	151	39.69	17.30	37.00	(8.1, 101.4)	151	40.73 (17.37)	-1.04	9.04	-1.00	(-30.5, 59.9)
	Week 10	150	39.63	17.31	37.85	(13.2, 96.4)	150	40.83 (17.42)	-1.20	7.48	-0.30	(-24.5, 17.0)
	Week 12	148	40.55	17.26	39.70	(11.6, 99.9)	148	40.60 (17.03)	-0.05	7.40	0.20	(-18.0, 22.7)
	Week 16	148	40.83	18.02	37.45	(11.3, 96.2)	148	40.65 (17.28)	0.18	9.34	0.70	(-37.1, 34.7)
	Week 20	144	42.43	20.65	36.75	(12.7, 112.4)	144	40.63 (17.48)	1.80	9.61	1.40	(-18.9, 45.2)
	Week 24	140	42.07	19.79	37.20	(13.7, 121.0)	140	39.69 (16.72)	2.38	10.02	1.80	(-26.2, 59.4)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Creatinine (mg/dL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	2.830	1.492	2.630	(0.82, 9.09)						
	Week 2	151	2.975	1.542	2.570	(0.89, 8.84)	151	2.830 (1.492)	0.144	0.346	0.120	(-1.48, 2.06)
	Week 4	149	2.941	1.528	2.570	(0.76, 8.47)	149	2.839 (1.494)	0.102	0.335	0.100	(-1.11, 1.13)
	Week 6	148	2.967	1.511	2.650	(0.88, 7.85)	148	2.833 (1.498)	0.134	0.363	0.135	(-1.24, 1.04)
	Week 8	145	2.982	1.523	2.810	(0.91, 7.94)	145	2.820 (1.497)	0.162	0.416	0.140	(-1.75, 1.31)
	Week 10	145	3.008	1.544	2.830	(0.93, 8.30)	145	2.837 (1.505)	0.171	0.432	0.170	(-2.33, 1.64)
	Week 12	145	3.000	1.535	2.870	(0.90, 8.30)	145	2.841 (1.504)	0.159	0.447	0.150	(-2.11, 1.97)
	Week 16	143	3.092	1.701	2.770	(0.91, 9.07)	143	2.830 (1.510)	0.262	0.498	0.170	(-1.31, 2.32)
	Week 20	140	3.114	1.802	2.830	(0.84, 9.49)	140	2.798 (1.504)	0.315	0.731	0.160	(-1.56, 4.52)
	Week 24	132	3.015	1.720	2.515	(0.89, 8.60)	132	2.723 (1.407)	0.292	0.643	0.150	(-1.25, 3.73)
darbepoetin	Baseline	153	2.616	1.441	2.400	(0.70, 7.60)						
	Week 2	153	2.633	1.484	2.300	(0.75, 8.77)	153	2.616 (1.441)	0.017	0.404	0.020	(-1.32, 3.40)
	Week 4	153	2.628	1.437	2.270	(0.71, 7.46)	153	2.616 (1.441)	0.011	0.349	0.010	(-2.32, 0.99)
	Week 6	152	2.625	1.452	2.260	(0.66, 7.93)	152	2.598 (1.428)	0.027	0.340	0.040	(-2.26, 0.96)
	Week 8	151	2.642	1.500	2.190	(0.55, 8.13)	151	2.596 (1.432)	0.046	0.379	0.040	(-2.42, 1.14)
	Week 10	150	2.684	1.567	2.315	(0.59, 8.10)	150	2.590 (1.433)	0.094	0.399	0.050	(-1.83, 2.17)
	Week 12	148	2.729	1.626	2.305	(0.60, 8.94)	148	2.577 (1.413)	0.152	0.445	0.100	(-1.61, 1.79)
	Week 16	148	2.795	1.772	2.315	(0.75, 9.23)	148	2.582 (1.413)	0.213	0.611	0.080	(-0.85, 2.67)
	Week 20	144	2.866	1.938	2.325	(0.73, 11.03)	144	2.583 (1.430)	0.283	0.692	0.090	(-0.72, 3.53)
	Week 24	140	2.802	1.825	2.225	(0.75, 11.04)	140	2.497 (1.323)	0.306	0.725	0.100	(-1.07, 4.84)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Estimated GFR (mL/min/1.73m²)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	21.28	11.66	18.10	(4.9, 53.1)						
	Week 2	151	19.97	10.81	16.90	(5.1, 48.5)	151	21.28 (11.66)	-1.31	2.81	-1.00	(-13.4, 10.1)
	Week 4	149	20.60	11.76	17.20	(5.3, 57.7)	149	21.22 (11.60)	-0.62	3.68	-0.70	(-9.0, 26.7)
	Week 6	148	20.09	11.05	16.60	(5.6, 50.7)	148	21.28 (11.63)	-1.18	3.23	-1.00	(-10.2, 16.4)
	Week 8	145	19.94	10.83	16.60	(5.3, 47.4)	145	21.34 (11.59)	-1.40	2.75	-1.10	(-8.4, 7.2)
	Week 10	145	19.70	10.60	17.00	(4.9, 44.8)	145	21.25 (11.63)	-1.55	3.19	-1.20	(-10.5, 9.8)
	Week 12	145	19.76	10.70	16.50	(4.7, 47.9)	145	21.25 (11.63)	-1.49	2.92	-1.30	(-10.9, 8.2)
	Week 16	143	19.69	10.97	16.50	(4.4, 46.5)	143	21.35 (11.68)	-1.66	3.49	-1.40	(-11.3, 13.2)
	Week 20	140	20.00	11.46	16.40	(3.8, 51.7)	140	21.58 (11.67)	-1.58	3.45	-1.45	(-10.2, 13.7)
	Week 24	132	20.41	11.33	17.40	(5.7, 48.5)	132	21.96 (11.69)	-1.56	3.19	-1.45	(-10.9, 13.3)
darbepoetin	Baseline	153	22.60	11.60	20.10	(6.0, 61.3)						
	Week 2	153	22.54	11.60	20.10	(5.2, 59.0)	153	22.60 (11.60)	-0.06	2.35	-0.20	(-9.5, 9.2)
	Week 4	153	22.60	11.77	20.50	(6.0, 60.4)	153	22.60 (11.60)	0.00	3.09	-0.20	(-13.9, 10.6)
	Week 6	152	22.48	11.64	19.95	(5.9, 62.5)	152	22.69 (11.58)	-0.21	3.25	-0.30	(-10.1, 16.3)
	Week 8	151	22.79	12.48	19.80	(5.3, 76.3)	151	22.73 (11.61)	0.07	3.92	-0.50	(-10.2, 30.1)
	Week 10	150	22.75	12.70	20.35	(5.2, 70.6)	150	22.79 (11.63)	-0.03	3.95	-0.40	(-9.0, 24.4)
	Week 12	148	22.33	12.38	19.10	(5.0, 69.4)	148	22.75 (11.44)	-0.42	4.33	-0.95	(-12.9, 23.2)
	Week 16	148	22.41	12.55	20.30	(5.0, 58.4)	148	22.68 (11.50)	-0.27	3.86	-0.65	(-10.0, 12.8)
	Week 20	144	22.20	12.52	19.95	(4.2, 58.8)	144	22.72 (11.62)	-0.53	3.41	-0.95	(-9.8, 13.7)
	Week 24	140	22.17	12.13	19.75	(4.3, 56.9)	140	23.16 (11.52)	-0.99	3.48	-1.50	(-10.0, 12.3)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Urate (mg/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	6.08	1.39	5.90	(3.1, 12.4)						
	Week 2	151	6.02	1.67	5.90	(2.3, 12.3)	151	6.08 (1.39)	-0.06	1.17	0.00	(-6.7, 3.4)
	Week 4	149	5.89	1.69	5.80	(2.0, 12.9)	149	6.10 (1.39)	-0.21	1.27	-0.10	(-7.0, 3.7)
	Week 6	148	5.88	1.73	5.65	(2.0, 11.8)	148	6.08 (1.37)	-0.20	1.42	0.00	(-7.1, 2.9)
	Week 8	145	5.92	1.81	5.70	(1.6, 12.4)	145	6.04 (1.27)	-0.12	1.40	-0.10	(-7.4, 6.6)
	Week 10	145	5.86	1.81	5.60	(1.7, 11.5)	145	6.04 (1.27)	-0.18	1.37	-0.10	(-7.3, 3.4)
	Week 12	145	5.85	1.76	5.80	(1.4, 11.7)	145	6.05 (1.28)	-0.20	1.40	-0.10	(-7.6, 4.6)
	Week 16	143	5.79	1.67	5.80	(1.7, 10.8)	143	6.06 (1.28)	-0.26	1.26	-0.10	(-7.3, 2.0)
	Week 20	140	5.88	1.68	5.80	(1.8, 12.2)	140	6.06 (1.28)	-0.18	1.37	-0.10	(-7.2, 4.0)
	Week 24	132	5.82	1.72	5.65	(2.1, 11.2)	132	6.05 (1.25)	-0.23	1.33	-0.10	(-6.9, 3.5)
darbepoetin	Baseline	153	6.18	1.38	6.20	(3.2, 11.1)						
	Week 2	153	6.24	1.37	6.10	(2.6, 10.7)	153	6.18 (1.38)	0.05	0.66	0.10	(-2.1, 2.8)
	Week 4	153	6.21	1.41	6.10	(2.8, 10.7)	153	6.18 (1.38)	0.03	0.89	0.00	(-3.5, 5.8)
	Week 6	152	6.30	1.49	6.15	(2.8, 10.6)	152	6.18 (1.39)	0.12	0.97	0.20	(-3.3, 5.9)
	Week 8	151	6.16	1.34	6.10	(2.6, 9.9)	151	6.18 (1.39)	-0.02	1.02	0.00	(-4.0, 6.1)
	Week 10	150	6.20	1.29	6.10	(2.3, 10.6)	150	6.16 (1.38)	0.04	0.95	0.15	(-3.7, 2.5)
	Week 12	148	6.13	1.36	6.05	(2.3, 10.6)	148	6.16 (1.39)	-0.03	0.91	0.00	(-3.9, 2.6)
	Week 16	148	6.03	1.36	5.90	(3.0, 12.3)	148	6.17 (1.40)	-0.14	1.06	0.00	(-4.2, 4.3)
	Week 20	144	5.96	1.29	6.00	(2.1, 9.8)	144	6.15 (1.39)	-0.20	1.02	0.00	(-4.1, 2.4)
	Week 24	140	6.01	1.43	5.80	(2.0, 10.8)	140	6.15 (1.40)	-0.14	1.21	0.00	(-4.6, 4.3)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Creatine Kinase (U/L)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	125.0	79.0	101.0	(24, 516)						
	Week 2	151	129.0	84.3	109.0	(18, 790)	151	125.0 (79.0)	4.1	66.8	3.0	(-194, 499)
	Week 4	149	134.5	88.3	108.0	(17, 563)	149	124.3 (79.0)	10.2	72.8	6.0	(-255, 412)
	Week 6	148	132.6	80.9	119.0	(24, 587)	148	124.6 (79.3)	8.1	68.6	9.0	(-269, 464)
	Week 8	145	145.6	122.3	109.0	(24, 922)	145	125.8 (79.5)	19.8	115.0	8.0	(-343, 847)
	Week 10	145	131.8	82.5	110.0	(21, 547)	145	124.2 (78.6)	7.6	79.6	7.0	(-318, 420)
	Week 12	145	144.3	152.5	112.0	(29, 1528)	145	125.4 (79.7)	19.9	142.5	10.0	(-272, 1271)
	Week 16	143	138.5	97.2	117.0	(24, 848)	143	124.8 (79.7)	13.7	93.7	7.0	(-258, 622)
	Week 20	140	143.2	106.5	121.0	(24, 929)	140	125.9 (80.9)	17.4	106.8	7.0	(-318, 770)
	Week 24	132	147.1	132.0	106.5	(23, 1184)	132	124.0 (80.6)	23.2	125.7	6.5	(-262, 1009)
darbepoetin	Baseline	153	128.6	100.1	98.0	(29, 742)						
	Week 2	153	131.4	99.8	97.0	(31, 658)	153	128.6 (100.1)	2.8	65.4	0.0	(-475, 311)
	Week 4	153	132.7	119.9	98.0	(30, 942)	153	128.6 (100.1)	4.1	71.9	-3.0	(-427, 449)
	Week 6	152	132.0	126.0	93.0	(25, 1026)	152	128.9 (100.4)	3.1	77.8	-3.0	(-303, 533)
	Week 8	151	139.0	154.6	94.0	(27, 1240)	151	129.5 (100.5)	9.5	109.9	-4.0	(-509, 747)
	Week 10	150	134.4	157.6	86.0	(27, 1395)	150	129.2 (101.0)	5.2	110.4	-4.5	(-327, 948)
	Week 12	148	135.4	149.5	89.0	(26, 1308)	148	128.1 (99.7)	7.3	106.4	-2.5	(-438, 861)
	Week 16	146	141.9	183.6	87.0	(21, 1652)	146	129.0 (101.4)	12.9	141.4	-3.0	(-522, 1230)
	Week 20	144	127.7	120.2	91.5	(26, 900)	144	128.2 (102.3)	-0.5	75.0	-6.0	(-246, 416)
	Week 24	140	149.5	170.0	104.5	(25, 1378)	140	129.0 (101.9)	20.5	117.6	0.0	(-214, 897)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Bilirubin (mg/dL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	0.55	0.19	0.50	(0.2, 1.2)						
	Week 2	151	0.53	0.19	0.50	(0.2, 1.5)	151	0.55 (0.19)	-0.02	0.13	0.00	(-0.5, 0.6)
	Week 4	149	0.53	0.16	0.50	(0.2, 1.1)	149	0.55 (0.19)	-0.02	0.14	0.00	(-0.4, 0.3)
	Week 6	148	0.53	0.19	0.50	(0.2, 1.2)	148	0.55 (0.19)	-0.02	0.14	0.00	(-0.4, 0.3)
	Week 8	145	0.53	0.17	0.50	(0.3, 1.1)	145	0.54 (0.19)	-0.01	0.14	0.00	(-0.5, 0.3)
	Week 10	145	0.54	0.20	0.50	(0.3, 1.5)	145	0.55 (0.19)	-0.01	0.17	0.00	(-0.7, 0.6)
	Week 12	145	0.54	0.18	0.50	(0.2, 1.0)	145	0.55 (0.19)	0.00	0.14	0.00	(-0.5, 0.4)
	Week 16	143	0.54	0.19	0.50	(0.3, 1.2)	143	0.55 (0.19)	0.00	0.16	0.00	(-0.7, 0.5)
	Week 20	140	0.57	0.20	0.50	(0.2, 1.6)	140	0.55 (0.19)	0.02	0.18	0.00	(-0.6, 0.7)
	Week 24	132	0.57	0.19	0.50	(0.2, 1.3)	132	0.55 (0.19)	0.02	0.16	0.00	(-0.5, 0.4)
darbepoetin	Baseline	153	0.53	0.18	0.50	(0.2, 1.4)						
	Week 2	153	0.57	0.20	0.50	(0.2, 1.5)	153	0.53 (0.18)	0.04	0.13	0.00	(-0.4, 0.5)
	Week 4	153	0.58	0.24	0.50	(0.2, 1.8)	153	0.53 (0.18)	0.05	0.13	0.00	(-0.2, 0.5)
