補遺 2. 死亡及びその他の重篤な有害事象の一覧

本申請の評価資料とした臨床試験で認められた以下の死亡及び重篤な有害事象の一覧を示した。

・海外試験で認められた試験期間中の死亡

・海外試験及び国内試験で認められた全ての重篤な有害事象（pretreatment event を含む）

なお、国内試験では、試験期間中の死亡は認められなかった。

全ての死亡及び重篤な有害事象の詳細については各臨床試験の総括報告書に記載した。

表 2.7.6-補遺 2-1　試験期間中の死亡の一覧（PN001 試験）

Subject ID Age/Sex /Race	Treatment Group	First Dose Date	Last Dose Date	Death Date (Study Day)	Related to Disease	Cause of Death (AE [preferred/verbatim])
[redacted] 7[redacted]/Female/White	30 mg	20[redacted]-10-13	*同年 -11-02	20[redacted] (44)	Not Related	悪性新生物 Neoplasm Malignant
[redacted] 5[redacted]/Female/Black or African American	60 mg	20[redacted]-05-14	*同年 -06-03	20[redacted] (42)	Not Related	悪性新生物 Neoplasm Malignant
[redacted] 4[redacted]/Female/White	210 mg	20[redacted]-11-10	*翌年 -03-22	20[redacted] (192)	Not Related	悪性新生物 Neoplasm Malignant
[redacted] 5[redacted]/Male/White	400 mg	20[redacted]-02-09	*同年 -05-03	20[redacted] (365)	Not Related	悪性新生物 Neoplasm Malignant
[redacted] 6[redacted]/Male/White	300 mg	20[redacted]-08-02	*同年 -08-16	20[redacted] (29)	Not Related	敗血症 Sepsis
[redacted] 6[redacted]/Male/White	300 mg	20[redacted]-10-04	*翌年 -01-06	20[redacted] (97)	Not Related	脳梗塞 Cerebral Infarction

出典：PN-001 試験　総括報告書　Listing16.2.2.1 及び Listing16.2.3.3b
試験期間中の死亡とは、治験薬投与期間及び試験終了 30 日後までの期間の死亡を指す。
MedDRA 第 18.0 版を使用した。

*新薬承認情報提供時に置き換え

表 2.7.6-補遺 2-2　試験期間中の死亡の一覧（PR-30-5011-C 試験）

Subject ID Age/Sex /Race	Treatment Group	First Dose Date	Last Dose Date	Death Date (Study Day)	Related to Disease	Cause of Death (AE [preferred/verbatim])
[redacted]-[redacted](1) 6[redacted]/Female/Unknown	Niraparib 300 mg	20[redacted]-06-01	*翌年-04-03	20[redacted]-[redacted]-[redacted]	RELATED	急性骨髄性白血病 Acute myeloid leukaemia

出典：PR-30-5011-C 試験　総括報告書　Listing16.2.1.1 及び Listing16.2.7.1

(1)　試験期間中（同意取得日～治験薬の最終投与 30 日後）に SAE として報告され、その後死亡に至った。

MedDRA 第 18.0 版を使用した。

*新薬承認情報提供時に置き換え

表 2.7.6-補遺 2-3　試験期間中の死亡の一覧（PR-30-5020-C 試験）

Subject ID Age/Sex /Race	Treatment Group	First Dose Date	Last Dose Date	Death Date (Study Day)	Related to Disease	Cause of Death (AE [preferred/verbatim])
[redacted]-[redacted] 6[redacted]/Female/White	Niraparib 300 mg	20[redacted]-10-06	*同年 -11-04	20[redacted]-[redacted]-[redacted]	Not Related	急性呼吸不全 acute respiratory failure

出典：PR-30-5020-C 試験　総括報告書　Listing16.2.4.1、Listing16.2.5.1A 及び Table14.3.2.1
試験期間中の死亡とは、同意取得日～治験薬の最終投与 30 日後の期間の死亡を指す。
MedDRA 第 20.0 版及びそれ以降を使用した。

