Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	13/13	低カルシウム血症 Hypocalcaemia	DOSE NOT CHANGED	UNRELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	19/21	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	19/26	好中球減少症 Neutropenia	DOSE NOT CHANGED	LIKELY RELATED	2	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	21/26	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	26/27	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	26/37	好中球減少症 Neutropenia	DRUG INTERRUPTED	LIKELY RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	27/37	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	2	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	96/105	貧血 Anaemia	NOT APPLICABLE	RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	182/184	発熱 Pyrexia	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	1	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	222/391	胃腸管瘻 Gastrointestinal fistula	DRUG WITHDRAWN	RELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	24/25	小腸閉塞 Small intestinal obstruction	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	24/25	脱水 Dehydration	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	33/84	リンパ球減少症 Lymphopenia	DOSE NOT CHANGED	RELATED	3	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	57/83	リンパ球減少症 Lymphopenia	DOSE NOT CHANGED	RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	92/97	腸閉塞 Intestinal obstruction	DRUG WITHDRAWN	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	11/30	腸閉塞 Intestinal obstruction	DRUG WITHDRAWN	UNRELATED	3	RECOVERED/RESOLVED

a' ・事象の発現日又は消失日が初回投与前の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし「-」（マイナス）符号を付けて表示した。
・事象の発現日又は消失日が投与期間中（初回投与後から最終投与の間）の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし符号なしとした。
・事象の発現日又は消失日が最終投与後の場合、そのRel Dayは最終投与日を起点として事象の発現日又は消失日までの日数をカウントし「+」（プラス）符号を付けて表示した。

*情報公開時に追記

Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	24/29	敗血症 Sepsis	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	24/29	関節膿瘍 Joint abscess	DRUG INTERRUPTED	UNRELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	105/120	関節膿瘍 Joint abscess	DRUG INTERRUPTED DOSE REDUCED	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	29/50	γ－グルタミルトランスフェラーゼ増加 Gamma-glutamyltransferase increased	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	ongoing	50/	γ－グルタミルトランスフェラーゼ増加 Gamma-glutamyltransferase increased	DRUG WITHDRAWN	UNRELATED	4	NOT RECOVERED/ NOT RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	84/89	貧血 Anaemia	DOSE REDUCED DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/ RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	ongoing	57/	貧血 Anaemia	NOT APPLICABLE	RELATED	3	NOT RECOVERED/ NOT RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	17/26	小腸閉塞 Small intestinal obstruction	DRUG WITHDRAWN	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	15/29	リンパ球減少症 Lymphopenia	DRUG INTERRUPTED	UNRELATED	4	RECOVERED/ RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	28/33	無力症 Asthenia	DRUG INTERRUPTED	RELATED	3	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	28/34	呼吸困難 Dyspnoea	DRUG INTERRUPTED	RELATED	3	RECOVERED/ RESOLVED WITH SEQUELAE
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	181/184	気管支炎 Bronchitis	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED

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Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	101/103	ウイルス性胃腸炎 Gastroenteritis viral	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	2	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	108/114	胃腸炎 Gastroenteritis	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/Other	20[redacted]	20[redacted]	2/6	小腸閉塞 Small intestinal obstruction	DRUG WITHDRAWN	UNRELATED	4	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	56/58	嘔吐 Vomiting	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	56/58	悪心 Nausea	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	73/77	悪性胸水 Malignant pleural effusion	DRUG WITHDRAWN	UNLIKELY TO BE RELATED	2	RECOVERED/ RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	16/22	高血圧 Hypertension	DOSE NOT CHANGED	UNLIKELY TO BE RELATED	2	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	22/27	血小板減少症 Thrombocytopenia	DRUG WITHDRAWN	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	ongoing	47/	腸管穿孔 Intestinal perforation	NOT APPLICABLE	UNRELATED	4	UNKNOWN
	20[redacted]	20[redacted]	47/47	心停止 Cardiac arrest	NOT APPLICABLE	UNLIKELY TO BE RELATED	5	FATAL
[redacted] 4[redacted]/Female/White	20[redacted]	20[redacted]	70/71	嘔吐 Vomiting	DRUG INTERRUPTED DOSE REDUCED	LIKELY RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	70/71	悪心 Nausea	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	70/71	腹痛 Abdominal pain	DRUG INTERRUPTED DOSE REDUCED	LIKELY RELATED	3	RECOVERED/ RESOLVED