	Week 6	152	0.60	0.25	0.50	(0.3, 1.7)	152	0.53 (0.18)	0.07	0.15	0.00	(-0.3, 1.1)
	Week 8	151	0.58	0.23	0.50	(0.3, 1.7)	151	0.53 (0.18)	0.05	0.14	0.00	(-0.3, 0.8)
	Week 10	150	0.59	0.23	0.50	(0.3, 1.5)	150	0.53 (0.18)	0.05	0.14	0.00	(-0.2, 0.5)
	Week 12	148	0.59	0.23	0.50	(0.3, 1.5)	148	0.53 (0.18)	0.06	0.15	0.10	(-0.2, 0.7)
	Week 16	148	0.58	0.23	0.50	(0.2, 1.7)	148	0.54 (0.18)	0.04	0.15	0.00	(-0.4, 0.6)
	Week 20	144	0.61	0.24	0.60	(0.2, 1.8)	144	0.54 (0.19)	0.07	0.15	0.10	(-0.2, 0.7)
	Week 24	140	0.66	0.38	0.60	(0.3, 4.0)	140	0.54 (0.19)	0.12	0.35	0.10	(-0.3, 3.6)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Aspartate Aminotransferase (U/L)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	19.6	9.6	17.0	(5, 86)						
	Week 2	151	18.0	8.8	16.0	(5, 84)	151	19.6 (9.6)	-1.5	8.7	-1.0	(-65, 65)
	Week 4	149	17.5	6.7	17.0	(4, 48)	149	19.4 (9.6)	-1.9	6.6	-1.0	(-65, 10)
	Week 6	148	17.8	7.9	17.0	(4, 64)	148	19.5 (9.6)	-1.7	6.8	-1.0	(-64, 16)
	Week 8	145	17.3	7.6	16.0	(4, 79)	145	19.4 (9.5)	-2.1	7.5	-1.0	(-66, 27)
	Week 10	145	17.0	6.2	16.0	(4, 43)	145	19.1 (9.1)	-2.1	7.3	-1.0	(-68, 14)
	Week 12	145	18.6	9.8	17.0	(4, 82)	145	19.4 (9.5)	-0.8	9.3	-1.0	(-69, 35)
	Week 16	143	18.5	7.6	17.0	(4, 59)	143	19.3 (9.5)	-0.8	8.4	-1.0	(-66, 27)
	Week 20	140	18.7	7.9	18.0	(3, 71)	140	19.4 (9.6)	-0.7	8.6	0.0	(-68, 19)
	Week 24	132	19.0	7.2	18.0	(6, 50)	132	19.4 (9.8)	-0.5	8.6	-0.5	(-63, 26)
darbepoetin	Baseline	153	20.0	8.7	18.0	(8, 88)						
	Week 2	153	19.8	8.2	18.0	(7, 68)	153	20.0 (8.7)	-0.3	4.5	0.0	(-20, 24)
	Week 4	153	20.8	10.7	18.0	(8, 85)	153	20.0 (8.7)	0.7	7.8	0.0	(-18, 71)
	Week 6	152	20.0	9.6	18.0	(7, 83)	152	20.1 (8.7)	-0.1	5.3	0.0	(-13, 24)
	Week 8	151	20.4	9.1	19.0	(7, 75)	151	20.2 (8.7)	0.3	5.2	0.0	(-19, 23)
	Week 10	150	21.5	14.2	18.0	(7, 134)	150	20.2 (8.8)	1.3	11.5	0.0	(-17, 116)
	Week 12	148	21.4	12.5	19.0	(8, 107)	148	20.2 (8.8)	1.3	7.6	0.0	(-13, 68)
	Week 16	148	20.9	8.9	19.0	(8, 68)	148	20.1 (8.8)	0.8	6.4	1.0	(-39, 29)
	Week 20	144	21.0	9.0	20.0	(8, 79)	144	20.1 (8.9)	1.0	6.5	1.0	(-41, 40)
	Week 24	140	24.6	29.2	20.0	(6, 344)	140	20.4 (8.9)	4.3	27.5	2.0	(-14, 320)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Alanine Aminotransferase (U/L)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	13.2	7.2	12.0	(4, 59)						
	Week 2	151	10.8	7.4	9.0	(4, 77)	151	13.2 (7.2)	-2.4	5.4	-2.0	(-26, 25)
	Week 4	149	10.5	5.2	9.0	(2, 33)	149	13.2 (7.2)	-2.7	5.3	-2.0	(-26, 18)
	Week 6	148	10.1	5.0	9.0	(3, 34)	148	13.2 (7.2)	-3.1	5.3	-2.0	(-38, 15)
	Week 8	145	10.0	5.0	9.0	(3, 37)	145	13.2 (7.3)	-3.3	5.9	-2.0	(-48, 10)
	Week 10	145	10.0	5.4	9.0	(3, 34)	145	13.1 (7.2)	-3.1	6.1	-2.0	(-45, 15)
	Week 12	145	10.8	6.7	9.0	(4, 57)	145	13.2 (7.3)	-2.5	7.3	-2.0	(-46, 30)
	Week 16	143	11.0	6.7	10.0	(3, 51)	143	13.1 (7.3)	-2.1	7.7	-2.0	(-47, 37)
	Week 20	140	11.0	6.1	10.0	(2, 38)	140	13.1 (7.3)	-2.2	7.3	-2.0	(-46, 27)
	Week 24	132	11.0	5.5	9.5	(3, 34)	132	13.1 (7.4)	-2.0	7.3	-1.0	(-45, 28)
darbepoetin	Baseline	153	14.0	7.6	12.0	(4, 49)						
	Week 2	153	14.0	8.6	12.0	(4, 70)	153	14.0 (7.6)	0.0	5.3	0.0	(-12, 41)
	Week 4	153	14.7	11.1	12.0	(4, 100)	153	14.0 (7.6)	0.6	8.9	0.0	(-19, 84)
	Week 6	152	13.5	7.8	11.0	(4, 51)	152	14.0 (7.6)	-0.6	4.8	0.0	(-19, 22)
	Week 8	151	14.2	7.6	12.0	(4, 49)	151	14.1 (7.6)	0.1	5.6	0.0	(-26, 24)
	Week 10	150	16.4	24.8	12.0	(4, 290)	150	14.1 (7.7)	2.3	23.5	0.0	(-23, 272)
	Week 12	148	15.0	10.3	12.0	(4, 74)	148	14.1 (7.7)	1.0	7.4	0.0	(-22, 56)
	Week 16	148	15.1	9.2	13.0	(4, 66)	148	14.0 (7.7)	1.0	6.9	0.0	(-25, 41)
	Week 20	144	15.0	8.2	12.0	(4, 55)	144	14.1 (7.8)	0.9	6.4	1.0	(-31, 19)
	Week 24	140	16.4	15.2	13.0	(4, 162)	140	14.2 (7.9)	2.3	13.5	1.0	(-19, 146)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Alkaline Phosphatase (U/L)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	255.7	99.2	235.0	(98, 802)						
	Week 2	151	255.3	98.0	236.0	(112, 718)	151	255.7 (99.2)	-0.4	34.4	0.0	(-120, 209)
	Week 4	149	254.2	99.2	232.0	(99, 602)	149	255.4 (99.4)	-1.3	43.6	-4.0	(-218, 288)
	Week 6	148	254.2	101.2	230.5	(101, 749)	148	255.6 (99.7)	-1.4	36.1	-1.5	(-72, 170)
	Week 8	145	254.7	105.0	226.0	(87, 787)	145	255.4 (100.1)	-0.8	36.9	-6.0	(-87, 196)
	Week 10	145	254.5	99.7	237.0	(99, 743)	145	255.8 (99.8)	-1.3	40.4	-4.0	(-159, 123)
	Week 12	145	255.5	102.5	237.0	(92, 761)	145	255.4 (100.1)	0.1	45.7	-3.0	(-159, 193)
	Week 16	143	257.3	105.7	230.0	(81, 849)	143	255.4 (100.7)	1.9	49.4	1.0	(-158, 143)
	Week 20	140	269.4	119.4	235.5	(99, 870)	140	255.3 (101.6)	14.1	60.0	11.0	(-162, 232)
	Week 24	132	267.1	109.1	245.0	(98, 761)	132	255.3 (102.4)	11.8	60.0	9.0	(-165, 309)
darbepoetin	Baseline	153	236.1	81.4	221.0	(75, 523)						
	Week 2	153	233.5	78.2	220.0	(71, 524)	153	236.1 (81.4)	-2.6	28.0	-2.0	(-145, 64)
	Week 4	153	235.2	79.3	224.0	(77, 548)	153	236.1 (81.4)	-0.9	31.1	1.0	(-128, 96)
	Week 6	152	235.3	83.3	220.5	(76, 550)	152	235.6 (81.5)	-0.3	29.7	1.5	(-108, 87)
	Week 8	151	240.1	86.2	224.0	(83, 551)	151	235.8 (81.7)	4.3	31.5	3.0	(-71, 92)
	Week 10	150	241.3	89.8	221.0	(77, 546)	150	235.5 (81.9)	5.8	39.4	4.0	(-108, 147)
	Week 12	148	242.3	86.1	224.0	(77, 549)	148	236.5 (82.1)	5.8	38.1	4.5	(-138, 148)
	Week 16	148	245.9	87.2	228.0	(79, 677)	148	237.1 (81.5)	8.9	50.6	6.5	(-169, 256)
	Week 20	144	245.3	78.5	228.5	(86, 501)	144	236.9 (81.5)	8.4	42.7	10.5	(-129, 128)
	Week 24	140	251.8	86.3	238.5	(86, 567)	140	235.6 (82.0)	16.2	55.5	10.5	(-139, 298)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Lactate Dehydrogenase (U/L)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	200.6	33.4	199.0	(124, 303)						
	Week 2	151	205.3	36.2	202.0	(133, 334)	151	200.6 (33.4)	4.7	18.2	3.0	(-35, 76)
	Week 4	149	204.7	37.7	201.0	(130, 354)	149	200.3 (33.5)	4.4	18.4	4.0	(-43, 77)
	Week 6	148	207.5	38.6	204.0	(137, 373)	148	200.4 (33.6)	7.2	21.8	6.0	(-42, 96)
	Week 8	145	209.8	39.2	206.0	(131, 396)	145	200.7 (33.7)	9.1	25.0	4.0	(-49, 119)
	Week 10	145	210.7	41.7	204.0	(135, 380)	145	200.3 (33.7)	10.4	26.4	11.0	(-57, 114)
	Week 12	145	212.8	40.6	203.0	(128, 383)	145	200.4 (33.8)	12.4	30.1	11.0	(-59, 114)
	Week 16	143	211.4	38.4	203.0	(131, 411)	143	199.7 (33.3)	11.8	32.4	11.0	(-85, 200)
	Week 20	140	216.3	44.8	206.0	(142, 377)	140	200.0 (33.9)	16.3	34.5	13.0	(-96, 174)
	Week 24	132	216.2	42.5	211.0	(142, 402)	132	199.3 (34.4)	16.9	33.8	14.5	(-86, 207)
darbepoetin	Baseline	153	204.2	55.4	190.0	(116, 495)						
	Week 2	153	203.4	55.3	188.0	(112, 457)	153	204.2 (55.4)	-0.8	18.8	-2.0	(-93, 63)
	Week 4	153	205.5	59.9	193.0	(97, 495)	153	204.2 (55.4)	1.2	23.9	-2.0	(-84, 104)
	Week 6	152	205.9	60.9	193.5	(115, 544)	152	204.3 (55.6)	1.7	29.0	-1.0	(-150, 156)
	Week 8	151	208.2	60.8	196.0	(126, 507)	151	204.6 (55.6)	3.6	30.1	2.0	(-137, 202)
	Week 10	150	211.3	67.9	194.0	(104, 558)	150	204.4 (55.9)	6.9	36.0	2.0	(-84, 259)
	Week 12	148	211.8	65.1	197.0	(122, 524)	148	203.8 (55.8)	8.0	32.0	7.5	(-108, 225)
	Week 16	148	212.2	62.7	199.0	(126, 537)	148	203.6 (55.5)	8.6	31.0	6.5	(-96, 177)
	Week 20	144	214.1	66.2	197.5	(114, 559)	144	201.6 (52.8)	12.5	37.6	7.0	(-76, 345)
	Week 24	140	218.2	64.0	203.0	(120, 548)	140	202.3 (53.2)	15.9	31.8	11.0	(-92, 178)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Gamma Glutamyl Transferase (U/L)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	29.6	39.0	19.0	(7, 400)						
	Week 2	151	26.8	32.3	18.0	(6, 355)	151	29.6 (39.0)	-2.8	10.9	-1.0	(-104, 10)
	Week 4	149	25.9	31.9	18.0	(7, 326)	149	29.6 (39.2)	-3.7	15.1	-2.0	(-125, 59)
	Week 6	148	24.2	26.8	17.0	(6, 248)	148	29.4 (39.2)	-5.2	17.3	-2.0	(-152, 58)
	Week 8	145	22.5	20.4	16.0	(6, 140)	145	26.9 (24.7)	-4.5	12.3	-3.0	(-90, 71)
	Week 10	145	21.6	19.4	16.0	(5, 131)	145	26.5 (24.2)	-4.8	14.1	-2.0	(-124, 62)
	Week 12	145	22.1	19.9	16.0	(6, 123)	145	26.9 (24.7)	-4.9	14.7	-2.0	(-123, 54)
	Week 16	143	21.7	19.4	16.0	(5, 116)	143	26.8 (24.9)	-5.1	16.0	-2.0	(-120, 31)
	Week 20	140	21.4	18.6	16.0	(6, 117)	140	26.6 (24.7)	-5.2	18.3	-2.0	(-143, 45)
	Week 24	132	22.0	19.9	16.0	(6, 125)	132	26.7 (25.1)	-4.7	18.2	-2.0	(-141, 49)
darbepoetin	Baseline	153	26.0	22.8	19.0	(8, 174)						
	Week 2	153	25.4	22.5	20.0	(8, 177)	153	26.0 (22.8)	-0.5	5.0	0.0	(-37, 26)
	Week 4	153	26.2	23.3	18.0	(8, 175)	153	26.0 (22.8)	0.2	9.4	0.0	(-42, 77)
	Week 6	152	25.3	21.1	19.0	(9, 153)	152	26.0 (22.9)	-0.7	6.8	0.0	(-37, 29)
	Week 8	151	25.7	23.2	20.0	(8, 202)	151	26.0 (22.9)	-0.3	6.6	0.0	(-32, 28)
	Week 10	150	26.3	23.2	20.0	(8, 201)	150	26.1 (23.0)	0.2	9.3	0.0	(-36, 63)
	Week 12	148	26.3	21.8	20.0	(8, 176)	148	26.2 (23.1)	0.1	8.8	0.0	(-38, 32)
	Week 16	148	27.8	28.2	20.0	(8, 240)	148	25.8 (22.8)	2.0	18.9	0.0	(-37, 209)
	Week 20	144	27.2	23.6	19.5	(8, 144)	144	25.9 (23.1)	1.3	11.1	1.0	(-38, 59)
	Week 24	140	29.4	35.2	20.0	(7, 330)	140	26.3 (23.3)	3.1	27.9	0.0	(-32, 299)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Sodium (mEq/L)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	140.3	3.3	141.0	(129, 150)						
	Week 2	151	140.1	3.0	140.0	(130, 147)	151	140.3 (3.3)	-0.2	2.7	0.0	(-9, 6)