*新薬承認情報提供時に置き換え

表 2.7.6-補遺 2-4　重篤な有害事象の一覧（PN001 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] 7[redacted]/Female/White	20[redacted]	-	44/	悪性新生物 Neoplasm Malignant	DOSE NOT CHANGED	NOT RELATED	5	FATAL
[redacted] 6[redacted]/Male/White	20[redacted]	20[redacted]	61/61	錯乱状態 Confusional State	DRUG INTERRUPTED	NOT RELATED	3	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/Black or African American	20[redacted]	-	21/	悪性新生物 Neoplasm Malignant	DOSE NOT CHANGED	NOT RELATED	5	FATAL
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	18/24	吐血 Haematemesis	DRUG INTERRUPTED	NOT RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	5/9	悪心 Nausea	DRUG INTERRUPTED	NOT RELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	18/24	悪心 Nausea	DRUG INTERRUPTED	NOT RELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	6/7	嘔吐 Vomiting	DOSE NOT CHANGED	NOT RELATED	2	RECOVERED/RESOLVED
[redacted] 4[redacted]/Female/White	20[redacted]	20[redacted]	2/10	便秘 Constipation	DOSE NOT CHANGED	NOT RELATED	2	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	21/22	悪心 Nausea	DRUG INTERRUPTED	NOT RELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	21/22	嘔吐 Vomiting	DRUG INTERRUPTED	NOT RELATED	2	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	2/18	悪心 Nausea	DOSE NOT CHANGED	RELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	8/18	嘔吐 Vomiting	DOSE NOT CHANGED	RELATED	2	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	9/12	胸痛 Chest Pain	DOSE NOT CHANGED	NOT RELATED	3	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	12/51	小腸閉塞 Small Intestinal Obstruction	DOSE NOT CHANGED	NOT RELATED	2	RECOVERED/RESOLVED
[redacted] 4[redacted]/Female/White	20[redacted]	20[redacted]	5/9	皮下組織膿瘍 Subcutaneous Abscess	DRUG INTERRUPTED	NOT RELATED	2	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] 7[redacted]/Male/White	20[redacted]	-	48/	胸水 Pleural Effusion	NOT APPLICABLE	NOT RELATED	2	NOT RECOVERED/NOT RESOLVED
	20[redacted]	20[redacted]	64/73	肺炎 Pneumonia	NOT APPLICABLE	NOT RELATED	3	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/Unknown	20[redacted]	20[redacted]	11/16	小腸閉塞 Small Intestinal Obstruction	DRUG INTERRUPTED	NOT RELATED	3	RECOVERED/RESOLVED
[redacted] 4[redacted]/Female/White	20[redacted]	20[redacted]	22/23	貧血 Anaemia	DOSE NOT CHANGED	RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	5/6	脱水 Dehydration	DRUG INTERRUPTED	NOT RELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	23/24	好中球減少症 Neutropenia	DOSE NOT CHANGED	RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	5/6	皮膚疼痛 Pain Of Skin	DRUG INTERRUPTED	NOT RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	16/16	胸水 Pleural Effusion	DOSE NOT CHANGED	NOT RELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	16/29	血小板減少症 Thrombocytopenia	DRUG WITHDRAWN	RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	6/8	心室性頻脈 Ventricular Tachycardia	DOSE NOT CHANGED	NOT RELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Male/White	20[redacted]	20[redacted]	62/78	尿路感染 Urinary Tract Infection	DOSE NOT CHANGED	NOT RELATED	3	RECOVERED/RESOLVED
[redacted] 7[redacted]/Male/White	20[redacted]	20[redacted]	321/322	下腹部痛 Abdominal Pain Lower	DOSE NOT CHANGED	NOT RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	321/322	尿路閉塞 Ureteric Tract Obstruction	DOSE NOT CHANGED	NOT RELATED	3	RECOVERED/RESOLVED
[redacted] 3[redacted]/Female/White	20[redacted]	20[redacted]	51/54	消化管運動障害 Gastrointestinal Motility Disorder	DOSE NOT CHANGED	NOT RELATED	3	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	50/52	嘔吐 Vomiting	DRUG WITHDRAWN	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。
・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]/Male/White	20[redacted]	20[redacted]	60/93	筋力低下 Muscular Weakness	DRUG INTERRUPTED	NOT RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	60/93	頚部痛 Neck Pain	DRUG INTERRUPTED	NOT RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	60/93	四肢痛 Pain In Extremity	DRUG INTERRUPTED	NOT RELATED	3	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	16/18	貧血 Anaemia	DOSE NOT CHANGED	RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	16/37	疲労 Fatigue	DOSE NOT CHANGED	NOT RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	16/19	低ナトリウム血症 Hyponatraemia	DOSE NOT CHANGED	NOT RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	