a' ・事象の発現日又は消失日が初回投与前の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし「-」（マイナス）符号を付けて表示した。
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Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	4/6	癌疼痛 Cancer pain	DRUG WITHDRAWN	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	4/6	悪心 Nausea	DRUG WITHDRAWN	LIKELY RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	16/16	突然死 Sudden death	NOT APPLICABLE	UNRELATED	5	FATAL
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	6/10	呼吸困難 Dyspnoea	DOSE NOT CHANGED	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	12/15	小腸閉塞 Small intestinal obstruction	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/ RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	33/37	小腸閉塞 Small intestinal obstruction	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	33/42	嘔吐 Vomiting	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	37/42	小腸閉塞 Small intestinal obstruction	NOT APPLICABLE	UNRELATED	2	RECOVERED/ RESOLVED WITH SEQUELAE
[redacted] 5[redacted]/Female/White	20[redacted]	ongoing	186/	嘔吐 Vomiting	NOT APPLICABLE	UNRELATED	3	NOT RECOVERED/ NOT RESOLVED
	20[redacted]	ongoing	186/	小腸閉塞 Small intestinal obstruction	NOT APPLICABLE	UNRELATED	3	NOT RECOVERED/ NOT RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	151/155	便秘 Constipation	NOT APPLICABLE	UNLIKELY TO BE RELATED	2	RECOVERED/ RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	36/40	尿路閉塞 Urinary tract obstruction	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED

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Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	7/13	小腸閉塞 Small intestinal obstruction	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	66/69	悪心 Nausea	DRUG WITHDRAWN	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	66/69	嘔吐 Vomiting	DRUG WITHDRAWN	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	44/46	精神状態変化 Mental status changes	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
[redacted] 7[redacted]/Female/Black or African American	20[redacted]	20[redacted]	7/11	嘔吐 Vomiting	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	697/712	胸水 Pleural effusion	DRUG WITHDRAWN	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	-9/-4	疼痛 Pain	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	16/24	疼痛 Pain	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 8[redacted]/Female/White	20[redacted]	20[redacted]	283/287	高血圧 Hypertension	DOSE NOT CHANGED	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	620/622	心房細動 Atrial fibrillation	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	25/31	尿路感染 Urinary tract infection	NOT APPLICABLE	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	25/31	便秘 Constipation	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	37/38	血小板減少症 Thrombocytopenia	NOT APPLICABLE	LIKELY RELATED	4	RECOVERED/ RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	37/49	腹痛 Abdominal pain	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED

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Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	-12/-6	小腸閉塞 Small intestinal obstruction	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	26/30	悪心 Nausea	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	26/30	嘔吐 Vomiting	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	21/25	脱水 Dehydration	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	21/25	悪心 Nausea	DRUG INTERRUPTED	RELATED	3	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	96/100	小腸閉塞 Small intestinal obstruction	DRUG WITHDRAWN	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	13/16	嘔吐 Vomiting	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	82/85	レンサ球菌性咽頭炎 Pharyngitis streptococcal	DOSE NOT CHANGED	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	7/15	腸閉塞 Intestinal obstruction	DOSE NOT CHANGED	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	51/53	腹痛 Abdominal pain	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	59/61	消化管ストーマ合併症 Gastrointestinal stoma complication	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	27/28	電解質失調 Electrolyte imbalance	NOT APPLICABLE	LIKELY RELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	121/122	尿路閉塞 Ureteric obstruction	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	20/25	好中球減少症 Neutropenia	NOT APPLICABLE	LIKELY RELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	8/12	悪心 Nausea	DRUG WITHDRAWN	LIKELY RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	8/12	嘔吐 Vomiting	DRUG WITHDRAWN	LIKELY RELATED	3	RECOVERED/RESOLVED

