表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 32）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-017-0[redacted] (Cont'd.)	精神障害/ 錯乱状態/ Confusion	Yes	03JAN20[redacted]* (15)/ 09JAN20[redacted]* (21)	Grade 3 Severe/ Not Related/ Concomitant drug	Improved/ Dose interrupted	Yes/ Inpatient hospitalization
	代謝および栄養障害/ 脱水/ Dehydration	Yes	17JAN20[redacted]* (29)/ 20JAN20[redacted]* (32)	Grade 3 Severe/ Related	Improved/ Dose interrupted	Yes/ Inpatient hospitalization
	血管障害/ 低血圧/ Hypotension	Yes	17JAN20[redacted]* (29)/ 20JAN20[redacted]* (32)	Grade 2 Moderate/ Related	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 多発性骨髄腫/ Multiple Myeloma Progression	Yes	23JAN20[redacted]* (35)/ 23JAN20[redacted]* (35)	Grade 5 Fatal/ Not Related/ Intercurrent disease	Death/ None	Yes/ Results in death

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

被験者識別コード，年齢以外のマスキングにおいて，
マークなし　：「同年」を意味する
＊　：「翌年」を意味する

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 33）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-017-0[redacted]	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 多発性骨髄腫/ Progressive Multiple Myeloma	Yes	18APR20[redacted] (70)/ 18APR20[redacted] (70)	Grade 5 Fatal/ Not Related/ Underlying disease	Death/ None	Yes/ Results in death
14-017-0[redacted]	感染症および寄生虫症/ 上気道感染/ Upper Respiratory Tract Infection	Yes	29MAR20[redacted] (45)/ 02APR20[redacted] (49)	Grade 3 Severe/ Related	Resolved/ None	Yes/ Inpatient hospitalization
	呼吸器、胸郭および縦隔障害/ 呼吸困難/ Shortness of breath	Yes	29MAR20[redacted] (45)/ 02APR20[redacted] (49)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization
14-018-0[redacted]	呼吸器、胸郭および縦隔障害/ 呼吸困難/ dyspnea	Yes	28OCT20[redacted] (2)/ 02NOV20[redacted] (7)	Grade 3 Severe/ Related	Improved/ None	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1.　In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 34）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-018-0[redacted] (Cont'd.)	心臓障害/ うっ血性心不全/ worsening CHF	Yes	04MAR20[redacted]*(130)/ 09MAR20[redacted](135)*	Grade 3 Severe/ Not Related/ Other: patient was not taking prescribed Lasix	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
14-018-0[redacted]	精神障害/ 錯乱状態/ Confusion	Yes	11JAN20[redacted](66)/ 16JAN20[redacted](71)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization
	一般・全身障害および投与部位の状態/ 疾患進行/ disease progression	Yes	16JAN20[redacted](71)/ 16JAN20[redacted](71)	Grade 5 Fatal/ Not Related/ Underlying disease	Death/ None	Yes/ Results in death
14-018-0[redacted]	臨床検査/ 総蛋白増加/ Elevated Total Serum Protein	Yes	06DEC20[redacted](29)/ 27DEC20[redacted](50)	Grade 4 Life threatening/ Not Related/ Underlying disease	Resolved/ None	Yes/ Life-threatening,Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1.　In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

被験者識別コード，年齢以外のマスキングにおいて，
マークなし　：「同年」を意味する
＊　：「翌年」を意味する

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 35）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-018-0[redacted] (Cont'd.)	代謝および栄養障害/ 高カルシウム血症/ hypercalcemia	Yes	06DEC20[redacted] (29)/ 08DEC20[redacted] (31)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization
14-018-0[redacted]	腎および尿路障害/ 慢性腎不全/ chronic kidney disease	Yes	07DEC20[redacted] (10)/ 27DEC20[redacted] (30)	Grade 3 Severe/ Not Related/ Concomitant disease	Improved/ Discontinued permanently	Yes/ Inpatient hospitalization
14-018-0[redacted]	一般・全身障害および投与部位の状態/ 発熱/ Fever	Yes	19MAY20[redacted] (125)/ 23MAY20[redacted] (129)	Grade 2 Moderate/ Not Related/ Underlying disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
14-018-0[redacted]	呼吸器、胸郭および縦隔障害/ 肺高血圧症/ pulmonary hypertension	Yes	27JAN20[redacted] (4)/ 15FEB20[redacted] (23)	Grade 3 Severe/ Not Related/ Underlying disease	Improved/ Dose interrupted	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 36）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-018-0[redacted] (Cont'd.)	一般・全身障害および投与部位の状態/ 疾患進行/ Progressive Disease	Yes	22FEB20[redacted] (30)/ 22FEB20[redacted] (30)	Grade 5 Fatal/ Not Related/ Underlying disease	Death/ None	Yes/ Results in death
14-018-0[redacted]	胃腸障害/ 直腸出血/ Rectal hemorrhage	Yes	14FEB20[redacted] (9)/ 16FEB20[redacted] (11)	Grade 3 Severe/ Not Related/ Other: thrombocytopenia	Resolved/ None	Yes/ Inpatient hospitalization
	臨床検査/ 血小板数減少/ platelet count decreased	Yes	16FEB20[redacted] (11)/ 27FEB20[redacted] (22)	Grade 4 Life threatening/ Related	Resolved/ Discontinued permanently	Yes/ Life-threatening
	一般・全身障害および投与部位の状態/ 疾患進行/ Disease Progression	Yes	27FEB20[redacted] (22)/ 27FEB20[redacted] (22)	Grade 5 Fatal/ Not Related/ Underlying disease	Death/ None	Yes/ Results in death

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 37）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-021-0[redacted]	胃腸障害/ 腹痛/ abdominal pain	Yes	01FEB20[redacted](99)/ 03FEB20[redacted](101)	Grade 3 Severe/ Related	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
14-021-0[redacted]	血液およびリンパ系障害/ 血小板減少症/ thrombocytopenia	No	28OCT20[redacted](-13)/ 09NOV20[redacted](-1)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization
	一般・全身障害および投与部位の状態/ 疾患進行/ progressive disease	Yes	22FEB20[redacted]*(105)/ 22FEB20[redacted](105)*	Grade 5 Fatal/ Not Related/ Underlying disease	Death/ None	Yes/ Results in death
14-021-0[redacted]	心臓障害/ 狭心症/ symptomatic angina	Yes	28DEC20[redacted](38)/ 29DEC20[redacted](39)	Grade 2 Moderate/ Not Related/ Other: unknown	Improved/ Dose interrupted	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1.　In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