16/30	肺臓炎 Pneumonitis	DRUG WITHDRAWN	RELATED	3	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	445/491	貧血 Anaemia	DOSE REDUCED	RELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	90/107	蜂巣炎 Cellulitis	DRUG INTERRUPTED	NOT RELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	143/172	蜂巣炎 Cellulitis	DRUG INTERRUPTED	NOT RELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	9/10	低カリウム血症 Hypokalaemia	DRUG INTERRUPTED	NOT RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	27/29	発熱 Pyrexia	DRUG INTERRUPTED	NOT RELATED	1	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	90/94	敗血症 Sepsis	DRUG INTERRUPTED	NOT RELATED	2	RECOVERED/RESOLVED
[redacted] 6[redacted]/Male/White	20[redacted]	20[redacted]	55/59	血尿 Haematuria	DOSE NOT CHANGED	NOT RELATED	1	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	55/59	尿閉 Urinary Retention	DOSE NOT CHANGED	NOT RELATED	3	RECOVERED/RESOLVED
[redacted] 4[redacted]/Female/White	20[redacted]	-	123	悪性新生物 Neoplasm Malignant	DOSE NOT CHANGED	NOT RELATED	5	FATAL
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	94/94	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]/Male/White	20[redacted]	20[redacted]	14/14	血中クレアチニン増加 Blood Creatinine Increased	DRUG INTERRUPTED	NOT RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	14/19	腎不全 Renal Failure	DRUG INTERRUPTED	NOT RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	14/21	尿路感染 Urinary Tract Infection	DRUG INTERRUPTED	NOT RELATED	3	RECOVERED/RESOLVED
[redacted] 5[redacted]/Male/White	20[redacted]	-	72/	悪性新生物 Neoplasm Malignant	DRUG WITHDRAWN	NOT RELATED	5	FATAL
[redacted] 6[redacted]/Female/Black or African American	20[redacted]	20[redacted]	336/340	嘔吐 Vomiting	DRUG INTERRUPTED	RELATED	2	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	4/5	低カリウム血症 Hypokalaemia	DOSE NOT CHANGED	NOT RELATED	1	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	4/5	低マグネシウム血症 Hypomagnesaemia	DOSE NOT CHANGED	NOT RELATED	1	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	471/482	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	4/14	心室性不整脈 Ventricular Arrhythmia	DRUG INTERRUPTED	RELATED	2	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	73/78	胸水 Pleural Effusion	DOSE NOT CHANGED	NOT RELATED	3	RECOVERED/RESOLVED
[redacted] 5[redacted]/Male/White	20[redacted]	20[redacted]	38/74	肺塞栓症 Pulmonary Embolism	DOSE NOT CHANGED	NOT RELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Male/White	20[redacted]	-	28/	敗血症 Sepsis	NOT APPLICABLE	NOT RELATED	5	FATAL
	20[redacted]	20[redacted]	25/29	脊髄圧迫 Spinal Cord Compression	NOT APPLICABLE	NOT RELATED	3	RECOVERED/RESOLVED WITH SEQUELAE
[redacted] 7[redacted]/Male/White	20[redacted]	20[redacted]	2/32	貧血 Anaemia	DOSE NOT CHANGED	RELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	33/86	貧血 Anaemia	DRUG INTERRUPTED	RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	78/113	下気道感染 Lower Respiratory Tract Infection	DRUG INTERRUPTED	NOT RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	187/228	下気道感染 Lower Respiratory Tract Infection	DRUG INTERRUPTED	NOT 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。
・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]/Male/White	20[redacted]	-	89/	脳梗塞 Cerebral Infarction	DRUG INTERRUPTED	NOT RELATED	5	FATAL
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	-29/-23	腹水 Ascites	NOT APPLICABLE	NOT RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	-22/-14	腸閉塞 Intestinal Obstruction	NOT APPLICABLE	NOT RELATED	3	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	-9/-2	腹痛 Abdominal Pain	NOT APPLICABLE	NOT RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	5/8	腸閉塞 Intestinal Obstruction	DRUG INTERRUPTED	NOT RELATED	1	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/Unknown	20[redacted]	20[redacted]	37/44	水腎症 Hydronephrosis	DOSE NOT CHANGED	NOT RELATED	2	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	3/7	腹水 Ascites	DRUG INTERRUPTED	NOT RELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Male/White	20[redacted]	20[redacted]	85/87	末梢性運動ニューロパチー Peripheral Motor Neuropathy	DRUG INTERRUPTED	NOT RELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	37/37	好中球減少症 Neutropenia	DOSE NOT CHANGED	RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	25/25	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	4	RECOVERED/RESOLVED