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Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	39/45	腸閉塞 Intestinal obstruction	DOSE NOT CHANGED	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	47/49	腹部不快感 Abdominal discomfort	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/Asian	20[redacted]	20[redacted]	7/11	心嚢液貯留 Pericardial effusion	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	15/22	急性肝不全 Acute hepatic failure	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	4	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/Unknown	20[redacted]	20[redacted]	14/15	嘔吐 Vomiting	DRUG INTERRUPTED	RELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/Other	20[redacted]	20[redacted]	9/12	悪心 Nausea	DRUG WITHDRAWN	RELATED	3	RECOVERED /RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	9/12	嘔吐 Vomiting	DRUG WITHDRAWN	RELATED	3	RECOVERED/RESOLVED WITH SEQUELAE
[redacted] 5[redacted]/Female/Black or African American	20[redacted]	20[redacted]	-6/1	腹痛 Abdominal pain	NOT APPLICABLE	UNRELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	6/34	腹痛 Abdominal pain	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	41/45	過小食 Hypophagia	DOSE NOT CHANGED	LIKELY RELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	41/45	頻脈 Tachycardia	DOSE NOT CHANGED	LIKELY RELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	54/94	骨髄機能不全 Bone marrow failure	DRUG WITHDRAWN	LIKELY RELATED	4	RECOVERED/RESOLVED

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Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	89/90	便秘 Constipation	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	89/90	腹痛 Abdominal pain	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	2	RECOVERED/RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	29/36	好中球数減少 Neutrophil count decreased	DOSE REDUCED DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED
[redacted] 8[redacted]/Female/White	20[redacted]	20[redacted]	14/14	心停止 Cardiac arrest	DRUG WITHDRAWN	UNLIKELY TO BE RELATED	5	FATAL
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	21/25	低血圧 Hypotension	DOSE REDUCED DRUG INTERRUPTED	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	ongoing	12/	嘔吐 Vomiting	DRUG WITHDRAWN DRUG INTERRUPTED	LIKELY RELATED	3	NOT RECOVERED/NOT RESOLVED
	20[redacted]	20[redacted]	20/20	胃出血 Gastric haemorrhage	NOT APPLICABLE	LIKELY RELATED	5	FATAL
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	18/20	動悸 Palpitations	DRUG INTERRUPTED	LIKELY RELATED	2	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	37/41	高血圧 Hypertension	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 8[redacted]/Female/White	20[redacted]	20[redacted]	28/29	腎結石症 Nephrolithiasis	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	22/23	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	23/34	血小板減少症 Thrombocytopenia	DRUG WITHDRAWN	RELATED	2	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	35/39	慢性閉塞性肺疾患 Chronic obstructive pulmonary disease	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/RESOLVED

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a' ・事象の発現日又は消失日が初回投与前の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし「-」（マイナス）符号を付けて表示した。
・事象の発現日又は消失日が投与期間中（初回投与後から最終投与の間）の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし符号なしとした。
・事象の発現日又は消失日が最終投与後の場合、そのRel Dayは最終投与日を起点として事象の発現日又は消失日までの日数をカウントし「+」（プラス）符号を付けて表示した。

*情報公開時に追記

Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 5[redacted]/Female/Unknown	20[redacted]	20[redacted]	68/71	小腸閉塞 Small intestinal obstruction	NOT APPLICABLE	UNRELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	80/103	腸閉塞 Intestinal obstruction	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	18/28	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	4/7	腸閉塞 Intestinal obstruction	DRUG INTERRUPTED	UNRELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	18/26	無力症 Asthenia	DRUG WITHDRAWN DRUG INTERRUPTED	RELATED	3	RECOVERED/RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	43/56	高ビリルビン血症 Hyperbilirubinaemia	DRUG WITHDRAWN	UNRELATED	5	FATAL
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	34/37	発熱 Pyrexia	NOT APPLICABLE	UNLIKELY TO BE RELATED	1	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	41/44	腹部膨満 Abdominal distension	NOT APPLICABLE	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED WITH SEQUELAE
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	270/280	敗血症 Sepsis	DOSE REDUCED DRUG INTERRUPTED	LIKELY RELATED	4	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	21/23	腹水 Ascites	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED

