被験者番号	[redacted]	人種	アジア人（日本人）
年齢／性別	5[redacted] 歳／男性	試験治療	カボザンチニブ（錠剤）60 mg（QD）
重篤な有害事象 (注)（MedDRA 基本語）／重症度／転帰	胆管結石／Grade 3／回復		
対象疾患	肺癌		
病歴	AST 増加、ALT 増加、GGT 増加、痔核、放射線性皮膚炎、癌疼痛（左頸部）、神経感覚障害（左下肢）、皮膚変化（指）、高尿酸血症、皮膚乾燥、便秘		
前治療	全身抗がん治療：シスプラチン、ペメトレキセド、ドセタキセル 外科的手術：なし		
併用薬（ベースライン時）	ラベプラゾールナトリウム、酸化マグネシウム、センノシド、メロキシカム、アロプリノール、テプレノン、イオパミドール		
経過・処置	Day 1：本剤 60 mg 投与開始。 Day 349：上腹部痛を発現し、Grade 3 の総胆管結石症のため入院。ブプレノルフィン塩酸塩などによる治療が行われた。 Day 350：総胆管結石症のため、本剤を休薬。同日、内視鏡的胆道ドレナージが実施され、結石が除去された。 Day 357：内視鏡的乳頭切開術（EST）が実施され、結石が除去された。 Day 366 及び Day 371：EST が再度実施され、結石が除去された。 Day 377：総胆管結石症は消失し、患者は退院した。 SAE 報告書によると、治験責任医師により、胆石は以前より認められており、本事象の発現時に増悪したと考えられた。 Day 380：治験責任医師の判断により、本剤の投与が中止された。SAE 報告書によると、中止の理由として、総胆管結石症及びその再発の懸念も挙げられた。本剤の最終投与日は Day 349 であった。		
治験責任医師の見解	治験責任医師は、胆嚢炎及び胆石症が類薬で報告されていることから、総胆管結石症は重篤な有害事象であり、本剤と関連ありと判断した。		
治験依頼者の見解	治験依頼者は、本剤の投与との時間的関連性に基づき、総胆管結石症は本剤と関連があるかもしれないと判断した。登録前より認められていた胆石が、本事象の発現に関与した可能性があると評価した。		

注：因果関係が否定できない事象

被験者番号	[redacted]	人種	アジア人（日本人）
年齢／性別	4[redacted] 歳／男性	試験治療	カボザンチニブ（錠剤）60 mg（QD）
重篤な有害事象 (注)（MedDRA 基本語）／重症度／転帰	肺感染／Grade 3／未回復		
対象疾患	非小細胞肺癌		
病歴	痰、咳嗽、低アルブミン血症、低ナトリウム血症、乳酸脱水素酵素増加、GGT 増加、ヘマトクリット減少、ヘモグロビン減少、癌疼痛、便秘、不眠症		
前治療	全身抗がん治療：ゲフィチニブ、シスプラチン、ペメトレキセド、ニボルマブ、エルロチニブ、ドセタキセル、TS-1 放射線療法：中枢神経系 外科的手術：なし		
併用薬 (ベースライン時)	オキシコドン塩酸塩水和物、ロキソプロフェンナトリウム水和物、オランザピン、酸化マグネシウム、センノシド A・B、コデインリン酸塩水和物、L-カルボシステイン、レボフロキサシン水和物、バルプロ酸ナトリウム、イオパミドール、ゾレドロン酸水和物、生理食塩水		
経過・処置	Day 1：本剤 60 mg 投与開始。 Day 33：Grade 2 の気管支出血を発現し、Grade 2 の肺感染と診断された。同日、悪心及び食欲減退のため、本剤を休薬。悪心に対してドンペリドン及び塩酸メトクロプラミド、肺感染に対してレボフロキサシン水和物、食欲減退に対してラクテック注、並びに気管支出血に対してトラネキサム酸及びカルバゾクロムスルホン酸ナトリウム水和物などによる治療が行われた。同日、塩酸メトクロプラミド及びラクテック注の投与を中止。 Day 36：Grade 1 の発熱を発現、気管支出血は消失。気管支出血の予防のため、トラネキサム酸及びカルバゾクロムスルホン酸ナトリウム水和物の投与は継続された。また、病歴である咳嗽に対してデキストロメトルファン臭化水素酸塩水和物及び発熱に対してアセトアミノフェンなどによる治療も行われた。 Day 38：肺感染が Grade 3 に増悪し、患者は入院した。胸部 CT の結果、原疾患の腫瘍空洞形成の進行が認められた。「空洞壁の肥厚は既存のものであるが、感染が示唆される。」と報告された。CT スキャンにより左胸水も認められた。同日、喀痰培養の結果、黄色ブドウ球菌が検出された。レボフロキサシン水和物の投与が中止され、肺感染に対しタゾバクタム／ピペラシリン水和物の静脈内投与が開始された。同日、発熱は消失。また、食欲減退に対してビーフリード輸液などによる治療も行われた。 Day 58：胸部 CT の結果、空洞への体液貯留を伴う腫瘍空洞の拡大、左上葉の肺尖区及び後上葉区の腫瘍拡大、左胸水の減少、左鎖骨上リンパ節転移巣の増加、縦隔リンパ節転移の発現、並びに気腫が認められた。腹部では、肝臓、副腎及びリンパ節への転移を示唆する所見が認められ、腹水は認められなかった。CT スキャンにより複数の脳転移が認められた。同日の RECIST に基づく総合効果は PD と判定された。同日、mRECIST に基づき PD と判定されたことから、本剤の投与を中止。本剤の最終投与日は Day 32 であった。タゾバクタム／ピペラシリン水和物の静脈内投与を中止し、メロペネム水和物の静脈内投与を開始。肺感染は未回復。 SAE 報告書の追跡調査により追加情報が得られた。本剤の投与開始から 91 日目に、被験者は死亡した。死因は原疾患の悪化であった。剖検は実施されなかった。入院し抗生物質の静脈内投与を行ったが、肺感染は改善しなかった。さらに、腫瘍空洞の皮下ドレナージも実施された。感染は増悪しなかったが、原疾患が急速に進行し、被験者は死亡した。		
治験責任医師の見解	治験責任医師は、Grade 3 の肺感染は重篤な有害事象であり、本剤と関連ありと判断した。治験責任医師は、本剤の投与による腫瘍空洞が、結果的に同部位の感染を引き起こしたと報告した。		
治験依頼者の見解	治験依頼者は、本剤の投与との時間的関連性に基づき、肺感染は本剤と関連があるかもしれないと判断した。血管内皮細胞増殖因子阻害薬の投与により、肺病変の空洞形成が引き起こされることが知られている。空洞性肺病変は感染の可能性がある。本事象の発現に関与した要因及び危険因子として、原疾患である非小細胞肺癌の進行及び癌に関連する免疫低下が挙げられた。		

注：因果関係が否定できない事象

被験者番号	[redacted]	人種	アジア人（日本人）
年齢／性別	6[redacted] 歳／女性	試験治療	カボザンチニブ（錠剤）60 mg（QD）
重篤な有害事象[注]（MedDRA 基本語）／重症度／転帰	肺炎／Grade 3／回復		
対象疾患	非小細胞肺癌		
病歴	角膜びらん、境界型糖尿病、白内障、便秘、子宮筋腫、胃潰瘍、低アルブミン血症		
前治療	全身抗がん治療：シスプラチン、ゲムシタビン、ペメトレキセド、アムルビシン、エルロチニブ、カルボプラチン、パクリタキセル、ベバシズマブ、テガフール／ギメラシル／オテラシルカリウム、バンデタニブ 放射線療法：なし 外科的手術：なし		
併用薬（ベースライン時）	ファモチジン、アンブロキソール塩酸塩、ビオスリー、尿素、ヘパリン類似物質		
経過・処置	Day 1：本剤 60 mg 投与開始。 Day 135：Grade 3 の肺炎を発現し入院。CT スキャンにより左下葉に肺炎が認められた。同日、肺炎のため本剤を休薬。肺炎に対してタゾバクタム／ピペラシリン水和物などによる治療が行われた。 Day 144：肺炎は消失し、被験者は退院した。 Day 149：帯状疱疹（Day 75 に発現）、肺炎及びビリルビン増加のため、本剤を 20 mg に減量して投与を再開した。 Day 329：Grade 1 の呼吸困難を発現。 Day 344：Grade 2 の活動状態低下を再発（1 回目：Day 135）。 Day 345：活動状態低下のため本剤を休薬。 Day 357：呼吸困難及び活動状態低下はいずれも Grade 3 に増悪し、被験者は両事象のために入院した。同日、状態悪化（Grade 3 の原疾患の悪化）と診断された。CT スキャンにより、原発巣の拡大及び左胸水の増加が認められ、病勢の進行と判断された。mRECIST に基づき PD と判定されたことから、本剤の投与を中止。本剤の最終投与日は Day 344 であった。 Day 358：胸水のドレナージが実施され、700 mL が排出された。胸水の細胞診の結果、腺癌陽性であった。心エコーにより心嚢液貯留が認められ、留置カテーテルより約 100 mL が排出された。 Day 370：心嚢液が更に 290 mL 排出された。心嚢液の細胞診の結果、腺癌陽性であった。		
治験責任医師の見解	治験責任医師は、肺炎は重篤な有害事象であり、本剤と関連ありと判断した。		
治験依頼者の見解	治験依頼者は、本剤の投与との時間的関連性に基づき、肺炎は本剤と関連があるかもしれないと判断した。交絡因子として、原疾患である肺癌、並びに胸水及び心嚢液で検出された悪性細胞等によって確認された事象発現時の病勢の進行が挙げられた。		

注：因果関係が否定できない事象

補遺 2. 重篤な有害事象の一覧

（1）XL184-308 試験

1）本剤群：Safety population

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Convulsion	痙攣	20[redacted]	100	20[redacted]	102	3	RELATED	1:2
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	General physical health deterioration	全身健康状態低下	20[redacted]	85	-	-	3	NOT RELATED	-
				Respiratory distress	呼吸窮迫	20[redacted]	85	20[redacted]	92	3	NOT RELATED	-
				Respiratory distress	呼吸窮迫	20[redacted]	93	20[redacted]	93	5	NOT RELATED	-
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Pleural effusion	胸水	20[redacted]	40	20[redacted]	50	2	NOT RELATED	1:2
				Pneumonia	肺炎	20[redacted]	41	20[redacted]	51	3	NOT RELATED	1:2
				Pleural effusion	胸水	20[redacted]	51	20[redacted]	51	3	NOT RELATED	2
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Ascites	腹水	20[redacted]	112	-	-	2	NOT RELATED	-
				Dyspnoea	呼吸困難	20[redacted]	112	-	-	2	NOT RELATED	-
				Fatigue	疲労	20[redacted]	112	-	-	2	NOT RELATED	-
				Renal cell carcinoma	腎細胞癌	20[redacted]	138	20[redacted]	138	5	NOT RELATED	-
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Back pain	背部痛	20[redacted]	90	-	-	3	NOT RELATED	-
				Asthenia	無力症	20[redacted]	102	-	-	3	NOT RELATED	-
				Nausea	悪心	20[redacted]	102	20[redacted]	108	3	NOT RELATED	-

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	4[redacted]/F/Black or African American	20[redacted]	20[redacted]	Dyspnoea	呼吸困難	20[redacted]	105	20[redacted]	114	3	NOT RELATED	-
				Pneumothorax	気胸	20[redacted]	125	-	-	2	NOT RELATED	-
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Gastrointestinal haemorrhage	胃腸出血	20[redacted]	309	20[redacted]	313	3	NOT RELATED	2
				Hyponatraemia	低ナトリウム血症	20[redacted]	337	20[redacted]	342	3	RELATED	2
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Musculoskeletal chest pain	筋骨格系胸痛	20[redacted]	21	20[redacted]	45	3	NOT RELATED	3
				Empyema	蓄膿	20[redacted]	56	20[redacted]	97	4	NOT RELATED	-
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Oedema peripheral	末梢性浮腫	20[redacted]	787	20[redacted]	796	2	NOT RELATED	2
				Dyspnoea	呼吸困難	20[redacted]	787	20[redacted]	811	3	NOT RELATED	2
				Pulmonary hypertension	肺高血圧症	20[redacted]	791	-	-	3	NOT RELATED	2
[redacted]	6[redacted]/F/Black or African American	20[redacted]	20[redacted]	Convulsion	痙攣	20[redacted]	95	20[redacted]	96	3	NOT RELATED	2
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Dehydration	脱水	20[redacted]	75	20[redacted]	83	2	RELATED	2:3
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Humerus fracture	上腕骨骨折	20[redacted]	13	20[redacted]	18	3	NOT RELATED	2
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Ulcer haemorrhage	潰瘍性出血	20[redacted]	32	20[redacted]	36	3	RELATED	3
				Abdominal pain	腹痛	20[redacted]	49	-	-	3	NOT RELATED	-
[redacted]	5[redacted]/F/White	20[redacted]	20[redacted]	Small intestinal perforation	小腸穿孔	20[redacted]	55	20[redacted]	61	3	RELATED	3
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Blood bilirubin increased	血中ビリルビン増加	20[redacted]	59	20[redacted]	60	3	NOT RELATED	-

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	5[redacted]/F/White	20[redacted]	20[redacted]	Hyponatraemia	低ナトリウム血症	20[redacted]	13	20[redacted]	16	3	RELATED	1:2
				Anaemia	貧血	20[redacted]	223	20[redacted]	224	3	NOT RELATED	2
				Haemoptysis	喀血	20[redacted]	223	20[redacted]	224	1	NOT RELATED	2
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Pulmonary embolism	肺塞栓症	20[redacted]	57	20[redacted]	113	3	RELATED	1:2
				Hypercalcaemia	高カルシウム血症	20[redacted]	336	20[redacted]	337	2	NOT RELATED	-
				Pain	疼痛	20[redacted]	336	20[redacted]	338	3	NOT RELATED	-
				Pericardial effusion	心嚢液貯留	20[redacted]	348	20[redacted]	350	3	NOT RELATED	-
				Pericardial effusion	心嚢液貯留	20[redacted]	350	20[redacted]	358	2	NOT RELATED	-
				Pleural effusion	胸水	20[redacted]	358	-	-	3	NOT RELATED	-
				Cardiac tamponade	心タンポナーデ	20[redacted]	358	20[redacted]	361	4	NOT RELATED	-
				Pericardial effusion	心嚢液貯留	20[redacted]	358	20[redacted]	361	4	NOT RELATED	-
				Pericardial effusion	心嚢液貯留	20[redacted]	361	-	-	2	NOT RELATED	-
[redacted]	5[redacted]/F/White	20[redacted]	20[redacted]	Dehydration	脱水	20[redacted]	39	20[redacted]	41	3	RELATED	2
				Renal cell carcinoma	腎細胞癌	20[redacted]	70	20[redacted]	70	5	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Abdominal pain	腹痛	20[redacted]	308	20[redacted]	312	3	NOT RELATED	2
				Bile duct obstruction	胆管閉塞	20[redacted]	358	20[redacted]	361	3	NOT RELATED	2