出典：PN001 試験　総括報告書 Listing 16.2.3.1

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 18.0 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 2-5　重篤な有害事象の一覧（Niraparib-1001 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] 4[redacted]/Female/Asian	20[redacted]-[redacted]-[redacted]	-	136	腎盂腎炎 Pyelonephritis	DRUG INTERRUPTED	NOT RELATED	3	-

出典：Niraparib-1001 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。

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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

表 2.7.6-補遺 2-6　重篤な有害事象の一覧（PR-30-5011-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] 4[redacted]/Female/White	20[redacted]	20[redacted]	56/57	低マグネシウム血症 Hypomagnesaemia	DOSE NOT CHANGED	UNLIKELY TO BE RELATED	1	RECOVERED/RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	22/23	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	200/205	小腸閉塞 Small intestinal obstruction	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	24/27	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/American	20[redacted]	20[redacted]	304/308	発熱 Pyrexia	DOSE NOT CHANGED	UNRELATED	1	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	-2/-1	貧血 Anaemia	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	20/21	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	LIKELY RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	27/28	貧血 Anaemia	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	27/28	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	LIKELY RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	139/139	貧血 Anaemia	DOSE NOT CHANGED	LIKELY RELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	140/141	貧血 Anaemia	DRUG WITHDRAWN	LIKELY RELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	27/32	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	4	RECOVERED/RESOLVED
[redacted] 4[redacted]/Female/White	20[redacted]	20[redacted]	23/27	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]	ongoing	562	骨髄異形成症候群 Myelodysplastic syndrome	NOT APPLICABLE	LIKELY RELATED	4	NOT RECOVERED/NOT 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/White	20[redacted]	20[redacted]	334/334	非心臓性胸痛 Non-cardiac chest pain	DRUG INTERRUPTED	UNRELATED	1	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	334/336	不安 Anxiety	DRUG INTERRUPTED	UNRELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	334/336	頻脈 Tachycardia	DRUG INTERRUPTED	UNRELATED	2	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	22/24	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	LIKELY RELATED	4	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	28/35	血小板減少症 Thrombocytopenia	DOSE REDUCED	LIKELY RELATED	4	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	28/49	好中球減少症 Neutropenia	NOT APPLICABLE	LIKELY RELATED	3	RECOVERED/RESOLVED
[redacted] 3[redacted]/Female/White	20[redacted]	20[redacted]	17/18	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	22/23	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	28/35	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	64/67	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED WITH SEQUELAE
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	22/24	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	10/11	腎結石症 Nephrolithiasis	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 4[redacted]/Female/Black	20[redacted]	ongoing	32	意識レベルの低下 Depressed level of consciousness	NOT APPLICABLE	UNRELATED	3	NOT RECOVERED/NOT RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	12/19	尿路感染 Urinary tract infection	DOSE NOT CHANGED	UNLIKELY TO BE RELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	205/211	小腸閉塞 Small intestinal obstruction	NOT APPLICABLE	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	148/149	便秘 Constipation	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	2	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	164/167	呼吸困難 Dyspnoea	NOT APPLICABLE	UNRELATED	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] 6[redacted]/Female/Unknown	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	21/28	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	28/32	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	3	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	63/67	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	4	RECOVERED/RESOLVED
[redacted]-[redacted] 5[redacted]/Female/Unknown	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	111/113	貧血 Anaemia	DOSE REDUCED	RELATED	3	RECOVERED/RESOLVED
[redacted]-[redacted] 6[redacted]/Female/Unknown	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	24/26	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	ongoing	312	骨髄異形成症候群 Myelodysplastic syndrome	DRUG WITHDRAWN	RELATED	4	NOT RECOVERED/NOT RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	666/673	急性骨髄性白血病 Acute myeloid leukaemia	NOT APPLICABLE	RELATED	5	FATAL
[redacted]-[redacted] 5[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	84/87	腸閉塞 Intestinal obstruction	DRUG WITHDRAWN	UNRELATED	3	RECOVERED/RESOLVED
[redacted]-[redacted] 6[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	29/30	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED
[redacted]-[redacted] 6[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	695/699	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	700/700	血小板減少症 Thrombocytopenia	NOT APPLICABLE	RELATED	3	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	701/702	血小板減少症 Thrombocytopenia	NOT APPLICABLE	RELATED	2	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	703/705	血小板減少症 Thrombocytopenia	NOT APPLICABLE	RELATED	3	RECOVERED/RESOLVED
[redacted]-[redacted] 8[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	165/172	心不全 Cardiac failure	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	4	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	187/191	急性腎不全 Acute kidney injury	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	4	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	210/215	急性肺水腫 Acute pulmonary oedema	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/RESOLVED
[redacted]-[redacted] 5[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	21/46	汎血球減少症 Pancytopenia	DRUG WITHDRAWN	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] 5[redacted]/Female/White	20[redacted]	20[redacted]	104/105	貧血 Anaemia	DOSE NOT CHANGED	RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	114/131	腹水 Ascites	NOT APPLICABLE	UNLIKELY TO BE RELATED	2	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	129/130	腹水 Ascites	NOT APPLICABLE	UNRELATED	2	RECOVERED/RESOLVED
[redacted] 5[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]	23/24	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	24/29	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	29/30	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	31/32	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	2	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	22/37	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	29/37	好中球数減少 Neutrophil count decreased	NOT APPLICABLE	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。