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a' ・事象の発現日又は消失日が初回投与前の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし「-」（マイナス）符号を付けて表示した。
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・事象の発現日又は消失日が最終投与後の場合、そのRel Dayは最終投与日を起点として事象の発現日又は消失日までの日数をカウントし「+」（プラス）符号を付けて表示した。

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Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 6[redacted]/Female/Black or African American	20[redacted]	20[redacted]	8/14	脱水 Dehydration	DRUG WITHDRAWN	LIKELY RELATED	3	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	8/14	電解質失調 Electrolyte imbalance	DRUG WITHDRAWN	LIKELY RELATED	3	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	8/14	嘔吐 Vomiting	DRUG WITHDRAWN	LIKELY RELATED	3	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	20/28	脱水 Dehydration	NOT APPLICABLE	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	20/28	悪心 Nausea	NOT APPLICABLE	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	20/28	嘔吐 Vomiting	NOT APPLICABLE	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	20/28	血小板減少症 Thrombocytopenia	NOT APPLICABLE	LIKELY RELATED	3	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	15/17	動悸 Palpitations	DRUG WITHDRAWN	RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	15/17	高血圧 Hypertension	DRUG INTERRUPTED	RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	20/24	血小板減少症 Thrombocytopenia	DRUG WITHDRAWN	RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	27/36	血小板減少症 Thrombocytopenia	NOT APPLICABLE	RELATED	2	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	15/22	好中球減少症 Neutropenia	DOSE REDUCED	LIKELY RELATED	4	RECOVERED/RESOLVED

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a' ・事象の発現日又は消失日が初回投与前の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし「-」（マイナス）符号を付けて表示した。
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・事象の発現日又は消失日が最終投与後の場合、そのRel Dayは最終投与日を起点として事象の発現日又は消失日までの日数をカウントし「+」（プラス）符号を付けて表示した。

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Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	22/26	悪心 Nausea	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	22/26	レンサ球菌性菌血症 Streptococcal bacteraemia	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	22/26	高血圧 Hypertension	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	167/195	水腎症 Hydronephrosis	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	-1/1	腹痛 Abdominal pain	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	3/15	小腸閉塞 Small intestinal obstruction	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	39/46	悪心 Nausea	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	635/636	一過性脳虚血発作 Transient ischaemic attack	DOSE NOT CHANGED	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	5/9	腹痛 Abdominal pain	DOSE REDUCED DOSE HELD	LIKELY RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	280/324	深部静脈血栓症 Deep vein thrombosis	NOT APPLICABLE	UNRELATED	2	RECOVERED/RESOLVED
[redacted] 4[redacted]/Female/White	20[redacted]	20[redacted]	104/150	小腸閉塞 Small intestinal obstruction	DRUG WITHDRAWN DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/Unknown	20[redacted]	20[redacted]	123/162	腹水 Ascites	NOT APPLICABLE	UNLIKELY TO BE RELATED	4	RECOVERED/RESOLVED

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Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 6[redacted]/Female/Unknown	20[redacted]	20[redacted]	49/52	小腸閉塞 Small intestinal obstruction	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	78/80	貧血 Anaemia	DOSE REDUCED DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	230/231	小腸閉塞 Small intestinal obstruction	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	231/239	低酸素症 Hypoxia	NOT APPLICABLE	LIKELY RELATED	3	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	251/268	小腸閉塞 Small intestinal obstruction	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED WITH SEQUELAE
[redacted] 8[redacted]/Female/White	20[redacted]	20[redacted]	376/378	小腸炎 Enteritis	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/Unknown	20[redacted]	20[redacted]	21/24	食道静脈瘤出血 Oesophageal varices haemorrhage	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	28/41	食道静脈瘤出血 Oesophageal varices haemorrhage	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	11/13	脱水 Dehydration	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	11/13	低ナトリウム血症 Hyponatraemia	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	13/22	高血圧 Hypertension	NOT APPLICABLE DOSE REDUCED	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	ongoing	2/	嘔吐 Vomiting	DRUG INTERRUPTED	UNRELATED	3	NOT RECOVERED/NOT RESOLVED
	20[redacted]	ongoing	2/	悪心 Nausea	DRUG INTERRUPTED	UNRELATED	3	NOT RECOVERED/NOT RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	19/22	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	22/29	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	2	RECOVERED/RESOLVED