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Dizziness	浮動性めまい	20[redacted]	7	-	-	2	RELATED	2
				Back pain	背部痛	20[redacted]	8	-	-	3	NOT RELATED	2
				Tinnitus	耳鳴	20[redacted]	8	20[redacted]	18	2	RELATED	2
				Delirium	譫妄	20[redacted]	9	20[redacted]	18	1	RELATED	2
				Somnolence	傾眠	20[redacted]	9	20[redacted]	18	1	RELATED	2
				Pain in extremity	四肢痛	20[redacted]	10	-	-	3	RELATED	2
				Delirium	譫妄	20[redacted]	62	20[redacted]	74	2	RELATED	2
				Fatigue	疲労	20[redacted]	63	20[redacted]	74	3	RELATED	2
				Hyperhidrosis	多汗症	20[redacted]	176	-	-	1	NOT RELATED	2
				Dizziness	浮動性めまい	20[redacted]	176	20[redacted]	177	2	NOT RELATED	2
				Nausea	悪心	20[redacted]	176	20[redacted]	177	2	NOT RELATED	2
				Palpitations	動悸	20[redacted]	176	20[redacted]	177	2	NOT RELATED	2
				Vomiting	嘔吐	20[redacted]	176	20[redacted]	177	2	NOT RELATED	2
				Diarrhoea	下痢	20[redacted]	249	20[redacted]	254	3	RELATED	2
				Confusional state	錯乱状態	20[redacted]	286	20[redacted]	296	2	RELATED	2
				Fall	転倒	20[redacted]	289	20[redacted]	289	2	NOT RELATED	-
				Diarrhoea	下痢	20[redacted]	293	20[redacted]	296	2	RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Fatigue	疲労	20[redacted]	17	20[redacted]	56	3	RELATED	2
				Vomiting	嘔吐	20[redacted]	19	20[redacted]	21	3	RELATED	2
				Hypothermia	低体温	20[redacted]	20	20[redacted]	23	2	RELATED	1:2
				Hyperkalaemia	高カリウム血症	20[redacted]	139	20[redacted]	141	3	RELATED	3

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted][d]	4[redacted]/M/White	20[redacted]	20[redacted]	Back pain	背部痛	20[redacted]	30	-	-	3	NOT RELATED	3
				Abdominal pain	腹痛	20[redacted]	36	20[redacted]	37	2	NOT RELATED	-
				Nausea	悪心	20[redacted]	36	20[redacted]	41	2	NOT RELATED	-
				Vomiting	嘔吐	20[redacted]	36	20[redacted]	41	2	NOT RELATED	-
				Hypercalcaemia	高カルシウム血症	20[redacted]	37	20[redacted]	38	4	NOT RELATED	-
				Hypercalcaemia	高カルシウム血症	20[redacted]	37	20[redacted]	40	2	NOT RELATED	-
				Constipation	便秘	20[redacted]	37	20[redacted]	41	2	NOT RELATED	-
				Anaemia	貧血	20[redacted]	57	20[redacted]	63	3	NOT RELATED	-
[redacted]	4[redacted]/M/White	20[redacted]	20[redacted]	Pleural effusion	胸水	20[redacted]	64	-	-	2	NOT RELATED	-
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Delirium	譫妄	20[redacted]	334	20[redacted]	336	4	RELATED	2
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Diarrhoea	下痢	20[redacted]	131	20[redacted]	134	3	RELATED	-
				Pathological fracture	病的骨折	20[redacted]	405	-	-	3	NOT RELATED	2:3
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Pulmonary embolism	肺塞栓症	20[redacted]	279	20[redacted]	343	3	RELATED	1:2
				Deep vein thrombosis	深部静脈血栓症	20[redacted]	281	20[redacted]	289	2	RELATED	1:2
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Thoracic vertebral fracture	胸椎骨折	20[redacted]	277	-	-	3	NOT RELATED	2:3

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	5[redacted]/F/White	20[redacted]	20[redacted]	Convulsion	痙攣	20[redacted]	367	20[redacted]	369	1	NOT RELATED	-
				Hemiparesis	不全片麻痺	20[redacted]	473	20[redacted]	475	2	NOT RELATED	2
				Acute psychosis	急性精神病	20[redacted]	649	20[redacted]	666	3	NOT RELATED	3
				Depression	うつ病	20[redacted]	649	20[redacted]	666	2	NOT RELATED	3
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Fall	転倒	20[redacted]	247	20[redacted]	247	3	RELATED	-
				Gastric haemorrhage	胃出血	20[redacted]	247	20[redacted]	250	3	RELATED	1:2
				Syncope	失神	20[redacted]	461	20[redacted]	463	3	NOT RELATED	2:3
				Fall	転倒	20[redacted]	463	20[redacted]	463	3	NOT RELATED	2
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Pancreatitis	膵炎	20[redacted]	19	20[redacted]	21	3	RELATED	2:3
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Miller Fisher syndrome	ミラー・フィッシャー症候群	20[redacted]	234	-	-	2	RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Hyperglycaemia	高血糖	20[redacted]	253	-	-	4	NOT RELATED	-

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Fracture	骨折	20[redacted]	83	20[redacted]	109	3	NOT RELATED	2
				Hyponatraemia	低ナトリウム血症	20[redacted]	85	20[redacted]	86	4	NOT RELATED	2
				Lung infection	肺感染	20[redacted]	85	20[redacted]	90	3	NOT RELATED	2
				Acute sinusitis	急性副鼻腔炎	20[redacted]	225	20[redacted]	229	3	NOT RELATED	2
				Carotid artery thrombosis	頚動脈血栓症	20[redacted]	225	20[redacted]	229	3	NOT RELATED	2
				Intracranial venous sinus thrombosis	頭蓋内静脈洞血栓症	20[redacted]	225	20[redacted]	229	3	NOT RELATED	2
				Hyponatraemia	低ナトリウム血症	20[redacted]	235	20[redacted]	236	4	NOT RELATED	-
				Cardiopulmonary failure	心肺不全	20[redacted]	260	20[redacted]	260	5	NOT RELATED	-
[redacted]	4[redacted]/M/White	20[redacted]	-	Bacteraemia	菌血症	20[redacted]	85	20[redacted]	93	3	NOT RELATED	2
[redacted]	4[redacted]/M/White	20[redacted]	20[redacted]	Dyspnoea	呼吸困難	20[redacted]	553	20[redacted]	561	2	NOT RELATED	-
[redacted]	4[redacted]/M/Other	20[redacted]	-	Anal abscess	肛門膿瘍	20[redacted]	263	20[redacted]	268	3	RELATED	1:2
				Rectal abscess	直腸膿瘍	20[redacted]	821	20[redacted]	823	3	RELATED	2
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Gastrointestinal haemorrhage	胃腸出血	20[redacted]	377	20[redacted]	399	2	NOT RELATED	-
				Renal cancer metastatic	遠隔転移を伴う腎癌	20[redacted]	399	20[redacted]	399	5	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Infection	感染	20[redacted]	85	20[redacted]	101	3	NOT RELATED	2
				Renal cell carcinoma	腎細胞癌	20[redacted]	101	20[redacted]	101	5	NOT RELATED	3

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	5[redacted]/F/White	20[redacted]	20[redacted]	Abdominal pain	腹痛	20[redacted]	153	20[redacted]	155	3	RELATED	2
				Adenocarcinoma of colon	結腸腺癌	20[redacted]	416	-	-	1	NOT RELATED	3
[redacted]	6[redacted]/M/Asian	20[redacted]	20[redacted]	Anorectal cellulitis	肛門直腸蜂巣炎	20[redacted]	167	20[redacted]	177	3	RELATED	2:3
				Anal abscess	肛門膿瘍	20[redacted]	170	20[redacted]	172	3	RELATED	3
				Anal fistula	痔瘻	20[redacted]	170	20[redacted]	172	3	RELATED	3
[redacted]	6[redacted]/M/White	20[redacted]	-	Klebsiella infection	クレブシエラ感染	20[redacted]	2	20[redacted]	7	3	NOT RELATED	2
				Device occlusion	医療機器閉塞	20[redacted]	4	20[redacted]	7	3	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Bronchitis	気管支炎	20[redacted]	181	20[redacted]	184	3	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Urosepsis	尿路性敗血症	20[redacted]	470	20[redacted]	476	4	NOT RELATED	2
				Skin infection	皮膚感染	20[redacted]	531	-	-	3	NOT RELATED	-
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	Pleural effusion	胸水	20[redacted]	85	20[redacted]	90	3	RELATED	2
				Fatigue	疲労	20[redacted]	111	-	-	3	RELATED	-
				Hyperkalaemia	高カリウム血症	20[redacted]	111	20[redacted]	113	3	RELATED	2
				Hyperkalaemia	高カリウム血症	20[redacted]	114	20[redacted]	121	2	RELATED	-
				Hyponatraemia	低ナトリウム血症	20[redacted]	118	-	-	3	RELATED	-
				Renal cell carcinoma	腎細胞癌	20[redacted]	132	20[redacted]	132	5	NOT RELATED	-
[redacted]	4[redacted]/M/White	20[redacted]	20[redacted]	Dyspnoea	呼吸困難	20[redacted]	155	20[redacted]	156	3	NOT RELATED	-
				Dyspnoea	呼吸困難	20[redacted]	169	20[redacted]	187	3	NOT RELATED	-
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	Adenocarcinoma	腺癌	20[redacted]	316	-	-	1	NOT RELATED	3
				Leiomyoma	平滑筋腫	20[redacted]	316	-	-	1	NOT RELATED	3

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	6[redacted]/M/White	20[redacted]	-	Kidney infection	腎感染	20[redacted]	37	20[redacted]	42	3	NOT RELATED	1:2
				Urosepsis	尿路性敗血症	20[redacted]	37	20[redacted]	42	3	NOT RELATED	1:2
				Diarrhoea	下痢	20[redacted]	314	20[redacted]	319	3	NOT RELATED	2
[redacted]	4[redacted]/M/White	20[redacted]	20[redacted]	Dyspnoea	呼吸困難	20[redacted]	92	-	-	2	NOT RELATED	-
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Ventricular arrhythmia	心室性不整脈	20[redacted]	393	20[redacted]	421	2	RELATED	3
				Atrial fibrillation	心房細動	20[redacted]	395	20[redacted]	421	2	RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Decreased appetite	食欲減退	20[redacted]	171	20[redacted]	198	3	RELATED	3
				Diarrhoea	下痢	20[redacted]	175	20[redacted]	198	2	RELATED	-
				Colitis ulcerative	潰瘍性大腸炎	20[redacted]	177	20[redacted]	186	2	RELATED	-
[redacted]	8[redacted]/M/White	20[redacted]	20[redacted]	Nausea	悪心	20[redacted]	522	20[redacted]	532	2	RELATED	2
				Presyncope	失神寸前の状態	20[redacted]	522	20[redacted]	532	2	RELATED	2
[redacted]	3[redacted]/M/White	20[redacted]	20[redacted]	Proctitis	直腸炎	20[redacted]	119	20[redacted]	124	3	RELATED	2
[redacted]	7[redacted]/M/Other	20[redacted]	20[redacted]	Epilepsy	てんかん	20[redacted]	200	20[redacted]	200	3	NOT RELATED	-
				Metastases to central nervous system	中枢神経系転移	20[redacted]	253	-	-	3	NOT RELATED	-
[redacted]	3[redacted]/M/Not reported	20[redacted]	20[redacted]	Pain	疼痛	20[redacted]	254	20[redacted]	274	4	NOT RELATED	3
[redacted]	5[redacted]/M/Other	20[redacted]	20[redacted]	Hypokalaemia	低カリウム血症	20[redacted]	105	20[redacted]	112	4	RELATED	-
				Hypomagnesaemia	低マグネシウム血症	20[redacted]	105	20[redacted]	112	4	RELATED	-
				Bone pain	骨痛	20[redacted]	465	20[redacted]	467	3	NOT RELATED	2
[redacted]	6[redacted]/M/Other	20[redacted]	20[redacted]	Atrial fibrillation	心房細動	20[redacted]	253	20[redacted]	254	3	RELATED	2
[redacted]	6[redacted]/M/Other	20[redacted]	20[redacted]	Hypercalcaemia	高カルシウム血症	20[redacted]	1	20[redacted]	4	2	NOT RELATED	-
				Osteolysis	骨溶解	20[redacted]	64	20[redacted]	66	3	NOT RELATED	-

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	7[redacted]/M/Other	20[redacted]	20[redacted]	Back pain	背部痛	20[redacted]	127	20[redacted]	160	3	NOT RELATED	2
[redacted]	5[redacted]/M/Other	20[redacted]	20[redacted]	Diabetes mellitus inadequate control	コントロール不良の糖尿病	20[redacted]	210	20[redacted]	223	3	RELATED	-
[redacted]	3[redacted]/F/Not reported	20[redacted]	20[redacted]	Dyspnoea	呼吸困難	20[redacted]	187	20[redacted]	189	3	NOT RELATED	2:3
				Dyspnoea	呼吸困難	20[redacted]	198	20[redacted]	218	3	NOT RELATED	2:3
				Motor dysfunction	運動機能障害	20[redacted]	229	20[redacted]	230	3	NOT RELATED	-
[redacted]	7[redacted]/M/Not reported	20[redacted]	20[redacted]	Pleural effusion	胸水	20[redacted]	210	20[redacted]	217	2	NOT RELATED	2
[redacted]	8[redacted]/M/Not reported	20[redacted]	20[redacted]	Osteonecrosis of jaw	顎骨壊死	20[redacted]	49	-	-	3	RELATED	2
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Metastatic renal cell carcinoma	遠隔転移を伴う腎細胞癌	20[redacted]	80	20[redacted]	80	5	NOT RELATED	-
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Hypertension	高血圧	20[redacted]	29	20[redacted]	35	3	RELATED	1:2
				Septic shock	敗血症性ショック	20[redacted]	202	20[redacted]	239	4	NOT RELATED	2
				Haemorrhagic anaemia	出血性貧血	20[redacted]	207	20[redacted]	209	4	NOT RELATED	-
				Haemarthrosis	出血性関節症	20[redacted]	207	20[redacted]	209	4	NOT RELATED	-
[redacted]	5[redacted]/F/White	20[redacted]	20[redacted]	Renal pain	腎臓痛	20[redacted]	79	20[redacted]	92	3	NOT RELATED	-
				Renal cell carcinoma	腎細胞癌	20[redacted]	92	20[redacted]	92	5	NOT RELATED	-
[redacted]	3[redacted]/M/Not reported	20[redacted]	20[redacted]	Small intestinal obstruction	小腸閉塞	20[redacted]	121	20[redacted]	128	3	NOT RELATED	2
				Rib fracture	肋骨骨折	20[redacted]	356	20[redacted]	380	2	NOT RELATED	-

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Abdominal pain	腹痛	20[redacted]	2	20[redacted]	9	3	NOT RELATED	2
				Anaemia	貧血	20[redacted]	182	20[redacted]	187	3	RELATED	-
				Anaemia	貧血	20[redacted]	195	20[redacted]	197	3	RELATED	-
				Anaemia	貧血	20[redacted]	197	-	-	2	RELATED	-
				Pyrexia	発熱	20[redacted]	217	20[redacted]	222	1	NOT RELATED	-
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Sepsis	敗血症	20[redacted]	91	20[redacted]	105	3	RELATED	2
				Sepsis	敗血症	20[redacted]	120	20[redacted]	139	3	RELATED	2
				Pulmonary embolism	肺塞栓症	20[redacted]	366	-	-	3	RELATED	2
				Lung infection	肺感染	20[redacted]	366	20[redacted]	381	2	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Gastrointestinal perforation	消化管穿孔	20[redacted]	280	20[redacted]	294	3	RELATED	2;3
[redacted]	6[redacted]/F/Not reported	20[redacted]	20[redacted]	Confusional state	錯乱状態	20[redacted]	29	-	-	3	NOT RELATED	2
				Renal cancer	腎癌	20[redacted]	73	20[redacted]	73	5	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	-	Metastases to testicle	精巣転移	20[redacted]	50	20[redacted]	51	3	NOT RELATED	2
				Adrenal insufficiency	副腎機能不全	20[redacted]	204	20[redacted]	210	3	NOT RELATED	2
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Pleural effusion	胸水	20[redacted]	244	20[redacted]	252	3	NOT RELATED	-
				Pleural infection	胸膜感染	20[redacted]	349	20[redacted]	358	3	NOT RELATED	-
				Asthenia	無力症	20[redacted]	432	-	-	3	NOT RELATED	2
				Pleural infection	胸膜感染	20[redacted]	432	20[redacted]	440	3	NOT RELATED	2
				Pleural infection	胸膜感染	20[redacted]	441	20[redacted]	441	5	NOT RELATED	3