	Week 4	149	140.1	3.0	140.0	(127, 149)	149	140.2 (3.2)	-0.1	2.8	0.0	(-6, 5)
	Week 6	148	140.0	2.7	140.0	(129, 146)	148	140.3 (3.2)	-0.3	2.5	-0.5	(-7, 8)
	Week 8	145	140.3	2.7	141.0	(131, 146)	145	140.3 (3.2)	0.0	2.6	0.0	(-7, 7)
	Week 10	145	140.2	2.9	140.0	(130, 146)	145	140.4 (3.2)	-0.2	2.6	-1.0	(-8, 7)
	Week 12	145	140.3	2.7	141.0	(130, 145)	145	140.3 (3.2)	0.0	2.6	0.0	(-9, 10)
	Week 16	143	140.1	3.1	140.0	(127, 149)	143	140.3 (3.2)	-0.2	2.7	0.0	(-8, 6)
	Week 20	140	140.4	3.4	141.0	(124, 147)	140	140.3 (3.1)	0.0	3.0	0.0	(-11, 11)
	Week 24	132	140.6	3.0	141.0	(126, 148)	132	140.3 (3.1)	0.2	2.9	0.0	(-9, 10)
darbepoetin	Baseline	153	140.5	2.7	140.0	(131, 146)						
	Week 2	153	140.4	2.3	140.0	(131, 146)	153	140.5 (2.7)	-0.1	2.5	0.0	(-11, 6)
	Week 4	153	140.3	2.5	141.0	(131, 146)	153	140.5 (2.7)	-0.1	2.5	0.0	(-6, 7)
	Week 6	152	140.4	2.5	141.0	(132, 147)	152	140.4 (2.6)	0.0	2.7	0.0	(-10, 7)
	Week 8	151	140.3	2.6	140.0	(131, 148)	151	140.5 (2.6)	-0.2	2.4	0.0	(-8, 7)
	Week 10	150	140.1	2.5	140.0	(131, 147)	150	140.4 (2.7)	-0.3	2.6	-0.5	(-9, 11)
	Week 12	148	140.2	2.4	140.0	(131, 146)	148	140.4 (2.7)	-0.2	2.6	0.0	(-7, 9)
	Week 16	148	140.3	2.7	140.0	(131, 148)	148	140.4 (2.7)	-0.1	2.8	0.0	(-10, 9)
	Week 20	144	140.4	2.6	140.0	(134, 147)	144	140.4 (2.7)	0.0	2.6	0.0	(-7, 8)
	Week 24	140	140.7	2.7	141.0	(133, 146)	140	140.4 (2.6)	0.3	3.0	0.0	(-7, 11)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Potassium (mEq/L)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	4.72	0.53	4.70	(3.8, 6.3)						
	Week 2	151	4.64	0.55	4.60	(3.6, 6.3)	151	4.72 (0.53)	-0.08	0.48	-0.10	(-1.6, 1.4)
	Week 4	149	4.62	0.52	4.60	(3.5, 6.4)	149	4.72 (0.53)	-0.10	0.42	-0.10	(-2.0, 0.9)
	Week 6	148	4.60	0.51	4.55	(3.6, 6.3)	148	4.72 (0.54)	-0.11	0.42	-0.10	(-1.4, 1.0)
	Week 8	145	4.64	0.48	4.60	(3.2, 6.1)	145	4.72 (0.54)	-0.08	0.47	-0.10	(-1.3, 1.6)
	Week 10	145	4.61	0.50	4.50	(3.6, 6.1)	145	4.72 (0.54)	-0.11	0.49	-0.10	(-1.7, 1.7)
	Week 12	145	4.57	0.48	4.60	(3.4, 6.0)	145	4.72 (0.54)	-0.15	0.45	-0.10	(-1.6, 1.3)
	Week 16	143	4.58	0.49	4.50	(3.6, 6.4)	143	4.72 (0.53)	-0.14	0.50	-0.10	(-1.8, 1.2)
	Week 20	140	4.59	0.54	4.60	(3.4, 6.8)	140	4.70 (0.52)	-0.11	0.53	-0.10	(-1.6, 2.0)
	Week 24	132	4.57	0.55	4.50	(3.3, 6.1)	132	4.71 (0.52)	-0.13	0.54	0.00	(-2.3, 1.2)
darbepoetin	Baseline	153	4.69	0.59	4.60	(3.3, 6.3)						
	Week 2	153	4.70	0.53	4.70	(3.5, 6.2)	153	4.69 (0.59)	0.01	0.47	0.10	(-1.8, 1.2)
	Week 4	153	4.67	0.64	4.60	(2.8, 6.6)	153	4.69 (0.59)	-0.02	0.56	0.00	(-2.5, 1.6)
	Week 6	152	4.65	0.56	4.60	(3.0, 6.5)	152	4.68 (0.58)	-0.03	0.49	0.00	(-2.0, 1.3)
	Week 8	151	4.60	0.59	4.50	(3.1, 6.3)	151	4.69 (0.58)	-0.08	0.51	0.00	(-1.7, 1.1)
	Week 10	150	4.63	0.53	4.60	(3.1, 6.2)	150	4.68 (0.59)	-0.05	0.49	0.00	(-1.8, 1.1)
	Week 12	148	4.64	0.62	4.50	(3.0, 6.5)	148	4.67 (0.58)	-0.03	0.57	0.00	(-2.1, 2.0)
	Week 16	148	4.60	0.55	4.55	(3.0, 6.0)	148	4.68 (0.59)	-0.08	0.54	-0.05	(-1.7, 1.8)
	Week 20	144	4.66	0.60	4.60	(3.2, 7.2)	144	4.69 (0.59)	-0.03	0.61	0.00	(-1.7, 2.7)
	Week 24	140	4.58	0.52	4.50	(3.6, 6.9)	140	4.69 (0.59)	-0.11	0.56	-0.10	(-2.1, 1.7)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Chloride (mEq/L)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	106.1	4.2	106.0	(91, 116)						
	Week 2	151	106.5	4.1	106.0	(92, 118)	151	106.1 (4.2)	0.4	2.9	0.0	(-7, 9)
	Week 4	149	106.6	4.0	107.0	(90, 116)	149	106.1 (4.2)	0.5	2.9	0.0	(-7, 11)
	Week 6	148	106.4	4.2	106.0	(91, 115)	148	106.1 (4.2)	0.3	3.2	0.0	(-6, 11)
	Week 8	145	106.7	3.8	107.0	(92, 117)	145	106.2 (4.0)	0.5	3.0	1.0	(-7, 10)
	Week 10	145	106.1	3.9	106.0	(91, 118)	145	106.2 (4.0)	-0.2	3.3	0.0	(-12, 9)
	Week 12	145	106.0	3.4	106.0	(93, 117)	145	106.3 (4.0)	-0.2	3.2	-1.0	(-8, 9)
	Week 16	143	105.9	4.2	106.0	(87, 118)	143	106.2 (4.1)	-0.4	3.2	-1.0	(-11, 9)
	Week 20	140	105.8	4.4	106.0	(87, 121)	140	106.2 (4.1)	-0.4	3.3	0.0	(-11, 8)
	Week 24	132	106.0	3.9	106.0	(88, 114)	132	106.1 (4.0)	-0.2	3.5	0.0	(-10, 9)
darbepoetin	Baseline	153	106.5	3.8	107.0	(94, 116)						
	Week 2	153	106.6	3.5	107.0	(97, 119)	153	106.5 (3.8)	0.1	2.9	0.0	(-14, 10)
	Week 4	153	106.3	3.9	107.0	(94, 117)	153	106.5 (3.8)	-0.2	2.9	0.0	(-8, 7)
	Week 6	152	106.4	3.8	106.5	(96, 118)	152	106.5 (3.8)	-0.1	3.1	0.0	(-8, 10)
	Week 8	151	105.8	3.9	106.0	(95, 118)	151	106.5 (3.8)	-0.7	3.0	-1.0	(-10, 8)
	Week 10	150	105.8	4.1	106.0	(91, 118)	150	106.4 (3.8)	-0.7	3.1	-1.0	(-13, 8)
	Week 12	148	105.8	3.5	106.0	(96, 115)	148	106.5 (3.8)	-0.6	3.2	-1.0	(-11, 8)
	Week 16	148	105.9	3.7	107.0	(96, 114)	148	106.5 (3.8)	-0.6	3.1	0.0	(-12, 5)
	Week 20	144	105.8	3.9	106.0	(91, 120)	144	106.5 (3.8)	-0.7	3.3	-1.0	(-8, 6)
	Week 24	140	105.8	3.8	106.0	(89, 120)	140	106.5 (3.8)	-0.7	3.1	-1.0	(-11, 7)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Calcium (mg/dL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	8.81	0.61	8.80	(6.0, 10.8)						
	Week 2	151	8.63	0.54	8.60	(6.7, 10.9)	151	8.81 (0.61)	-0.19	0.35	-0.20	(-1.0, 1.7)
	Week 4	149	8.59	0.55	8.60	(6.7, 10.3)	149	8.81 (0.61)	-0.22	0.35	-0.20	(-1.2, 1.4)
	Week 6	148	8.58	0.54	8.60	(6.7, 10.8)	148	8.81 (0.61)	-0.22	0.38	-0.20	(-1.7, 1.5)
	Week 8	145	8.62	0.51	8.60	(6.7, 10.5)	145	8.81 (0.62)	-0.18	0.40	-0.20	(-2.0, 1.5)
	Week 10	145	8.60	0.53	8.60	(6.6, 11.0)	145	8.81 (0.62)	-0.21	0.45	-0.20	(-2.0, 2.0)
	Week 12	145	8.63	0.54	8.60	(6.5, 11.4)	145	8.80 (0.62)	-0.17	0.41	-0.20	(-2.2, 1.8)
	Week 16	143	8.61	0.53	8.60	(7.2, 10.1)	143	8.81 (0.61)	-0.20	0.50	-0.20	(-2.5, 2.0)
	Week 20	140	8.67	0.60	8.70	(6.4, 10.5)	140	8.81 (0.62)	-0.15	0.48	-0.10	(-2.2, 1.8)
	Week 24	132	8.81	0.57	8.90	(6.7, 10.4)	132	8.84 (0.55)	-0.03	0.46	0.00	(-1.9, 1.3)
darbepoetin	Baseline	153	8.76	0.49	8.80	(6.9, 9.6)						
	Week 2	153	8.65	0.55	8.70	(6.2, 9.8)	153	8.76 (0.49)	-0.11	0.33	-0.10	(-1.4, 0.7)
	Week 4	153	8.65	0.59	8.70	(6.1, 10.3)	153	8.76 (0.49)	-0.11	0.41	-0.10	(-2.1, 1.0)
	Week 6	152	8.65	0.56	8.70	(6.6, 10.4)	152	8.76 (0.50)	-0.11	0.34	-0.10	(-1.0, 0.8)
	Week 8	151	8.68	0.57	8.70	(6.6, 10.0)	151	8.76 (0.50)	-0.08	0.33	-0.10	(-1.0, 0.8)
	Week 10	150	8.66	0.54	8.70	(6.7, 10.2)	150	8.77 (0.48)	-0.11	0.39	-0.10	(-1.3, 0.7)
	Week 12	148	8.69	0.58	8.70	(6.7, 10.3)	148	8.75 (0.49)	-0.06	0.40	-0.10	(-1.5, 0.8)
	Week 16	148	8.66	0.58	8.70	(6.8, 10.1)	148	8.75 (0.50)	-0.09	0.42	-0.10	(-1.4, 1.2)
	Week 20	144	8.71	0.58	8.80	(6.8, 10.1)	144	8.76 (0.48)	-0.05	0.44	-0.10	(-1.1, 1.2)
	Week 24	140	8.86	0.63	8.90	(6.5, 10.1)	140	8.78 (0.48)	0.08	0.47	0.10	(-1.2, 1.5)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Phosphate (mg/dL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	3.99	0.88	3.90	(2.3, 10.8)						
	Week 2	151	4.02	0.74	4.00	(2.1, 6.7)	151	3.99 (0.88)	0.03	0.62	0.00	(-4.1, 2.6)
	Week 4	149	3.97	0.75	3.90	(2.0, 6.8)	149	3.99 (0.88)	-0.02	0.66	0.00	(-4.5, 1.4)
	Week 6	148	3.90	0.67	3.80	(2.1, 6.0)	148	3.99 (0.88)	-0.09	0.61	0.00	(-4.8, 1.5)
	Week 8	145	3.94	0.70	3.80	(2.2, 6.5)	145	3.98 (0.87)	-0.04	0.64	0.00	(-4.3, 1.3)
	Week 10	145	3.90	0.85	3.80	(2.2, 6.9)	145	4.00 (0.88)	-0.09	0.75	-0.10	(-4.0, 2.0)
	Week 12	145	3.87	0.71	3.80	(2.3, 6.7)	145	4.00 (0.88)	-0.13	0.65	-0.10	(-4.1, 1.6)
	Week 16	143	3.89	0.77	3.70	(2.7, 7.6)	143	4.00 (0.88)	-0.10	0.66	-0.10	(-3.2, 1.4)
	Week 20	140	3.97	0.94	3.85	(2.3, 10.7)	140	3.99 (0.87)	-0.02	0.84	-0.05	(-3.7, 5.6)
	Week 24	132	3.88	0.77	3.80	(1.4, 7.0)	132	3.93 (0.85)	-0.05	0.59	0.00	(-2.5, 1.6)
darbepoetin	Baseline	153	3.91	0.86	3.90	(2.3, 7.4)						
	Week 2	153	3.99	0.85	3.90	(2.2, 7.5)	153	3.91 (0.86)	0.08	0.57	0.00	(-2.2, 1.9)
	Week 4	153	3.89	0.83	3.80	(1.7, 7.1)	153	3.91 (0.86)	-0.02	0.55	0.00	(-2.0, 1.9)
	Week 6	152	3.94	0.89	3.80	(2.1, 8.0)	152	3.90 (0.86)	0.04	0.55	0.10	(-1.9, 2.1)
	Week 8	151	3.96	0.92	3.80	(2.3, 7.5)	151	3.90 (0.86)	0.06	0.57	0.10	(-1.9, 1.7)
	Week 10	150	3.98	0.87	3.85	(2.5, 7.6)	150	3.89 (0.86)	0.09	0.58	0.10	(-1.4, 2.0)
	Week 12	148	3.94	0.94	3.85	(1.6, 7.8)	148	3.88 (0.86)	0.05	0.60	0.10	(-1.3, 2.2)
	Week 16	148	3.95	1.01	3.80	(2.1, 9.6)	148	3.90 (0.85)	0.05	0.66	0.00	(-1.6, 2.5)
	Week 20	144	4.09	1.15	3.90	(2.2, 8.4)	144	3.89 (0.86)	0.20	0.72	0.20	(-1.5, 2.7)
	Week 24	140	4.01	1.11	3.80	(2.5, 9.2)	140	3.87 (0.83)	0.14	0.72	0.10	(-1.0, 3.8)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Magnesium (mg/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	2.00	0.30	2.00	(1.3, 2.9)						
	Week 2	151	2.02	0.29	2.00	(1.4, 3.3)	151	2.00 (0.30)	0.02	0.16	0.00	(-0.4, 0.5)
	Week 4	149	2.00	0.32	2.00	(1.2, 3.2)	149	2.00 (0.30)	0.00	0.16	0.00	(-0.4, 0.5)
	Week 6	148	2.00	0.30	2.00	(1.3, 3.4)	148	2.00 (0.30)	0.01	0.17	0.00	(-0.3, 0.5)
	Week 8	145	2.03	0.31	2.00	(1.4, 3.5)	145	2.00 (0.30)	0.03	0.18	0.00	(-0.4, 0.8)
	Week 10	145	2.00	0.30	2.00	(1.3, 3.2)	145	2.00 (0.30)	0.00	0.18	0.00	(-0.4, 0.5)
	Week 12	145	2.01	0.29	2.00	(1.3, 3.0)	145	2.00 (0.30)	0.01	0.18	0.00	(-0.4, 0.6)
	Week 16	143	1.99	0.29	2.00	(1.3, 3.0)	143	2.00 (0.30)	-0.01	0.19	0.00	(-0.5, 0.6)
	Week 20	140	2.04	0.32	2.00	(1.2, 3.2)	140	2.00 (0.30)	0.04	0.18	0.00	(-0.3, 0.5)