被験者識別コード，年齢以外のマスキングにおいて，
マークなし　：「同年」を意味する
＊　：「翌年」を意味する

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 38）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-021-0[redacted]	感染症および寄生虫症/ 上気道感染/ Upper respiratory tract infection	Yes	17MAY20[redacted] (100)/ 22MAY20[redacted] (105)	Grade 3 Severe/ Not Related/ Intercurrent disease	Resolved/ None	Yes/ Inpatient hospitalization
14-021-0[redacted]	神経系障害/ 一過性脳虚血発作/ transient ischemic attack	Yes	06MAY20[redacted] (82)/ 15MAY20[redacted] (91)	Grade 4 Life threatening/ Not Related/ Concomitant drug	Resolved/ None	Yes/ Life-threatening,Inpatient hospitalization
14-022-0[redacted]	神経系障害/ 錯感覚/ Paraesthesia	Yes	17DEC20[redacted] (4)/ 19DEC20[redacted] (6)	Grade 2 Moderate/ Not Related/ Concomitant disease	Improved/ None	Yes/ Inpatient hospitalization
	神経系障害/ 脊髄圧迫/ T 5 spinal cord compression	Yes	17DEC20[redacted] (4)/ 19DEC20[redacted] (6)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1.　In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 39）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-027-0[redacted]	呼吸器、胸郭および縦隔障害/ 気胸/ pneumothorax	Yes	03NOV20[redacted] (44)/ 04NOV20[redacted] (45)	Grade 3 Severe/ Not Related/ Other: pneumothorax r/t improper port access	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
14-027-0[redacted]	一般・全身障害および投与部位の状態/ 胸痛/ (atypical) Chest Pain	Yes	06OCT20[redacted] (10)/ 09OCT20[redacted] (13)	Grade 3 Severe/ Not Related/ Intercurrent disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	胃腸障害/ 上腹部痛/ epigastric abdominal pain	Yes	27OCT20[redacted] (31)/ 30OCT20[redacted] (34)	Grade 2 Moderate/ Not Related/ Concomitant disease	Resolved/ None	Yes/ Inpatient hospitalization
	胃腸障害/ 出血性びらん性胃炎/ erosive gastritis	Yes	27OCT20[redacted] (31)/ 30OCT20[redacted] (34)	Grade 1 Mild/ Not Related/ Concomitant disease	Resolved/ None	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 40）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-027-0[redacted] (Cont'd.)	血管障害/ 低血圧/ hypotension	Yes	27OCT20[redacted] (31)/ 30OCT20[redacted] (34)	Grade 1 Mild/ Not Related/ Intercurrent disease	Resolved/ None	Yes/ Inpatient hospitalization
	傷害、中毒および処置合併症/ 転倒/ Fall	Yes	04NOV20[redacted] (39)/ 04NOV20[redacted] (39)	Grade 3 Severe/ Not Related/ Concomitant disease	Resolved/ None	Yes/ Inpatient hospitalization
	代謝および栄養障害/ 高カルシウム血症/ hypercalcemia	Yes	06DEC20[redacted] (71)/ 23DEC20[redacted] (88)	Grade 3 Severe/ Not Related/ Concomitant disease	Resolved/ None	Yes/ Inpatient hospitalization
14-027-0[redacted]	腎および尿路障害/ 急性腎不全/ acute renal failure	Yes	04JAN20[redacted] (37)/	Grade 3 Severe/ Related	Unchanged/ Discontinued permanently	Yes/ Inpatient hospitalization
14-027-0[redacted]	神経系障害/ 失神寸前の状態/ near syncope	Yes	08JUL20[redacted] (251)/ 10JUL20[redacted] (253)	Grade 3 Severe/ Not Related/ Concomitant disease	Resolved/ None	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 41）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-027-0[redacted] (Cont'd.)	心臓障害/ 冠動脈疾患/ worsening of coronary artery disease	Yes	10JUL20[redacted] (253)/ 16JUL20[redacted] (259)	Grade 4 Life threatening/ Not Related/ Concomitant disease	Resolved/ Dose interrupted	Yes/ Life-threatening
14-027-0[redacted]	感染症および寄生虫症/ 肺炎/ Pneumonia	Yes	09DEC20[redacted] (3)/ 16DEC20[redacted] (10)	Grade 3 Severe/ Not Related/ Intercurrent disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	感染症および寄生虫症/ 肺炎/ Pneumonia	Yes	30DEC20[redacted] (24)/ 04JAN20[redacted] (29) *	Grade 3 Severe/ Not Related/ Intercurrent disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	血液およびリンパ系障害/ 発熱性好中球減少症/ Neutropenic fever	Yes	* 20JAN20[redacted] (45)/ 23JAN20[redacted] (48) *	Grade 2 Moderate/ Not Related/ Concomitant disease	Resolved/ None	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