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・事象の発現日又は消失日が最終投与後の場合、そのRel Dayは最終投与日を起点として事象の発現日又は消失日までの日数をカウントし「+」（プラス）符号を付けて表示した。

*情報公開時に追記

Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 4[redacted]/Female/Black or African American	20[redacted]	20[redacted]	15/41	腹痛 Abdominal pain	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	15/50	大腸炎 Colitis	DRUG WITHDRAWN	LIKELY RELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	23/24	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	23/30	貧血 Anaemia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	25/25	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	32/35	急性呼吸不全 Acute respiratory failure	DRUG WITHDRAWN	UNRELATED	5	FATAL
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	4/6	側腹部痛 Flank pain	DRUG WITHDRAWN	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	4/6	背部痛 Back pain	DRUG WITHDRAWN	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	15/16	悪心 Nausea	NOT APPLICABLE	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	15/16	嘔吐 Vomiting	DRUG WITHDRAWN	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
[redacted] 4[redacted]/Female/Other	20[redacted]	20[redacted]	7/11	小腸閉塞 Small intestinal obstruction	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	101/258	呼吸困難 Dyspnoea	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	4	RECOVERED/RESOLVED
[redacted] 3[redacted]/Female/White	20[redacted]	20[redacted]	58/63	小腸閉塞 Small intestinal obstruction	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	68/82	小腸閉塞 Small intestinal obstruction	DRUG WITHDRAWN	UNRELATED	3	RECOVERED/RESOLVED

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Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	88/90	脱水 Dehydration	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	88/90	低カリウム血症 Hypokalaemia	DOSE NOT CHANGED	UNRELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	88/90	正色素性正球性貧血 Normochromic normocytic anaemia	DOSE NOT CHANGED	RELATED	1	RECOVERED/RESOLVED WITH SEQUELAE
[redacted] 7[redacted]/Female/White	20[redacted]	ongoing	275/	硬膜下血腫 Subdural haematoma	NOT APPLICABLE	LIKELY RELATED	2	NOT RECOVERED/NOT RESOLVED
	20[redacted]	20[redacted]	275/278	貧血 Anaemia	NOT APPLICABLE	RELATED	3	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	275/293	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	15/24	イレウス Ileus	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]	ongoing	91/	胸水 Pleural effusion	NOT APPLICABLE	UNRELATED	3	NOT RECOVERED/NOT RESOLVED
	20[redacted]	20[redacted]	82/88	胸水 Pleural effusion	DRUG WITHDRAWN DRUG INTERRUPTED	UNRELATED	3	RECOVERED/RESOLVED WITH SEQUELAE
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	84/86	塞栓症 Embolism	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	12/14	悪心 Nausea	DOSE NOT CHANGED	LIKELY RELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	12/14	嘔吐 Vomiting	DOSE NOT CHANGED	LIKELY RELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	17/32	腸閉塞 Intestinal obstruction	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	52/60	汎血球減少症 Pancytopenia	DRUG INTERRUPTED	RELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	ongoing	37/	無力症 Asthenia	DRUG INTERRUPTED	UNRELATED	3	NOT RECOVERED/NOT RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	23/25	便秘 Constipation	DOSE NOT CHANGED	LIKELY RELATED	2	RECOVERED/RESOLVED