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	5[redacted]/M/White	20[redacted]	-	Osteonecrosis of jaw	顎骨壊死	20[redacted]	317	20[redacted]	333	3	NOT RELATED	2
				Osteomyelitis	骨髄炎	20[redacted]	359	20[redacted]	387	3	NOT RELATED	2
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Death	死亡	20[redacted]	94	20[redacted]	94	5	RELATED	3
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Implant site infection	埋込み部位感染	20[redacted]	38	20[redacted]	56	3	NOT RELATED	2
				Device related infection	医療機器関連感染	20[redacted]	232	20[redacted]	261	3	NOT RELATED	3
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Respiratory failure	呼吸不全	20[redacted]	94	20[redacted]	95	3	NOT RELATED	-
				Back pain	背部痛	20[redacted]	145	-	-	3	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	-	Cholangitis	胆管炎	20[redacted]	260	20[redacted]	292	3	NOT RELATED	2
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Dizziness	浮動性めまい	20[redacted]	226	20[redacted]	233	2	RELATED	2
				Malaise	倦怠感	20[redacted]	367	20[redacted]	376	2	NOT RELATED	2
				Renal cell carcinoma	腎細胞癌	20[redacted]	376	20[redacted]	376	5	NOT RELATED	3
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	Renal cancer	腎癌	20[redacted]	700	20[redacted]	700	5	NOT RELATED	-
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Pancreatitis	膵炎	20[redacted]	30	20[redacted]	48	3	NOT RELATED	2
				Pancreatitis	膵炎	20[redacted]	58	20[redacted]	66	3	NOT RELATED	-
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	General physical health deterioration	全身健康状態低下	20[redacted]	4	20[redacted]	7	4	NOT RELATED	2:3
				Cognitive disorder	認知障害	20[redacted]	4	20[redacted]	8	3	NOT RELATED	2:3
				General physical health deterioration	全身健康状態低下	20[redacted]	8	20[redacted]	8	5	NOT RELATED	2:3

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Dehydration	脱水	20[redacted]	30	20[redacted]	32	3	RELATED	-
				Fatigue	疲労	20[redacted]	30	20[redacted]	50	3	RELATED	1:2
				Spinal fracture	脊椎骨折	20[redacted]	459	20[redacted]	467	3	RELATED	-
				Spinal fracture	脊椎骨折	20[redacted]	474	-	-	3	RELATED	3
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	Death	死亡	20[redacted]	106	20[redacted]	106	5	NOT RELATED	3
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Hypocalcaemia	低カルシウム血症	20[redacted]	113	20[redacted]	149	3	RELATED	-
				Hypokalaemia	低カリウム血症	20[redacted]	113	20[redacted]	149	3	RELATED	-
				Hypomagnesaemia	低マグネシウム血症	20[redacted]	141	20[redacted]	149	3	RELATED	-
				Hypocalcaemia	低カルシウム血症	20[redacted]	149	20[redacted]	169	2	RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Anaemia	貧血	20[redacted]	132	20[redacted]	134	2	RELATED	2
				Deep vein thrombosis	深部静脈血栓症	20[redacted]	227	20[redacted]	238	2	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Dermatitis bullous	水疱性皮膚炎	20[redacted]	32	20[redacted]	197	1	RELATED	2
[redacted]	7[redacted]/F/White	20[redacted]	-	Abdominal pain	腹痛	20[redacted]	24	20[redacted]	36	3	RELATED	1:2
				Decreased appetite	食欲減退	20[redacted]	24	20[redacted]	45	3	RELATED	1:2
				Nausea	悪心	20[redacted]	24	20[redacted]	45	3	RELATED	1:2
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Diarrhoea	下痢	20[redacted]	66	20[redacted]	76	3	RELATED	2
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Cholecystitis acute	急性胆嚢炎	20[redacted]	125	20[redacted]	132	3	NOT RELATED	-
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Anaemia	貧血	20[redacted]	43	20[redacted]	57	3	NOT RELATED	-
				Asthenia	無力症	20[redacted]	113	-	-	3	NOT RELATED	2:3
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Pathological fracture	病的骨折	20[redacted]	33	20[redacted]	50	2	NOT RELATED	2
				Vomiting	嘔吐	20[redacted]	84	20[redacted]	85	3	NOT RELATED	2
[redacted]	6[redacted]/F/Not reported	20[redacted]	20[redacted]	Hepatitis cholestatic	胆汁うっ滞性肝炎	20[redacted]	36	20[redacted]	117	4	RELATED	2:3
[redacted]	4[redacted]/F/White	20[redacted]	20[redacted]	Metastases to ovary	卵巣転移	20[redacted]	337	20[redacted]	410	3	NOT RELATED	2

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Urinary tract infection	尿路感染	20[redacted]	33	20[redacted]	45	2	NOT RELATED	-
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Cerebral haematoma	脳血腫	20[redacted]	29	20[redacted]	46	3	RELATED	3
				Metastatic renal cell carcinoma	遠隔転移を伴う腎細胞癌	20[redacted]	46	20[redacted]	46	5	NOT RELATED	-
[redacted]	4[redacted]/M/White	20[redacted]	20[redacted]	Renal cell carcinoma	腎細胞癌	20[redacted]	205	20[redacted]	205	5	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Pleural effusion	胸水	20[redacted]	301	20[redacted]	306	3	NOT RELATED	2
				Dyspnoea	呼吸困難	20[redacted]	381	-	-	3	NOT RELATED	-
				General physical health deterioration	全身健康状態低下	20[redacted]	381	-	-	3	NOT RELATED	-
				Renal cell carcinoma	腎細胞癌	20[redacted]	400	20[redacted]	400	5	NOT RELATED	-
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Asthenia	無力症	20[redacted]	20	-	-	2	NOT RELATED	-
				Nausea	悪心	20[redacted]	20	-	-	2	NOT RELATED	-
				Stomatitis	口内炎	20[redacted]	20	-	-	3	NOT RELATED	-
				Vomiting	嘔吐	20[redacted]	20	-	-	2	NOT RELATED	2
				Renal cell carcinoma	腎細胞癌	20[redacted]	83	20[redacted]	83	5	NOT RELATED	-
[redacted]	4[redacted]/M/White	20[redacted]	20[redacted]	Pyrexia	発熱	20[redacted]	14	20[redacted]	16	3	NOT RELATED	2

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Pain in extremity	四肢痛	20[redacted]	266	20[redacted]	309	3	NOT RELATED	2
				Mobility decreased	運動性低下	20[redacted]	266	20[redacted]	309	3	NOT RELATED	1:2:3
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Thoracic vertebral fracture	胸椎骨折	20[redacted]	77	-	-	2	NOT RELATED	-
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Asthenia	無力症	20[redacted]	2	20[redacted]	115	2	RELATED	1
				Hypomagnesaemia	低マグネシウム血症	20[redacted]	85	20[redacted]	91	4	RELATED	2
				Inguinal hernia	鼠径ヘルニア	20[redacted]	107	20[redacted]	146	2	NOT RELATED	2
				Squamous cell carcinoma	扁平上皮癌	20[redacted]	290	20[redacted]	357	3	NOT RELATED	2
				Presyncope	失神寸前の状態	20[redacted]	504	20[redacted]	504	2	NOT RELATED	-
				Pyrexia	発熱	20[redacted]	593	20[redacted]	594	1	NOT RELATED	-
				Wound infection bacterial	細菌性創感染	20[redacted]	595	-	-	3	NOT RELATED	-
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Pneumonia	肺炎	20[redacted]	42	20[redacted]	42	5	NOT RELATED	2:3
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Renal cell carcinoma	腎細胞癌	20[redacted]	99	20[redacted]	99	5	NOT RELATED	-
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Abdominal pain	腹痛	20[redacted]	31	20[redacted]	34	3	RELATED	2
				Peripheral ischaemia	末梢性虚血	20[redacted]	41	20[redacted]	52	3	NOT RELATED	3
				Post procedural haemorrhage	処置後出血	20[redacted]	52	20[redacted]	52	5	NOT RELATED	-
[redacted]	7[redacted]/M/Asian	20[redacted]	20[redacted]	Abdominal pain	腹痛	20[redacted]	472	20[redacted]	475	2	NOT RELATED	-
				Constipation	便秘	20[redacted]	472	20[redacted]	475	2	NOT RELATED	-

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Pericardial effusion	心嚢液貯留	20[redacted]	608	20[redacted]	613	3	NOT RELATED	-
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Lower respiratory tract infection	下気道感染	20[redacted]	71	20[redacted]	97	3	NOT RELATED	2
				Pneumonia	肺炎	20[redacted]	149	-	-	3	NOT RELATED	-
				Pulmonary embolism	肺塞栓症	20[redacted]	150	-	-	3	RELATED	-
				General physical health deterioration	全身健康状態低下	20[redacted]	217	20[redacted]	223	4	NOT RELATED	3
				Renal cell carcinoma	腎細胞癌	20[redacted]	223	20[redacted]	223	5	NOT RELATED	-
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	Pneumonia	肺炎	20[redacted]	348	-	-	3	NOT RELATED	-
				Extradural haematoma	硬膜外血腫	20[redacted]	362	20[redacted]	363	4	NOT RELATED	-
				Extradural haematoma	硬膜外血腫	20[redacted]	364	20[redacted]	364	5	NOT RELATED	-
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	Pneumothorax	気胸	20[redacted]	136	20[redacted]	149	4	NOT RELATED	2
				Rib fracture	肋骨骨折	20[redacted]	136	20[redacted]	166	3	NOT RELATED	-
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	Pleural effusion	胸水	20[redacted]	130	20[redacted]	140	3	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Deep vein thrombosis	深部静脈血栓症	20[redacted]	250	-	-	3	NOT RELATED	-
				Pleural effusion	胸水	20[redacted]	250	20[redacted]	251	2	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	-	Haematuria	血尿	20[redacted]	331	20[redacted]	345	3	NOT RELATED	2
				Urinary tract infection	尿路感染	20[redacted]	345	20[redacted]	356	3	NOT RELATED	2

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Pneumonia	肺炎	20[redacted]	15	20[redacted]	20	3	NOT RELATED	2
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Pyrexia	発熱	20[redacted]	70	20[redacted]	82	3	RELATED	-
				Back pain	背部痛	20[redacted]	150	20[redacted]	157	3	NOT RELATED	-
				Back pain	背部痛	20[redacted]	174	20[redacted]	178	3	NOT RELATED	-
				Pain	疼痛	20[redacted]	228	20[redacted]	233	3	NOT RELATED	-
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Pneumonia	肺炎	20[redacted]	91	20[redacted]	96	3	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Anaemia	貧血	20[redacted]	441	20[redacted]	442	2	NOT RELATED	2
				Hyponatraemia	低ナトリウム血症	20[redacted]	441	20[redacted]	447	3	NOT RELATED	2
				General physical health deterioration	全身健康状態低下	20[redacted]	447	20[redacted]	470	4	NOT RELATED	2
				Renal cell carcinoma	腎細胞癌	20[redacted]	470	20[redacted]	470	5	NOT RELATED	-
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Pleural effusion	胸水	20[redacted]	105	20[redacted]	121	3	NOT RELATED	2:3
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Oesophageal pain	食道痛	20[redacted]	70	20[redacted]	74	3	RELATED	2
				Pulmonary embolism	肺塞栓症	20[redacted]	88	20[redacted]	99	3	RELATED	2:3
				Syncope	失神	20[redacted]	125	20[redacted]	126	3	NOT RELATED	-

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Pelvic venous thrombosis	骨盤静脈血栓症	20[redacted]	8	-	-	2	NOT RELATED	-
				Hypercalcaemia	高カルシウム血症	20[redacted]	258	-	-	3	NOT RELATED	-
				Nausea	悪心	20[redacted]	258	-	-	3	NOT RELATED	-
				Vomiting	嘔吐	20[redacted]	258	-	-	3	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	-	Cerebrovascular disorder	脳血管障害	20[redacted]	64	-	-	3	NOT RELATED	2
				Transient ischaemic attack	一過性脳虚血発作	20[redacted]	64	20[redacted]	65	2	NOT RELATED	2
				Carotid artery occlusion	頚動脈閉塞	20[redacted]	64	20[redacted]	168	3	NOT RELATED	1:2
				Dizziness	浮動性めまい	20[redacted]	216	20[redacted]	216	3	NOT RELATED	-
				Urinary incontinence	尿失禁	20[redacted]	216	20[redacted]	216	3	NOT RELATED	-
				Loss of consciousness	意識消失	20[redacted]	216	20[redacted]	216	3	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Coronary artery occlusion	冠動脈閉塞	20[redacted]	370	-	-	3	NOT RELATED	3
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Metastases to bone	骨転移	20[redacted]	15	-	-	2	NOT RELATED	-
[redacted]	5[redacted]/F/White	20[redacted]	20[redacted]	Renal failure	腎不全	20[redacted]	23	20[redacted]	42	3	NOT RELATED	3
				General physical health deterioration	全身健康状態低下	20[redacted]	49	20[redacted]	77	4	NOT RELATED	-
				Renal cell carcinoma	腎細胞癌	20[redacted]	77	20[redacted]	77	5	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Pneumothorax	気胸	20[redacted]	58	20[redacted]	75	3	NOT RELATED	3

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Metastases to spine	脊椎転移	20[redacted]	189	20[redacted]	204	3	NOT RELATED	-
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Death	死亡	20[redacted]	496	20[redacted]	496	5	NOT RELATED	3
[redacted]	4[redacted]/M/White	20[redacted]	20[redacted]	Pneumonia	肺炎	20[redacted]	728	20[redacted]	732	2	NOT RELATED	2
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Hypocalcaemia	低カルシウム血症	20[redacted]	365	20[redacted]	389	4	RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Non-cardiac chest pain	非心臓性胸痛	20[redacted]	150	-	-	2	NOT RELATED	2
				Dyspnoea	呼吸困難	20[redacted]	150	20[redacted]	155	2	NOT RELATED	2
				Metastases to bone	骨転移	20[redacted]	169	20[redacted]	175	3	NOT RELATED	2
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Local swelling	局所腫脹	20[redacted]	157	20[redacted]	159	2	NOT RELATED	-
				Pain	疼痛	20[redacted]	556	-	-	3	NOT RELATED	2
				Anaemia	貧血	20[redacted]	557	20[redacted]	565	3	RELATED	2
				Lower respiratory tract infection	下気道感染	20[redacted]	585	20[redacted]	590	3	NOT RELATED	-
				Lower respiratory tract infection	下気道感染	20[redacted]	591	20[redacted]	591	5	NOT RELATED	3
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Foreign body in eye	眼内異物	20[redacted]	138	20[redacted]	145	3	NOT RELATED	-
				Haematuria	血尿	20[redacted]	146	20[redacted]	181	3	NOT RELATED	-
				Chronic lymphocytic leukaemia	慢性リンパ性白血病	20[redacted]	204	-	-	1	NOT RELATED	-
				Deep vein thrombosis	深部静脈血栓症	20[redacted]	226	-	-	2	NOT RELATED	-