被験者識別コード，年齢以外のマスキングにおいて，
マークなし　：「同年」を意味する
＊　：「翌年」を意味する

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 42）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-027-0[redacted]	血液およびリンパ系障害/ 血小板減少症/ thrombocytopenia	Yes	19JAN20[redacted] (36)/ 07FEB20[redacted] (55)	Grade 4 Life threatening/ Related	Resolved/ Dose reduced	Yes/ Life-threatening,Important medical event
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 悪性胸水/ malignant right pleural effusion	Yes	09FEB20[redacted] (57)/ 16FEB20[redacted] (64)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	呼吸器、胸郭および縦隔障害/ 呼吸困難/ dyspnea	Yes	09FEB20[redacted] (57)/ 16FEB20[redacted] (64)	Grade 3 Severe/ Related	Improved/ Dose interrupted	Yes/ Inpatient hospitalization
	呼吸器、胸郭および縦隔障害/ 気胸/ right pneumothorax	Yes	09FEB20[redacted] (57)/ 16FEB20[redacted] (64)	Grade 2 Moderate/ Not Related/ Underlying disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 43）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-027-0[redacted]	免疫系障害/ 肺移植片対宿主病/ Graft Versus Host Disease of the Lung	Yes	13MAR20[redacted] (58)/ 22MAR20[redacted] (67)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
14-029-0[redacted]	感染症および寄生虫症/ 尿路感染/ urinary tract infection	Yes	12JAN20[redacted] (2)/ 22JAN20[redacted] (12)	Grade 2 Moderate/ Not Related/ Intercurrent disease	Resolved/ None	Yes/ Inpatient hospitalization
	感染症および寄生虫症/ クロストリジウム・ディフィシレ大腸炎/ c. difficile infection	Yes	27JAN20[redacted] (17)/ 02FEB20[redacted] (23)	Grade 2 Moderate/ Not Related/ Concomitant disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	感染症および寄生虫症/ 肺炎/ possible pneumonia	Yes	27JAN20[redacted] (17)/ 02FEB20[redacted] (23)	Grade 3 Severe/ Not Related/ Intercurrent disease	Resolved/ None	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1.　In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 44）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-029-0[redacted]	代謝および栄養障害/ 水分過負荷/ Fluid Overload	Yes	02FEB20[redacted] (4)/ 05FEB20[redacted] (7)	Grade 3 Severe/ Not Related/ Related to study procedure	Resolved/ None	Yes/ Inpatient hospitalization
	腎および尿路障害/ 急性腎不全/ Renal-Acute Kidney injury	Yes	22FEB20[redacted] (24)/ 29FEB20[redacted] (31)	Grade 2 Moderate/ Related	Improved/ Discontinued permanently	Yes/ Inpatient hospitalization
14-029-0[redacted]	血管障害/ 高血圧/ Hypertension	Yes	16FEB20[redacted] (10)/ 19FEB20[redacted] (13)	Grade 3 Severe/ Related	Resolved/ None	Yes/ Inpatient hospitalization
14-029-0[redacted]	神経系障害/ 頭痛/ acute headache	Yes	22AUG20[redacted] (191)/ 04SEP20[redacted] (204)	Grade 3 Severe/ Not Related/ Concomitant drug	Resolved/ None	Yes/ Important medical event

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 45）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-029-0[redacted]	神経系障害/ 頭蓋内出血/ intracranial bleed	Yes	01MAY20[redacted] (29)/ 19MAY20[redacted] (47)	Grade 4 Life threatening/ Not Related/ Other: Fall- patient hit her head after sustaining a fall when she got out of bed. This led to the bleed and her hospitalization.	Improved/ Dose interrupted	Yes/ Life-threatening,Inpatient hospitalization
14-030-0[redacted]	感染症および寄生虫症/ 敗血症/ Sepsis	Yes	14DEC20[redacted] (8)/ 21DEC20[redacted] (15)	Grade 4 Life threatening/ Not Related/ Intercurrent disease	Improved/ Dose interrupted	Yes/ Life-threatening,Inpatient hospitalization
	腎および尿路障害/ 急性腎不全/ Acute Renal Failure	Yes	04JAN20[redacted]* (29)/ 08JAN20[redacted] (33)*	Grade 3 Severe/ Not Related/ Intercurrent disease	Resolved/ Discontinued permanently	Yes/ Inpatient hospitalization
14-030-0[redacted]	感染症および寄生虫症/ 肺炎/ Pneumonia	Yes	07JAN20[redacted] (18)/ 12JAN20[redacted] (23)	Grade 3 Severe/ Not Related/ Intercurrent disease	Resolved/ None	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

