表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 22）

REGIMEN C							
Subject ID	**System Organ Class PREFERRED TERM Reported Term (AE #)**	**Date (#Days from First Dose) [Duration(days)]**	**Severity (NCI Grade)**	**Study Drug Relationship**	**Action Taken Regarding Study Drug**	**Other Action Taken**	**Outcome**
	心臓障害 急性左室不全 Acute Left Ventrical Failure (7)	20[redacted]-02-15 (44) to 20[redacted]-02-15 (44) [1]	3	Not Related	Drug Interrupted	Concomitant Medication, Hospitalization	Recovered/ Resolved
18-455-1[redacted]	呼吸器、胸郭および縦隔障害 肺浸潤 Infiltration Of The Right Lung (4)	20[redacted]-03-18 (-6) to 20[redacted]-03-22 (-2) [5]	3	Not Related	Drug Interrupted	Concomitant Medication	Recovering/ Resolving
	代謝および栄養障害 腫瘍崩壊症候群 Tumor Lysis Syndrome (1)	20[redacted]-04-03 (10) to 20[redacted]-04-09 (16) [7]	4	Related	Drug Withdrawn	Concomitant Medication, Procedure Required, Hospitalization	Recovering/ Resolving
	免疫系障害 アナフィラキシー反応 Anafilactic Reaction (2)	20[redacted]-04-08 (15) to 20[redacted]-04-08 (15) [1]	4	Not Related	Dose Not Changed	None	Recovered/ Resolved
	心臓障害 心停止 Cardiac Arrest (3)	20[redacted]-04-22 (29) to 20[redacted]-04-22 (29) [1]	5	Not Related	Dose Not Changed	Concomitant Medication	Fatal
18-455-1[redacted]	腎および尿路障害 腎機能障害 Worsening Of Renal Function (2)	20[redacted]-01-17 (127) to 20[redacted]-02-01 (142) [16]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved With Sequelae
	血液およびリンパ系障害 血小板減少症 Thrombocytopenia (9)	20[redacted]-02-09 (150) to 20[redacted]-02-10 (151) [2]	4	Not Related	Dose Not Changed	Procedure Required, Hospitalization	Recovered/ Resolved With Sequelae
	血液およびリンパ系障害 血小板減少症 Thrombocytopenia (13)	20[redacted]-02-22 (163) to 20[redacted]-02-23 (164) [2]	4	Not Related	Dose Not Changed	Concomitant Medication	Recovered/ Resolved With Sequelae
	血液およびリンパ系障害 血小板減少症 Thrombocytopenia (16)	20[redacted]-02-26 (167) to Continuing	4	Not Related	Dose Not Changed	Concomitant Medication	Not Recovered/ Not Resolved

表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 23）

REGIMEN C							
Subject ID	**System Organ Class PREFERRED TERM Reported Term (AE #)**	**Date (#Days from First Dose) [Duration(days)]**	**Severity (NCI Grade)**	**Study Drug Relationship**	**Action Taken Regarding Study Drug**	**Other Action Taken**	**Outcome**
	一般・全身障害および投与部位の状態 疾患進行 Multiple Myeloma Progression (17)	20[redacted]-02-26 (167) to 20[redacted]-02-26 (167) [1]	5	Not Related	Dose Not Changed	None	Fatal
18-458-1[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） 悪性胸水 Plasmacytic Pleural Effusion (1)	20[redacted]-11-01 (39) to 20[redacted]-11-12 (50) [12]	4	Not Related	Dose Not Changed	Procedure Required, Hospitalization	Recovered/ Resolved
22-526-1[redacted]	血管障害 低血圧 Severe Hypothension (5)	20[redacted]-02-15 (30) to 20[redacted]-03-04 (47) [18]	4	Related	Drug Withdrawn	Hospitalization	Recovered/ Resolved With Sequelae
22-526-1[redacted]	血液およびリンパ系障害 貧血 Anemia (6)	20[redacted]-04-07 (29) to Continuing	3	Related	Drug Withdrawn	Hospitalization	Unknown
	代謝および栄養障害 高カルシウム血症 Hypercalcemia (5)	20[redacted]-04-07 (29) to Continuing	3	Related	Drug Withdrawn	Hospitalization	Unknown
	腎および尿路障害 急性腎不全 Acute Renal Insufficiency (4)	20[redacted]-04-07 (29) to Continuing	3	Not Related	Drug Withdrawn	Hospitalization	Unknown
22-526-1[redacted]	胃腸障害 吐血 Vomiting Of Blood (1)	20[redacted]-04-12 (1) to 20[redacted]-04-15 (4) [4]	3	Related	Drug Interrupted	Hospitalization	Recovered/ Resolved
22-526-1[redacted]	胃腸障害 悪心 Nausea (2)	20[redacted]-10-01 (17) to 20[redacted]-10-11 (27) [11]	3	Related	Drug Interrupted	Hospitalization	Recovered/ Resolved