	Week 24	132	2.03	0.30	2.10	(1.2, 2.9)	132	2.01 (0.30)	0.02	0.19	0.00	(-0.8, 0.5)
darbepoetin	Baseline	153	2.03	0.50	2.00	(0.8, 6.9)						
	Week 2	153	2.04	0.42	2.00	(0.6, 5.6)	153	2.03 (0.50)	0.01	0.21	0.00	(-1.3, 0.5)
	Week 4	153	2.03	0.43	2.00	(0.6, 5.8)	153	2.03 (0.50)	0.00	0.19	0.00	(-1.1, 0.5)
	Week 6	152	2.03	0.46	2.00	(0.8, 6.4)	152	2.03 (0.50)	0.00	0.17	0.00	(-0.5, 0.5)
	Week 8	151	2.03	0.49	2.00	(0.8, 6.6)	151	2.03 (0.50)	0.00	0.17	0.00	(-0.4, 0.7)
	Week 10	150	2.03	0.56	2.00	(0.8, 7.6)	150	2.03 (0.50)	0.00	0.21	0.00	(-0.5, 1.1)
	Week 12	148	2.04	0.49	2.00	(0.8, 6.5)	148	2.03 (0.50)	0.01	0.21	0.00	(-0.6, 1.0)
	Week 16	148	2.00	0.45	1.95	(0.7, 5.7)	148	2.04 (0.50)	-0.04	0.24	-0.10	(-1.2, 1.4)
	Week 20	144	2.02	0.53	2.00	(0.7, 6.9)	144	2.03 (0.51)	-0.01	0.26	0.00	(-0.9, 1.2)
	Week 24	140	2.07	0.66	2.00	(0.7, 8.8)	140	2.03 (0.51)	0.03	0.29	0.00	(-0.7, 1.9)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Bicarbonate (mmol/L)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	19.57	3.31	19.50	(7.2, 26.4)						
	Week 2	151	18.48	3.67	18.50	(7.2, 25.6)	151	19.57 (3.31)	-1.09	1.82	-1.00	(-8.3, 3.5)
	Week 4	149	18.69	3.44	18.60	(5.5, 26.4)	149	19.58 (3.32)	-0.89	1.73	-0.90	(-6.2, 3.6)
	Week 6	148	18.50	3.39	18.40	(6.3, 25.2)	148	19.56 (3.32)	-1.07	1.68	-1.15	(-5.2, 3.8)
	Week 8	145	18.48	3.60	18.70	(7.5, 25.8)	145	19.59 (3.33)	-1.11	2.14	-1.20	(-7.2, 5.1)
	Week 10	145	18.62	3.63	19.10	(7.2, 25.7)	145	19.57 (3.33)	-0.96	2.51	-0.90	(-8.2, 6.7)
	Week 12	145	18.72	3.55	19.10	(7.0, 26.8)	145	19.55 (3.32)	-0.83	2.36	-0.70	(-7.4, 5.8)
	Week 16	143	18.97	3.23	19.00	(8.0, 27.1)	143	19.54 (3.34)	-0.57	2.38	-0.70	(-7.7, 8.2)
	Week 20	140	19.09	3.41	19.10	(3.2, 25.9)	140	19.65 (3.30)	-0.57	2.45	-0.50	(-7.0, 6.9)
	Week 24	132	19.02	3.17	18.80	(11.2, 26.8)	132	19.71 (3.15)	-0.69	2.63	-0.55	(-8.0, 7.4)
darbepoetin	Baseline	153	19.69	3.22	20.00	(8.4, 26.1)						
	Week 2	153	19.66	3.21	19.80	(7.6, 25.7)	153	19.69 (3.22)	-0.03	1.97	0.10	(-7.1, 5.3)
	Week 4	153	19.61	3.05	20.00	(9.7, 27.6)	153	19.69 (3.22)	-0.08	2.09	-0.20	(-5.2, 7.3)
	Week 6	152	19.64	3.21	20.10	(8.4, 27.6)	152	19.71 (3.22)	-0.07	2.33	-0.20	(-6.6, 6.4)
	Week 8	151	19.70	3.28	20.10	(9.5, 28.7)	151	19.74 (3.21)	-0.04	2.31	-0.10	(-5.9, 7.4)
	Week 10	150	19.74	3.15	19.90	(8.9, 26.6)	150	19.72 (3.24)	0.02	2.36	0.10	(-5.6, 7.5)
	Week 12	148	19.56	3.13	19.70	(9.0, 26.1)	148	19.71 (3.25)	-0.15	2.46	-0.20	(-6.0, 6.7)
	Week 16	148	19.68	3.09	20.10	(9.4, 26.7)	148	19.68 (3.24)	0.00	2.48	-0.10	(-6.1, 6.7)
	Week 20	144	19.84	3.23	20.20	(5.2, 28.7)	144	19.67 (3.27)	0.17	2.61	0.00	(-7.3, 6.3)
	Week 24	140	20.09	3.17	20.30	(5.6, 27.8)	140	19.70 (3.21)	0.39	2.41	0.30	(-5.1, 6.7)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Total Cholesterol (mg/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	179.9	37.1	176.0	(108, 282)						
	Week 2	151	179.7	41.0	176.0	(101, 313)	151	179.9 (37.1)	-0.2	17.3	3.0	(-58, 47)
	Week 4	149	176.1	41.3	169.0	(103, 321)	149	179.6 (37.0)	-3.5	20.3	-4.0	(-65, 98)
	Week 6	148	175.4	40.8	171.5	(97, 345)	148	179.6 (37.1)	-4.2	23.1	-3.5	(-92, 88)
	Week 8	145	177.7	42.3	176.0	(99, 359)	145	179.2 (37.3)	-1.5	24.7	-4.0	(-132, 85)
	Week 10	145	177.0	41.5	174.0	(101, 330)	145	179.0 (37.2)	-2.0	25.9	-2.0	(-131, 59)
	Week 12	145	179.3	42.9	172.0	(103, 350)	145	179.0 (37.2)	0.2	28.1	1.0	(-134, 97)
	Week 16	143	181.8	44.0	174.0	(104, 368)	143	179.3 (37.4)	2.5	30.5	2.0	(-154, 94)
	Week 20	140	182.1	42.4	178.5	(96, 308)	140	179.8 (37.1)	2.3	30.7	0.5	(-128, 106)
	Week 24	132	184.7	40.6	181.0	(98, 289)	132	180.0 (36.2)	4.8	28.3	4.0	(-134, 80)
darbepoetin	Baseline	153	175.9	36.9	171.0	(101, 277)						
	Week 2	153	176.1	37.4	176.0	(93, 305)	153	175.9 (36.9)	0.2	15.4	0.0	(-36, 46)
	Week 4	153	173.4	38.8	166.0	(98, 281)	153	175.9 (36.9)	-2.5	16.5	-2.0	(-47, 48)
	Week 6	152	174.9	38.5	171.0	(104, 293)	152	176.0 (37.0)	-1.2	17.4	-2.5	(-43, 72)
	Week 8	151	175.1	36.9	169.0	(103, 296)	151	176.3 (37.0)	-1.2	16.9	-2.0	(-51, 63)
	Week 10	150	173.9	36.8	168.0	(106, 297)	150	175.3 (36.5)	-1.4	18.6	-3.0	(-55, 62)
	Week 12	148	175.8	37.7	171.0	(117, 295)	148	175.9 (37.3)	-0.1	17.1	1.0	(-66, 62)
	Week 16	148	176.0	38.8	173.0	(109, 293)	148	176.0 (37.2)	0.0	22.1	0.0	(-44, 103)
	Week 20	144	180.3	39.4	176.0	(98, 308)	144	174.1 (35.8)	6.2	24.3	3.5	(-41, 112)
	Week 24	140	181.9	40.5	176.5	(106, 311)	140	175.4 (35.8)	6.5	23.6	4.0	(-48, 80)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:LDL Cholesterol (mg/dL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	100.4	29.7	95.0	(45, 205)						
	Week 2	151	99.5	32.2	94.0	(43, 222)	151	100.4 (29.7)	-0.9	14.2	-1.0	(-57, 40)
	Week 4	149	97.4	31.6	90.0	(38, 213)	149	100.3 (29.6)	-2.9	15.8	-3.0	(-51, 51)
	Week 6	148	96.5	31.6	90.5	(34, 254)	148	100.3 (29.7)	-3.9	17.7	-4.0	(-89, 70)
	Week 8	145	98.7	32.8	94.0	(35, 269)	145	100.1 (29.8)	-1.4	20.7	-1.0	(-130, 85)
	Week 10	145	98.5	32.5	92.0	(33, 201)	145	100.4 (30.0)	-1.9	21.4	-4.0	(-129, 64)
	Week 12	145	99.8	33.5	94.0	(33, 220)	145	100.2 (29.9)	-0.4	21.6	-2.0	(-130, 63)
	Week 16	143	101.2	36.7	94.0	(39, 264)	143	100.3 (30.1)	0.9	24.5	1.0	(-148, 80)
	Week 20	140	100.4	33.7	93.5	(34, 199)	140	100.9 (30.1)	-0.6	24.1	-1.0	(-129, 69)
	Week 24	132	101.1	32.8	96.5	(36, 196)	132	100.8 (29.5)	0.3	23.0	0.0	(-125, 60)
darbepoetin	Baseline	153	95.0	29.2	90.0	(36, 186)						
	Week 2	153	95.0	29.4	94.0	(33, 214)	153	95.0 (29.2)	0.1	12.0	0.0	(-32, 43)
	Week 4	153	93.9	29.5	90.0	(24, 181)	153	95.0 (29.2)	-1.1	12.8	-1.0	(-31, 40)
	Week 6	152	95.1	30.3	91.0	(25, 205)	152	95.0 (29.3)	0.1	14.4	-0.5	(-36, 72)
	Week 8	151	94.0	29.1	90.0	(13, 201)	151	95.2 (29.3)	-1.1	14.4	-1.0	(-48, 54)
	Week 10	150	94.3	30.0	88.5	(30, 198)	150	94.5 (29.0)	-0.1	14.1	-1.0	(-33, 51)
	Week 12	148	94.8	30.2	85.5	(24, 194)	148	94.8 (29.4)	0.0	14.6	0.0	(-60, 55)
	Week 16	148	94.3	30.4	90.0	(21, 192)	148	94.9 (29.3)	-0.5	17.1	-3.0	(-32, 73)
	Week 20	144	96.4	31.9	92.5	(33, 204)	144	94.0 (28.7)	2.4	17.7	0.0	(-33, 83)
	Week 24	140	96.4	32.0	91.0	(35, 204)	140	94.6 (28.7)	1.8	18.1	1.5	(-68, 74)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:HDL Cholesterol (mg/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	54.5	16.8	51.0	(24, 111)						
	Week 2	151	50.2	16.4	48.0	(22, 102)	151	54.5 (16.8)	-4.3	5.9	-4.0	(-21, 11)
	Week 4	149	50.0	15.9	48.0	(22, 114)	149	54.2 (16.7)	-4.2	6.1	-5.0	(-20, 23)
	Week 6	148	49.1	16.1	47.0	(22, 129)	148	54.3 (16.7)	-5.2	7.1	-5.5	(-36, 38)
	Week 8	145	49.2	15.1	47.0	(22, 105)	145	54.3 (16.8)	-5.1	8.3	-5.0	(-48, 22)
	Week 10	145	48.8	14.2	48.0	(23, 86)	145	53.9 (16.6)	-5.2	9.3	-6.0	(-68, 26)
	Week 12	145	49.3	15.2	47.0	(21, 115)	145	53.9 (16.5)	-4.6	9.7	-5.0	(-75, 24)
	Week 16	143	49.8	15.3	48.0	(25, 119)	143	54.1 (16.5)	-4.3	11.3	-5.0	(-77, 30)
	Week 20	140	51.5	16.2	49.0	(24, 122)	140	53.9 (15.8)	-2.4	9.2	-2.5	(-22, 31)
	Week 24	132	53.2	16.5	50.5	(25, 115)	132	54.4 (15.5)	-1.2	10.0	-2.0	(-25, 45)
darbepoetin	Baseline	153	56.4	18.7	52.0	(20, 160)						
	Week 2	153	55.6	18.3	51.0	(20, 151)	153	56.4 (18.7)	-0.8	5.6	-1.0	(-19, 22)
	Week 4	153	55.3	18.7	50.0	(18, 157)	153	56.4 (18.7)	-1.0	6.5	-1.0	(-25, 22)
	Week 6	152	55.6	18.1	52.5	(19, 160)	152	56.5 (18.7)	-0.9	6.4	-1.0	(-25, 17)
	Week 8	151	55.8	17.4	52.0	(20, 138)	151	56.6 (18.8)	-0.8	7.1	0.0	(-22, 22)
	Week 10	150	56.2	17.3	54.0	(21, 137)	150	56.7 (18.8)	-0.4	8.4	0.0	(-25, 28)
	Week 12	148	56.7	16.8	55.0	(21, 127)	148	56.6 (18.8)	0.1	8.6	-1.0	(-33, 25)
	Week 16	148	56.6	17.1	54.0	(21, 138)	148	56.6 (18.7)	0.1	9.7	0.0	(-33, 39)
	Week 20	144	57.7	16.7	56.0	(19, 114)	144	55.8 (16.7)	1.9	9.8	2.0	(-34, 42)
	Week 24	140	59.5	19.8	57.0	(19, 181)	140	56.4 (18.9)	3.2	10.9	3.0	(-30, 44)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Triglycerides (mg/dL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	142.4	78.3	126.0	(56, 509)						
	Week 2	151	165.4	78.5	158.0	(50, 502)	151	142.4 (78.3)	23.0	58.3	21.0	(-180, 161)
	Week 4	149	160.0	90.7	143.0	(23, 568)	149	142.9 (78.7)	17.1	62.1	10.0	(-153, 265)
	Week 6	148	169.9	94.9	149.0	(44, 616)	148	142.8 (78.9)	27.1	67.8	27.0	(-186, 279)
	Week 8	145	171.1	106.0	149.0	(39, 825)	145	142.2 (79.6)	28.9	83.7	19.0	(-148, 662)
	Week 10	145	169.1	82.0	151.0	(40, 446)	145	141.7 (79.2)	27.4	65.2	27.0	(-218, 281)
	Week 12	145	165.4	94.7	154.0	(34, 771)	145	142.6 (79.6)	22.8	74.9	13.0	(-163, 392)
	Week 16	143	173.1	97.3	148.0	(33, 688)	143	142.5 (79.9)	30.6	71.4	26.0	(-253, 278)
	Week 20	140	163.5	92.6	137.5	(30, 616)	140	143.6 (80.4)	19.8	77.5	17.5	(-248, 453)
	Week 24	132	169.6	134.4	142.5	(29, 1339)	132	143.4 (82.1)	26.2	113.9	16.0	(-301, 966)
darbepoetin	Baseline	153	143.2	81.5	122.0	(30, 583)						
	Week 2	153	142.4	80.5	127.0	(33, 759)	153	143.2 (81.5)	-0.8	50.7	-2.0	(-187, 176)
	Week 4	153	138.3	76.8	123.0	(35, 528)	153	143.2 (81.5)	-4.9	52.7	-6.0	(-173, 180)
	Week 6	152	141.7	86.4	126.0	(36, 696)	152	143.0 (81.7)	-1.3	45.8	-4.5	(-195, 138)
	Week 8	151	148.2	87.1	131.0	(27, 573)	151	143.4 (81.8)	4.7	52.0	1.0	(-176, 197)