被験者識別コード，年齢以外のマスキングにおいて，
マークなし　：「同年」を意味する
＊　：「翌年」を意味する

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 46）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-030-0[redacted] (Cont'd.)	呼吸器、胸郭および縦隔障害/ 肺臓炎/ Pneumonitis	Yes	15JAN20[redacted] (26)/ 23JAN20[redacted] (34)	Grade 3 Severe/ Not Related/ Intercurrent disease	Improved/ Discontinued permanently	Yes/ Inpatient hospitalization
14-030-0[redacted]	血管障害/ 高血圧/ Uncontrolled Hypertension	Yes	16JAN20[redacted] (5)/ 19JAN20[redacted] (8)	Grade 4 Life threatening/ Not Related/ Intercurrent disease	Resolved/ Dose interrupted	Yes/ Life-threatening,Inpatient hospitalization
14-030-0[redacted]	胃腸障害/ 胃穿孔/ Gastric Perforation	Yes	26APR20[redacted] (107)/ 08MAY20[redacted] (119)	Grade 3 Severe/ Not Related/ Other: Elderly patient with currently unknown etiology	Resolved/ Discontinued permanently	Yes/ Inpatient hospitalization
14-030-0[redacted]	腎および尿路障害/ 急性腎不全/ Acute Renal Failure	No	09JAN20[redacted] (-3)/ 13JAN20[redacted] (2)	Grade 3 Severe/ Not Related/ Intercurrent disease	Resolved/ None	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1.　In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 47）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-030-0[redacted]	内分泌障害/ 副腎機能不全/ Adrenal Insufficiency	Yes	06FEB20[redacted](14)/ 10FEB20[redacted](18)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ Discontinued permanently	Yes/ Inpatient hospitalization
14-030-0[redacted]	腎および尿路障害/ 腎結石症/ Nephrolithiasis	Yes	28JUL20[redacted](166)/ 31JUL20[redacted](169)	Grade 3 Severe/ Not Related/ Intercurrent disease	Resolved/ None	Yes/ Inpatient hospitalization
14-030-0[redacted]	呼吸器、胸郭および縦隔障害/ 肺水腫/ Pulmonary Edema	Yes	26FEB20[redacted](3)/ 28FEB20[redacted](5)	Grade 3 Severe/ Related	Resolved/ None	Yes/ Inpatient hospitalization
14-030-0[redacted]	感染症および寄生虫症/ 蜂巣炎/ Cellulitis	Yes	26AUG20[redacted](74)/ 06SEP20[redacted](85)	Grade 3 Severe/ Not Related/ Other: Fall	Resolved/ None	Yes/ Inpatient hospitalization
14-031-0[redacted]	代謝および栄養障害/ 低カリウム血症/ hypokalemia	Yes	30JAN20[redacted](125)/ 03FEB20[redacted](129)	Grade 2 Moderate/ Not Related/ Concomitant disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1.　In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 48）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-031-0[redacted] (Cont'd.)	感染症および寄生虫症/ 蜂巣炎/ left leg cellulitis	Yes	04FEB20[redacted] (130)/ 10FEB20[redacted] (136)	Grade 3 Severe/ Not Related/ Intercurrent disease	Resolved/ None	Yes/ Inpatient hospitalization
	腎および尿路障害/ 腎不全/ renal failure	Yes	14FEB20[redacted] (140)/ 22FEB20[redacted] (148)	Grade 5 Fatal/ Not Related/ Concomitant disease	Death/ None	Yes/ Results in death
14-032-0[redacted]	一般・全身障害および投与部位の状態/ 非心臓性胸痛/ Chest Pain - non Cardiac	Yes	05FEB20[redacted] (19)/ 06FEB20[redacted] (20)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization
14-032-0[redacted]	感染症および寄生虫症/ 副鼻腔炎/ Sinusitis	Yes	20JUN20[redacted] (139)/ 22JUN20[redacted] (141)	Grade 3 Severe/ Not Related/ Concomitant disease	Improved/ Dose interrupted	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 49）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-032-0[redacted] (Cont'd.)	血管障害/ 高血圧緊急症/ Hypertensive Emergency	Yes	20JUL20[redacted](169)/ 24JUL20[redacted](173)	Grade 4 Life threatening/ Not Related/ Concomitant disease	Resolved/ None	Yes/ Life-threatening,Inpatient hospitalization
14-032-0[redacted]	呼吸器、胸郭および縦隔障害/ 呼吸困難/ Dyspnea	Yes	25JUL20[redacted](150)/ 27JUL20[redacted](152)	Grade 2 Moderate/ Related	Improved/ Dose interrupted	Yes/ Important medical event
14-032-0[redacted]	外科および内科処置/ 股関節形成/ Right Hip Arthroplasty	Yes	15AUG20[redacted](169)/ 20AUG20[redacted](174)	Grade 3 Severe/ Not Related/ Concomitant disease	Improved/ None	Yes/ Inpatient hospitalization
14-032-0[redacted]	心臓障害/ うっ血性心不全/ Congestive Heart Failure	Yes	20JUL20[redacted](149)/ 27JUL20[redacted](156)	Grade 4 Life threatening/ Related	Improved/ Discontinued permanently	Yes/ Life-threatening,Inpatient hospitalization
14-033-0[redacted]	血液およびリンパ系障害/ 発熱性好中球減少症/ neutropenic fever	Yes	23DEC20[redacted](3)/ 25DEC20[redacted](5)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ Dose reduced	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 50）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-033-0[redacted]	代謝および栄養障害/ 高カルシウム血症/ hypercalcemia	No	07JAN20[redacted] (-2)/ 08JAN20[redacted] (-1)	Grade 4 Life threatening/ Not Related/ Underlying disease	Resolved/ None	Yes/ Life-threatening,Inpatient hospitalization
	代謝および栄養障害/ 高カルシウム血症/ hypercalcemia	Yes	18JAN20[redacted] (10)/ 19JAN20[redacted] (11)	Grade 4 Life threatening/ Not Related/ Underlying disease	Resolved/ None	Yes/ Life-threatening,Inpatient hospitalization
	感染症および寄生虫症/ 肺炎/ pneumonia	Yes	21JAN20[redacted] (13)/ 30JAN20[redacted] (22)	Grade 3 Severe/ Not Related/ Concomitant disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	代謝および栄養障害/ 高カルシウム血症/ hypercalcemia	Yes	01FEB20[redacted] (24)/ 01FEB20[redacted] (24)	Grade 3 Severe/ Not Related/ Underlying disease	Improved/ None	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 51）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-033-0[redacted] (Cont'd.)	代謝および栄養障害/ 高カルシウム血症/ hypercalcemia	Yes	10FEB20[redacted] (33)/ 10FEB20[redacted] (33)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization
	感染症および寄生虫症/ 壊疽/ gangrene right 2nd toe	Yes	07JUN20[redacted] (151)/ 14JUN20[redacted] (158)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization,Important medical event
	感染症および寄生虫症/ 肺炎/ pneumonia	Yes	07JUN20[redacted] (151)/ 18JUN20[redacted] (162)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	代謝および栄養障害/ 高カルシウム血症/ hypercalcemia	Yes	25JUN20[redacted] (169)/ 25JUN20[redacted] (169)	Grade 4 Life threatening/ Not Related/ Underlying disease	Resolved/ None	Yes/ Life-threatening,Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 52）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-033-0[redacted] (Cont'd.)	代謝および栄養障害/ 高カルシウム血症/ hypercalcemia	Yes	09JUL20[redacted] (183)/ 10JUL20[redacted] (184)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization
	代謝および栄養障害/ 高カルシウム血症/ hypercalcemia	Yes	22JUL20[redacted] (196)/ 23JUL20[redacted] (197)	Grade 4 Life threatening/ Not Related/ Underlying disease	Resolved/ None	Yes/ Life-threatening,Inpatient hospitalization
14-033-0[redacted]	代謝および栄養障害/ 高カルシウム血症/ hypercalcemia	Yes	08MAY20[redacted] (91)/ 16MAY20[redacted] (99)	Grade 4 Life threatening/ Not Related/ Underlying disease	Resolved/ None	Yes/ Life-threatening,Inpatient hospitalization
14-033-0[redacted]	臨床検査/ 血中クレアチニン増加/ elevated creatinine	Yes	25APR20[redacted] (71)/ 04MAY20[redacted] (80)	Grade 4 Life threatening/ Not Related/ Underlying disease	Resolved/ Discontinued permanently	Yes/ Life-threatening