表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 24）

REGIMEN C							
Subject ID	**System Organ Class PREFERRED TERM Reported Term (AE #)**	**Date (#Days from First Dose) [Duration(days)]**	**Severity (NCI Grade)**	**Study Drug Relationship**	**Action Taken Regarding Study Drug**	**Other Action Taken**	**Outcome**
	一般・全身障害および投与部位の状態 発熱 Fever (1)	20[redacted]-10-01 (17) to 20[redacted]-10-11 (27) [11]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
	一般・全身障害および投与部位の状態 発熱 Fever (3)	20[redacted]-10-12 (28) to 20[redacted]-10-18 (34) [7]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
	一般・全身障害および投与部位の状態 疾患進行 Deterioration Of Clinical Condition (Worsening Of Mm) (27)	20[redacted]-12-03 (80) to 20[redacted]-12-03 (80) [1]	5	Not Related	Dose Not Changed	None	Fatal
22-526-1[redacted]	胃腸障害 腸閉塞 Intestinal Subocclusion (18)	20[redacted]-01-05 (92) to 20[redacted]-01-13 (100) [9]	3	Not Related	Dose Not Changed	Hospitalization	Recovered/ Resolved
	感染症および寄生虫症 肺炎 Pneumonia (17)	20[redacted]-01-05 (92) to 20[redacted]-01-13 (100) [9]	3	Related	Dose Not Changed	Hospitalization	Recovered/ Resolved
22-526-1[redacted]	感染症および寄生虫症 感染 Infection (3)	20[redacted]-05-11 (24) to 20[redacted]-06-22 (66) [43]	3	Not Related	Dose Not Changed	Hospitalization	Recovered/ Resolved
	腎および尿路障害 腎不全 Renal Failure (4)	20[redacted]-05-11 (24) to 20[redacted]-06-22 (66) [43]	3	Not Related	Dose Not Changed	Hospitalization	Recovered/ Resolved
22-532-1[redacted]	肝胆道系障害 胆石症 Abdominal Pain Due To Gallstones (1)	20[redacted]-11-06 (7) to Continuing	3	Not Related	Dose Not Changed	Hospitalization	Not Recovered/ Not Resolved

表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 25）

REGIMEN C							
Subject ID	**System Organ Class PREFERRED TERM Reported Term (AE #)**	**Date (#Days from First Dose) [Duration(days)]**	**Severity (NCI Grade)**	**Study Drug Relationship**	**Action Taken Regarding Study Drug**	**Other Action Taken**	**Outcome**
	一般・全身障害および投与部位の状態 多臓器不全 Multi Organ Failure (2)	20[redacted]-11-14 (15) to 20[redacted]-11-14 (15) [1]	5	Not Related	Drug Withdrawn	Hospitalization	Fatal
22-532-1[redacted]	感染症および寄生虫症 気管支肺炎 Bronchopneumonia (9)	20[redacted]-09-27 (87) to 20[redacted]-10-04 (94) [8]	4	Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
	呼吸器、胸郭および縦隔障害 肺塞栓症 Pulmonary Embolism (3)	20[redacted]-09-27 (87) to 20[redacted]-10-04 (94) [8]	4	Related	Drug Interrupted	Concomitant Medication, Procedure Required, Hospitalization	Recovered/ Resolved
	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） 肝の悪性新生物 Liver Cancer (12)	20[redacted]-10-15 (105) to Continuing	4	Related	Drug Withdrawn, Drug Interrupted	Hospitalization	Not Recovered/ Not Resolved
22-539-1[redacted]	一般・全身障害および投与部位の状態 疾患進行 Disease Progression (11)	20[redacted]-04-14 (46) to 20[redacted]-04-14 (46) [1]	5	Not Related	Dose Not Changed	None	Fatal
22-539-1[redacted]	腎および尿路障害 急性腎不全 Acute Renal Failure (1)	20[redacted]-03-29 (29) to 20[redacted]-04-06 (37) [9]	4	Not Related	Drug Interrupted	Concomitant Medication, Hospitalization	Recovered/ Resolved With Sequelae
22-539-1[redacted]	腎および尿路障害 急性腎不全 Acute Renal Failure (1)	20[redacted]-05-13 (9) to Continuing	4	Not Related	Drug Interrupted	Concomitant Medication, Hospitalization	Not Recovered/ Not Resolved
22-539-1[redacted]	代謝および栄養障害 高血糖 Hyperglicemia (1)	20[redacted]-06-08 (2) to 20[redacted]-06-13 (7) [6]	4	Not Related	Drug Interrupted	Concomitant Medication	Recovered/ Resolved