	Week 10	150	139.8	88.7	114.0	(27, 671)	150	140.0 (73.8)	-0.3	59.8	-5.5	(-129, 352)
	Week 12	148	137.7	76.9	121.5	(34, 626)	148	143.7 (82.6)	-6.1	56.4	-2.5	(-159, 307)
	Week 16	148	145.4	91.1	125.5	(30, 573)	148	143.7 (82.6)	1.7	64.6	-2.0	(-185, 254)
	Week 20	144	141.8	88.1	128.0	(36, 768)	144	141.2 (73.9)	0.5	66.7	0.5	(-196, 380)
	Week 24	140	141.3	98.3	130.0	(35, 976)	140	142.2 (74.3)	-0.9	81.6	-4.0	(-212, 588)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:C Reactive Protein (mg/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	151	0.2501	0.6092	0.0500	(0.009, 5.390)						
	Week 24	132	0.2183	0.6149	0.0400	(0.010, 5.610)	132	0.2433 (0.6230)	-0.0249	0.7376	0.0000	(-3.550, 5.360)
darbepoetin	Baseline	153	0.1872	0.4744	0.0400	(0.009, 4.020)						
	Week 24	140	0.1872	0.4216	0.0600	(0.009, 3.100)	140	0.1932 (0.4943)	-0.0060	0.5497	0.0100	(-3.980, 2.110)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Vascular Endothelial Growth Factor (pg/mL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	149	36.863	51.010	24.900	(15.59, 549.00)						
	Week 12	145	41.207	58.818	29.200	(15.59, 557.00)	143	35.806 (48.704)	4.741	26.046	0.000	(-53.10, 230.00)
	Week 24	132	43.164	49.223	31.250	(15.59, 413.00)	130	36.951 (50.834)	6.197	31.065	3.300	(-136.00, 187.80)
darbepoetin	Baseline	153	35.720	25.083	28.900	(15.59, 227.00)						
	Week 12	148	31.338	19.823	25.500	(15.59, 146.00)	148	36.179 (25.356)	-4.841	19.727	-0.855	(-118.00, 80.60)
	Week 24	140	32.415	19.534	27.650	(15.59, 163.00)	140	34.486 (19.944)	-2.071	16.771	0.000	(-56.01, 80.80)

表 2.7.4.9－29　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J01 試験）（続き）

Parameter:Dehydroepiandrosterone Sulfate (ug/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	149	90.38	66.82	74.00	(4.0, 361.0)						
	Week 12	145	84.81	64.42	67.00	(5.0, 333.0)	143	89.16 (64.21)	-5.87	19.20	-4.00	(-69.0, 50.0)
	Week 24	132	89.36	69.80	74.50	(5.0, 348.0)	130	89.75 (63.47)	-1.85	24.58	-2.00	(-87.0, 91.0)
darbepoetin	Baseline	153	89.13	77.43	66.00	(2.0, 481.0)						
	Week 12	148	95.16	73.85	65.00	(1.9, 538.0)	148	87.32 (75.20)	-2.16	26.61	-0.55	(-166.0, 116.0)
	Week 24	140	91.83	81.13	69.50	(11.0, 618.0)	140	87.60 (74.94)	4.23	27.47	2.50	(-161.0, 137.0)

Data Source: Listing 16.2.6.1, Listing 16.2.6.2, Listing 16.2.6.3, Listing 16.2.6.4
Source: t_14_3_2_1.sas

5.3.5.1—6 表 14.3.2.1 より引用

表 2.7.4.9－30　規定した基準（臨床検査値）に該当した被験者数及び割合（MT-6548-J01 試験）

Criteria	MT-6548(N=151) n (%)	darbepoetin(N=153) n (%)
Uric Acid		
Any post-baseline value		
25% increase and >7.0 mg/dL	0 (0.0)	0 (0.0)
Potassium		
Any post-baseline value		
>6.0 - 7.0 mmol/L	9 (6.0)	12 (7.8)
>7.0 mmol/L	0 (0.0)	1 (0.7)
VEGF		
Any post-baseline value		
>= 2 x baseline and 200 pg/mL	3 (2.0)	0 (0.0)
Hb		
Any post-baseline value		
NDD: > 13 g/dL	27 (17.9)	52 (34.0)
NDD: > 14 g/dL	3 (2.0)	5 (3.3)
eGFR		
Any post-baseline value		
NDD : 30% decrease from BL	14 (9.3)	21 (13.7)
AST, ALT		
Any post-baseline value		
AST >3.0 x ULN	0 (0.0)	2 (1.3)
AST >5.0 x ULN	0 (0.0)	1 (0.7)
ALT >3.0 x ULN	0 (0.0)	2 (1.3)
ALT >5.0 x ULN	0 (0.0)	1 (0.7)
AST >3.0 x ULN + T-bil > 2.0 x ULN	0 (0.0)	1 (0.7)
ALT >3.0 x ULN + T-bil > 2.0 x ULN	0 (0.0)	1 (0.7)
AST or ALT >3.0 x ULN + ALP < 2.0 x ULN + T-bil > 2.0 x ULN	0 (0.0)	0 (0.0)

Note(s): Percentages are calculated using the number of subjects with post-baseline values as the denominator.
Source: t_14_3_7_1_1_1.sas

5.3.5.3—2 Table 14.3.7.1.1.1 より引用（一部改変）

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）

Parameter:Ery. Mean Corpuscular Volume (fL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	95.6	5.3	95.0	(78, 111)						
	Week 2	160	95.8	5.2	95.0	(77, 110)	160	95.6 (5.3)	0.2	1.1	0.0	(-2, 4)
	Week 4	157	95.7	5.1	96.0	(78, 110)	157	95.6 (5.3)	0.1	1.6	0.0	(-4, 4)
	Week 6	155	95.9	5.2	96.0	(78, 110)	155	95.6 (5.3)	0.3	1.8	0.0	(-4, 6)
	Week 8	152	96.3	5.2	96.0	(78, 110)	152	95.5 (5.3)	0.8	2.1	0.0	(-4, 8)
	Week 10	150	96.7	5.2	97.0	(81, 110)	150	95.6 (5.3)	1.1	2.4	1.0	(-5, 9)
	Week 12	148	97.2	5.3	97.0	(81, 111)	148	95.6 (5.3)	1.6	2.5	2.0	(-5, 10)
	Week 16	144	97.8	5.3	98.0	(85, 114)	144	95.6 (5.0)	2.2	2.8	2.0	(-5, 12)
	Week 20	140	97.5	5.1	98.0	(85, 111)	140	95.5 (4.9)	2.1	3.0	2.0	(-7, 12)
	Week 24	138	97.1	5.1	97.0	(84, 111)	138	95.4 (4.9)	1.7	3.0	1.0	(-8, 13)
darbepoetin	Baseline	161	95.5	4.2	95.0	(85, 109)						
	Week 2	160	95.6	4.1	95.0	(86, 110)	160	95.5 (4.2)	0.1	0.9	0.0	(-3, 3)
	Week 4	159	95.6	4.0	95.0	(86, 108)	159	95.5 (4.2)	0.1	1.3	0.0	(-4, 3)
	Week 6	159	95.7	4.1	96.0	(85, 108)	159	95.5 (4.2)	0.2	1.5	0.0	(-6, 5)
	Week 8	158	95.6	4.1	95.0	(86, 109)	158	95.5 (4.2)	0.2	1.8	0.0	(-7, 5)
	Week 10	157	95.7	4.1	96.0	(86, 108)	157	95.5 (4.2)	0.2	2.0	0.0	(-7, 7)
	Week 12	157	95.8	4.2	95.0	(86, 109)	157	95.5 (4.2)	0.3	2.2	0.0	(-9, 6)
	Week 16	156	95.6	4.2	95.0	(84, 108)	156	95.4 (4.2)	0.1	2.5	0.0	(-6, 6)
	Week 20	154	95.6	4.2	95.0	(84, 106)	154	95.4 (4.1)	0.3	2.5	0.0	(-6, 8)
	Week 24	153	95.8	4.4	95.0	(80, 107)	153	95.4 (4.1)	0.4	2.7	0.0	(-8, 8)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Ery. Mean Corpuscular Hemoglobin (pg)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	31.63	1.92	31.50	(25.1, 36.8)						
	Week 2	160	31.65	1.89	31.70	(25.4, 36.7)	160	31.64 (1.93)	0.01	0.51	0.00	(-1.3, 1.7)
	Week 4	157	31.73	1.85	31.80	(25.1, 36.7)	157	31.66 (1.94)	0.08	0.63	0.00	(-1.4, 2.0)
	Week 6	155	31.77	1.88	31.80	(25.7, 36.9)	155	31.64 (1.94)	0.13	0.76	0.10	(-1.5, 3.1)
	Week 8	152	31.94	1.89	32.00	(25.6, 37.0)	152	31.61 (1.94)	0.33	0.96	0.30	(-1.9, 3.7)
	Week 10	150	32.12	1.91	32.10	(26.7, 36.9)	150	31.64 (1.94)	0.48	1.00	0.40	(-1.7, 4.0)
	Week 12	148	32.36	1.92	32.40	(27.1, 37.6)	148	31.65 (1.95)	0.72	1.02	0.60	(-1.9, 4.1)
	Week 16	144	32.53	1.95	32.60	(27.1, 38.9)	144	31.64 (1.84)	0.89	1.12	0.75	(-2.1, 5.2)
	Week 20	140	32.50	1.87	32.60	(27.9, 37.7)	140	31.60 (1.83)	0.90	1.17	0.80	(-2.4, 5.0)
	Week 24	138	32.54	1.90	32.60	(26.9, 38.4)	138	31.61 (1.82)	0.94	1.20	0.80	(-2.1, 5.6)
darbepoetin	Baseline	161	31.57	1.55	31.60	(28.1, 35.4)						
	Week 2	160	31.56	1.53	31.50	(27.7, 35.7)	160	31.56 (1.55)	0.00	0.51	0.00	(-2.0, 1.1)
	Week 4	159	31.53	1.47	31.40	(28.3, 35.4)	159	31.56 (1.55)	-0.03	0.61	0.00	(-2.3, 1.3)
	Week 6	159	31.58	1.57	31.30	(28.0, 36.6)	159	31.56 (1.55)	0.02	0.71	0.10	(-2.6, 2.2)
	Week 8	158	31.53	1.48	31.50	(27.9, 36.0)	158	31.57 (1.55)	-0.04	0.81	0.00	(-2.6, 2.1)
	Week 10	157	31.60	1.59	31.50	(27.5, 35.8)	157	31.55 (1.55)	0.05	0.90	0.10	(-2.7, 2.8)
	Week 12	157	31.60	1.57	31.70	(27.5, 35.3)	157	31.55 (1.55)	0.05	0.97	0.10	(-3.2, 2.8)
	Week 16	156	31.64	1.57	31.50	(27.0, 35.7)	156	31.54 (1.55)	0.09	1.07	0.15	(-3.8, 2.7)
	Week 20	154	31.67	1.59	31.70	(26.9, 35.1)	154	31.52 (1.53)	0.15	1.11	0.20	(-3.9, 3.2)
	Week 24	153	31.87	1.71	31.80	(25.6, 37.5)	153	31.53 (1.53)	0.33	1.24	0.30	(-3.7, 4.6)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Ery. Mean Corpuscular HGB Concentration (%)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	33.09	0.50	33.10	(31.8, 34.3)						
	Week 2	160	33.06	0.59	33.00	(31.5, 35.2)	160	33.09 (0.50)	-0.03	0.52	-0.10	(-1.6, 1.5)
	Week 4	157	33.14	0.56	33.10	(31.8, 35.2)	157	33.10 (0.51)	0.04	0.49	0.00	(-1.6, 1.2)
	Week 6	155	33.10	0.63	33.10	(31.1, 35.0)	155	33.09 (0.51)	0.01	0.58	0.00	(-1.7, 1.6)
	Week 8	152	33.18	0.64	33.10	(31.3, 37.1)	152	33.09 (0.50)	0.09	0.59	0.05	(-1.9, 3.1)
	Week 10	150	33.17	0.52	33.20	(31.3, 34.9)	150	33.09 (0.51)	0.09	0.51	0.10	(-1.3, 2.2)
	Week 12	148	33.28	0.55	33.30	(31.3, 35.1)	148	33.09 (0.51)	0.19	0.50	0.20	(-1.1, 1.6)
	Week 16	144	33.25	0.57	33.20	(31.3, 35.2)	144	33.09 (0.51)	0.16	0.53	0.20	(-1.5, 1.6)
	Week 20	140	33.32	0.55	33.30	(31.8, 35.2)	140	33.09 (0.51)	0.22	0.51	0.20	(-1.5, 1.5)
	Week 24	138	33.49	0.59	33.40	(31.5, 35.4)	138	33.10 (0.51)	0.39	0.57	0.40	(-1.4, 2.1)
darbepoetin	Baseline	161	33.04	0.59	33.10	(31.2, 34.6)						
	Week 2	160	33.02	0.61	33.00	(31.3, 34.3)	160	33.04 (0.59)	-0.02	0.44	0.00	(-1.2, 0.9)
	Week 4	159	32.97	0.55	32.90	(31.3, 34.4)	159	33.05 (0.59)	-0.08	0.50	-0.10	(-1.8, 1.3)
	Week 6	159	32.99	0.59	32.90	(31.4, 36.0)	159	33.05 (0.59)	-0.06	0.51	-0.10	(-1.4, 2.1)
	Week 8	158	32.96	0.60	32.90	(31.4, 35.5)	158	33.05 (0.59)	-0.09	0.58	-0.10	(-1.6, 1.6)
	Week 10	157	33.02	0.58	33.00	(31.6, 35.2)	157	33.04 (0.58)	-0.02	0.55	0.00	(-1.2, 1.7)
	Week 12	157	33.00	0.54	33.00	(31.4, 34.3)	157	33.04 (0.58)	-0.04	0.56	-0.10	(-1.5, 1.5)
	Week 16	156	33.08	0.54	33.10	(31.6, 34.5)	156	33.04 (0.58)	0.04	0.57	0.10	(-1.8, 1.5)
	Week 20	154	33.12	0.53	33.10	(31.7, 34.5)	154	33.04 (0.58)	0.08	0.56	0.10	(-1.8, 1.3)
	Week 24	153	33.24	0.60	33.20	(31.8, 35.9)	153	33.04 (0.59)	0.20	0.62	0.20	(-1.6, 3.0)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Erythrocytes Distribution Width (%)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	14.74	1.31	14.50	(12.0, 19.9)						
	Week 2	160	14.64	1.31	14.45	(12.3, 21.1)	160	14.75 (1.32)	-0.11	0.59	-0.10	(-1.6, 1.3)
	Week 4	157	14.56	1.33	14.30	(12.4, 20.7)	157	14.74 (1.32)	-0.17	0.77	-0.20	(-2.1, 2.1)