*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]	5/7	気管支炎 Bronchitis	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	29/30	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	30/32	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	3	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	33/34	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	34/37	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	3	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	35/43	粘膜の炎症 Mucosal inflammation	DRUG INTERRUPTED	RELATED	3	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	37/38	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	38/43	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	1	RECOVERED/RESOLVED
[redacted]-[redacted] 7[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	295/296	胸水 Pleural effusion	DOSE NOT CHANGED	UNLIKELY TO BE RELATED	2	RECOVERED/RESOLVED
[redacted]-[redacted] 4[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	214/217	肺塞栓症 Pulmonary embolism	NOT APPLICABLE	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
[redacted]-[redacted] 5[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	-3/-3	麻痺性イレウス Ileus paralytic	NOT APPLICABLE	UNRELATED	2	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	175/178	麻痺性イレウス Ileus paralytic	DOSE NOT CHANGED	UNRELATED	2	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	555/556	麻痺性イレウス Ileus paralytic	DOSE NOT CHANGED	UNRELATED	2	RECOVERED/RESOLVED
[redacted]-[redacted] 4[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	84/85	貧血 Anaemia	DRUG INTERRUPTED	LIKELY RELATED	4	RECOVERED/RESOLVED
[redacted]-[redacted] 4[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	238/241	腹膜転移 Metastases to peritoneum	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] 4[redacted]/Female/White	20[redacted]	20[redacted]	380/386	感染 Infection	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	393/396	上腹部痛 Abdominal pain upper	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	400/410	発熱 Pyrexia	NOT APPLICABLE	UNLIKELY TO BE RELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	415/416	発熱 Pyrexia	NOT APPLICABLE	UNRELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	418/422	上腹部痛 Abdominal pain upper	NOT APPLICABLE	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
	20[redacted]	ongoing	427	骨髄異形成症候群 Myelodysplastic syndrome	NOT APPLICABLE	LIKELY RELATED	2	NOT RECOVERED/NOT RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	118/123	肺炎 Pneumonia	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	43/44	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	44/46	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	22/24	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	4	RECOVERED/RESOLVED WITH SEQUELAE
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	280/284	腹痛 Abdominal pain	DRUG INTERRUPTED	UNRELATED	2	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	ongoing	234	2 型糖尿病 Type 2 diabetes mellitus	DOSE NOT CHANGED	UNLIKELY TO BE RELATED	2	NOT RECOVERED/NOT RESOLVED
[redacted] 4[redacted]/Female/White	20[redacted]	20[redacted]	232/238	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	LIKELY RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	408/419	悪心 Nausea	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	51/56	高血圧クリーゼ Hypertensive crisis	NOT APPLICABLE	RELATED	3	RECOVERED/RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	19/19	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	LIKELY RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	24/26	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	LIKELY 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。
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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 /Female/White	20[redacted]	20[redacted]	220/344	肺塞栓症 Pulmonary embolism	DOSE NOT CHANGED	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