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*情報公開時に追記

Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted]-[redacted] 7[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	7/20	尿路感染 Urinary tract infection	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/RESOLVED
[redacted]-[redacted] 5[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	30/64	疲労 Fatigue	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/RESOLVED
[redacted]-[redacted] 5[redacted]/Female/Other	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	33/39	腹痛 Abdominal pain	DOSE NOT CHANGED	UNRELATED	2	RECOVERED/RESOLVED
[redacted]-[redacted] 7[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	8/18	嘔吐 Vomiting	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	8/18	小腸閉塞 Small intestinal obstruction	DRUG INTERRUPTED	UNRELATED	2	RECOVERED/RESOLVED
[redacted]-[redacted] 5[redacted]/Female/Asian	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	56/108	腹痛 Abdominal pain	NOT APPLICABLE	UNRELATED	2	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	11/18	悪心 Nausea	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	11/18	嘔吐 Vomiting	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	29/29	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	LIKELY RELATED	4	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	29/34	悪心 Nausea	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	29/34	嘔吐 Vomiting	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	37/40	悪心 Nausea	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	37/40	嘔吐 Vomiting	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	56/98	敗血症 Sepsis	NOT APPLICABLE	UNRELATED	4	RECOVERED/RESOLVED

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a' ・事象の発現日又は消失日が初回投与前の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし「-」（マイナス）符号を付けて表示した。
・事象の発現日又は消失日が投与期間中（初回投与後から最終投与の間）の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし符号なしとした。
・事象の発現日又は消失日が最終投与後の場合、そのRel Dayは最終投与日を起点として事象の発現日又は消失日までの日数をカウントし「+」（プラス）符号を付けて表示した。

*情報公開時に追記

Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 4[redacted]/Female/White	20[redacted]	20[redacted]	308/317	腹痛 Abdominal pain	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]	ongoing	286/	肝膿瘍 Liver abscess	DOSE NOT CHANGED	UNRELATED	3	NOT RECOVERED/NOT RESOLVED
	20[redacted]	20[redacted]	-7/7	嘔吐 Vomiting	NOT APPLICABLE	UNRELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	-7/7	倦怠感 Malaise	NOT APPLICABLE	UNRELATED	2	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	127/128	貧血 Anaemia	DOSE REDUCED	RELATED	3	RECOVERED/RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	25/36	便秘 Constipation	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/Unknown	20[redacted]	20[redacted]	19/19	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	19/20	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	3	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	25/26	胸水 Pleural effusion	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	23/36	イレウス Ileus	DOSE NOT CHANGED	UNRELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	96/99	脱水 Dehydration	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	96/99	低ナトリウム血症 Hyponatraemia	DRUG WITHDRAWN	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	16/19	急性腎障害 Acute kidney injury	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	38/44	深部静脈血栓症 Deep vein thrombosis	NOT APPLICABLE	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED WITH SEQUELAE

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a' ・事象の発現日又は消失日が初回投与前の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし「-」（マイナス）符号を付けて表示した。
・事象の発現日又は消失日が投与期間中（初回投与後から最終投与の間）の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし符号なしとした。
・事象の発現日又は消失日が最終投与後の場合、そのRel Dayは最終投与日を起点として事象の発現日又は消失日までの日数をカウントし「+」（プラス）符号を付けて表示した。

*情報公開時に追記

Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted]-[redacted] 5[redacted]/Female/Asian	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	63/66	インフルエンザ Influenza	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	29/34	好中球減少症 Neutropenia	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	35/41	好中球減少症 Neutropenia	NOT APPLICABLE	LIKELY RELATED	4	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	19/23	敗血症 Sepsis	DRUG INTERRUPTED	UNRELATED	4	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	20/28	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	LIKELY RELATED	2	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	63/75	上気道感染 Upper respiratory tract infection	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/RESOLVED
[redacted]-[redacted] 4[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	5/29	背部痛 Back pain	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	4	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	14/15	白血球減少症 Leukopenia	DRUG INTERRUPTED	LIKELY RELATED	4	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	11/21	血小板減少症 Thrombocytopenia	NOT APPLICABLE	LIKELY RELATED	4	RECOVERED/RESOLVED WITH SEQUELAE
[redacted]-[redacted] 6[redacted]/Female/Unknown	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	115/122	小腸閉塞 Small intestinal obstruction	DOSE NOT CHANGED	UNRELATED	2	RECOVERED/RESOLVED

出典：PR-30-5020-C 試験　総括報告書　Table 14.3.2.3、Table 14.3.2.4、Table 14.3.2.5、Listing 16.2.4.1、Listing 16.2.5.2 及び Listing 16.2.7.1

a Rel Day is calculated as start date minus first dose date (plus one if start date >= first dose date). Rel Day for events with a start date after last dose date is calculated using last dose date. Rel Day is signed negative for events with onset prior to first dose date. Rel Day is signed positive for events with onset after last dose date. Otherwise Rel Day is unsigned.