	Week 6	155	14.68	1.31	14.60	(11.9, 20.2)	155	14.75 (1.33)	-0.07	0.93	0.00	(-2.7, 3.3)
	Week 8	152	14.77	1.36	14.50	(12.2, 19.3)	152	14.77 (1.32)	0.00	1.08	0.05	(-3.1, 3.5)
	Week 10	150	14.82	1.30	14.60	(12.2, 20.0)	150	14.75 (1.31)	0.08	1.17	0.10	(-3.9, 4.1)
	Week 12	148	14.72	1.29	14.50	(12.6, 21.0)	148	14.72 (1.28)	-0.01	1.30	0.00	(-4.9, 4.5)
	Week 16	144	14.36	1.10	14.20	(12.1, 19.5)	144	14.70 (1.27)	-0.34	1.28	-0.30	(-6.0, 2.5)
	Week 20	140	14.12	1.14	13.90	(12.2, 20.1)	140	14.69 (1.29)	-0.57	1.42	-0.40	(-6.2, 3.6)
	Week 24	138	14.06	1.17	13.80	(12.3, 19.2)	138	14.70 (1.30)	-0.63	1.49	-0.40	(-5.9, 3.8)
darbepoetin	Baseline	161	14.80	1.51	14.40	(12.1, 20.5)						
	Week 2	160	14.82	1.42	14.55	(12.7, 21.3)	160	14.78 (1.49)	0.03	0.49	0.00	(-1.7, 1.2)
	Week 4	159	14.78	1.33	14.50	(12.4, 20.8)	159	14.77 (1.49)	0.01	0.67	0.00	(-2.6, 2.2)
	Week 6	159	14.71	1.26	14.50	(12.5, 19.6)	159	14.77 (1.49)	-0.06	0.89	0.00	(-3.2, 3.6)
	Week 8	158	14.67	1.15	14.45	(12.3, 18.1)	158	14.77 (1.50)	-0.10	1.04	0.00	(-3.5, 2.8)
	Week 10	157	14.64	1.13	14.50	(12.6, 18.7)	157	14.78 (1.50)	-0.14	1.05	-0.10	(-3.8, 2.0)
	Week 12	157	14.68	1.08	14.50	(12.6, 18.1)	157	14.78 (1.50)	-0.10	1.11	0.00	(-4.1, 2.5)
	Week 16	156	14.69	1.12	14.40	(12.7, 18.1)	156	14.78 (1.50)	-0.09	1.20	0.10	(-4.7, 3.3)
	Week 20	154	14.62	1.17	14.35	(12.7, 17.8)	154	14.78 (1.51)	-0.16	1.25	-0.05	(-5.0, 3.2)
	Week 24	153	14.69	1.18	14.40	(12.5, 17.9)	153	14.77 (1.51)	-0.08	1.33	-0.10	(-6.0, 3.6)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Leukocytes (/uL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	5852.5	1816.3	5500.0	(2500, 13100)						
	Week 2	160	5886.9	1762.1	5500.0	(3100, 14400)	160	5863.1 (1825.1)	23.8	1025.4	-150.0	(-3000, 4600)
	Week 4	157	5886.6	1843.6	5400.0	(2600, 14600)	157	5863.7 (1830.3)	22.9	1063.7	0.0	(-3200, 3800)
	Week 6	155	5835.5	1758.0	5600.0	(2800, 12900)	155	5876.8 (1835.9)	-41.3	1050.5	0.0	(-3600, 3700)
	Week 8	152	5846.1	1745.6	5600.0	(2300, 12600)	152	5902.6 (1844.3)	-56.6	1159.2	-100.0	(-5000, 4700)
	Week 10	150	5872.0	1892.8	5400.0	(2600, 12400)	150	5891.3 (1850.7)	-19.3	1224.3	-150.0	(-4100, 3400)
	Week 12	148	5830.4	1970.9	5400.0	(2800, 14100)	148	5879.1 (1851.9)	-48.6	1190.5	-200.0	(-5100, 4800)
	Week 16	144	5860.4	1931.2	5500.0	(2700, 14100)	144	5894.4 (1864.3)	-34.0	1140.5	0.0	(-5000, 4900)
	Week 20	140	5915.7	1865.5	5550.0	(2800, 11800)	140	5936.4 (1872.6)	-20.7	1009.1	0.0	(-3200, 3000)
	Week 24	138	5845.7	1823.2	5650.0	(2400, 12600)	138	5946.4 (1862.9)	-100.7	1145.4	-100.0	(-4400, 4700)
darbepoetin	Baseline	161	5623.0	1568.1	5500.0	(2000, 15400)						
	Week 2	160	5695.0	1632.4	5500.0	(2400, 17900)	160	5645.6 (1546.4)	49.4	789.4	50.0	(-2500, 2500)
	Week 4	159	5578.6	1406.8	5500.0	(2700, 12800)	159	5644.0 (1551.1)	-65.4	840.0	-100.0	(-4200, 1900)
	Week 6	159	5636.5	1563.9	5400.0	(2800, 14200)	159	5644.0 (1551.1)	-7.5	954.1	100.0	(-3600, 3600)
	Week 8	158	5694.3	1458.5	5550.0	(3400, 11700)	158	5634.8 (1551.7)	59.5	1008.2	100.0	(-3700, 3000)
	Week 10	157	5679.0	1544.2	5500.0	(2900, 12800)	157	5637.6 (1556.3)	41.4	1073.5	0.0	(-3500, 5800)
	Week 12	157	5756.7	1684.3	5500.0	(2900, 15200)	157	5637.6 (1556.3)	119.1	1223.2	100.0	(-4900, 4500)
	Week 16	156	5625.6	1623.0	5400.0	(3000, 17600)	156	5637.8 (1561.3)	-12.2	1063.7	100.0	(-4000, 5300)
	Week 20	154	5851.3	1914.7	5550.0	(2700, 19000)	154	5637.0 (1568.1)	214.3	1466.7	100.0	(-4500, 13400)
	Week 24	153	5774.5	1663.3	5500.0	(2400, 16100)	153	5641.2 (1572.4)	133.3	997.5	0.0	(-3600, 3400)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Neutrophils/Leukocytes (%)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	67.60	8.40	67.85	(42.0, 88.5)						
	Week 2	159	66.94	8.37	67.10	(40.1, 88.5)	159	67.77 (8.27)	-0.83	5.82	-1.00	(-12.9, 17.5)
	Week 4	156	67.27	7.80	67.55	(41.0, 85.5)	156	67.78 (8.34)	-0.51	5.89	-0.70	(-18.0, 16.0)
	Week 6	154	66.74	7.43	66.85	(48.6, 86.5)	154	67.77 (8.39)	-1.03	6.17	-0.80	(-18.5, 17.0)
	Week 8	151	67.30	7.77	67.00	(47.3, 84.6)	151	68.01 (8.28)	-0.71	6.65	-1.20	(-18.1, 28.1)
	Week 10	149	66.90	8.41	67.60	(41.6, 88.0)	149	68.08 (8.10)	-1.18	7.05	-1.50	(-31.1, 23.0)
	Week 12	147	66.63	7.99	66.60	(45.6, 85.5)	147	67.96 (8.09)	-1.33	6.61	-1.50	(-29.5, 21.5)
	Week 16	144	67.48	7.90	67.95	(45.7, 85.7)	144	67.78 (8.27)	-0.30	6.85	-0.60	(-23.2, 17.9)
	Week 20	139	68.36	8.15	68.00	(43.3, 89.0)	139	67.87 (8.40)	0.49	6.88	0.00	(-16.7, 26.3)
	Week 24	137	69.59	8.00	69.50	(46.0, 90.5)	137	67.89 (8.34)	1.69	6.46	1.20	(-15.0, 24.5)
darbepoetin	Baseline	160	67.17	7.44	67.20	(45.0, 83.0)						
	Week 2	159	68.05	6.83	68.40	(46.0, 84.0)	158	67.33 (7.30)	0.86	5.13	0.60	(-12.8, 19.9)
	Week 4	159	67.29	7.15	67.60	(48.2, 84.0)	158	67.22 (7.47)	0.15	5.58	0.40	(-15.0, 19.2)
	Week 6	159	67.51	7.32	68.00	(46.0, 86.5)	158	67.22 (7.47)	0.33	5.76	0.05	(-14.9, 16.1)
	Week 8	157	67.45	7.32	67.20	(48.5, 83.0)	156	67.30 (7.48)	0.21	6.01	0.80	(-24.0, 15.9)
	Week 10	157	67.26	7.35	68.00	(52.0, 84.0)	156	67.22 (7.47)	0.10	6.56	0.45	(-20.0, 19.4)
	Week 12	157	67.79	7.54	68.00	(45.0, 83.9)	156	67.22 (7.47)	0.63	6.42	1.20	(-16.9, 19.1)
	Week 16	156	68.29	7.46	69.15	(48.5, 83.5)	155	67.22 (7.49)	1.14	6.00	1.50	(-15.9, 15.6)
	Week 20	154	68.65	7.82	68.95	(48.0, 89.0)	153	67.22 (7.53)	1.49	6.35	1.50	(-14.2, 26.5)
	Week 24	153	69.41	7.37	69.80	(37.5, 87.2)	152	67.24 (7.56)	2.23	6.14	2.10	(-20.0, 19.1)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Eosinophils/Leukocytes (%)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	4.72	3.58	4.00	(0.5, 23.0)						
	Week 2	159	4.85	3.76	4.00	(0.5, 27.0)	159	4.75 (3.60)	0.10	2.05	0.10	(-6.0, 5.1)
	Week 4	156	4.53	3.55	4.00	(0.0, 26.5)	156	4.76 (3.60)	-0.23	2.17	0.00	(-9.0, 5.2)
	Week 6	154	4.56	3.72	3.35	(0.0, 28.0)	154	4.79 (3.61)	-0.23	2.30	0.00	(-6.7, 5.5)
	Week 8	151	4.72	3.66	4.00	(0.0, 30.0)	151	4.78 (3.62)	-0.06	2.32	0.00	(-9.4, 7.4)
	Week 10	149	4.74	3.70	4.00	(0.0, 26.0)	149	4.73 (3.56)	0.01	3.00	0.00	(-10.2, 22.2)
	Week 12	147	4.69	3.85	3.60	(0.0, 19.6)	147	4.74 (3.58)	-0.05	2.68	-0.10	(-9.7, 14.6)
	Week 16	144	4.58	3.63	3.40	(0.0, 22.0)	144	4.73 (3.59)	-0.14	2.83	-0.20	(-8.7, 10.4)
	Week 20	139	4.37	3.25	3.90	(0.4, 19.6)	139	4.75 (3.63)	-0.38	2.33	-0.10	(-10.4, 4.7)
	Week 24	137	4.44	3.16	3.80	(0.0, 15.9)	137	4.75 (3.65)	-0.31	2.23	0.00	(-7.1, 5.7)
darbepoetin	Baseline	160	4.37	3.64	3.40	(0.0, 24.0)						
	Week 2	159	4.31	3.29	3.40	(0.0, 25.0)	158	4.29 (3.48)	0.00	2.03	0.00	(-11.5, 5.3)
	Week 4	159	4.35	3.49	3.40	(0.0, 22.5)	158	4.38 (3.65)	-0.04	2.15	-0.05	(-10.0, 6.7)
	Week 6	159	4.43	3.74	3.50	(0.0, 28.5)	158	4.38 (3.65)	0.05	2.26	0.00	(-11.0, 8.5)
	Week 8	157	4.12	3.20	3.20	(0.0, 20.0)	156	4.27 (3.48)	-0.16	2.28	0.00	(-11.0, 6.9)
	Week 10	157	4.37	3.26	3.70	(0.0, 22.5)	156	4.30 (3.48)	0.04	2.05	0.10	(-12.0, 6.5)
	Week 12	157	4.22	3.33	3.50	(0.0, 22.0)	156	4.30 (3.48)	-0.11	2.24	0.00	(-11.5, 7.4)
	Week 16	156	4.45	3.35	3.50	(0.0, 20.0)	155	4.31 (3.49)	0.11	2.40	0.00	(-10.0, 9.0)
	Week 20	154	4.72	3.62	4.00	(0.0, 24.0)	153	4.35 (3.49)	0.34	2.55	0.10	(-10.0, 9.6)
	Week 24	153	4.41	3.72	3.50	(0.0, 26.5)	152	4.31 (3.47)	0.07	2.88	0.00	(-12.0, 12.6)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Monocytes/Leukocytes (%)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	6.57	2.10	6.25	(2.0, 12.6)						
	Week 2	159	6.72	2.19	6.60	(3.0, 12.2)	159	6.55 (2.02)	0.17	2.10	0.20	(-5.6, 5.9)
	Week 4	156	6.60	1.88	6.50	(2.6, 12.9)	156	6.51 (2.02)	0.09	2.00	0.00	(-5.0, 4.7)
	Week 6	154	7.05	1.95	7.10	(1.2, 12.3)	154	6.52 (2.03)	0.52	2.15	0.60	(-7.8, 6.0)
	Week 8	151	6.84	2.05	6.70	(0.5, 12.0)	151	6.52 (2.04)	0.32	2.19	0.50	(-5.5, 5.9)
	Week 10	149	6.64	1.98	6.80	(2.0, 12.2)	149	6.52 (2.05)	0.13	2.33	0.00	(-7.0, 7.0)
	Week 12	147	6.90	2.02	6.80	(1.4, 11.8)	147	6.56 (2.03)	0.33	2.00	0.30	(-4.4, 5.6)
	Week 16	144	6.94	2.28	6.95	(2.0, 12.6)	144	6.59 (2.08)	0.36	2.28	0.50	(-7.5, 7.3)
	Week 20	139	6.82	2.15	7.00	(1.8, 11.6)	139	6.58 (2.07)	0.24	2.06	0.20	(-6.5, 5.0)
	Week 24	137	6.55	2.32	6.60	(1.0, 12.7)	137	6.56 (2.06)	-0.01	2.47	0.10	(-6.5, 7.3)
darbepoetin	Baseline	160	6.96	2.20	7.00	(2.0, 13.5)						
	Week 2	159	6.80	2.23	6.90	(2.0, 12.4)	158	6.94 (2.20)	-0.17	2.09	-0.20	(-7.7, 7.0)
	Week 4	159	6.81	2.12	6.50	(2.0, 12.4)	158	6.95 (2.21)	-0.15	1.99	0.00	(-6.6, 5.0)
	Week 6	159	6.66	2.13	6.50	(1.7, 15.0)	158	6.95 (2.21)	-0.27	2.03	-0.40	(-7.1, 5.0)
	Week 8	157	6.76	2.20	6.80	(2.8, 14.5)	156	6.94 (2.22)	-0.15	2.20	0.00	(-5.6, 6.0)
	Week 10	157	7.17	2.30	7.00	(2.0, 15.5)	156	6.97 (2.21)	0.23	2.02	0.00	(-5.7, 6.0)
	Week 12	157	6.88	2.21	6.70	(3.1, 12.3)	156	6.97 (2.21)	-0.07	2.11	0.00	(-5.5, 6.0)
	Week 16	156	6.62	2.07	6.50	(2.0, 13.5)	155	6.97 (2.21)	-0.34	1.96	-0.10	(-6.0, 4.0)
	Week 20	154	6.68	2.07	6.50	(1.5, 12.8)	153	6.96 (2.22)	-0.26	2.05	0.00	(-6.1, 5.5)
	Week 24	153	6.48	2.20	6.00	(1.9, 14.5)	152	6.95 (2.23)	-0.47	2.01	-0.50	(-7.1, 4.3)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Lymphocytes/Leukocytes (%)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	20.77	6.81	20.00	(6.5, 42.0)						