[redacted] 6 /Female/Asian	20[redacted]	20[redacted]	27/29	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	4	RECOVERED/RESOLVED
[redacted] 4 /Female/White	20[redacted]	20[redacted]	-17/-14	肺塞栓症 Pulmonary embolism	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED WITH SEQUELAE
[redacted] 6 /Female/White	20[redacted]	20[redacted]	20/21	血小板減少症 Thrombocytopenia	NOT APPLICABLE	LIKELY RELATED	4	RECOVERED/RESOLVED
[redacted] 6 /Female/White	20[redacted]	20[redacted]	29/30	血小板減少症 Thrombocytopenia	DOSE REDUCED	LIKELY RELATED	4	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	29/31	輸血反応 Transfusion reaction	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	2	RECOVERED/RESOLVED
[redacted] 5 /Female/White	20[redacted]	20[redacted]	461/464	気管気管支炎 Tracheobronchitis	DOSE NOT CHANGED	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
[redacted] 4 /Female/White	20[redacted]	20[redacted]	238/240	尿路感染 Urinary tract infection	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 5 /Female/White	20[redacted]	20[redacted]	360/364	小腸閉塞 Small intestinal obstruction	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 5 /Female/Unknown	20[redacted]	20[redacted]	87/95	貧血 Anaemia	DOSE REDUCED	RELATED	3	RECOVERED/RESOLVED
[redacted] 6 /Female/Unknown	20[redacted]	20[redacted]	48/113	未分化型肉腫 Undifferentiated sarcoma	DRUG WITHDRAWN	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 7 /Female/White	20[redacted]	20[redacted]	118/124	腹部ヘルニア Abdominal hernia	DRUG INTERRUPTED	UNRELATED	2	RECOVERED/RESOLVED
[redacted] 6 /Female/White	20[redacted]	20[redacted]	132/136	喘息 Asthma	DOSE NOT CHANGED	UNRELATED	4	RECOVERED/RESOLVED
[redacted] 5 /Female/White	20[redacted]	20[redacted]	21/22	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED
[redacted] 5 /Female/White	20[redacted]	20[redacted]	85/87	貧血 Anaemia	DOSE REDUCED	RELATED	3	RECOVERED/RESOLVED
[redacted] 8 /Female/Unknown	20[redacted]	20[redacted]	156/157	胸水 Pleural effusion	DRUG WITHDRAWN	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 6 /Female/White	20[redacted]	20[redacted]	83/84	胸膜痛 Pleuritic pain	DOSE NOT CHANGED	UNRELATED	3	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] 5[redacted]/Female/White	20[redacted]	20[redacted]	414/415	狭心症 Angina pectoris	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	21/22	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	31/34	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	4	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	189/190	瘢痕ヘルニア Incisional hernia	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	293/295	瘢痕ヘルニア Incisional hernia	DOSE NOT CHANGED	UNRELATED	2	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	46/47	丹毒 Erysipelas	NOT APPLICABLE	UNRELATED	2	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	68/69	便秘 Constipation	DOSE NOT CHANGED	UNRELATED	2	RECOVERED/RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	25/26	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	54/58	肺臓炎 Pneumonitis	DOSE NOT CHANGED	UNLIKELY TO BE RELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	192/193	処置後不快感 Post procedural discomfort	DOSE NOT CHANGED	UNRELATED	1	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	210/220	発熱 Pyrexia	NOT APPLICABLE	UNRELATED	2	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
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	85/86	貧血 Anaemia	DOSE REDUCED	LIKELY RELATED	3	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	56/58	貧血 Anaemia	DRUG INTERRUPTED	RELATED	3	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	126/133	貧血 Anaemia	DOSE REDUCED	RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	269/272	胆嚢炎 Cholecystitis	DRUG INTERRUPTED	UNRELATED	4	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	287/328	肝不全 Hepatic failure	DRUG WITHDRAWN	UNRELATED	3	RECOVERED/RESOLVED