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Abdominal pain	腹痛	20[redacted]	18	-	-	3	NOT RELATED	-
				Cardiac failure	心不全	20[redacted]	44	20[redacted]	44	5	NOT RELATED	3
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	Anaemia	貧血	20[redacted]	169	20[redacted]	176	3	NOT RELATED	-
				Fatigue	疲労	20[redacted]	187	20[redacted]	201	3	NOT RELATED	-
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Diarrhoea	下痢	20[redacted]	74	20[redacted]	77	3	RELATED	1:2
				Nausea	悪心	20[redacted]	74	20[redacted]	77	3	RELATED	1:2
				Fall	転倒	20[redacted]	116	20[redacted]	116	3	NOT RELATED	-
				Lymphadenopathy	リンパ節症	20[redacted]	182	20[redacted]	202	3	NOT RELATED	2
				Abdominal lymphadenopathy	腹部リンパ節腫脹	20[redacted]	211	-	-	3	NOT RELATED	3
[redacted]	3[redacted]/M/White	20[redacted]	20[redacted]	Abdominal pain	腹痛	20[redacted]	176	-	-	3	NOT RELATED	-
				Pulmonary embolism	肺塞栓症	20[redacted]	193	-	-	4	NOT RELATED	-
[redacted]	5[redacted]/M/Other	20[redacted]	20[redacted]	Abdominal pain	腹痛	20[redacted]	265	-	-	3	NOT RELATED	-
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Faecaloma	糞塊	20[redacted]	190	20[redacted]	200	2	NOT RELATED	-
				Urosepsis	尿路性敗血症	20[redacted]	233	20[redacted]	238	4	NOT RELATED	-
				Urosepsis	尿路性敗血症	20[redacted]	239	20[redacted]	239	5	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Pneumonia	肺炎	20[redacted]	386	20[redacted]	393	3	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Swollen tongue	舌腫脹	20[redacted]	30	20[redacted]	31	2	NOT RELATED	-

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Back pain	背部痛	20[redacted]	112	20[redacted]	116	2	NOT RELATED	-
				Pain	疼痛	20[redacted]	168	20[redacted]	200	2	NOT RELATED	-
				Rectal haemorrhage	直腸出血	20[redacted]	182	20[redacted]	187	2	NOT RELATED	2
[redacted]	6[redacted]/M/Other	20[redacted]	20[redacted]	Metastases to spine	脊椎転移	20[redacted]	449	20[redacted]	466	3	NOT RELATED	3
[redacted]	3[redacted]/F/White	20[redacted]	20[redacted]	Pneumothorax	気胸	20[redacted]	145	20[redacted]	192	3	NOT RELATED	2
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Appendicitis	虫垂炎	20[redacted]	151	20[redacted]	154	3	NOT RELATED	2
				Pulmonary embolism	肺塞栓症	20[redacted]	565	-	-	3	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Diarrhoea	下痢	20[redacted]	31	20[redacted]	38	3	RELATED	1:2
				Bile duct obstruction	胆管閉塞	20[redacted]	300	20[redacted]	305	3	NOT RELATED	-
				Haematuria	血尿	20[redacted]	337	20[redacted]	367	3	NOT RELATED	2
				Abdominal pain	腹痛	20[redacted]	689	20[redacted]	701	3	NOT RELATED	2
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Hyponatraemia	低ナトリウム血症	20[redacted]	215	20[redacted]	218	3	RELATED	2
				Abdominal pain upper	上腹部痛	20[redacted]	304	20[redacted]	306	3	NOT RELATED	2
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	Electrolyte imbalance	電解質失調	20[redacted]	141	20[redacted]	154	4	RELATED	1:2
				Vulval cellulitis	女性外陰部蜂巣炎	20[redacted]	291	20[redacted]	308	3	NOT RELATED	-
				Bacterial sepsis	細菌性敗血症	20[redacted]	291	20[redacted]	308	3	NOT RELATED	-

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Pleural effusion	胸水	20[redacted]	579	20[redacted]	579	2	NOT RELATED	-
				Malignant pleural effusion	悪性胸水	20[redacted]	586	20[redacted]	602	2	NOT RELATED	2
				Pathological fracture	病的骨折	20[redacted]	666	20[redacted]	668	3	NOT RELATED	2:3
				Metastases to central nervous system	中枢神経系転移	20[redacted]	670	-	-	3	NOT RELATED	2:3
				Pneumonia	肺炎	20[redacted]	683	20[redacted]	706	2	NOT RELATED	-
				Melaena	メレナ	20[redacted]	683	20[redacted]	706	2	NOT RELATED	-
				Fall	転倒	20[redacted]	692	-	-	3	NOT RELATED	-
[redacted]	4[redacted]/F/White	20[redacted]	20[redacted]	Pancreatitis acute	急性膵炎	20[redacted]	18	20[redacted]	27	3	RELATED	1:2
[redacted]	6[redacted]/M/White	20[redacted]	-	Osteomyelitis	骨髄炎	20[redacted]	486	20[redacted]	494	3	RELATED	2
				Osteomyelitis	骨髄炎	20[redacted]	588	20[redacted]	599	1	RELATED	1:2
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Pleural effusion	胸水	20[redacted]	148	-	-	3	NOT RELATED	-
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Neck pain	頚部痛	20[redacted]	468	-	-	3	NOT RELATED	-
				Renal cell carcinoma	腎細胞癌	20[redacted]	489	20[redacted]	489	5	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	-	Jaw fracture	顎の骨折	20[redacted]	335	20[redacted]	482	3	NOT RELATED	2
				Osteomyelitis	骨髄炎	20[redacted]	482	20[redacted]	486	3	NOT RELATED	-

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	5[redacted]/M/Asian	20[redacted]	20[redacted]	Metastases to pelvis	骨盤転移	20[redacted]	280	-	-	3	NOT RELATED	1:2
				Pleural effusion	胸水	20[redacted]	473	-	-	2	NOT RELATED	-
				Respiratory failure	呼吸不全	20[redacted]	744	20[redacted]	744	5	NOT RELATED	-
[redacted]	5[redacted]/M/Asian	20[redacted]	20[redacted]	Appendicitis perforated	穿孔性虫垂炎	20[redacted]	70	20[redacted]	223	2	RELATED	1:2
				Abdominal abscess	腹部膿瘍	20[redacted]	70	20[redacted]	223	3	NOT RELATED	2
[redacted]	7[redacted]/M/Asian	20[redacted]	20[redacted]	Aortic dissection	大動脈解離	20[redacted]	291	20[redacted]	316	3	NOT RELATED	2
[redacted]	5[redacted]/F/Asian	20[redacted]	20[redacted]	Fracture	骨折	20[redacted]	21	20[redacted]	28	1	NOT RELATED	-
[redacted]	5[redacted]/M/Asian	20[redacted]	20[redacted]	Incisional hernia	瘢痕ヘルニア	20[redacted]	331	20[redacted]	393	2	NOT RELATED	2
[redacted]	5[redacted]/M/Asian	20[redacted]	20[redacted]	Metastases to spine	脊椎転移	20[redacted]	212	-	-	3	NOT RELATED	-
				Spinal cord compression	脊髄圧迫	20[redacted]	212	20[redacted]	285	3	NOT RELATED	2
				Pathological fracture	病的骨折	20[redacted]	394	20[redacted]	400	3	NOT RELATED	-
[redacted]	4[redacted]/M/Asian	20[redacted]	20[redacted]	Pelvic pain	骨盤痛	20[redacted]	115	20[redacted]	194	2	NOT RELATED	2
[redacted]	5[redacted]/F/Asian	20[redacted]	20[redacted]	Urinary tract obstruction	尿路閉塞	20[redacted]	752	20[redacted]	769	3	NOT RELATED	-
[redacted]	4[redacted]/M/Asian	20[redacted]	20[redacted]	Spinal cord compression	脊髄圧迫	20[redacted]	438	20[redacted]	453	3	NOT RELATED	3

Abbreviations: CTCAE=Common Terminology Criteria for Adverse Events; F=female; M=male; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term; SAE=serious adverse event.
From the Exelixis dictionary based on MedDRA version 17.0.

a Days after first dose=SAE start date – first dose date + 1, or SAE start date – first dose date for days before the first dose.

b Days after first dose=SAE end date – first dose date + 1, or SAE end date – first dose date for days before the first dose.

c 1=dose reduced, 2=dose interrupted, 3=treatment permanently discontinued.

d Subject [redacted] was randomized to receive everolimus but received cabozantinib as study treatment and therefore was evaluated in the cabozantinib arm for the Safety population.

Source: XL184-308 試験　総括報告書補遺 2 Listing 16.2.4.1、Listing 16.2.5.1、Listing 16.2.7.3、Listing 16.2.7.4

2）エベロリムス群：Safety population

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Back pain	背部痛	20[redacted]	195	-	-	3	NOT RELATED	-
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Syncope	失神	20[redacted]	107	20[redacted]	109	3	NOT RELATED	2:3
[redacted]	6[redacted]/M/Asian	20[redacted]	20[redacted]	Bone pain	骨痛	20[redacted]	13	20[redacted]	19	2	NOT RELATED	2
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Dyspnoea	呼吸困難	20[redacted]	37	20[redacted]	47	2	RELATED	2:3
				Pneumonitis	肺臓炎	20[redacted]	47	-	-	3	RELATED	-
				Hypoxia	低酸素症	20[redacted]	47	20[redacted]	51	2	RELATED	-
[redacted]	5[redacted]/M/Asian	20[redacted]	20[redacted]	Hypercalcaemia of malignancy	悪性腫瘍に伴う高カルシウム血症	20[redacted]	38	20[redacted]	41	3	NOT RELATED	-
				Hyperkalaemia	高カリウム血症	20[redacted]	38	20[redacted]	41	2	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Dyspnoea	呼吸困難	20[redacted]	43	20[redacted]	44	3	RELATED	1:2
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Non-cardiac chest pain	非心臓性胸痛	20[redacted]	37	20[redacted]	43	3	NOT RELATED	2
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Rash maculo-papular	斑状丘疹状皮疹	20[redacted]	43	-	-	3	NOT RELATED	2:3
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	Diverticulitis	憩室炎	20[redacted]	87	20[redacted]	91	3	NOT RELATED	2
				Metastases to spine	脊椎転移	20[redacted]	414	-	-	3	NOT RELATED	2:3
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Blood creatinine increased	血中クレアチニン増加	20[redacted]	335	-	-	2	NOT RELATED	-
				Hyperkalaemia	高カリウム血症	20[redacted]	335	20[redacted]	336	3	NOT RELATED	-
[redacted]	4[redacted]/F/White	20[redacted]	20[redacted]	Liver injury	肝損傷	20[redacted]	427	20[redacted]	433	2	NOT RELATED	2
				Pneumothorax	気胸	20[redacted]	538	20[redacted]	559	2	NOT RELATED	2

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	4[redacted]/M/White	20[redacted]	20[redacted]	Arthralgia	関節痛	20[redacted]	2	20[redacted]	21	3	NOT RELATED	3
				Renal cell carcinoma	腎細胞癌	20[redacted]	21	20[redacted]	21	5	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Cardiac failure congestive	うっ血性心不全	20[redacted]	592	20[redacted]	596	3	NOT RELATED	3
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Hyponatraemia	低ナトリウム血症	20[redacted]	21	20[redacted]	27	3	RELATED	2
[redacted]	5[redacted]/F/White	20[redacted]	20[redacted]	Dyspnoea	呼吸困難	20[redacted]	35	20[redacted]	36	3	NOT RELATED	2
				Pleural effusion	胸水	20[redacted]	35	20[redacted]	46	3	NOT RELATED	-
[redacted]	8[redacted]/M/White	20[redacted]	20[redacted]	Spinal cord compression	脊髄圧迫	20[redacted]	69	20[redacted]	75	3	NOT RELATED	-
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Colitis	大腸炎	20[redacted]	339	-	-	3	RELATED	-
[redacted]	6[redacted]/M/Black or African American	20[redacted]	20[redacted]	Gastroenteritis	胃腸炎	20[redacted]	172	20[redacted]	174	3	NOT RELATED	2
				Haemoptysis	喀血	20[redacted]	280	20[redacted]	296	3	NOT RELATED	2
				Haemoptysis	喀血	20[redacted]	300	20[redacted]	301	4	NOT RELATED	3
				Renal failure acute	急性腎不全	20[redacted]	300	20[redacted]	304	1	NOT RELATED	3
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	Renal failure acute	急性腎不全	20[redacted]	88	20[redacted]	104	3	RELATED	2:3
				Myocardial infarction	心筋梗塞	20[redacted]	113	20[redacted]	114	3	NOT RELATED	-
				Cardiac failure congestive	うっ血性心不全	20[redacted]	125	20[redacted]	125	5	NOT RELATED	-
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Mucosal inflammation	粘膜の炎症	20[redacted]	16	20[redacted]	23	3	RELATED	1:2

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Pleural effusion	胸水	20[redacted]	9	20[redacted]	85	3	NOT RELATED	-
				Abdominal pain	腹痛	20[redacted]	293	20[redacted]	297	3	NOT RELATED	-
				Delirium	譫妄	20[redacted]	298	20[redacted]	302	3	NOT RELATED	-
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Anaemia	貧血	20[redacted]	89	20[redacted]	96	3	RELATED	-
				Anaemia	貧血	20[redacted]	104	20[redacted]	112	3	RELATED	-
				Anaemia	貧血	20[redacted]	141	20[redacted]	204	3	RELATED	1
				Anaemia	貧血	20[redacted]	244	-	-	3	RELATED	-
				Tooth abscess	歯膿瘍	20[redacted]	244	20[redacted]	247	3	NOT RELATED	-
[redacted]	5[redacted]/F/White	20[redacted]	20[redacted]	Pelvic pain	骨盤痛	20[redacted]	134	20[redacted]	174	2	NOT RELATED	2
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Dehydration	脱水	20[redacted]	144	20[redacted]	146	3	RELATED	2
				Pain	疼痛	20[redacted]	144	20[redacted]	146	3	NOT RELATED	2
				Dehydration	脱水	20[redacted]	183	20[redacted]	186	3	NOT RELATED	-
				Back pain	背部痛	20[redacted]	183	20[redacted]	186	3	NOT RELATED	-
				Vomiting	嘔吐	20[redacted]	189	20[redacted]	197	3	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Cholecystitis acute	急性胆嚢炎	20[redacted]	47	20[redacted]	52	3	NOT RELATED	2
				Sepsis	敗血症	20[redacted]	71	20[redacted]	74	4	NOT RELATED	2
				Wound infection	創傷感染	20[redacted]	146	20[redacted]	149	3	NOT RELATED	2
[redacted]	5[redacted]/F/White	20[redacted]	20[redacted]	Cardiac tamponade	心タンポナーデ	20[redacted]	50	20[redacted]	55	4	RELATED	3
				Dyspnoea	呼吸困難	20[redacted]	72	20[redacted]	75	4	RELATED	-

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Acetabulum fracture	寛骨臼骨折	20[redacted]	20	20[redacted]	47	3	NOT RELATED	2
				Lung infection	肺感染	20[redacted]	55	20[redacted]	57	3	NOT RELATED	2
[redacted]	6[redacted]/F/Black or African American	20[redacted]	20[redacted]	Pneumonia	肺炎	20[redacted]	85	20[redacted]	90	3	NOT RELATED	-
[redacted]	5[redacted]/M/Asian	20[redacted]	20[redacted]	Dyspnoea	呼吸困難	20[redacted]	86	20[redacted]	120	3	NOT RELATED	-
				Dyspnoea	呼吸困難	20[redacted]	120	20[redacted]	127	4	NOT RELATED	-
				Respiratory failure	呼吸不全	20[redacted]	127	20[redacted]	127	5	NOT RELATED	-
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Anaemia	貧血	20[redacted]	86	-	-	3	NOT RELATED	3
				Dyspnoea	呼吸困難	20[redacted]	86	-	-	3	NOT RELATED	2
				Pneumonia	肺炎	20[redacted]	86	-	-	3	NOT RELATED	2:3
				Pleural effusion	胸水	20[redacted]	86	-	-	3	NOT RELATED	2:3
				Renal failure acute	急性腎不全	20[redacted]	87	-	-	3	NOT RELATED	2:3
				Generalised oedema	全身性浮腫	20[redacted]	87	-	-	3	NOT RELATED	2:3
				Nausea	悪心	20[redacted]	99	-	-	1	NOT RELATED	-
				Confusional state	錯乱状態	20[redacted]	118	-	-	2	NOT RELATED	-
				Hypotension	低血圧	20[redacted]	118	-	-	4	NOT RELATED	-