	Week 2	159	21.13	6.43	21.00	(5.5, 38.3)	159	20.59 (6.72)	0.53	4.34	0.90	(-14.0, 10.6)
	Week 4	156	21.23	6.47	20.85	(7.5, 39.0)	156	20.61 (6.74)	0.62	4.48	1.00	(-13.0, 16.5)
	Week 6	154	21.34	6.13	21.00	(7.0, 37.3)	154	20.57 (6.77)	0.76	4.67	0.85	(-12.1, 12.0)
	Week 8	151	20.81	6.24	20.90	(7.5, 36.0)	151	20.35 (6.63)	0.47	4.94	1.00	(-19.3, 10.0)
	Week 10	149	21.38	6.83	20.40	(7.5, 40.1)	149	20.33 (6.60)	1.05	5.35	1.70	(-19.4, 14.0)
	Week 12	147	21.43	6.62	21.10	(7.0, 39.3)	147	20.40 (6.61)	1.03	5.42	0.90	(-20.0, 14.9)
	Week 16	144	20.70	6.25	20.50	(7.0, 39.6)	144	20.56 (6.64)	0.14	5.25	0.00	(-13.0, 13.6)
	Week 20	139	20.10	6.36	20.00	(6.5, 42.9)	139	20.45 (6.70)	-0.34	5.60	0.00	(-17.2, 13.5)
	Week 24	137	19.16	6.35	19.10	(5.5, 37.1)	137	20.45 (6.68)	-1.29	4.96	-1.00	(-16.5, 11.5)
darbepoetin	Baseline	160	21.15	6.02	21.00	(8.5, 42.6)						
	Week 2	159	20.46	5.53	20.00	(8.3, 35.5)	158	21.09 (6.03)	-0.73	4.25	-1.00	(-14.6, 10.5)
	Week 4	159	21.20	5.76	21.00	(8.3, 42.5)	158	21.10 (6.03)	0.04	4.08	-0.05	(-12.5, 12.7)
	Week 6	159	21.04	5.82	20.90	(8.0, 41.1)	158	21.10 (6.03)	-0.12	4.68	-0.05	(-12.9, 12.1)
	Week 8	157	21.36	5.86	21.00	(8.5, 38.5)	156	21.13 (6.05)	0.15	4.71	0.00	(-12.6, 18.5)
	Week 10	157	20.86	5.98	20.00	(8.6, 36.7)	156	21.16 (6.05)	-0.35	5.31	-0.30	(-17.3, 15.0)
	Week 12	157	20.75	5.80	20.10	(8.7, 37.8)	156	21.16 (6.05)	-0.46	5.10	-1.00	(-15.9, 14.5)
	Week 16	156	20.26	5.83	20.00	(6.0, 40.0)	155	21.14 (6.06)	-0.92	4.73	-1.00	(-13.0, 11.4)
	Week 20	154	19.66	6.26	19.00	(6.0, 36.9)	153	21.10 (6.08)	-1.48	4.79	-1.20	(-18.0, 11.6)
	Week 24	153	19.41	5.83	19.00	(6.7, 40.0)	152	21.13 (6.09)	-1.75	4.55	-1.65	(-14.0, 9.1)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Basophils/Leukocytes (%)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	0.34	0.37	0.30	(0.0, 2.2)						
	Week 2	159	0.37	0.40	0.30	(0.0, 2.0)	159	0.34 (0.37)	0.03	0.50	0.00	(-2.2, 2.0)
	Week 4	156	0.36	0.36	0.30	(0.0, 2.0)	156	0.34 (0.37)	0.02	0.48	0.00	(-2.0, 1.2)
	Week 6	154	0.32	0.33	0.30	(0.0, 1.3)	154	0.34 (0.37)	-0.03	0.47	0.00	(-2.2, 1.1)
	Week 8	151	0.33	0.35	0.30	(0.0, 1.7)	151	0.35 (0.38)	-0.02	0.49	0.00	(-1.8, 1.2)
	Week 10	149	0.34	0.36	0.30	(0.0, 1.7)	149	0.34 (0.38)	0.00	0.48	0.00	(-2.0, 1.4)
	Week 12	147	0.36	0.35	0.30	(0.0, 1.2)	147	0.34 (0.38)	0.02	0.45	0.00	(-1.2, 1.0)
	Week 16	144	0.29	0.34	0.20	(0.0, 1.5)	144	0.35 (0.38)	-0.06	0.48	0.00	(-1.5, 1.3)
	Week 20	139	0.34	0.38	0.20	(0.0, 2.0)	139	0.35 (0.38)	-0.01	0.53	0.00	(-2.0, 2.0)
	Week 24	137	0.27	0.32	0.20	(0.0, 1.7)	137	0.35 (0.38)	-0.08	0.47	0.00	(-2.2, 1.3)
darbepoetin	Baseline	160	0.35	0.36	0.30	(0.0, 1.8)						
	Week 2	159	0.38	0.39	0.30	(0.0, 2.0)	158	0.35 (0.36)	0.03	0.44	0.00	(-1.2, 1.6)
	Week 4	159	0.35	0.34	0.30	(0.0, 1.5)	158	0.35 (0.36)	-0.01	0.46	0.00	(-1.0, 1.1)
	Week 6	159	0.36	0.38	0.30	(0.0, 2.0)	158	0.35 (0.36)	0.01	0.47	0.00	(-1.1, 2.0)
	Week 8	157	0.31	0.28	0.30	(0.0, 1.0)	156	0.36 (0.36)	-0.04	0.45	0.00	(-1.8, 1.0)
	Week 10	157	0.34	0.31	0.30	(0.0, 1.4)	156	0.36 (0.36)	-0.02	0.49	0.00	(-1.5, 1.1)
	Week 12	157	0.36	0.44	0.30	(0.0, 2.3)	156	0.36 (0.36)	0.01	0.52	0.00	(-1.3, 2.0)
	Week 16	156	0.37	0.38	0.30	(0.0, 2.0)	155	0.36 (0.36)	0.00	0.46	0.00	(-1.1, 1.2)
	Week 20	154	0.29	0.30	0.20	(0.0, 1.6)	153	0.37 (0.36)	-0.08	0.44	0.00	(-1.5, 1.6)
	Week 24	153	0.28	0.33	0.20	(0.0, 2.0)	152	0.37 (0.36)	-0.08	0.49	-0.05	(-1.8, 1.5)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Platelets (10^4/uL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	161	18.41	5.37	17.80	(5.7, 38.4)						
	Week 2	156	17.26	5.17	16.25	(6.1, 35.7)	155	18.42 (5.41)	-1.17	2.82	-1.10	(-10.8, 10.1)
	Week 4	155	17.36	5.03	16.90	(5.7, 35.3)	154	18.29 (5.33)	-0.92	2.47	-1.00	(-8.3, 7.6)
	Week 6	154	17.47	4.94	16.85	(6.2, 34.1)	153	18.39 (5.38)	-0.91	2.48	-0.80	(-9.1, 5.8)
	Week 8	150	17.67	4.68	17.20	(8.4, 33.9)	149	18.43 (5.34)	-0.77	2.45	-0.70	(-8.4, 9.0)
	Week 10	148	18.06	5.05	17.05	(6.3, 37.1)	148	18.34 (5.46)	-0.28	2.47	-0.40	(-8.0, 9.0)
	Week 12	146	18.39	5.00	17.65	(7.3, 35.1)	146	18.39 (5.44)	0.00	2.42	0.00	(-10.4, 8.1)
	Week 16	142	18.28	5.28	17.40	(7.4, 35.3)	141	18.46 (5.53)	-0.16	2.50	-0.40	(-6.7, 8.7)
	Week 20	139	18.08	4.94	17.50	(6.4, 33.9)	138	18.52 (5.47)	-0.42	2.43	-0.40	(-6.3, 9.4)
	Week 24	135	18.22	4.96	17.50	(7.6, 35.5)	134	18.67 (5.45)	-0.44	2.56	-0.45	(-8.7, 7.1)
darbepoetin	Baseline	160	18.37	5.16	17.90	(6.9, 37.9)						
	Week 2	158	18.53	5.34	18.15	(7.3, 42.5)	158	18.45 (5.11)	0.09	2.19	0.00	(-7.5, 8.2)
	Week 4	158	18.35	5.21	17.40	(8.2, 35.3)	158	18.45 (5.11)	-0.09	2.05	0.10	(-9.0, 4.5)
	Week 6	157	17.93	5.10	17.40	(7.2, 38.7)	157	18.45 (5.13)	-0.51	2.27	-0.50	(-10.5, 11.1)
	Week 8	156	17.98	5.14	17.55	(8.2, 32.8)	156	18.41 (5.13)	-0.43	2.51	-0.30	(-9.0, 7.6)
	Week 10	156	18.05	5.10	17.65	(7.4, 38.3)	156	18.42 (5.13)	-0.38	2.55	-0.40	(-11.5, 11.4)
	Week 12	155	18.01	4.97	17.40	(7.8, 31.9)	155	18.44 (5.14)	-0.43	2.51	-0.40	(-10.3, 6.8)
	Week 16	153	18.07	4.90	17.70	(7.1, 33.9)	153	18.49 (5.15)	-0.41	2.63	-0.20	(-14.6, 6.8)
	Week 20	153	18.67	5.42	17.90	(6.8, 42.1)	153	18.46 (5.16)	0.21	3.08	0.20	(-13.8, 13.3)
	Week 24	152	18.50	5.04	18.20	(6.3, 39.1)	152	18.46 (5.18)	0.04	3.02	0.40	(-16.1, 10.3)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Protein (g/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	6.34	0.44	6.30	(5.0, 7.9)						
	Week 2	160	6.34	0.44	6.30	(5.1, 7.9)	160	6.34 (0.45)	0.01	0.24	0.00	(-0.6, 0.6)
	Week 4	157	6.33	0.45	6.30	(5.0, 7.8)	157	6.33 (0.45)	-0.01	0.27	0.00	(-0.7, 0.9)
	Week 6	155	6.33	0.46	6.30	(5.0, 7.7)	155	6.33 (0.45)	0.00	0.28	0.00	(-0.8, 0.8)
	Week 8	152	6.32	0.44	6.30	(5.2, 7.4)	152	6.33 (0.45)	-0.01	0.30	0.00	(-0.8, 0.9)
	Week 10	150	6.32	0.44	6.30	(5.3, 7.8)	150	6.33 (0.45)	-0.01	0.31	0.00	(-0.7, 0.9)
	Week 12	148	6.35	0.43	6.40	(5.2, 7.7)	148	6.33 (0.45)	0.02	0.30	0.00	(-1.0, 0.8)
	Week 16	144	6.32	0.44	6.30	(5.1, 7.6)	144	6.33 (0.45)	-0.02	0.31	0.00	(-0.9, 0.7)
	Week 20	140	6.33	0.44	6.30	(5.3, 7.6)	140	6.34 (0.45)	0.00	0.32	0.00	(-0.9, 0.8)
	Week 24	138	6.32	0.44	6.40	(5.3, 7.6)	138	6.34 (0.45)	-0.02	0.28	0.00	(-0.8, 0.6)
darbepoetin	Baseline	161	6.36	0.41	6.30	(5.1, 7.7)						
	Week 2	160	6.36	0.42	6.30	(5.1, 7.5)	160	6.36 (0.42)	0.00	0.28	0.00	(-0.7, 0.7)
	Week 4	159	6.37	0.39	6.40	(5.3, 7.4)	159	6.36 (0.42)	0.01	0.25	0.00	(-0.5, 0.7)
	Week 6	159	6.33	0.41	6.30	(5.3, 7.4)	159	6.36 (0.42)	-0.03	0.26	0.00	(-0.7, 0.6)
	Week 8	158	6.35	0.38	6.30	(5.1, 7.5)	158	6.36 (0.42)	-0.01	0.28	0.00	(-0.8, 0.8)
	Week 10	157	6.33	0.40	6.30	(5.3, 7.5)	157	6.35 (0.42)	-0.02	0.30	0.00	(-0.8, 0.8)
	Week 12	157	6.37	0.38	6.40	(5.2, 7.6)	157	6.35 (0.42)	0.01	0.29	0.00	(-0.8, 0.8)
	Week 16	156	6.36	0.41	6.40	(5.3, 7.6)	156	6.35 (0.42)	0.01	0.33	0.00	(-0.9, 1.0)
	Week 20	154	6.35	0.40	6.40	(5.2, 8.0)	154	6.36 (0.41)	-0.01	0.29	0.00	(-0.9, 0.8)
	Week 24	153	6.36	0.41	6.30	(5.2, 7.8)	153	6.36 (0.41)	0.00	0.27	0.00	(-0.8, 0.7)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Albumin (g/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	3.54	0.27	3.50	(2.6, 4.3)						
	Week 2	160	3.51	0.28	3.50	(2.6, 4.2)	160	3.54 (0.27)	-0.03	0.17	0.00	(-0.6, 0.4)
	Week 4	157	3.47	0.29	3.50	(2.6, 4.2)	157	3.55 (0.27)	-0.07	0.17	-0.10	(-0.7, 0.7)
	Week 6	155	3.45	0.27	3.40	(2.7, 4.2)	155	3.54 (0.27)	-0.09	0.17	-0.10	(-0.7, 0.3)
	Week 8	152	3.44	0.29	3.40	(2.6, 4.2)	152	3.54 (0.27)	-0.11	0.19	-0.10	(-0.6, 0.6)
	Week 10	150	3.44	0.29	3.40	(2.7, 4.2)	150	3.54 (0.27)	-0.10	0.20	-0.10	(-0.6, 0.6)
	Week 12	148	3.45	0.28	3.50	(2.8, 4.1)	148	3.55 (0.27)	-0.09	0.19	-0.10	(-0.6, 0.3)
	Week 16	144	3.45	0.28	3.40	(2.8, 4.2)	144	3.54 (0.27)	-0.10	0.19	-0.10	(-0.6, 0.4)
	Week 20	140	3.47	0.30	3.50	(2.5, 4.4)	140	3.55 (0.27)	-0.08	0.21	-0.10	(-0.6, 0.4)
	Week 24	138	3.48	0.28	3.50	(2.5, 4.2)	138	3.55 (0.27)	-0.08	0.19	-0.10	(-0.5, 0.5)
darbepoetin	Baseline	161	3.58	0.29	3.60	(2.8, 4.2)						
	Week 2	160	3.58	0.31	3.60	(2.7, 4.3)	160	3.58 (0.29)	0.00	0.18	0.00	(-0.5, 0.4)
	Week 4	159	3.59	0.31	3.60	(2.7, 4.2)	159	3.58 (0.30)	0.01	0.18	0.00	(-0.4, 0.4)
	Week 6	159	3.55	0.30	3.60	(2.7, 4.3)	159	3.58 (0.30)	-0.03	0.20	0.00	(-0.6, 0.4)
	Week 8	158	3.56	0.31	3.60	(2.5, 4.3)	158	3.58 (0.30)	-0.02	0.20	0.00	(-0.5, 0.5)
	Week 10	157	3.55	0.32	3.60	(2.6, 4.4)	157	3.58 (0.29)	-0.03	0.21	0.00	(-0.6, 0.5)
	Week 12	157	3.57	0.31	3.60	(2.7, 4.5)	157	3.58 (0.29)	-0.01	0.22	0.00	(-0.6, 0.8)
	Week 16	156	3.58	0.31	3.60	(2.7, 4.4)	156	3.58 (0.30)	0.00	0.23	0.00	(-0.7, 0.7)
	Week 20	154	3.56	0.31	3.60	(2.2, 4.2)	154	3.58 (0.29)	-0.03	0.23	0.00	(-1.0, 0.6)
	Week 24	153	3.59	0.32	3.60	(2.5, 4.4)	153	3.59 (0.29)	0.01	0.21	0.00	(-0.6, 0.6)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Glucose (mg/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	120.8	28.7	116.0	(52, 225)						
	Week 2	160	119.4	32.4	111.5	(70, 259)	160	121.0 (28.9)	-1.6	25.7	-4.0	(-53, 101)
	Week 4	157	119.7	30.4	113.0	(73, 273)	157	121.2 (29.1)	-1.5	28.9	-2.0	(-92, 194)