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[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	22/22	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	291/317	胆汁うっ滞 Cholestasis	DRUG WITHDRAWN	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 6[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]	22/22	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	2	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	23/24	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	3	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	24/29	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	4	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	29/33	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	2	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	33/37	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	3	RECOVERED/RESOLVED
[redacted] 4[redacted]/Female/White	20[redacted]	20[redacted]	19/24	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	4	RECOVERED/RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	379/387	トランスアミナーゼ上昇 Transaminases increased	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	389/396	腹痛 Abdominal pain	NOT APPLICABLE	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	399/410	腹痛 Abdominal pain	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	2/8	幻覚 Hallucination	DRUG WITHDRAWN	LIKELY RELATED	2	RECOVERED/RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	23/34	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	4	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	31/32	血小板数減少 Platelet count decreased	DRUG INTERRUPTED	LIKELY RELATED	4	RECOVERED/RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	109/112	疼痛管理 Pain management	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	89/93	貧血 Anaemia	DOSE REDUCED	RELATED	4	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] 6[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	20/21	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	21/22	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	3	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	22/24	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	24/27	血小板減少症 Thrombocytopenia	DOSE NOT CHANGED	RELATED	3	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	24/27	好中球減少症 Neutropenia	NOT APPLICABLE	RELATED	4	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	71/78	貧血 Anaemia	DOSE REDUCED	RELATED	3	RECOVERED/RESOLVED
[redacted]-[redacted] 5[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	22/24	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	24/28	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	3	RECOVERED/RESOLVED
[redacted]-[redacted] 7[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	54/57	小腸閉塞 Small intestinal obstruction	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	97/98	小腸閉塞 Small intestinal obstruction	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
[redacted]-[redacted] 5[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	88/100	疾患進行 Disease progression	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
[redacted]-[redacted] 5[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	91/92	心嚢液貯留 Pericardial effusion	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
[redacted]-[redacted] 8[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	22/27	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED
[redacted]-[redacted] 6[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	93/99	尿路感染 Urinary tract infection	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/RESOLVED
[redacted]-[redacted] 6[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	-70/-62	便秘 Constipation	NOT APPLICABLE	UNLIKELY TO BE RELATED	2	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	210/225	胃排出不全 Impaired gastric emptying	DOSE REDUCED	LIKELY RELATED	3	RECOVERED/RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	256/277	胃閉塞 Obstruction gastric	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]	80/87	肺炎 Pneumonia	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	644/686	乳管内増殖性病変 Intraductal proliferative breast lesion	DOSE NOT CHANGED	UNRELATED	2	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/Asian	20[redacted]	20[redacted]	348/348	アナフィラキシー様反応 Anaphylactoid reaction	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	19/29	末梢動脈血栓症 Peripheral artery thrombosis	NOT APPLICABLE	UNRELATED	2	RECOVERED/RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	372/377	小腸閉塞 Small intestinal obstruction	NOT APPLICABLE	UNRELATED	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] 5[redacted]/Female/Unknown	20[redacted]	20[redacted]	28/36	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	154/164	亜イレウス Subileus	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/Unknown	20[redacted]	20[redacted]	82/85	貧血 Anaemia	DOSE REDUCED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	85/89	貧血 Anaemia	DRUG INTERRUPTED	