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Upper gastrointestinal haemorrhage	上部消化管出血	20[redacted]	112	20[redacted]	115	3	NOT RELATED	2
				Haemoglobin decreased	ヘモグロビン減少	20[redacted]	117	20[redacted]	128	3	NOT RELATED	2
				Sepsis	敗血症	20[redacted]	137	20[redacted]	151	4	NOT RELATED	2
				Dehydration	脱水	20[redacted]	166	20[redacted]	168	3	NOT RELATED	-
				Renal cell carcinoma	腎細胞癌	20[redacted]	188	20[redacted]	188	5	NOT RELATED	-
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Conduction disorder	伝導障害	20[redacted]	28	-	-	1	NOT RELATED	2
[redacted]	4[redacted]/M/White	20[redacted]	20[redacted]	Hypercalcaemia	高カルシウム血症	20[redacted]	69	20[redacted]	76	2	NOT RELATED	-
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Pneumonia	肺炎	20[redacted]	85	20[redacted]	106	3	RELATED	1:2
				Urinary tract infection	尿路感染	20[redacted]	85	20[redacted]	106	3	NOT RELATED	2
				Muscular weakness	筋力低下	20[redacted]	244	-	-	3	NOT RELATED	-
				Urinary tract infection	尿路感染	20[redacted]	244	-	-	3	NOT RELATED	-
				Pyrexia	発熱	20[redacted]	244	20[redacted]	244	1	NOT RELATED	-
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Pyelonephritis	腎盂腎炎	20[redacted]	26	20[redacted]	30	3	RELATED	3
				Renal cell carcinoma	腎細胞癌	20[redacted]	58	20[redacted]	58	5	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Dyspnoea[d]	呼吸困難	20[redacted]	-16	20[redacted]	-9	2	NOT RELATED	-
				Peritonitis bacterial	細菌性腹膜炎	20[redacted]	7	20[redacted]	10	2	NOT RELATED	-

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	5[redacted]/-/-	20[redacted]	20[redacted]	Acute coronary syndrome	急性冠動脈症候群	20[redacted]	37	20[redacted]	43	3	NOT RELATED	2
				Dyspnoea	呼吸困難	20[redacted]	491	20[redacted]	492	4	NOT RELATED	-
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Tumour thrombosis	腫瘍性血栓症	20[redacted]	59	-	-	3	NOT RELATED	3
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Atrial fibrillation	心房細動	20[redacted]	274	20[redacted]	275	2	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Renal failure acute	急性腎不全	20[redacted]	68	20[redacted]	85	2	NOT RELATED	1:2
				Fall	転倒	20[redacted]	78	20[redacted]	79	2	NOT RELATED	1:2
				Dehydration	脱水	20[redacted]	78	20[redacted]	81	3	RELATED	1:2
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Metastases to peritoneum	腹膜転移	20[redacted]	399	20[redacted]	401	3	NOT RELATED	3
				Metastases to peritoneum	腹膜転移	20[redacted]	407	20[redacted]	444	4	NOT RELATED	-
				Metastases to peritoneum	腹膜転移	20[redacted]	445	20[redacted]	445	5	NOT RELATED	-
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Diarrhoea	下痢	20[redacted]	43	20[redacted]	47	1	NOT RELATED	-
				Nausea	悪心	20[redacted]	43	20[redacted]	48	2	NOT RELATED	2
				Vomiting	嘔吐	20[redacted]	44	20[redacted]	46	2	NOT RELATED	2
				Dehydration	脱水	20[redacted]	45	20[redacted]	46	2	NOT RELATED	-
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Metastases to central nervous system	中枢神経系転移	20[redacted]	134	-	-	4	NOT RELATED	3
[redacted]	5[redacted]/M/Other	20[redacted]	20[redacted]	Abdominal pain	腹痛	20[redacted]	26	20[redacted]	36	3	NOT RELATED	-

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Fatigue	疲労	20[redacted]	69	20[redacted]	73	3	NOT RELATED	-
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	Diarrhoea	下痢	20[redacted]	38	20[redacted]	44	3	RELATED	2
				Vomiting	嘔吐	20[redacted]	38	20[redacted]	65	2	NOT RELATED	-
				Dehydration	脱水	20[redacted]	41	20[redacted]	44	3	RELATED	1:2
[redacted]	4[redacted]/M/White	20[redacted]	20[redacted]	Renal cell carcinoma	腎細胞癌	20[redacted]	196	20[redacted]	196	5	NOT RELATED	-
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Small intestinal obstruction	小腸閉塞	20[redacted]	878	20[redacted]	882	3	NOT RELATED	2
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Constipation	便秘	20[redacted]	53	20[redacted]	54	3	NOT RELATED	-
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Dyspnoea	呼吸困難	20[redacted]	1	20[redacted]	3	3	NOT RELATED	-
				Pneumocystis jirovecii pneumonia	ニューモシスチス・イロベチイ肺炎	20[redacted]	57	-	-	3	RELATED	2:3
				Aspergillus infection	アスペルギルス感染	20[redacted]	67	20[redacted]	69	4	RELATED	3
				Aspergillus infection	アスペルギルス感染	20[redacted]	70	20[redacted]	70	5	RELATED	-
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	Metastases to central nervous system	中枢神経系転移	20[redacted]	66	-	-	2	NOT RELATED	-
[redacted]	4[redacted]/F/Not reported	20[redacted]	20[redacted]	Hypercalcaemia	高カルシウム血症	20[redacted]	249	20[redacted]	256	3	NOT RELATED	-
[redacted]	7[redacted]/M/Not reported	20[redacted]	20[redacted]	Hyponatraemia	低ナトリウム血症	20[redacted]	56	20[redacted]	62	4	RELATED	2
				Pleural effusion	胸水	20[redacted]	85	-	-	3	NOT RELATED	3
				Hyponatraemia	低ナトリウム血症	20[redacted]	85	20[redacted]	86	4	NOT RELATED	3

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	5[redacted]/M/Other	20[redacted]	20[redacted]-	Pain	疼痛	20[redacted]	30	-	-	3	NOT RELATED	2
				General physical health deterioration	全身健康状態低下	20[redacted]	61	20[redacted]	62	4	NOT RELATED	3
				General physical health deterioration	全身健康状態低下	20[redacted]	62	20[redacted]	62	5	NOT RELATED	3
[redacted]	6[redacted]/M/Other	20[redacted]	20[redacted]	Oedema	浮腫	20[redacted]	119	20[redacted]	123	3	RELATED	-
[redacted]	6[redacted]/M/Not reported	20[redacted]	20[redacted]	Malignant melanoma	悪性黒色腫	20[redacted]	143	-	-	3	NOT RELATED	-
[redacted]	5[redacted]/M/Not reported	20[redacted]	20[redacted]	Cough	咳嗽	20[redacted]	13	20[redacted]	97	1	RELATED	1
				Oedema peripheral	末梢性浮腫	20[redacted]	83	20[redacted]	105	3	NOT RELATED	-
				Stress fracture	ストレス骨折	20[redacted]	83	20[redacted]-	-	3	NOT RELATED	2
				Pyrexia	発熱	20[redacted]	96	20[redacted]	105	3	NOT RELATED	2
				Cough	咳嗽	20[redacted]	97	20[redacted]-	-	3	RELATED	-
				Prostatitis	前立腺炎	20[redacted]	242	20[redacted]	266	3	NOT RELATED	2
[redacted]	5[redacted]/M/Other	20[redacted]	20[redacted]	Pyrexia	発熱	20[redacted]	85	20[redacted]	99	2	NOT RELATED	-
				Decreased appetite	食欲減退	20[redacted]	126	-	-	3	NOT RELATED	-
				General physical health deterioration	全身健康状態低下	20[redacted]	139	-	-	3	NOT RELATED	-
				Weight decreased	体重減少	20[redacted]	139	-	-	1	NOT RELATED	-
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	Pneumonia	肺炎	20[redacted]	98	20[redacted]	126	3	NOT RELATED	2
				Pleural effusion	胸水	20[redacted]	137	20[redacted]	142	3	NOT RELATED	-

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	4[redacted]/M/White	20[redacted]	20[redacted]	Back pain	背部痛	20[redacted]	381	20[redacted]	387	3	NOT RELATED	3
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Anaemia	貧血	20[redacted]	18	-	-	2	NOT RELATED	3
				Renal failure	腎不全	20[redacted]	18	20[redacted]	30	2	NOT RELATED	3
				Renal cell carcinoma	腎細胞癌	20[redacted]	31	20[redacted]	31	5	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Pyrexia	発熱	20[redacted]	87	20[redacted]	110	1	NOT RELATED	-
				Respiratory tract infection	気道感染	20[redacted]	195	20[redacted]	197	2	NOT RELATED	2
				Tumour associated fever	腫瘍熱	20[redacted]	274	20[redacted]	275	1	NOT RELATED	-
				Tumour associated fever	腫瘍熱	20[redacted]	279	20[redacted]	282	2	NOT RELATED	-
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Interstitial lung disease	間質性肺疾患	20[redacted]	48	20[redacted]	78	3	RELATED	2:3
				Acute respiratory failure	急性呼吸不全	20[redacted]	59	20[redacted]	78	3	RELATED	-
[redacted]	8[redacted]/F/White	20[redacted]	20[redacted]	Pneumonitis	肺臓炎	20[redacted]	34	20[redacted]	43	2	RELATED	1:2
				Pneumonitis	肺臓炎	20[redacted]	93	20[redacted]	100	2	RELATED	2:3
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Vomiting	嘔吐	20[redacted]	61	20[redacted]	62	2	NOT RELATED	-
				Dyspnoea	呼吸困難	20[redacted]	61	20[redacted]	84	2	NOT RELATED	-
[redacted]	3[redacted]/M/White	20[redacted]	20[redacted]	Metastases to spine	脊椎転移	20[redacted]	136	20[redacted]	147	3	NOT RELATED	3

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Bronchitis	気管支炎	20[redacted]	43	20[redacted]	46	2	NOT RELATED	-
				Renal failure	腎不全	20[redacted]	43	20[redacted]	46	3	NOT RELATED	2
				Anaemia	貧血	20[redacted]	43	20[redacted]	93	2	NOT RELATED	2
				Respiratory tract infection	気道感染	20[redacted]	50	20[redacted]	56	3	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Bronchitis	気管支炎	20[redacted]	145	20[redacted]	152	3	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Pneumonia	肺炎	20[redacted]	54	20[redacted]	65	3	NOT RELATED	3
				Metastatic renal cell carcinoma	遠隔転移を伴う腎細胞癌	20[redacted]	66	20[redacted]	66	5	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Fatigue	疲労	20[redacted]	86	-	-	3	NOT RELATED	1:2:3
				Pneumonia	肺炎	20[redacted]	87	20[redacted]	108	3	NOT RELATED	1
				Renal cell carcinoma	腎細胞癌	20[redacted]	115	20[redacted]	135	4	NOT RELATED	-
				Renal cell carcinoma	腎細胞癌	20[redacted]	136	20[redacted]	136	5	NOT RELATED	-
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Fatigue	疲労	20[redacted]	107	-	-	3	NOT RELATED	3
				Renal cell carcinoma	腎細胞癌	20[redacted]	134	20[redacted]	134	5	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Fatigue	疲労	20[redacted]	86	20[redacted]	95	2	NOT RELATED	2
				Anaemia	貧血	20[redacted]	141	20[redacted]	168	3	RELATED	-

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE		Start		End		CTCAE Grade	Relation to study drug	Action taken[c]
				PT	基本語	Date	Days after first dose[a]	Date	Days after first dose[b]			
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	General physical health deterioration	全身健康状態低下	20[redacted]	33	20[redacted]	44	3	NOT RELATED	3
				Pneumonitis	肺臓炎	20[redacted]	39	20[redacted]	44	3	RELATED	3
				Circulatory collapse	循環虚脱	20[redacted]	44	20[redacted]	44	5	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	-	Cerebral artery occlusion	大脳動脈閉塞	20[redacted]	680	20[redacted]	687	3	NOT RELATED	2
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Back pain	背部痛	20[redacted]	35	20[redacted]	36	3	NOT RELATED	-
				Spinal cord compression	脊髄圧迫	20[redacted]	35	20[redacted]	37	3	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Bronchopneumonia	気管支肺炎	20[redacted]	45	20[redacted]	52	3	NOT RELATED	-
[redacted]	8[redacted]/M/White	20[redacted]	-	Cholangitis	胆管炎	20[redacted]	17	20[redacted]	27	3	NOT RELATED	1:2
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Hydrothorax	胸水症	20[redacted]	37	20[redacted]	38	3	NOT RELATED	2
				Hydrothorax	胸水症	20[redacted]	39	20[redacted]	39	5	NOT RELATED	2:3
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Pleural effusion	胸水	20[redacted]	2	-	-	3	NOT RELATED	-
				Renal cancer	腎癌	20[redacted]	6	20[redacted]	6	5	NOT RELATED	3
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Malignant melanoma	悪性黒色腫	20[redacted]	253	20[redacted]	274	3	NOT RELATED	3
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Anaemia	貧血	20[redacted]	90	20[redacted]	139	3	RELATED	-
				Anaemia	貧血	20[redacted]	139	20[redacted]	152	2	RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Intestinal obstruction	腸閉塞	20[redacted]	429	20[redacted]	433	3	NOT RELATED	2
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Metastases to central nervous system	中枢神経系転移	20[redacted]	201	-	-	3	NOT RELATED	-

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Pulmonary haemorrhage	肺出血	20[redacted]	31	20[redacted]	36	2	NOT RELATED	2:3
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Intestinal perforation	腸管穿孔	20[redacted]	37	20[redacted]	48	4	NOT RELATED	2:3
				Peritonitis	腹膜炎	20[redacted]	37	20[redacted]	48	4	NOT RELATED	2
[redacted]	5[redacted]/F/White	20[redacted]	20[redacted]	Abdominal pain	腹痛	20[redacted]	153	20[redacted]	155	3	NOT RELATED	2
				General physical health deterioration	全身健康状態低下	20[redacted]	250	-	-	3	NOT RELATED	-
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Confusional state	錯乱状態	20[redacted]	27	-	-	2	NOT RELATED	-
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Gastrointestinal perforation	消化管穿孔	20[redacted]	32	20[redacted]	44	3	NOT RELATED	-
				Gastrointestinal perforation	消化管穿孔	20[redacted]	44	20[redacted]	44	5	NOT RELATED	-
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Cholecystitis	胆嚢炎	20[redacted]	55	20[redacted]	66	3	NOT RELATED	2
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	Pneumonitis	肺臓炎	20[redacted]	91	20[redacted]	94	3	RELATED	2:3
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Pneumonitis	肺臓炎	20[redacted]	53	20[redacted]	60	3	RELATED	2:3
				Femoral neck fracture	大腿骨頚部骨折	20[redacted]	97	20[redacted]	103	3	NOT RELATED	-
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Pneumonia	肺炎	20[redacted]	29	20[redacted]	31	2	NOT RELATED	1:2
				Pneumonitis	肺臓炎	20[redacted]	51	20[redacted]	107	2	RELATED	1:2
				Pneumonia	肺炎	20[redacted]	166	20[redacted]	172	3	NOT RELATED	2
[redacted]	4[redacted]/M/White	20[redacted]	20[redacted]	Pain	疼痛	20[redacted]	168	20[redacted]	169	3	NOT RELATED	-
				Pneumonia	肺炎	20[redacted]	181	20[redacted]	197	3	NOT RELATED	-