	Week 6	155	116.9	29.9	112.0	(77, 248)	155	121.1 (29.2)	-4.2	25.5	-6.0	(-81, 115)
	Week 8	152	117.8	34.0	108.0	(66, 288)	152	120.6 (29.1)	-2.8	29.8	-6.0	(-74, 133)
	Week 10	150	117.2	28.9	112.0	(70, 253)	150	120.8 (29.3)	-3.6	25.5	-4.0	(-84, 87)
	Week 12	148	119.3	34.5	110.0	(73, 271)	148	120.9 (29.4)	-1.6	24.0	-2.0	(-71, 98)
	Week 16	144	117.9	30.9	111.0	(69, 231)	144	120.5 (29.4)	-2.6	27.5	-5.0	(-59, 146)
	Week 20	140	119.5	37.6	108.0	(74, 301)	140	120.3 (29.7)	-0.8	28.9	-5.0	(-61, 113)
	Week 24	138	117.6	30.7	109.5	(72, 228)	138	120.0 (29.3)	-2.4	27.4	-5.0	(-64, 149)
darbepoetin	Baseline	161	127.0	39.9	118.0	(68, 307)						
	Week 2	160	127.3	41.4	115.5	(68, 297)	160	126.7 (39.8)	0.6	25.7	-2.0	(-65, 88)
	Week 4	159	125.0	37.0	117.0	(78, 256)	159	126.6 (39.9)	-1.6	30.1	-2.0	(-89, 128)
	Week 6	159	126.4	37.0	116.0	(70, 259)	159	126.6 (39.9)	-0.2	27.9	-1.0	(-116, 99)
	Week 8	158	122.8	36.9	113.0	(66, 350)	158	126.6 (40.0)	-3.8	25.3	-3.0	(-123, 68)
	Week 10	157	126.2	40.9	115.0	(69, 319)	157	126.4 (40.1)	-0.2	27.9	1.0	(-104, 103)
	Week 12	157	124.8	42.6	114.0	(74, 300)	157	126.4 (40.1)	-1.6	33.6	-2.0	(-123, 165)
	Week 16	156	128.7	44.9	117.5	(74, 406)	156	126.5 (40.2)	2.2	28.8	2.5	(-96, 116)
	Week 20	154	128.9	50.5	119.0	(36, 489)	154	126.8 (40.3)	2.1	32.3	3.0	(-99, 182)
	Week 24	153	127.2	44.7	116.0	(75, 349)	153	126.9 (40.4)	0.3	32.6	0.0	(-110, 150)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Urea Nitrogen (mg/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	64.67	13.70	62.65	(31.4, 112.7)						
	Week 2	160	64.49	12.93	64.45	(29.5, 113.8)	160	64.57 (13.76)	-0.08	9.30	1.00	(-27.9, 21.9)
	Week 4	157	62.71	12.77	61.60	(31.5, 103.3)	157	64.64 (13.86)	-1.93	10.67	-2.60	(-34.5, 33.9)
	Week 6	155	61.18	13.27	60.70	(31.1, 113.4)	155	64.68 (13.83)	-3.51	11.03	-4.10	(-50.0, 24.6)
	Week 8	152	60.16	11.79	61.15	(27.5, 105.0)	152	64.57 (13.76)	-4.41	10.34	-4.35	(-37.3, 19.9)
	Week 10	150	60.22	13.08	59.30	(31.8, 105.3)	150	64.60 (13.64)	-4.38	11.81	-3.65	(-41.6, 38.1)
	Week 12	148	59.97	13.25	59.35	(24.6, 105.8)	148	64.64 (13.73)	-4.68	11.53	-5.00	(-44.5, 38.3)
	Week 16	144	58.79	13.67	57.80	(25.4, 99.3)	144	64.29 (13.70)	-5.50	12.52	-5.25	(-31.2, 44.7)
	Week 20	140	60.71	14.61	59.55	(28.4, 118.5)	140	64.47 (13.72)	-3.76	12.26	-4.30	(-29.2, 46.8)
	Week 24	138	62.11	14.30	62.05	(26.4, 108.3)	138	64.55 (13.80)	-2.44	11.76	-2.95	(-28.6, 50.6)
darbepoetin	Baseline	161	65.00	13.75	65.50	(29.1, 104.6)						
	Week 2	160	63.29	13.35	63.85	(27.6, 108.0)	160	64.94 (13.78)	-1.65	8.84	-1.20	(-24.8, 29.6)
	Week 4	159	62.49	13.13	61.80	(30.6, 94.0)	159	64.94 (13.82)	-2.44	9.83	-2.20	(-32.6, 24.7)
	Week 6	159	61.75	14.17	61.30	(27.2, 117.2)	159	64.94 (13.82)	-3.19	10.44	-4.00	(-39.1, 35.6)
	Week 8	158	61.12	13.34	59.95	(32.2, 112.8)	158	64.96 (13.86)	-3.84	10.07	-3.95	(-41.8, 24.7)
	Week 10	157	60.76	14.36	59.90	(25.8, 102.6)	157	64.84 (13.83)	-4.08	10.21	-2.80	(-38.1, 21.7)
	Week 12	157	60.81	14.64	59.70	(25.1, 105.8)	157	64.84 (13.83)	-4.03	11.33	-4.10	(-45.1, 42.0)
	Week 16	156	61.03	13.90	61.30	(20.9, 95.4)	156	64.88 (13.86)	-3.84	10.61	-4.05	(-44.1, 29.3)
	Week 20	154	61.67	13.81	61.45	(25.0, 109.5)	154	64.85 (13.92)	-3.18	10.45	-3.35	(-34.6, 20.6)
	Week 24	153	64.00	14.37	64.40	(26.0, 107.1)	153	64.90 (13.96)	-0.90	11.05	-0.80	(-31.0, 36.4)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Creatinine (mg/dL)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	10.981	2.408	11.055	(3.87, 21.14)						
	Week 2	160	11.087	2.396	11.140	(4.15, 21.19)	160	10.990 (2.414)	0.097	0.591	0.085	(-2.49, 1.82)
	Week 4	157	11.104	2.372	11.200	(4.15, 21.26)	157	11.029 (2.416)	0.074	0.660	0.060	(-1.86, 3.76)
	Week 6	155	11.090	2.385	11.220	(4.27, 21.28)	155	11.053 (2.423)	0.037	0.777	-0.050	(-2.08, 2.70)
	Week 8	152	11.020	2.406	11.015	(4.04, 20.39)	152	11.024 (2.422)	-0.004	0.809	-0.105	(-2.26, 3.35)
	Week 10	150	10.997	2.366	11.140	(4.10, 19.11)	150	11.030 (2.438)	-0.033	0.787	-0.070	(-2.03, 3.51)
	Week 12	148	10.939	2.366	10.975	(4.06, 19.76)	148	11.006 (2.440)	-0.067	0.862	-0.120	(-2.82, 3.73)
	Week 16	144	10.752	2.401	10.655	(4.19, 19.77)	144	11.014 (2.469)	-0.262	0.995	-0.255	(-3.43, 4.25)
	Week 20	140	10.844	2.416	10.855	(4.38, 19.72)	140	11.061 (2.471)	-0.217	0.978	-0.205	(-3.32, 4.76)
	Week 24	138	10.844	2.464	10.880	(4.12, 19.09)	138	11.063 (2.472)	-0.220	1.102	-0.135	(-3.23, 4.97)
darbepoetin	Baseline	161	10.846	2.444	11.110	(2.96, 16.62)						
	Week 2	160	10.905	2.495	11.030	(3.10, 16.46)	160	10.869 (2.435)	0.036	0.573	0.040	(-2.71, 2.18)
	Week 4	159	11.026	2.460	11.300	(3.31, 15.83)	159	10.861 (2.441)	0.165	0.601	0.130	(-1.88, 2.34)
	Week 6	159	11.016	2.411	11.440	(3.43, 15.70)	159	10.861 (2.441)	0.155	0.644	0.200	(-2.83, 2.33)
	Week 8	158	11.017	2.482	11.190	(3.88, 16.33)	158	10.850 (2.444)	0.168	0.793	0.190	(-5.37, 2.91)
	Week 10	157	11.032	2.505	11.070	(2.93, 15.78)	157	10.863 (2.446)	0.169	0.800	0.230	(-4.68, 2.70)
	Week 12	157	10.981	2.451	11.220	(2.95, 16.26)	157	10.863 (2.446)	0.118	0.689	0.170	(-2.42, 1.95)
	Week 16	156	10.872	2.409	11.055	(3.00, 15.40)	156	10.876 (2.449)	-0.004	0.883	0.145	(-2.73, 2.75)
	Week 20	154	10.846	2.432	10.960	(3.02, 15.55)	154	10.885 (2.461)	-0.038	0.863	0.035	(-2.31, 2.31)
	Week 24	153	10.918	2.395	11.080	(3.07, 15.68)	153	10.890 (2.468)	0.028	0.844	0.040	(-2.51, 2.03)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Urate (mg/dL)

		Absolute					Change from Baseline				
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	6.86	1.52	6.90	(3.0, 13.2)						
	Week 2	160	6.81	1.58	6.90	(2.8, 11.2)	160	6.87 (1.52)	-0.06	0.94	0.00	(-2.4, 4.0)
	Week 4	157	6.73	1.64	6.90	(2.9, 11.8)	157	6.86 (1.53)	-0.13	1.07	-0.10	(-2.6, 6.7)
	Week 6	155	6.69	1.63	6.90	(2.8, 10.8)	155	6.87 (1.54)	-0.19	1.01	-0.20	(-2.7, 4.5)
	Week 8	152	6.64	1.60	6.80	(2.3, 10.5)	152	6.84 (1.44)	-0.20	0.91	-0.10	(-2.9, 2.6)
	Week 10	150	6.74	1.71	6.95	(3.2, 11.0)	150	6.83 (1.44)	-0.10	1.04	-0.20	(-3.5, 4.3)
	Week 12	148	6.59	1.67	6.70	(3.2, 11.8)	148	6.83 (1.45)	-0.25	0.99	-0.30	(-2.8, 4.7)
	Week 16	144	6.64	1.64	6.80	(2.3, 10.5)	144	6.86 (1.45)	-0.22	0.99	-0.30	(-3.3, 2.6)
	Week 20	140	6.80	1.62	6.90	(3.1, 10.4)	140	6.86 (1.45)	-0.06	1.04	-0.10	(-2.4, 4.7)
	Week 24	138	6.80	1.63	6.90	(3.0, 10.4)	138	6.87 (1.44)	-0.07	1.05	-0.10	(-2.4, 3.3)
darbepoetin	Baseline	161	6.76	1.63	6.80	(1.4, 11.6)						
	Week 2	160	6.91	1.65	7.10	(1.3, 10.6)	160	6.78 (1.62)	0.12	0.88	0.10	(-2.6, 3.2)
	Week 4	159	6.91	1.66	7.00	(2.0, 11.5)	159	6.79 (1.62)	0.11	0.80	0.00	(-1.8, 3.9)
	Week 6	159	6.90	1.65	7.10	(2.0, 10.7)	159	6.79 (1.62)	0.10	1.04	0.10	(-2.8, 3.8)
	Week 8	158	6.94	1.63	7.15	(2.0, 11.1)	158	6.81 (1.61)	0.13	1.04	0.20	(-3.0, 3.8)
	Week 10	157	6.83	1.66	7.00	(2.2, 11.2)	157	6.80 (1.61)	0.03	1.00	0.00	(-3.1, 4.7)
	Week 12	157	6.82	1.54	6.90	(3.1, 11.9)	157	6.80 (1.61)	0.02	1.09	0.00	(-2.7, 3.5)
	Week 16	156	6.74	1.57	6.90	(2.0, 10.2)	156	6.78 (1.61)	-0.04	1.04	-0.10	(-2.8, 4.3)
	Week 20	154	6.81	1.58	6.90	(3.1, 11.0)	154	6.78 (1.61)	0.04	1.18	-0.15	(-2.7, 5.5)
	Week 24	153	6.89	1.58	7.10	(3.0, 10.9)	153	6.77 (1.62)	0.11	1.15	0.00	(-2.9, 6.3)

表 2.7.4.9－31　臨床検査値：実測値及びベースラインからの変化量（MT-6548-J03 試験）（続き）

Parameter:Creatine Kinase (U/L)

		Absolute					Change from Baseline					
Treatment Group	Visit	N	Mean	SD	Median	Minimum, Maximum	N	Mean at Baseline (SD)	Mean	SD	Median	Minimum, Maximum
MT-6548	Baseline	162	112.4	69.6	88.0	(28, 431)						
	Week 2	160	121.1	82.8	98.0	(27, 589)	160	112.3 (69.8)	8.8	56.2	5.0	(-133, 308)
	Week 4	157	123.0	81.0	101.0	(27, 429)	157	113.2 (70.0)	9.9	59.5	8.0	(-246, 330)
	Week 6	155	134.1	92.3	105.0	(32, 642)	155	112.2 (68.5)	21.9	63.8	11.0	(-149, 361)
	Week 8	152	124.0	79.5	101.0	(26, 531)	152	113.1 (68.9)	10.9	57.1	8.5	(-141, 284)
	Week 10	150	128.8	84.7	106.0	(37, 508)	150	113.3 (69.3)	15.5	55.9	11.0	(-155, 261)
	Week 12	148	124.7	82.0	100.0	(37, 491)	148	113.4 (69.7)	11.2	60.8	10.5	(-162, 334)
	Week 16	144	133.9	115.9	109.5	(32, 1188)	144	114.0 (69.8)	19.9	104.1	8.5	(-149, 1078)
	Week 20	140	126.6	73.1	108.0	(40, 485)	140	114.8 (70.3)	11.8	47.5	13.5	(-147, 167)
	Week 24	138	122.7	75.7	98.5	(27, 490)	138	115.2 (70.7)	7.4	55.5	6.5	(-217, 248)
darbepoetin	Baseline	161	115.0	97.3	92.0	(17, 957)						
	Week 2	160	116.9	108.6	88.0	(17, 1049)	160	115.4 (97.4)	1.5	95.6	0.0	(-818, 572)
	Week 4	159	117.3	90.7	90.0	(18, 718)	159	115.7 (97.7)	1.6	89.0	-1.0	(-812, 609)
	Week 6	159	117.1	86.7	93.0	(14, 663)	159	115.7 (97.7)	1.3	82.2	0.0	(-805, 263)
	Week 8	158	118.5	100.7	89.0	(13, 766)	158	116.2 (97.8)	2.3	90.8	1.0	(-694, 679)
	Week 10	157	116.4	103.7	91.0	(16, 965)	157	116.0 (98.1)	0.4	87.4	-1.0	(-793, 488)
	Week 12	157	115.9	84.1	89.0	(16, 530)	157	116.0 (98.1)	0.0	80.3	0.0	(-801, 239)
	Week 16	156	123.4	120.9	89.0	(16, 1186)	156	116.4 (98.3)	7.1	121.0	0.0	(-799, 1021)
	Week 20	154	112.3	69.8	90.5	(18, 362)	154	117.1 (98.7)	-4.8	69.7	1.0	(-693, 221)
	Week 24	153	116.7	87.4	98.0	(18, 789)	153	117.6 (98.8)	-1.0	70.4	0.0	(-662, 312)