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 53）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-033-0[redacted]	呼吸器、胸郭および縦隔障害/ 呼吸不全/ hypoxemic respiratory failure	Yes	25APR20[redacted] (64)/ 01MAY20[redacted] (70)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
14-033-0[redacted]	血液およびリンパ系障害/ 過粘稠度症候群/ hyperviscosity syndrome	No	17JUN20[redacted] (-2)/ 22JUN20[redacted] (4)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization
14-034-0[redacted]	血液およびリンパ系障害/ 貧血/ Anemia	Yes	29SEP20[redacted] (11)/ 01OCT20[redacted] (13)	Grade 2 Moderate/ Not Related/ Underlying disease	Improved/ None	Yes/ Inpatient hospitalization
	胃腸障害/ 胃腸出血/ GI Bleed	Yes	22OCT20[redacted] (34)/ 28OCT20[redacted] (40)	Grade 2 Moderate/ Not Related/ Underlying disease	Improved/ None	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 54）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-034-0[redacted] (Cont'd.)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 多発性骨髄腫/ Multiple Myeloma	Yes	31OCT20[redacted] (43)/ 31OCT20[redacted] (43)	Grade 5 Fatal/ Not Related/ Underlying disease	Death/ None	Yes/ Results in death
14-034-0[redacted]	血液およびリンパ系障害/ 汎血球減少症/ Pancytopenia	No	05OCT20[redacted] (-1)/ 06OCT20[redacted] (1)	Grade 2 Moderate/ Not Related/ Underlying disease	Improved/ None	Yes/ Inpatient hospitalization
14-034-0[redacted]	感染症および寄生虫症/ サルモネラ症/ Salmonella	Yes	19MAY20[redacted] (214)/ 13JUN20[redacted] (239)	Grade 3 Severe/ Not Related/ Intercurrent disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
14-034-0[redacted]	血液およびリンパ系障害/ 汎血球減少症/ Pancytopenia	Yes	31OCT20[redacted] (8)/ 01NOV20[redacted] (9)	Grade 2 Moderate/ Related	Improved/ Dose interrupted	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 55）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-034-0[redacted] (Cont'd.)	血液およびリンパ系障害/ 汎血球減少症/ Pancytopenia	Yes	23FEB20[redacted]*(123)/ 14MAR20[redacted]*(143)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization
14-034-0[redacted]	感染症および寄生虫症/ 気管支炎/ Bronchitis	No	19OCT20[redacted](-6)/ 22OCT20[redacted](-3)	Grade 2 Moderate/ Not Related/ Underlying disease	Improved/ None	Yes/ Inpatient hospitalization
14-034-0[redacted]	胃腸障害/ 胃腸出血/ GI Bleed	Yes	14NOV20[redacted](19)/ 22NOV20[redacted](27)	Grade 3 Severe/ Not Related/ Underlying disease	Improved/ None	Yes/ Inpatient hospitalization
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/	Yes	05DEC20[redacted](40)/	Grade 5 Fatal/	Death/	Yes/
	多発性骨髄腫/ Multiple Myeloma Progression		05DEC20[redacted](40)	Not Related/ Underlying disease	None	Results in death

Note: Adverse events coded using MedDRA version 14.1.　In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

被験者識別コード，年齢以外のマスキングにおいて，
マークなし　：「同年」を意味する
＊　：「翌年」を意味する

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 56）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-034-0[redacted]	感染症および寄生虫症/ 副鼻腔炎/ Sinusitis	Yes	25JUN20[redacted] (210)/ 10JUL20[redacted] (225)	Grade 3 Severe/ Not Related/ Intercurrent disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
14-034-0[redacted]	代謝および栄養障害/ 高カルシウム血症/ Hypercalcemia	No	24NOV20[redacted] (-11)/ 04DEC20[redacted] (-1)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization
	腎および尿路障害/ 腎不全/ Renal Failure	Yes	10DEC20[redacted] (6)/	Grade 4 Life threatening/ Not Related/ Underlying disease	Unchanged/ Discontinued permanently	Yes/ Life-threatening,Inpatient hospitalization
14-034-0[redacted]	血液およびリンパ系障害/ 貧血/ Anemia	Yes	19DEC20[redacted] (8)/ 20DEC20[redacted] (9)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1.　In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 57）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-034-0[redacted] (Cont'd.)	血液およびリンパ系障害/ 血小板減少症/ thrombocytopenia	Yes	19DEC20[redacted] (8)/ 27DEC20[redacted] (16)	Grade 4 Life threatening/ Not Related/ Underlying disease	Resolved/ None	Yes/ Life-threatening,Inpatient hospitalization
	腎および尿路障害/ 血尿/ Hematuria	Yes	01JAN20[redacted] (21)*/ 05JAN20[redacted] (25)*	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ Discontinued permanently	Yes/ Inpatient hospitalization
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 多発性骨髄腫/ Multiple Myeloma Progression	Yes	09JAN20[redacted] (29)*/ 09JAN20[redacted] (29)*	Grade 5 Fatal/ Not Related/ Underlying disease	Death/ None	Yes/ Results in death
14-034-0[redacted]	筋骨格系および結合組織障害/ 背部痛/ Back Pain	No	29DEC20[redacted] (-6)/ 03JAN20[redacted] (-1)*	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

被験者識別コード，年齢以外のマスキングにおいて，
マークなし　：「同年」を意味する
＊　：「翌年」を意味する

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 58）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-034-0[redacted] (Cont'd.)	感染症および寄生虫症/ 敗血症/ Sepsis	Yes	04MAR20[redacted] (61)/ 29MAR20[redacted] (86) *	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	感染症および寄生虫症/ 肺炎/ Pneumonia	Yes	30JUL20[redacted] (209)/ 07AUG20[redacted] (217) *	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ Discontinued permanently	Yes/ Inpatient hospitalization
	感染症および寄生虫症/ 敗血症/ Sepsis	Yes	30JUL20[redacted] (209)/ 07AUG20[redacted] (217) *	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ Discontinued permanently	Yes/ Inpatient hospitalization
	胃腸障害/ 嚥下障害/ Dysphagia	Yes	20AUG20[redacted] (230)/ 04SEP20[redacted] (245) *	Grade 3 Severe/ Not Related/ Underlying disease	Improved/ None	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