MedDRA 第 20.0 版及びそれ以降を使用した。

*

a'・事象の発現日又は消失日が初回投与前の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし「-」（マイナス）符号を付けて表示した。
・事象の発現日又は消失日が投与期間中（初回投与後から最終投与の間）の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし符号なしとした。
・事象の発現日又は消失日が最終投与後の場合、そのRel Dayは最終投与日を起点として事象の発現日又は消失日までの日数をカウントし「+」（プラス）符号を付けて表示した。

*情報公開時に追記

表 2.7.6-補遺 2-9　重篤な有害事象の一覧（Niraparib-2002 試験）

Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 6[redacted]/Female/Asian	20[redacted]	20[redacted]	-3/9	腹水 Ascites	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	15/37	腹水 Ascites	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	22/36	血小板数減少 Platelet count decreased	DOSE REDUCED DOSE INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	-	125	呼吸困難 Dyspnoea	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/Asian	20[redacted]	20[redacted]	22/29	血小板数減少 Platelet count decreased	DRUG DISCONTINUATION	RELATED	4	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/Asian	20[redacted]	20[redacted]	74/102	貧血 Anaemia	DRUG DISCONTINUATION	RELATED	3	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/Asian	20[redacted]	20[redacted]	85/106	貧血 Anaemia	DRUG DISCONTINUATION	RELATED	3	RECOVERED/ RESOLVED

出典：Niraparib-2002 試験　総括報告書 Listing 16.2.7

a Rel Day is calculated as start date minus first dose date (plus one if start date >= first dose date). Rel Day for events with a start date after last dose date is calculated using last dose date. Rel Day is signed negative for events with onset prior to first dose date. Rel Day is signed positive for events with onset after last dose date. Otherwise Rel Day is unsigned.

MedDRA 第 21.0 版を使用した

*

a'・事象の発現日又は消失日が初回投与前の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし「-」（マイナス）符号を付けて表示した。
・事象の発現日又は消失日が投与期間中（初回投与後から最終投与の間）の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし符号なしとした。
・事象の発現日又は消失日が最終投与後の場合、そのRel Dayは最終投与日を起点として事象の発現日又は消失日までの日数をカウントし「+」（プラス）符号を付けて表示した。

*情報公開時に追記

表 2.7.6-補遺 2-10　重篤な有害事象の一覧（P-30-5017-C 試験、本剤群）

Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 5 /Female/White	20[redacted]	20[redacted]	40/44	小腸閉塞 Small Intestinal obstruction	DOSE REDUCED, DRUG INTERRUPTED	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 6 /Female/White	20[redacted]	20[redacted]	47/49	貧血 Anaemia	DOSE REDUCED, DRUG INTERRUPTED	RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	47/47	血小板減少症 Thrombocytopenia	DOSE REDUCED, DRUG INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED
[redacted] 5 /Female/Unknown	20[redacted]	20[redacted]	79/+84	肺臓炎 Pneumonitis	DRUG WITHDRAWN	RELATED	2	RECOVERED/ RESOLVED
[redacted] 7 /Female/White	20[redacted]	20[redacted]	+7/+7	血小板減少症 Thrombocytopenia	NOT APPLICABLE	RELATED	4	RECOVERED/ RESOLVED
[redacted] 6 /Female/White	20[redacted]	20[redacted]	21/26	血小板減少症 Thrombocytopenia	DOSE REDUCED, DRUG INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED
[redacted] 4 /Female/White	20[redacted]	20[redacted]	20/20	血小板減少症 Thrombocytopenia	DOSE REDUCED, DRUG INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	589L/+26	肺臓炎 Pneumonitis	DOSE NOT CHANGED	POSSIBLY RELATED	2	RECOVERED/ RESOLVED
[redacted] 6 /Female/White	20[redacted]	20[redacted]	73/73	貧血 Anaemia	DOSE REDUCED, DRUG INTERRUPTED	RELATED	3	RECOVERED/ RESOLVED
[redacted] 7 /Female/White	20[redacted]	20[redacted]	22L/+13	血小板数減少 Platelet count decreased	DRUG INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED
[redacted] 5 /Female/White	20[redacted]	20[redacted]	22/34	血小板数減少 Platelet count decreased	DOSE REDUCED, DRUG INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	+1/+52	小腸閉塞 Small Intestinal obstruction	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 5 /Female/White	20[redacted]	20[redacted]	14/36	食欲減退 Decreased appetite	DOSE REDUCED, DRUG INTERRUPTED	RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	19/22	発熱性好中球減少症 Febrile Neutropenia	NOT APPLICABLE	RELATED	3	RECOVERED/ RESOLVED
[redacted] 7 /Female/White	20[redacted]	20[redacted]	+1/+29	肺炎 Pneumonia	DRUG INTERRUPTED, DRUG WITHDRAWN	POSSIBLY RELATED	3	RECOVERED/ RESOLVED
[redacted] 5 /Female/White	20[redacted]	20[redacted]	21/21	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED