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Pneumonia	肺炎	20[redacted]	43	20[redacted]	48	3	NOT RELATED	2
				Left ventricular dysfunction	左室機能不全	20[redacted]	420	20[redacted]	702	3	RELATED	-
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Hypercalcaemia	高カルシウム血症	20[redacted]	143	20[redacted]	148	4	NOT RELATED	-
				Pyrexia	発熱	20[redacted]	158	20[redacted]	161	2	RELATED	-
[redacted]	5[redacted]/F/White	20[redacted]	-	Otitis externa	外耳炎	20[redacted]	38	20[redacted]	43	3	RELATED	2
				Anaemia	貧血	20[redacted]	619	20[redacted]	638	3	RELATED	2
[redacted]	4[redacted]/F/White	20[redacted]	-	Anaemia	貧血	20[redacted]	55	20[redacted]	62	3	RELATED	1:2
				Mucosal inflammation	粘膜の炎症	20[redacted]	56	20[redacted]	62	4	RELATED	1:2
				Dehydration	脱水	20[redacted]	57	20[redacted]	62	4	RELATED	1
				Asthenia	無力症	20[redacted]	98	-	-	3	NOT RELATED	3
				Renal cell carcinoma	腎細胞癌	20[redacted]	142	20[redacted]	142	5	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Hydrothorax	胸水症	20[redacted]	188	20[redacted]	217	4	NOT RELATED	2:3
				Hydrothorax	胸水症	20[redacted]	218	20[redacted]	218	5	NOT RELATED	-
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	Anaemia	貧血	20[redacted]	86	20[redacted]	88	3	RELATED	1:2
				Anaemia	貧血	20[redacted]	128	20[redacted]	130	3	RELATED	-
				Metastases to central nervous system	中枢神経系転移	20[redacted]	143	20[redacted]	143	2	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Anaemia	貧血	20[redacted]	45	20[redacted]	54	3	RELATED	-
				Anaemia	貧血	20[redacted]	77	20[redacted]	86	2	NOT RELATED	-
				Hyperkalaemia	高カリウム血症	20[redacted]	77	20[redacted]	86	3	NOT RELATED	-
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Diabetes mellitus	糖尿病	20[redacted]	84	20[redacted]	147	3	NOT RELATED	-

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Metastases to bone	骨転移	20[redacted]	316	-	-	3	NOT RELATED	-
				Spinal cord compression	脊髄圧迫	20[redacted]	385	-	-	3	NOT RELATED	3
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Type 2 diabetes mellitus	２型糖尿病	20[redacted]	45	20[redacted]	55	4	NOT RELATED	1:2
				General physical health deterioration	全身健康状態低下	20[redacted]	410	20[redacted]	416	3	NOT RELATED	2
				General physical health deterioration	全身健康状態低下	20[redacted]	463	20[redacted]	470	3	NOT RELATED	3
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Dyspnoea	呼吸困難	20[redacted]	121	20[redacted]	128	3	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Abscess neck	頚部膿瘍	20[redacted]	216	20[redacted]	226	3	NOT RELATED	2
				Osteonecrosis of jaw	顎骨壊死	20[redacted]	392	20[redacted]	414	3	NOT RELATED	2
[redacted]	5[redacted]/F/White	20[redacted]	20[redacted]	Metastatic pain	転移部痛	20[redacted]	70	20[redacted]	77	3	NOT RELATED	-
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	Viral pharyngitis	ウイルス性咽頭炎	20[redacted]	28	20[redacted]	30	2	RELATED	-
				Pathological fracture	病的骨折	20[redacted]	55	20[redacted]	139	3	NOT RELATED	2
				Metastases to bone	骨転移	20[redacted]	99	20[redacted]	139	3	NOT RELATED	-
				Haematuria	血尿	20[redacted]	139	20[redacted]	146	3	NOT RELATED	3
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Somnolence	傾眠	20[redacted]	164	20[redacted]	165	3	NOT RELATED	-
				Ankle fracture	足関節部骨折	20[redacted]	248	20[redacted]	258	3	NOT RELATED	-

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Dizziness	浮動性めまい	20[redacted]	124	20[redacted]	125	2	NOT RELATED	-
				Dyspnoea	呼吸困難	20[redacted]	124	20[redacted]	125	3	NOT RELATED	-
				Dyspnoea	呼吸困難	20[redacted]	295	20[redacted]	306	3	RELATED	2:3
				Pneumonia aspiration	誤嚥性肺炎	20[redacted]	318	20[redacted]	318	5	NOT RELATED	-
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Pneumonia aspiration	誤嚥性肺炎	20[redacted]	75	20[redacted]	86	4	NOT RELATED	-
				General physical health deterioration	全身健康状態低下	20[redacted]	75	20[redacted]	87	2	NOT RELATED	-
				Pneumonia aspiration	誤嚥性肺炎	20[redacted]	87	20[redacted]	87	5	NOT RELATED	-
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Femoral neck fracture	大腿骨頚部骨折	20[redacted]	207	20[redacted]	218	3	NOT RELATED	-
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Anaemia	貧血	20[redacted]	79	20[redacted]	84	3	NOT RELATED	2
				Dehydration	脱水	20[redacted]	84	20[redacted]	89	3	NOT RELATED	2
				Atrial fibrillation	心房細動	20[redacted]	84	20[redacted]	93	2	NOT RELATED	2
				Sepsis	敗血症	20[redacted]	84	20[redacted]	95	3	NOT RELATED	2
[redacted]	3[redacted]/F/White	20[redacted]	20[redacted]	Ovarian cyst	卵巣嚢胞	20[redacted]	259	-	-	2	NOT RELATED	-
[redacted]	4[redacted]/M/White	20[redacted]	20[redacted]	Lumbar spinal stenosis	腰部脊柱管狭窄症	20[redacted]	141	20[redacted]	168	3	NOT RELATED	-
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Osteonecrosis of jaw	顎骨壊死	20[redacted]	225	-	-	3	NOT RELATED	-

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	8[redacted]/M/White	20[redacted]	20[redacted]	Hypercalcaemia	高カルシウム血症	20[redacted]	112	-	-	2	NOT RELATED	2:3
				Renal cell carcinoma	腎細胞癌	20[redacted]	128	20[redacted]	128	5	NOT RELATED	-
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Dyspnoea	呼吸困難	20[redacted]	96	20[redacted]	106	2	NOT RELATED	3
				Obstructive airways disorder	閉塞性気道障害	20[redacted]	112	20[redacted]	125	3	NOT RELATED	-
				Lower respiratory tract infection	下気道感染	20[redacted]	133	20[redacted]	136	3	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Fatigue	疲労	20[redacted]	165	20[redacted]	172	3	NOT RELATED	-
				Renal cell carcinoma	腎細胞癌	20[redacted]	200	20[redacted]	200	5	NOT RELATED	-
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Musculoskeletal chest pain	筋骨格系胸痛	20[redacted]	195	20[redacted]	197	3	NOT RELATED	-
				Metastases to spine	脊椎転移	20[redacted]	205	-	-	3	NOT RELATED	3
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Malignant neoplasm of orbit	眼窩の悪性新生物	20[redacted]	38	-	-	3	NOT RELATED	-
				Musculoskeletal chest pain	筋骨格系胸痛	20[redacted]	109	-	-	3	NOT RELATED	-
				Pneumonia	肺炎	20[redacted]	110	20[redacted]	112	4	NOT RELATED	-
				Pneumonia	肺炎	20[redacted]	113	20[redacted]	113	5	NOT RELATED	3
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Chest pain	胸痛	20[redacted]	674	20[redacted]	675	2	NOT RELATED	-

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Gastritis	胃炎	20[redacted]	343	20[redacted]	344	3	RELATED	-
				Malignant pleural effusion	悪性胸水	20[redacted]	558	20[redacted]	560	2	NOT RELATED	-
				Malignant pleural effusion	悪性胸水	20[redacted]	579	20[redacted]	583	3	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Pneumonia	肺炎	20[redacted]	394	20[redacted]	400	4	NOT RELATED	-
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Orthostatic hypotension	起立性低血圧	20[redacted]	15	20[redacted]	18	2	NOT RELATED	2
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Lower respiratory tract infection	下気道感染	20[redacted]	61	20[redacted]	70	3	NOT RELATED	2
				Fall	転倒	20[redacted]	336	20[redacted]	338	2	NOT RELATED	-
[redacted]	5[redacted]/F/White	20[redacted]	20[redacted]	Pneumonia	肺炎	20[redacted]	229	-	-	3	NOT RELATED	-
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Pneumonitis	肺臓炎	20[redacted]	46	-	-	2	RELATED	2:3
				Pancreatitis	膵炎	20[redacted]	57	-	-	3	NOT RELATED	-
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Ascites	腹水	20[redacted]	15	20[redacted]	19	2	NOT RELATED	-
				Lower respiratory tract infection	下気道感染	20[redacted]	106	20[redacted]	114	2	NOT RELATED	3
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	Renal cell carcinoma	腎細胞癌	20[redacted]	237	20[redacted]	237	5	NOT RELATED	-
[redacted]	7[redacted]/F/Asian	20[redacted]	20[redacted]	Flank pain	側腹部痛	20[redacted]	42	20[redacted]	92	2	NOT RELATED	2
				Pain	疼痛	20[redacted]	133	-	-	3	NOT RELATED	2
[redacted]	6[redacted]/F/Not reported	20[redacted]	20[redacted]	Pyrexia	発熱	20[redacted]	400	-	-	3	NOT RELATED	-
[redacted]	5[redacted]/M/White	20[redacted]	-	Musculoskeletal chest pain	筋骨格系胸痛	20[redacted]	613	20[redacted]	618	3	NOT RELATED	-

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	5[redacted]/F/White	20[redacted]	20[redacted]	Periorbital cellulitis	眼窩周囲蜂巣炎	20[redacted]	24	20[redacted]	36	3	NOT RELATED	2:3
[redacted]	7[redacted]/F/Other	20[redacted]	20[redacted]	General physical health deterioration	全身健康状態低下	20[redacted]	119	-	-	3	NOT RELATED	2:3
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Anaemia	貧血	20[redacted]	87	20[redacted]	90	3	RELATED	2:3
				Renal impairment	腎機能障害	20[redacted]	87	20[redacted]	90	3	NOT RELATED	2:3
				Renal cell carcinoma	腎細胞癌	20[redacted]	131	20[redacted]	131	5	NOT RELATED	-
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Haemorrhagic stroke	出血性卒中	20[redacted]	234	20[redacted]	256	3	NOT RELATED	2:3
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Anaemia	貧血	20[redacted]	57	20[redacted]	74	3	NOT RELATED	2
				Anaemia	貧血	20[redacted]	113	20[redacted]	142	3	NOT RELATED	2
				Anaemia	貧血	20[redacted]	142	20[redacted]	144	2	NOT RELATED	2
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Hydrothorax	胸水症	20[redacted]	83	20[redacted]	103	2	NOT RELATED	-
				Hydrothorax	胸水症	20[redacted]	104	-	-	3	NOT RELATED	-
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Renal haemorrhage	腎出血	20[redacted]	144	-	-	4	NOT RELATED	3
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Cataract	白内障	20[redacted]	714	20[redacted]	715	2	NOT RELATED	2
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Disease progression	疾患進行	20[redacted]	798	20[redacted]	826	4	NOT RELATED	3
				Disease progression	疾患進行	20[redacted]	827	20[redacted]	827	5	NOT RELATED	-
[redacted]	4[redacted]/M/White	20[redacted]	20[redacted]	Multi-organ failure	多臓器不全	20[redacted]	81	20[redacted]	81	5	NOT RELATED	-

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken[c]
[redacted]	5[redacted]/F/White	20[redacted]	20[redacted]	Rash	発疹	20[redacted]	37	20[redacted]	48	3	RELATED	2
				Hyperglycaemia	高血糖	20[redacted]	37	20[redacted]	48	2	RELATED	2
				Skin infection	皮膚感染	20[redacted]	37	20[redacted]	48	3	RELATED	2
[redacted]	8[redacted]/M/White	20[redacted]	20[redacted]	Pulmonary embolism	肺塞栓症	20[redacted]	112	20[redacted]	177	3	RELATED	-
[redacted]	3[redacted]/M/White	20[redacted]	20[redacted]	Pleural effusion	胸水	20[redacted]	484	20[redacted]	497	3	NOT RELATED	-
[redacted]	8[redacted]/M/White	20[redacted]	20[redacted]	Pneumonia	肺炎	20[redacted]	34	20[redacted]	51	3	RELATED	-
				Pneumonitis	肺臓炎	20[redacted]	34	20[redacted]	51	3	RELATED	2
				Pneumonia	肺炎	20[redacted]	52	20[redacted]	57	3	RELATED	-
				Pneumonitis	肺臓炎	20[redacted]	52	20[redacted]	57	3	RELATED	-
				Pneumonia	肺炎	20[redacted]	58	-	-	4	RELATED	-
				Pneumonitis	肺臓炎	20[redacted]	58	-	-	4	RELATED	-
				Pneumonia aspiration	誤嚥性肺炎	20[redacted]	58	20[redacted]	62	4	RELATED	2
				Pneumonia aspiration	誤嚥性肺炎	20[redacted]	63	20[redacted]	63	5	RELATED	3
[redacted]	6[redacted]/F/Asian	20[redacted]	20[redacted]	Renal failure acute	急性腎不全	20[redacted]	63	20[redacted]	75	1	NOT RELATED	2:3
				Renal cell carcinoma	腎細胞癌	20[redacted]	80	20[redacted]	80	5	NOT RELATED	-
[redacted]	5[redacted]/F/Asian	20[redacted]	20[redacted]	Spinal cord compression	脊髄圧迫	20[redacted]	116	20[redacted]	142	3	NOT RELATED	3
[redacted]	3[redacted]/F/Asian	20[redacted]	20[redacted]	Metastases to central nervous system	中枢神経系転移	20[redacted]	199	-	-	2	NOT RELATED	3
[redacted]	6[redacted]/M/Asian	20[redacted]	20[redacted]	Pneumothorax	気胸	20[redacted]	110	20[redacted]	119	3	NOT RELATED	2
				Tuberculosis	結核	20[redacted]	160	20[redacted]	180	3	NOT RELATED	2:3
[redacted]	6[redacted]/M/Asian	20[redacted]	20[redacted]	Contusion	挫傷	20[redacted]	117	20[redacted]	172	2	NOT RELATED	-
				Pruritus	そう痒症	20[redacted]	184	20[redacted]	197	3	RELATED	-
[redacted]	5[redacted]/F/Asian	20[redacted]	20[redacted]	Atrial fibrillation	心房細動	20[redacted]	142	20[redacted]	142	3	RELATED	-
				Gastric haemorrhage	胃出血	20[redacted]	362	20[redacted]	362	3	NOT RELATED	2

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE		Start		End		CTCAE Grade	Relation to study drug	Action taken[c]
				PT	基本語	Date	Days after first dose[a]	Date	Days after first dose[b]			
[redacted]	5[redacted]/M/Asian	20[redacted]	20[redacted]	Dyspnoea	呼吸困難	20[redacted]	243	-	-	3	NOT RELATED	-
[redacted]	4[redacted]/M/Asian	20[redacted]	20[redacted]	Empyema	蓄膿	20[redacted]	9	20[redacted]	14	2	NOT RELATED	2

Abbreviations: CTCAE=Common Terminology Criteria for Adverse Events; F=female; M=male; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term; SAE=serious adverse event.
From the Exelixis dictionary based on MedDRA version 17.0.

a Days after first dose=SAE start date – first dose date + 1, or SAE start date – first dose date for days before the first dose.

b Days after first dose=SAE end date – first dose date + 1, or SAE end date – first dose date for days before the first dose.

c 1=dose reduced, 2=dose interrupted, 3=treatment permanently discontinued.

d The event was not included in the SAE summaries because it did not meet the definition of TEAE.