被験者識別コード，年齢以外のマスキングにおいて，
マークなし　：「同年」を意味する
＊　：「翌年」を意味する

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 59）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-034-0[redacted] (Cont'd.)	一般・全身障害および投与部位の状態/ 疼痛/ Intractable Pain	Yes	20AUG20[redacted]* (230)/ 04SEP20[redacted]* (245)	Grade 3 Severe/ Not Related/ Underlying disease	Improved/ None	Yes/ Inpatient hospitalization
	血管障害/ 深部静脈血栓症/ Bilateral lower extremity DVT	Yes	22AUG20[redacted]* (232)/ 08SEP20[redacted]* (249)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Important medical event
	神経系障害/ 代謝性脳症/ Metabolic Encephalopathy	No	26AUG20[redacted]* (236)/	Grade 3 Severe/ Not Related/ Underlying disease	Unchanged/ None	Yes/ Persistent or significant incapacity
14-034-0[redacted]	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 多発性骨髄腫/ Multiple Myeloma Progression	Yes	13JAN20[redacted] (3)/ 13JAN20[redacted] (3)	Grade 5 Fatal/ Not Related/ Underlying disease	Death/ None	Yes/ Results in death

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

被験者識別コード，年齢以外のマスキングにおいて，
マークなし　：「同年」を意味する
＊　：「翌年」を意味する

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 60）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-034-0[redacted]	心臓障害/ 急性心筋梗塞/ Acute Myocardial Infarction	Yes	25FEB20[redacted] (31)/ 08MAR20[redacted] (43)	Grade 3 Severe/ Not Related/ Intercurrent disease	Resolved/ Discontinued permanently	Yes/ Inpatient hospitalization
14-034-0[redacted]	心臓障害/ うっ血性心不全/ Acute Congestive Heart Failure	Yes	17FEB20[redacted] (10)/ 19FEB20[redacted] (12)	Grade 2 Moderate/ Related	Resolved/ None	Yes/ Inpatient hospitalization
14-035-0[redacted]	臨床検査/ 血中アルカリホスファターゼ増加/ Increase Alkaline phosphatase	Yes	23JAN20[redacted] (7)/ 27JAN20[redacted] (11)	Grade 3 Severe/ Not Related/ Underlying disease	Improved/ None	Yes/ Inpatient hospitalization
	腎および尿路障害/ 急性腎不全/ Acute Renal Failure	Yes	23JAN20[redacted] (7)/ 27JAN20[redacted] (11)	Grade 2 Moderate/ Not Related/ Underlying disease	Improved/ None	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 61）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-035-0[redacted] (Cont'd.)	一般・全身障害および投与部位の状態/ 疾患進行/ Progressive disease	Yes	16APR20[redacted] (91)/ 16APR20[redacted] (91)	Grade 5 Fatal/ Not Related/ Underlying disease	Death/ None	Yes/ Results in death
14-035-0[redacted]	傷害、中毒および処置合併症/ 転倒/ Fall	Yes	24MAY20[redacted] (116)/ 04JUN20[redacted] (127)	Grade 3 Severe/ Not Related/ Concomitant disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	生殖系および乳房障害/ 骨盤痛/ Pelvic pain	Yes	24MAY20[redacted] (116)/ 04JUN20[redacted] (127)	Grade 3 Severe/ Not Related/ Concomitant disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
14-035-0[redacted]	臨床検査/ 血中乳酸脱水素酵素増加/ Elevated LDH	Yes	22AUG20[redacted] (205)/ 22SEP20[redacted] (236)	Grade 3 Severe/ Not Related/ Concomitant disease	Improved/ None	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 62）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-035-0[redacted]	代謝および栄養障害/ 高血糖/ Hyperglycemia	Yes	23JUL20[redacted](155)/ 23JUL20[redacted](155)	Grade 4 Life threatening/ Not Related/ Intercurrent disease	Resolved/ None	Yes/ Life-threatening
14-035-0[redacted]	血液およびリンパ系障害/ 貧血/ worsening anemia	Yes	10APR20[redacted](57)/ 12APR20[redacted](59)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization
	一般・全身障害および投与部位の状態/ 疼痛/ Increased body pain	Yes	10APR20[redacted](57)/ 12APR20[redacted](59)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 多発性骨髄腫/ Multiple myeloma progression	Yes	10APR20[redacted](57)/ 08MAY20[redacted](85)	Grade 2 Moderate/ Not Related/ Underlying disease	Improved/ None	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 63）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-035-0[redacted]	神経系障害/ 脊髄圧迫/ Spinal Cord Compression	Yes	25JUN20[redacted](120)/ 28JUN20[redacted](123)	Grade 3 Severe/ Not Related/ Concomitant disease	Resolved/ Discontinued permanently	Yes/ Inpatient hospitalization
14-035-0[redacted]	感染症および寄生虫症/ 大葉性肺炎/ Left sided pneumonia	Yes	22MAR20[redacted](17)/ 24MAR20[redacted](19)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization
	筋骨格系および結合組織障害/ 背部痛/ lower back pain	Yes	10APR20[redacted](36)/ 11APR20[redacted](37)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization
14-035-0[redacted]	神経系障害/ 脊髄圧迫/ Spinal cord compression	Yes	24JUL20[redacted](30)/ 31JUL20[redacted](37)	Grade 3 Severe/ Not Related/ Concomitant disease	Resolved/ None	Yes/ Inpatient hospitalization
14-037-0[redacted]	臨床検査/ 血中クレアチニン増加/ Elevated Creatinine	No	24JUL20[redacted](-2)/ 26JUL20[redacted](1)	Grade 2 Moderate/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 64）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-037-0[redacted] (Cont'd.)	臨床検査/ 好中球数減少/ Neutrophil count decreased	No	24JUL20[redacted] (-2)/ 27JUL20[redacted] (2)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization
14-039-0[redacted]	呼吸器、胸郭および縦隔障害/ 低酸素症/ hypoxia	Yes	15FEB20[redacted] (14)/ 20FEB20[redacted] (19)	Grade 3 Severe/ Related	Resolved/ None	Yes/ Inpatient hospitalization
14-039-0[redacted]	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 多発性骨髄腫/ progressed MM	Yes	29FEB20[redacted] (15)/ 23MAR20[redacted] (38)	Grade 5 Fatal/ Not Related/ Underlying disease	Death/ None	Yes/ Results in death,Important medical event
	傷害、中毒および処置合併症/ 上腕骨骨折/ right humerus fracture	Yes	05MAR20[redacted] (20)/ 09MAR20[redacted] (24)	Grade 3 Severe/ Not Related/ Concomitant drug	Improved/ None	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 65）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-039-0[redacted] (Cont'd.)	傷害、中毒および処置合併症/ 硬膜下血腫/ left frontal parasagittal subdural hematoma	Yes	05MAR20[redacted] (20)/	Grade 3 Severe/ Not Related/ Concomitant drug	Unchanged/ None	Yes/ Inpatient hospitalization
14-039-0[redacted]	筋骨格系および結合組織障害/ 背部痛/ low back pain	Yes	14MAY20[redacted] (76)/	Grade 3 Severe/ Not Related/ Underlying disease	Unchanged/ None	Yes/ Inpatient hospitalization
14-039-0[redacted]	血液およびリンパ系障害/ 発熱性好中球減少症/ neutropenic fever	Yes	07JUL20[redacted] (3)/ 13JUL20[redacted] (9)	Grade 3 Severe/ Related	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	血液およびリンパ系障害/ 発熱性好中球減少症/ Neutropenic Fever	Yes	31AUG20[redacted] (58)/ 02SEP20[redacted] (60)	Grade 2 Moderate/ Related	Resolved/ None	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 66）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-040-0[redacted]	血液およびリンパ系障害/ 血小板減少症/ Thrombocytopenia	Yes	04MAR20[redacted](68)/ 05MAR20[redacted](69)	Grade 4 Life threatening/ Related	Resolved/ None	Yes/ Life-threatening,Inpatient hospitalization
	血液およびリンパ系障害/ 過粘稠度症候群/ Blood and lymphatic system disorders - Other, specify Hyperviscosity syndrome	Yes	11MAR20[redacted](75)/ 30MAR20[redacted](94)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization
14-040-0[redacted]	血液およびリンパ系障害/ 貧血/ Anemia	Yes	20JAN20[redacted](24)/ 29JAN20[redacted](33)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization
	代謝および栄養障害/ 高カルシウム血症/ Hypercalcemia	Yes	20JAN20[redacted](24)/ 22JAN20[redacted](26)	Grade 4 Life threatening/ Not Related/ Underlying disease	Resolved/ None	Yes/ Life-threatening,Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1.　In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 67）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-040-0[redacted] (Cont'd.)	代謝および栄養障害/ 高カルシウム血症/ Hypercalcemia	Yes	04FEB20[redacted](39)/ 05FEB20[redacted](40)	Grade 4 Life threatening/ Not Related/ Underlying disease	Resolved/ None	Yes/ Life-threatening,Inpatient hospitalization
14-040-0[redacted]	血管障害/ 高血圧/ Hypertension	Yes	22FEB20[redacted](43)/ 24FEB20[redacted](45)	Grade 4 Life threatening/ Related	Resolved/ Discontinued permanently	Yes/ Life-threatening,Inpatient hospitalization
14-040-0[redacted]	血管障害/ 大動脈瘤/ Vascular disorders- Other, specify: Aortic Aneurysm	Yes	13MAR20[redacted](56)/ 19MAR20[redacted](62)	Grade 3 Severe/ Not Related/ Concomitant disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	心臓障害/ 心筋梗塞/ Myocardial Infarction	Yes	25MAY20[redacted](129)/ 30MAY20[redacted](134)	Grade 3 Severe/ Related	Resolved/ Discontinued permanently	Yes/ Inpatient hospitalization
14-040-0[redacted]	感染症および寄生虫症/ 肺炎/ Pneumonia	Yes	11MAR20[redacted](40)/ 14MAR20[redacted](43)	Grade 3 Severe/ Related	Resolved/ None	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1.　In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 68）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-040-0[redacted]	一般・全身障害および投与部位の状態/ 疾患進行/ Progressive disease	Yes	26MAR20[redacted] (41)/ 26MAR20[redacted] (41)	Grade 5 Fatal/ Not Related/ Underlying disease	Death/ None	Yes/ Results in death
14-044-0[redacted]	胃腸障害/ 胃腸出血/ GI Bleeding	Yes	31JAN20[redacted] (22)/ 08FEB20[redacted] (30)	Grade 3 Severe/ Not Related/ Concomitant disease	Resolved/ None	Yes/ Inpatient hospitalization
	胃腸障害/ 大腸穿孔/ Large Bowel Perforation	Yes	11FEB20[redacted] (33)/ 14FEB20[redacted] (36)	Grade 5 Fatal/ Not Related/ Underlying disease	Death/ None	Yes/ Results in death,Inpatient hospitalization
14-044-0[redacted]	腎および尿路障害/ 高窒素血症/ Transient Azotemia	Yes	13JUN20[redacted] (149)/ 17JUN20[redacted] (153)	Grade 3 Severe/ Not Related/ Other: 100 cc Omnipaque contrast per standard of care	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 69）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-044-0[redacted] (Cont'd.)	一般・全身障害および投与部位の状態/ 疼痛/ Intractable Pain Syndrome	Yes	07JUL20[redacted](173)/ 27JUL20[redacted](193)	Grade 3 Severe/ Not Related/ Concomitant disease	Improved/ Dose interrupted	Yes/ Inpatient hospitalization
14-044-0[redacted]	腎および尿路障害/ 急性腎不全/ ACUTE KIDNEY INJURY	Yes	18MAR20[redacted](28)/ 27MAR20[redacted](37)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ Discontinued permanently	Yes/ Inpatient hospitalization
14-045-0[redacted]	一般・全身障害および投与部位の状態/ 発熱/ Fever of Unknown Origin	Yes	06AUG20[redacted](190)/ 08AUG20[redacted](192)	Grade 3 Severe/ Not Related/ Concomitant disease	Resolved/ None	Yes/ Inpatient hospitalization
14-045-0[redacted]	感染症および寄生虫症/ 肺炎/ Community Acquired Pneumonia	Yes	21JUN20[redacted](116)/ 22JUN20[redacted](117)	Grade 3 Severe/ Not Related/ Underlying disease	Improved/ Dose reduced	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 70）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-045-0[redacted]	一般・全身障害および投与部位の状態/ 発熱/ Multiple Myeloma Fever	Yes	23JUN20[redacted](4)/ 25JUN20[redacted](6)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization
14-045-0[redacted]	血液およびリンパ系障害/ 貧血/ anemia	Yes	12AUG20[redacted](54)/ 15AUG20[redacted](57)	Grade 3 Severe/ Related	Resolved/ None	Yes/ Inpatient hospitalization
14-048-0[redacted]	呼吸器、胸郭および縦隔障害/ 肺塞栓症/ pulmonary embolism	Yes	14DEC20[redacted](52)/ 16DEC20[redacted](54)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization
14-048-0[redacted]	感染症および寄生虫症/ セラチア性敗血症/ Sepsis due to Serratia	Yes	09AUG20[redacted](263)/ 10AUG20[redacted](264)	Grade 4 Life threatening/ Not Related/ Intercurrent disease	Resolved/ Dose interrupted	Yes/ Life-threatening,Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1.　In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 71）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-052-0[redacted]	精神障害/ 錯乱状態/ CONFUSION	Yes	27FEB20[redacted](20)/ 08MAR20[redacted](30)	Grade 3 Severe/ Related	Resolved/ None	Yes/ Inpatient hospitalization
14-053-0[redacted]	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 多発性骨髄腫/ Multiple Myeloma	Yes	12DEC20[redacted](5)/ 20DEC20[redacted](13)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 多発性骨髄腫/ multiple myeloma progression	Yes	26DEC20[redacted](19)/ 26DEC20[redacted](19)	Grade 5 Fatal/ Not Related/ Underlying disease	Death/ None	Yes/ Results in death
14-053-0[redacted]	感染症および寄生虫症/ クロストリジウム・ディフィシレ大腸炎/ clostridium difficile colitis	Yes	10FEB20[redacted](60)/ 17FEB20[redacted](67)	Grade 3 Severe/ Not Related/ Other: combination of immunosuprression/antibactics	Resolved/ None	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 72）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-053-0[redacted] (Cont'd.)	腎および尿路障害/ 急性腎不全/ acute renal failure	Yes	30APR20[redacted] (140)/ 02MAY20[redacted] (142)	Grade 2 Moderate/ Not Related/ Underlying disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	感染症および寄生虫症/ 肺炎/ Pneumonia	Yes	10MAY20[redacted] (150)/ 29MAY20[redacted] (169)	Grade 3 Severe/ Not Related/ Other: neutropenia	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	腎および尿路障害/ 急性腎不全/ Acute Renal Failure	Yes	21JUN20[redacted] (192)/ 29JUN20[redacted] (200)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization
14-053-0[redacted]	血管障害/ 深部静脈血栓症/ DVT	Yes	04JAN20[redacted] (23)/ 10JAN20[redacted] (29)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 73）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-053-0[redacted] (Cont'd.)	代謝および栄養障害/ 高カルシウム血症/ Intermittent Hypercalcemia	Yes	07FEB20[redacted] (57)/ 15FEB20[redacted] (65)	Grade 3 Severe/ Not Related/ Concomitant disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/	Yes	25MAR20[redacted] (104)/	Grade 4 Life threatening/	Resolved/	Yes/
	多発性骨髄腫/ multiple myeloma progression		29MAR20[redacted] (108)	Not Related/ Underlying disease	None	Life-threatening,Inpatient hospitalization
14-053-0[redacted]	感染症および寄生虫症/ 敗血症/ Sepsis	Yes	22DEC20[redacted] (2)/ 24DEC20[redacted] (4)	Grade 5 Fatal/ Not Related/ Concomitant disease	Death/ Discontinued permanently	Yes/ Results in death,Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 74）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-053-0[redacted]	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 多発性骨髄腫/ Multiple Myeloma Progression	No	01JAN20[redacted](-5)/ 16JAN20[redacted](11)	Grade 5 Fatal/ Not Related/ Underlying disease	Death/ None	Yes/ Results in death,Inpatient hospitalization
14-053-0[redacted]	感染症および寄生虫症/ クロストリジウム・ディフィシレ大腸炎/ clostridium difficile colitis	Yes	10MAY20[redacted](116)/ 23MAY20[redacted](129)	Grade 3 Severe/ Not Related/ Intercurrent disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
14-054-0[redacted]	心臓障害/ 心不全/ Heart Failure	Yes	16NOV20[redacted](2)/ 23NOV20[redacted](9)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ Discontinued permanently	Yes/ Inpatient hospitalization,Important medical event