RELATED	2	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/Unknown	20[redacted]	20[redacted]	81/82	腸閉塞 Intestinal obstruction	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	143/143	失神 Syncope	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	121/124	疾患進行 Disease progression	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	1	RECOVERED/RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	5/6	嘔吐 Vomiting	DOSE REDUCED	LIKELY RELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	11/13	嘔吐 Vomiting	DRUG INTERRUPTED	LIKELY RELATED	1	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	102/103	上気道感染 Upper respiratory tract infection	DOSE NOT CHANGED	UNRELATED	2	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]	249/305	心筋症 Cardiomyopathy	NOT APPLICABLE	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	156/157	一過性脳虚血発作 Transient ischaemic attack	DOSE NOT CHANGED	LIKELY RELATED	2	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	22/29	血小板減少症 Thrombocytopenia	DOSE REDUCED	LIKELY RELATED	4	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	22/25	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	113/114	貧血 Anaemia	DOSE REDUCED	RELATED	3	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	79/82	貧血 Anaemia	DRUG INTERRUPTED	RELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	9/25	便秘 Constipation	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	2	RECOVERED/RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	29/45	呼吸困難 Dyspnoea	DRUG INTERRUPTED	LIKELY RELATED	2	RECOVERED/RESOLVED
[redacted] 3[redacted]/Female/White	20[redacted]	20[redacted]	12/27	腎盂腎炎 Pyelonephritis	DOSE NOT CHANGED	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	12/33	汎血球減少症 Pancytopenia	DOSE REDUCED	LIKELY RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	12/57	亜イレウス Subileus	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	47/58	汎血球減少症 Pancytopenia	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	64/76	便秘 Constipation	NOT APPLICABLE	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	66/81	創傷感染 Wound infection	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	15/16	洞性頻脈 Sinus tachycardia	DOSE NOT CHANGED	UNRELATED	2	RECOVERED/RESOLVED
[redacted] 4[redacted]/Female/Unknown	20[redacted]	20[redacted]	22/22	血小板減少症 Thrombocytopenia	DRUG WITHDRAWN	RELATED	4	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/Unknown	20[redacted]	20[redacted]	117/118	貧血 Anaemia	DRUG INTERRUPTED	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] 6[redacted]/Female/White	20[redacted]	20[redacted]	238/239	胃食道逆流性疾患 Gastrooesophageal reflux disease	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	21/23	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	103/105	胸水 Pleural effusion	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	118/120	発熱性好中球減少症 Febrile neutropenia	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/Asian	20[redacted]	20[redacted]	15/22	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	22/29	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	LIKELY RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	71/83	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	3	RECOVERED/RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	23/24	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	4	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	901/905	股関節部骨折 Hip fracture	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	641/644	小腸閉塞 Small intestinal obstruction	DRUG WITHDRAWN	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/Unknown	20[redacted]	20[redacted]	886/893	小腸閉塞 Small intestinal obstruction	DRUG WITHDRAWN	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	900/913	小腸閉塞 Small intestinal obstruction	DRUG WITHDRAWN	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 4[redacted]/Female/White	20[redacted]	20[redacted]	1009/1021	中枢神経系転移 Metastases to central nervous system	DRUG WITHDRAWN	UNRELATED	3	RECOVERED/RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	856/865	高血糖 Hyperglycaemia	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	656/668	膵炎 Pancreatitis	DRUG INTERRUPTED	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]-[redacted] 7[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	934/939	貧血 Anaemia	DRUG INTERRUPTED	LIKELY RELATED	2	RECOVERED/RESOLVED

出典：PR-30-5011-C 試験　総括報告書　Listing 16.2.4.1 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 18.0 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 2-7　重篤な有害事象の一覧（Niraparib-2001 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] 5[redacted]/Female/Asian	20[redacted]-[redacted]-[redacted]	-	15	血小板減少症 Thrombocytopenia	MULTIPLE	RELATED	4	RECOVERING /RESOLVING
[redacted] 6[redacted]/Female/Asian	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	-16/-7	腎盂腎炎 Pyelonephritis	NOT APPLICABLE	NOT RELATED	2	RECOVERED/ RESOLVED

出典：Niraparib-2001 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