Source: XL184-308 試験　総括報告書補遺 2 Listing 16.2.4.1、Listing 16.2.5.2、Listing 16.2.7.3、Listing 16.2.7.4

（2）A031203 試験

1）本剤群：Safety population

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE		Cycle	CTCAE Grade	Relation to study drug[a]
				PT	基本語			
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Hypertension	高血圧	1	3	PROBABLE
				Stomatitis	口内炎	2	3	POSSIBLE
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Embolism	塞栓症	2	3	POSSIBLE
				Angiopathy	血管障害	6	3	POSSIBLE
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Confusional state	錯乱状態	1	3	POSSIBLE
				Fracture	骨折	1	3	UNLIKELY
				Pain	疼痛	1	3	POSSIBLE
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Hypertension	高血圧	4	3	POSSIBLE
				Musculoskeletal chest pain	筋骨格系胸痛	4	3	UNLIKELY
				Oesophageal pain	食道痛	4	3	UNLIKELY
				Palpitations	動悸	4	1	UNLIKELY
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Hypertension	高血圧	1	3	PROBABLE
				Palmar-plantar erythrodysaesthesia syndrome	手掌・足底発赤知覚不全症候群	2	2	DEFINITE
				Stomatitis	口内炎	4	3	PROBABLE
				Stomatitis	口内炎	5	3	PROBABLE
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Alanine aminotransferase increased	アラニンアミノトランスフェラーゼ増加	11	4	UNRELATED
				Anaemia	貧血	11	3	UNLIKELY
				Aspartate aminotransferase increased	アスパラギン酸アミノトランスフェラーゼ増加	11	4	UNRELATED
				Embolism	塞栓症	11	2	UNRELATED
				Hypocalcaemia	低カルシウム血症	11	2	UNRELATED
				Large intestine perforation	大腸穿孔	11	4	PROBABLE
				Nervous system disorder	神経系障害	11	3	UNRELATED
				Oedema peripheral	末梢性浮腫	11	2	UNRELATED
				Pain in extremity	四肢痛	11	3	UNRELATED
				Sepsis	敗血症	11	5	PROBABLE
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Renal failure acute	急性腎不全	1	4	UNLIKELY

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE		Cycle	CTCAE Grade	Relation to study drug[a]
				PT	基本語			
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Skin infection	皮膚感染	4	3	DEFINITE
				Skin ulcer	皮膚潰瘍	4	3	DEFINITE
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Hypertension	高血圧	1	3	PROBABLE
				Embolism	塞栓症	2	4	POSSIBLE
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Back pain	背部痛	3	3	POSSIBLE
				Decreased appetite	食欲減退	3	3	POSSIBLE
				Diarrhoea	下痢	3	3	PROBABLE
				Weight decreased	体重減少	3	3	POSSIBLE
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Hyperthyroidism	甲状腺機能亢進症	2	3	PROBABLE
				Tooth infection	歯感染	2	3	UNRELATED
[redacted]	8[redacted]/M/White	20[redacted]	20[redacted]	Death	死亡	3	5	UNRELATED
[redacted]	7[redacted]/M/Black or African American	20[redacted]	20[redacted]	Arthralgia	関節痛	1	3	POSSIBLE
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Electrocardiogram QT prolonged[b]	心電図ＱＴ延長	1	0	-
				Palmar-plantar erythrodysaesthesia syndrome	手掌・足底発赤知覚不全症候群	1	3	DEFINITE
				Palmar-plantar erythrodysaesthesia syndrome	手掌・足底発赤知覚不全症候群	2	1	DEFINITE
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Embolism	塞栓症	2	3	PROBABLE
				Decreased appetite	食欲減退	8	3	POSSIBLE
				Depression	うつ病	8	3	UNLIKELY
				Nausea	悪心	8	3	POSSIBLE
				Syncope	失神	8	3	POSSIBLE
				Weight decreased	体重減少	8	3	PROBABLE
[redacted]	5[redacted]/M/American Indian or Alaska Native	20[redacted]	20[redacted]	Nausea	悪心	2	2	POSSIBLE

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE		Cycle	CTCAE Grade	Relation to study drug[a]
				PT	基本語			
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Blood creatinine increased	血中クレアチニン増加	1	3	POSSIBLE
				Dehydration	脱水	1	3	PROBABLE
				Diarrhoea	下痢	1	1	PROBABLE
				Fatigue[b]	疲労	1	2	PROBABLE
				Vasculitis	血管炎	1	3	POSSIBLE
				Renal failure acute	急性腎不全	1	5	PROBABLE
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Hyperkalaemia	高カリウム血症	8	3	UNRELATED
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Lung infection	肺感染	1	3	POSSIBLE
[redacted]	4[redacted]/M/White	20[redacted]	20[redacted]	Not Coded	-	16	3	UNRELATED
[redacted]	7[redacted]/F/Black or African American	20[redacted]	20[redacted]	Embolism	塞栓症	2	2	UNRELATED
				Skin ulcer	皮膚潰瘍	2	3	DEFINITE
				Renal failure acute	急性腎不全	4	3	POSSIBLE
				Dehydration	脱水	5	3	PROBABLE
				Hypotension	低血圧	5	3	PROBABLE
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	Alopecia	脱毛症	6	1	POSSIBLE
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Hyponatraemia	低ナトリウム血症	1	3	POSSIBLE
				Hyponatraemia	低ナトリウム血症	2	3	POSSIBLE
				Hypophosphataemia	低リン酸血症	2	3	POSSIBLE
				Renal failure chronic	慢性腎不全	2	3	POSSIBLE
				Hypertension	高血圧	3	3	POSSIBLE
				Weight decreased	体重減少	7	1	POSSIBLE
				Gallbladder pain	胆嚢痛	13	3	UNLIKELY
				Lung infection	肺感染	13	3	POSSIBLE
[redacted]	4[redacted]/M/White	20[redacted]	20[redacted]	Diarrhoea	下痢	1	3	PROBABLE
				Respiratory failure[b]	呼吸不全	3	5	UNRELATED
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Bone pain	骨痛	2	3	UNRELATED
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Haemorrhage intracranial	頭蓋内出血	6	4	UNLIKELY
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Hyperglycaemia	高血糖	1	1	UNRELATED
				Jejunal perforation	空腸穿孔	1	4	POSSIBLE
				Renal failure acute	急性腎不全	1	3	UNRELATED
				Sepsis	敗血症	1	4	UNRELATED

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Cycle	CTCAE Grade	Relation to study drug[a]
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Dehydration	脱水	2	3	PROBABLE
				Hypokalaemia	低カリウム血症	2	3	PROBABLE
				Hypotension	低血圧	2	3	PROBABLE
				Syncope	失神	2	3	PROBABLE
				Embolism	塞栓症	6	3	POSSIBLE
				Not Coded	-	8	3	UNRELATED
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Dizziness	浮動性めまい	3	3	UNRELATED
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Hypertension	高血圧	12	1	DEFINITE
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Facial paresis	顔面不全麻痺	7	2	UNRELATED
				Depression	うつ病	12	3	POSSIBLE
				Palmar-plantar erythrodysaesthesia syndrome	手掌・足底発赤知覚不全症候群	12	2	PROBABLE
[redacted]	7[redacted]/M/Asian	20[redacted]	20[redacted]	Anaemia	貧血	1	2	UNLIKELY
				Diarrhoea	下痢	1	2	PROBABLE
				Gastric haemorrhage	胃出血	1	3	UNLIKELY
				Gastric ulcer	胃潰瘍	1	3	UNLIKELY
				Vomiting	嘔吐	1	2	POSSIBLE
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Embolism	塞栓症	5	3	UNRELATED
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Hypertension	高血圧	1	3	DEFINITE
				Hypertension	高血圧	2	3	DEFINITE
				Hypophosphataemia	低リン酸血症	2	3	PROBABLE
				Hypotension	低血圧	2	3	UNLIKELY
				Palmar-plantar erythrodysaesthesia syndrome	手掌・足底発赤知覚不全症候群	2	3	DEFINITE
				Syncope	失神	2	3	UNLIKELY
				Not Coded	-	3	3	PROBABLE
[redacted]	5[redacted]/F/Black or African American	20[redacted]	20[redacted]	Tumour pain	腫瘍疼痛	1	3	UNRELATED
				Back pain	背部痛	3	3	UNRELATED

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE		Cycle	CTCAE Grade	Relation to study drug[a]
				PT	基本語			
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Alanine aminotransferase increased	アラニンアミノトランスフェラーゼ増加	2	3	DEFINITE
				Alanine aminotransferase increased	アラニンアミノトランスフェラーゼ増加	4	3	DEFINITE
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Hypomagnesaemia	低マグネシウム血症	6	4	POSSIBLE
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Blood creatinine increased	血中クレアチニン増加	4	1	UNRELATED

Abbreviations: CTCAE=Common Terminology Criteria for Adverse Events; F=female; M=male; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term; SAE=serious adverse event; TEAE=treatment-emergent adverse events.

From the Exelixis dictionary based on MedDRA version 17.0.

a SAEs assessed as possibly, probably, or definitely related to study treatment by the investigator were considered related to study treatment.

b The event was not included in the SAE summaries because it did not meet the definition of TEAE.

Source: A031203 試験　総括報告書 Listing 16.2.2.1、Listing 16.2.3.1、Listing 16.2.5.3、Listing 16.2.5.4

2）スニチニブ群：Safety population

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE		Cycle	CTCAE Grade	Relation to study drug[a]
				PT	基本語			
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Hyperglycaemia	高血糖	1	3	UNRELATED
				Hypophosphataemia	低リン酸血症	1	3	PROBABLE
				Hyperglycaemia	高血糖	2	3	UNRELATED
				Hypertension	高血圧	2	3	POSSIBLE
				Headache	頭痛	9	1	POSSIBLE
[redacted]	5[redacted]/F/White	20[redacted]	20[redacted]	Anaemia	貧血	1	2	PROBABLE
				Bronchial obstruction	気管支閉塞	1	2	UNRELATED
				Constipation	便秘	1	1	POSSIBLE
				Dehydration	脱水	1	2	PROBABLE
				Diarrhoea	下痢	1	2	POSSIBLE
				Dyspnoea	呼吸困難	1	3	UNLIKELY
				Encephalitis	脳炎	1	3	PROBABLE
				Fatigue	疲労	1	3	PROBABLE
				Headache	頭痛	1	3	DEFINITE
				Hypocalcaemia	低カルシウム血症	1	2	PROBABLE
				Investigation	検査	1	3	PROBABLE
				Nausea	悪心	1	2	PROBABLE
				Platelet count decreased	血小板数減少	1	2	PROBABLE
				Pleural effusion	胸水	1	2	UNLIKELY
				Stomatitis	口内炎	1	3	DEFINITE
				Vomiting	嘔吐	1	1	PROBABLE
				White blood cell count decreased	白血球数減少	1	3	PROBABLE
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Proteinuria	蛋白尿	1	3	PROBABLE
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Amylase increased	アミラーゼ増加	1	3	PROBABLE
				Lipase increased	リパーゼ増加	1	4	PROBABLE
				Pyrexia	発熱	1	3	UNLIKELY
				Vomiting	嘔吐	1	1	POSSIBLE
[redacted]	8[redacted]/M/White	20[redacted]	20[redacted]	Electrocardiogram QT prolonged	心電図ＱＴ延長	1	3	POSSIBLE
				Dizziness	浮動性めまい	3	2	UNLIKELY
				Hypotension	低血圧	3	4	UNLIKELY
				Muscular weakness	筋力低下	3	2	UNLIKELY
				Sepsis	敗血症	3	5	POSSIBLE

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Cycle	CTCAE Grade	Relation to study drug[a]
[redacted]	7[redacted]/M/Unknown	20[redacted]	20[redacted]	Hyponatraemia	低ナトリウム血症	4	3	POSSIBLE
				Hyperkalaemia	高カリウム血症	5	3	POSSIBLE
				Hyponatraemia	低ナトリウム血症	5	3	POSSIBLE
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Cerebrovascular accident	脳血管発作	1	2	POSSIBLE
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Investigation	検査	4	1	POSSIBLE
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Hypoglossal nerve disorder	舌下神経障害	1	3	UNRELATED
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Hypertension	高血圧	1	3	PROBABLE
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Hypophosphataemia	低リン酸血症	1	3	PROBABLE
[redacted]	6[redacted]/F/White	20[redacted]	20[redacted]	Colitis	大腸炎	3	3	POSSIBLE
				Renal failure acute	急性腎不全	3	3	POSSIBLE
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	Respiratory failure	呼吸不全	1	5	UNRELATED
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Abdominal distension	腹部膨満	1	3	UNRELATED
				Atrial fibrillation	心房細動	1	3	UNRELATED
				Diarrhoea	下痢	1	3	UNRELATED
				Nausea	悪心	1	3	UNRELATED
				Vomiting	嘔吐	1	3	UNRELATED
				Diarrhoea	下痢	2	2	UNRELATED
				Nausea	悪心	2	3	UNRELATED
				Vomiting	嘔吐	2	3	UNRELATED
				Hypotension	低血圧	3	5	UNRELATED
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	Neutrophil count decreased	好中球数減少	2	3	POSSIBLE
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Respiratory failure	呼吸不全	5	5	UNRELATED
[redacted]	5[redacted]/F/White	20[redacted]	20[redacted]	Cystitis	膀胱炎	3	2	POSSIBLE
				Dehydration	脱水	3	3	POSSIBLE
				Diarrhoea	下痢	3	3	POSSIBLE
				Nausea	悪心	3	3	POSSIBLE
				Small intestinal obstruction	小腸閉塞	3	3	POSSIBLE
				Vomiting	嘔吐	3	1	POSSIBLE
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Lipase increased	リパーゼ増加	6	4	UNRELATED
				Pancreatitis	膵炎	6	3	UNRELATED
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Somnolence	傾眠	5	3	UNRELATED

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE		Cycle	CTCAE Grade	Relation to study drug[a]
				PT	基本語			
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	Pain in extremity	四肢痛	2	1	PROBABLE
				Palmar-plantar erythrodysaesthesia syndrome	手掌・足底発赤知覚不全症候群	8	1	DEFINITE
				Dysgeusia	味覚異常	12	1	DEFINITE
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Nervous system disorder	神経系障害	4	4	UNRELATED
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Hypophosphataemia	低リン酸血症	2	3	POSSIBLE
[redacted]	5[redacted]/M/Black or African American	20[redacted]	20[redacted]	Diarrhoea	下痢	7	1	PROBABLE
				Fatigue	疲労	7	1	PROBABLE
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Renal failure chronic	慢性腎不全	5	2	UNLIKELY
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Headache	頭痛	7	1	PROBABLE
[redacted]	5[redacted]/M/White	20[redacted]	20[redacted]	Haemorrhage intracranial[b]	頭蓋内出血	5	5	UNRELATED
[redacted]	7[redacted]/M/White	20[redacted]	20[redacted]	Nail infection	爪感染	6	3	POSSIBLE
[redacted]	8[redacted]/M/White	20[redacted]	20[redacted]	Abdominal pain	腹痛	1	2	UNRELATED
[redacted]	8[redacted]/M/White	20[redacted]	20[redacted]	Fatigue	疲労	2	2	POSSIBLE
				Gastric ulcer	胃潰瘍	2	2	POSSIBLE
				Renal failure acute	急性腎不全	2	1	POSSIBLE
[redacted]	4[redacted]/M/White	20[redacted]	20[redacted]	Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	7	3	UNLIKELY
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Hyponatraemia	低ナトリウム血症	1	3	POSSIBLE
				Transient ischaemic attack	一過性脳虚血発作	9	2	UNLIKELY
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	Angiopathy	血管障害	1	5	PROBABLE