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 75）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatment Emergent?	AE Start Date (Study Day)/ AE End Date (Study Day) [1]	Severity Grade [2] / Relationship/ If not related, specify	Outcome/ Study Drug Action Taken	AE Serious?/ SAE Category
14-054-0[redacted]	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）/ 多発性骨髄腫/ multiple myeloma progression	Yes	01MAY20[redacted] (98)/ 04MAY20[redacted] (101)	Grade 3 Severe/ Not Related/ Underlying disease	Improved/ None	Yes/ Inpatient hospitalization,Important medical event
14-055-0[redacted]	心臓障害/ うっ血性心不全/ congestive heart failure	Yes	12JUL20[redacted] (3)/ 19JUL20[redacted] (10)	Grade 3 Severe/ Related	Resolved/ Dose reduced	Yes/ Inpatient hospitalization

Note: Adverse events coded using MedDRA version 14.1. In determining treatment emergent AEs and study day, partial dates were imputed based on the SAP (Section 4.2.1).
Treatment emergent adverse events are AEs that start on or after the first study day treatment is administered and within 30 days of the last administration of study treatment.
[1] Study Day is calculated relative to the date of the first administration of study drug.
[2] Adverse event severity grades are reported according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

出典［総括報告書5.3.5.4-2（2011-002），Listing 16.2.7.2］

2.7.4 臨床的安全性
カルフィルゾミブ