* a'・事象の発現日又は消失日が初回投与前の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし「-」（マイナス）符号を付けて表示した。
・事象の発現日又は消失日が投与期間中（初回投与後から最終投与の間）の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし符号なしとした。
・事象の発現日又は消失日が最終投与日の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし「L」を付けて表示した。
・事象の発現日又は消失日が最終投与後の場合、そのRel Dayは最終投与日を起点として事象の発現日又は消失日までの日数をカウントし「+」（プラス）符号を付けて表示した。

*情報公開時に追記

Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
	20[redacted]	20[redacted]	27/43	発熱性好中球減少症 Febrile Neutropenia	DRUG INTERRUPTED	POSSIBLY RELATED	3	RECOVERED/ RESOLVED
[redacted] 3[redacted]/Female/White	20[redacted]	20[redacted]	21/22	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	26/37	汎血球減少症 Pancytopenia	DOSE REDUCED, DRUG INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	273/277	小腸閉塞 Small Intestinal obstruction	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	ongoing	282	小腸閉塞 Small Intestinal obstruction	DRUG WITHDRAWN	UNRELATED	3	NOT RECOVERED/ NOT RESOLVED
	20[redacted]	ongoing	+1	骨髄異形成症候群 Myelodysplastic syndrome	NOT APPLICABLE	RELATED	4	NOT RECOVERED/ NOT RESOLVED
	20[redacted]	20[redacted]	+10/+11	腸管穿孔 Intestinal perforation	NOT APPLICABLE	UNRELATED	5	FATAL
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	81/111	肺塞栓症 Pulmonary embolism	DOSE NOT CHANGED	POSSIBLY RELATED	3	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	22/23	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	+4/+9	血小板減少症 Thrombocytopenia	DRUG WITHDRAWN	RELATED	4	RECOVERED/ RESOLVED WITH SEQUELAE
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	19/22	血小板減少症 Thrombocytopenia	DOSE REDUCED, DRUG INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	19/19	輸血反応 Transfusion reaction	DOSE NOT CHANGED	UNRELATED	2	RECOVERED/ RESOLVED
[redacted] 4[redacted]/Female/White	20[redacted]	20[redacted]	254L/254L	過量投与 Overdose	DRUG INTERRUPTED	RELATED	1	RECOVERED/ RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	21/21	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	26/34	好中球減少症 Neutropenia	DOSE NOT CHANGED	RELATED	4	RECOVERED/ RESOLVED

* a' ・事象の発現日又は消失日が初回投与前の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし「-」（マイナス）符号を付けて表示した。
・事象の発現日又は消失日が投与期間中（初回投与後から最終投与の間）の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし符号なしとした。
・事象の発現日又は消失日が最終投与日の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし「L」を付けて表示した。
・事象の発現日又は消失日が最終投与後の場合、そのRel Dayは最終投与日を起点として事象の発現日又は消失日までの日数をカウントし「+」（プラス）符号を付けて表示した。

*情報公開時に追記