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Cycle	CTCAE Grade	Relation to study drug[a]
[redacted]	8[redacted]/F/Black or African American	20[redacted]	20[redacted]	Alanine aminotransferase increased	アラニンアミノトランスフェラーゼ増加	1	2	PROBABLE
				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	3	PROBABLE
				Atrial fibrillation	心房細動	1	1	PROBABLE
				Blood bilirubin increased	血中ビリルビン増加	1	1	PROBABLE
				Neutrophil count decreased	好中球数減少	1	2	PROBABLE
				Platelet count decreased	血小板数減少	1	4	PROBABLE
				Portal vein thrombosis	門脈血栓症	1	3	PROBABLE
				Pyrexia	発熱	1	2	PROBABLE
				Sudden death	突然死	2	5	POSSIBLE
[redacted]	8[redacted]/M/White	20[redacted]	20[redacted]	Diarrhoea	下痢	2	3	DEFINITE
				Fatigue	疲労	2	2	PROBABLE
[redacted]	8[redacted]/M/White	20[redacted]	20[redacted]	Nausea	悪心	1	2	POSSIBLE
				Neutrophil count decreased	好中球数減少	1	1	DEFINITE
				Multi-organ failure[b]	多臓器不全	11	5	UNLIKELY
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	Alanine aminotransferase increased	アラニンアミノトランスフェラーゼ増加	1	1	PROBABLE
				Gastric haemorrhage	胃出血	1	4	DEFINITE
				Hypertension	高血圧	1	4	DEFINITE
				Platelet count decreased	血小板数減少	1	2	PROBABLE
				Respiratory failure	呼吸不全	2	5	PROBABLE
[redacted]	6[redacted]/M/White	20[redacted]	20[redacted]	Nervous system disorder	神経系障害	4	3	UNRELATED
				Not Coded	-	4	3	UNRELATED
[redacted]	7[redacted]/F/White	20[redacted]	20[redacted]	Confusional state	錯乱状態	2	3	PROBABLE
				Hypoglycaemia	低血糖症	2	4	POSSIBLE

Abbreviations: CTCAE=Common Terminology Criteria for Adverse Events; F=female; M=male; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term; SAE=serious adverse event; TEAE=treatment-emergent adverse events.

From the Exelixis dictionary based on MedDRA version 17.0.

a SAEs assessed as possibly, probably, or definitely related to study treatment by the investigator were considered related to study treatment.

b The event was not included in the SAE summaries because it did not meet the definition of TEAE.

Source: A031203 試験　総括報告書 Listing 16.2.2.1、Listing 16.2.3.2、Listing 16.2.5.3、Listing 16.2.5.4

（3）Cabozantinib-2001 試験：Safety analysis set

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken	Outcome
[redacted]	6[redacted]/M/Asian	20[redacted]	20[redacted]	Bone pain	骨痛	20[redacted]	12	20[redacted]	37	2	NOT RELATED	DOSE NOT CHANGED	RECOVERED /RESOLVED
				Bone pain	骨痛	20[redacted]	120	20[redacted]	160	2	NOT RELATED	DOSE NOT CHANGED	RECOVERED /RESOLVED
				Hypercalcaemia	高カルシウム血症	20[redacted]	168	-	-	4	NOT RELATED	DRUG WITHDRAWN	NOT RECOVERED /NOT RESOLVED
				Lung infection	肺感染	20[redacted]	169	-	-	3	NOT RELATED	NA	NOT RECOVERED /NOT RESOLVED
[redacted]	4[redacted]/M/Asian	20[redacted]	20[redacted]	Ileus	イレウス	20[redacted]	15	-	-	3	NOT RELATED	DRUG INTERRUPTED	NOT RECOVERED /NOT RESOLVED
				Renal cell carcinoma	腎細胞癌	20[redacted]	36	20[redacted]	36	5	NOT RELATED	DRUG WITHDRAWN	FATAL
[redacted]	6[redacted]/M/Asian	20[redacted]	20[redacted]	Renal cell carcinoma	腎細胞癌	20[redacted]	85	-	-	3	NOT RELATED	DRUG INTERRUPTED	NOT RECOVERED /NOT RESOLVED
[redacted]	7[redacted]/F/Asian	20[redacted]	20[redacted]	Spinal column stenosis[c]	脊柱管狭窄症	20[redacted]	-8	-	-	2	NOT RELATED	NA	RECOVERING/ RESOLVING
[redacted]	7[redacted]/M/Asian	20[redacted]	-	Cancer pain	癌疼痛	20[redacted]	25	20[redacted]	58	2	NOT RELATED	DOSE NOT CHANGED	RECOVERED /RESOLVED
[redacted]	6[redacted]/M/Asian	20[redacted]	-	Cholecystitis	胆嚢炎	20[redacted]	68	20[redacted]	84	3	RELATED	DRUG INTERRUPTED, DOSE REDUCED	RECOVERED /RESOLVED

Subject No.	Age/Sex/Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[a]	End Date	End Days after first dose[b]	CTCAE Grade	Relation to study drug	Action taken	Outcome
[redacted]	6[redacted]/F/Asian	20[redacted]	-	Brain oedema	脳浮腫	20[redacted]	92	20[redacted]	245	4	NOT RELATED	DOSE NOT CHANGED	RECOVERED /RESOLVED
				Pancreatic enzymes increased	膵酵素増加	20[redacted]	29	20[redacted]	35	3	RELATED	DRUG INTERRUPTED, DOSE REDUCED	RECOVERED /RESOLVED
				Pancreatic enzymes increased	膵酵素増加	20[redacted]	36	20[redacted]	95	4	RELATED	DRUG INTERRUPTED, DOSE REDUCED	RECOVERED /RESOLVED
				Pathological fracture	病的骨折	20[redacted]	177	-	-	3	NOT RELATED	DOSE NOT CHANGED	NOT RECOVERED /NOT RESOLVED
[redacted]	6[redacted]/M/Asian	20[redacted]	-	Pneumonia	肺炎	20[redacted]	121	20[redacted]	169	3	RELATED	DRUG INTERRUPTED	RECOVERED /RESOLVED
[redacted]	6[redacted]/F/Asian	20[redacted]	20[redacted]	Amylase increased	アミラーゼ増加	20[redacted]	2	20[redacted]	22	4	NOT RELATED	DRUG INTERRUPTED	RECOVERED /RESOLVED
				Lipase increased	リパーゼ増加	20[redacted]	2	20[redacted]	22	4	NOT RELATED	DRUG INTERRUPTED	RECOVERED /RESOLVED
[redacted]	6[redacted]/M/Asian	20[redacted]	20[redacted]	Decreased appetite	食欲減退	20[redacted]	54	20[redacted]	80	3	NOT RELATED	DRUG INTERRUPTED	RECOVERED /RESOLVED

Abbreviations: CTCAE=Common Terminology Criteria for Adverse Events; F=female; M=male; MedDRA=Medical Dictionary for Regulatory Activities; NA=not applicable; PT=preferred term; SAE=serious adverse event.

SAEs were coded using MedDRA version 21.0.

a Days after first dose=SAE start date – first dose date + 1, or SAE start date – first dose date for days before the first dose.

b Days after first dose=SAE end date – first dose date + 1, or SAE end date – first dose date for days before the first dose.

c The event was not included in the SAE summaries because it did not meet the definition of TEAE.

Source: Cabozantinib-2001 試験　総括報告書 Listing 16.2.1.1、Listing 16.2.4.1a、Listing 16.2.4.1b、Listing 16.2.7a、Listing 16.2.7b、Listing 16.2.7c

（4）XL184-014 試験：Safety population

Cohort[a]	Subject No.	Age/Sex/ Race	Date of first dose	Date of last dose	SAE PT	SAE 基本語	Start Date	Start Days after first dose[b]	End Date	End Days after first dose[c]	CTCAE Grade	Relation to study drug	Action taken	Outcome
1	[redacted]	5[redacted]/F/ Asian	20[redacted]	20[redacted]	Pleural effusion	胸水	20[redacted]	279	20[redacted]	299	2	NOT RELATED	NA	RECOVERED /RESOLVED
2	[redacted]	6[redacted]/M/ Asian	20[redacted]	20[redacted]	Intestinal obstruction	腸閉塞	20[redacted]	149	20[redacted]	155	2	RELATED	DRUG INTERRUPTED	RECOVERED /RESOLVED
3	[redacted]	5[redacted]/M/ Asian	20[redacted]	20[redacted]	Haematemesis	吐血	20[redacted]	36	20[redacted]	42	3	RELATED	NA	RECOVERED /RESOLVED
					Anaemia	貧血	20[redacted]	37	20[redacted]	69	4	RELATED	NA	RECOVERED /RESOLVED
					Melaena	メレナ	20[redacted]	41	20[redacted]	42	3	RELATED	NA	RECOVERED /RESOLVED
2T	[redacted]	4[redacted]/M/ Asian	20[redacted]	20[redacted]	Dyspnoea	呼吸困難	20[redacted]	199	-	-	3	NOT RELATED	NA	NOT RECOVERED /NOT RESOLVED
2T	[redacted]	6[redacted]/M/ Asian	20[redacted]	20[redacted]	Protein urine	尿蛋白	20[redacted]	29	20[redacted]	33	1	RELATED	DRUG INTERRUPTED	RECOVERED /RESOLVED
					Embolism venous	静脈塞栓症	20[redacted]	30	20[redacted]	35	3	RELATED	DRUG INTERRUPTED	RECOVERED /RESOLVED WITH SEQUELAE
2T	[redacted]	5[redacted]/M/ Asian	20[redacted]	20[redacted]	Bile duct stone	胆管結石	20[redacted]	349	20[redacted]	377	3	RELATED	DRUG INTERRUPTED	RECOVERED /RESOLVED
1E	[redacted]	5[redacted]/F/ Asian	20[redacted]	20[redacted]	Disease progression	疾患進行	20[redacted]	171	-	-	2	NOT RELATED	NA	NOT RECOVERED /NOT RESOLVED
					Pleural effusion	胸水	20[redacted]	171	20[redacted]	184	3	NOT RELATED	NA	RECOVERED /RESOLVED

Cohort[a]	Subject No.	Age/Sex/ Race	Date of first dose	Date of last dose	SAE		Start		End		CTCAE Grade	Relation to study drug	Action taken	Outcome
					PT	基本語	Date	Days after first dose[b]	Date	Days after first dose[c]				
1E	[redacted]	6[redacted]/F/ Asian	20[redacted]	20[redacted]	Pericardial effusion	心嚢液貯留	20[redacted]	107	-	-	3	NOT RELATED	NA	NOT RECOVERED /NOT RESOLVED
1E	[redacted]	6[redacted]/M/ Asian	20[redacted]	20[redacted]	Pleural effusion	胸水	20[redacted]	94	20[redacted]	106	2	NOT RELATED	NA	RECOVERED /RESOLVED
1E	[redacted]	4[redacted]/M/ Asian	20[redacted]	20[redacted]	Lung infection	肺感染	20[redacted]	38	-	-	3	RELATED	NA	NOT RECOVERED /NOT RESOLVED

Cohort[a]	Subject No.	Age/Sex/ Race	Date of first dose	Date of last dose	SAE		Start		End		CTCAE Grade	Relation to study drug	Action taken	Outcome
					PT	基本語	Date	Days after first dose[b]	Date	Days after first dose[c]				
1E	[redacted]	7[redacted]/F/ Asian	20[redacted]	20[redacted]	Diarrhoea	下痢	20[redacted]	29	20[redacted]	45	3	RELATED	DOSE REDUCED	NOT RECOVERED /NOT RESOLVED
					Hypotension	低血圧	20[redacted]	38	20[redacted]	47	2	RELATED	DOSE REDUCED, DRUG INTERRUPTED	RECOVERED /RESOLVED
					Decreased appetite	食欲減退	20[redacted]	71	20[redacted]	90	3	RELATED	DRUG INTERRUPTED	NOT RECOVERED /NOT RESOLVED
					Dyspnoea	呼吸困難	20[redacted]	89	-	-	3	RELATED	DOSE NOT CHANGED	NOT RECOVERED /NOT RESOLVED
					Hypertension	高血圧	20[redacted]	89	-	-	4	RELATED	DOSE NOT CHANGED	NOT RECOVERED /NOT RESOLVED
					Performance status decreased	活動状態低下	20[redacted]	89	20[redacted]	93	3	RELATED	DOSE NOT CHANGED	NOT RECOVERED /NOT RESOLVED
					Performance status decreased	活動状態低下	20[redacted]	93	20[redacted]	96	4	RELATED	DOSE NOT CHANGED	NOT RECOVERED /NOT RESOLVED
					Respiratory failure	呼吸不全	20[redacted]	96	20[redacted]	96	5	RELATED	NA	FATAL

Cohort[a]	Subject No.	Age/Sex/ Race	Date of first dose	Date of last dose	SAE		Start		End		CTCAE Grade	Relation to study drug	Action taken	Outcome
					PT	基本語	Date	Days after first dose[b]	Date	Days after first dose[c]				
1E	[redacted]	7[redacted]/M/ Asian	20[redacted]	20[redacted]	Malignant neoplasm progression	悪性新生物進行	20[redacted]	114	-	-	3	NOT RELATED	NA	NOT RECOVERED /NOT RESOLVED
					Pneumocystis jirovecii pneumonia	ニューモシスチス・イロベチイ肺炎	20[redacted]	114	-	-	2	NOT RELATED	NA	NOT RECOVERED /NOT RESOLVED
					Cardiac failure	心不全	20[redacted]	114	20[redacted]	125	3	NOT RELATED	DOSE NOT CHANGED	RECOVERED /RESOLVED
3E	[redacted]	6[redacted]/F/ Asian	20[redacted]	20[redacted]	Pneumonia	肺炎	20[redacted]	135	20[redacted]	144	3	RELATED	DOSE REDUCED, DRUG INTERRUPTED	RECOVERED /RESOLVED
					Dyspnoea	呼吸困難	20[redacted]	357	-	-	3	NOT RELATED	DOSE NOT CHANGED	NOT RECOVERED /NOT RESOLVED
					Performance status decreased	活動状態低下	20[redacted]	357	20[redacted]	371	3	NOT RELATED	DOSE NOT CHANGED	NOT RECOVERED /NOT RESOLVED
					Performance status decreased	活動状態低下	20[redacted]	371	-	-	4	NOT RELATED	NA	NOT RECOVERED /NOT RESOLVED
					Sepsis	敗血症	20[redacted]	371	20[redacted]	378	4	NOT RELATED	NA	RECOVERED /RESOLVED

Abbreviations: CTCAE=Common Terminology Criteria for Adverse Events; F=female; FBE=freebase equivalent; M=male; MedDRA=Medical Dictionary for Regulatory Activities; NA=not applicable; NSCLC=non-small cell lung cancer; PT=preferred term; SAE=serious adverse event.

From the Exelixis dictionary based on MedDRA version 17.0.

a Cohort 1=40 mg FBE weight or 50 mg malate salt weight Capsule; Cohort 2=60 mg FBE weight or 75 mg malate salt weight Capsule; Cohort 3=80 mg FBE weight or 100 mg malate salt weight Capsule; Cohort 1T=40 mg FBE weight Tablet; Cohort 2T=60 mg FBE weight Tablet; Cohort 1-3 E=molecularly defined NSCLC expansion.

b Days after first dose=SAE start date – first dose date + 1.

c Days after first dose=SAE end date – first dose date + 1.

Source: XL184-014 試験　総括報告書 Listing 16.2.4.1、Listing 16.2.5.1、Listing 16.2.7.2