表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 26）

REGIMEN C							
Subject ID	System Organ Class PREFERRED TERM Reported Term (AE #)	Date (#Days from First Dose) [Duration(days)]	Severity (NCI Grade)	Study Drug Relationship	Action Taken Regarding Study Drug	Other Action Taken	Outcome
	一般・全身障害および投与部位の状態 疾患進行 Clinical Disease Progression (3)	20[redacted]-06-19 (13) to 20[redacted]-07-12 (36) [24]	5	Not Related	Dose Not Changed	Hospitalization	Fatal
22-541-1[redacted]	心臓障害 心不全 Cardiac Insufficiency (1)	20[redacted]-10-03 (3) to 20[redacted]-10-12 (12) [10]	3	Related	Drug Interrupted	Concomitant Medication, Hospitalization	Recovered/ Resolved
24-716-1[redacted]	感染症および寄生虫症 肺炎 Pneumonia (20)	20[redacted]-04-09 (261) to 20[redacted]-04-25 (277) [17]	3	Related	Drug Interrupted, Drug Interrupted	Hospitalization	Recovered/ Resolved
24-717-1[redacted]	呼吸器、胸郭および縦隔障害 労作性呼吸困難 Effort Dyspnea (4)	20[redacted]-12-26 (66) to Continuing	4	Not Related	Drug Interrupted	Hospitalization	Not Recovered/ Not Resolved
	心臓障害 心房粗動 Atrial Flutter (7)	20[redacted]-01-22 (93) ＊ to 20[redacted]-02-02 (104) ＊ [12]	4	Not Related	Drug Withdrawn	Hospitalization	Recovering/ Resolving
	心臓障害 心肺停止 Cardiorespiratory Arrest (6)	20[redacted]-02-01 (103) ＊ to 20[redacted]-02-02 (104) ＊ [2]	5	Not Related	Dose Not Changed	Hospitalization	Fatal
24-719-1[redacted]	心臓障害 心房細動 Atrial Fibrilation (4)	20[redacted]-06-18 (94) to 20[redacted]-06-18 (94) [1]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
	心臓障害 うっ血性心不全 Congestive Heart Failure (11)	20[redacted]-06-18 (94) to 20[redacted]-06-20 (96) [3]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved

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 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 27）

REGIMEN C							
Subject ID	System Organ Class PREFERRED TERM Reported Term (AE #)	Date (#Days from First Dose) [Duration(days)]	Severity (NCI Grade)	Study Drug Relationship	Action Taken Regarding Study Drug	Other Action Taken	Outcome
	呼吸器、胸郭および縦隔障害 急性肺水腫 Acute Pulmonary Edema (12)	20[redacted]-06-18 (94) to 20[redacted]-06-20 (96) [3]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
24-719-1[redacted]	眼障害 網膜炎 Retinitis (2)	20[redacted]-07-09 (-204) to 20[redacted]-08-01 (-181) [24]	2	Not Related	Dose Not Changed	Hospitalization	Recovered/ Resolved
	感染症および寄生虫症 ヘルペス性髄膜脳炎 Herpetic Meningoencephalitis (1)	20[redacted]-07-09 (-204) to 20[redacted]-08-01 (-181) [24]	4	Not Related	Dose Not Changed	Hospitalization	Recovered/ Resolved
	筋骨格系および結合組織障害 背部痛 Back Pain (3)	20[redacted]-03-09 (40) ＊ to 20[redacted]-03-21 (52) ＊ [13]	3	Not Related	Drug Interrupted	Concomitant Medication, Hospitalization	Recovering/ Resolving
	血液およびリンパ系障害 好中球減少症 Neutropenia (11)	20[redacted]-12-05 (311) ＊ to Continuing	1	Not Related	Dose Not Changed	Hospitalization	Not Recovered/ Not Resolved
	血液およびリンパ系障害 血小板減少症 Thrombocitopenia (12)	20[redacted]-12-05 (311) ＊ to Continuing	1	Not Related	Dose Not Changed	Hospitalization	Not Recovered/ Not Resolved
	筋骨格系および結合組織障害 骨痛 Bone Pain (10)	20[redacted]-12-05 (311) ＊ to Continuing	3	Not Related	Dose Not Changed	Hospitalization	Not Recovered/ Not Resolved
	一般・全身障害および投与部位の状態 疾患進行 Disease Progression (16)	20[redacted]-12-07 (313) ＊ to 20[redacted]-12-07 (313) ＊ [1]	5	Not Related	Dose Not Changed	None	Fatal
24-719-1[redacted]	胃腸障害 腸憩室 Diverticula In The Sigmoid Colon (3)	20[redacted]-06-21 (-5) to Continuing	3	Not Related	Dose Not Changed	Hospitalization	Not Recovered/ Not Resolved

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 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 28）

REGIMEN C							
Subject ID	System Organ Class PREFERRED TERM Reported Term (AE #)	Date (#Days from First Dose) [Duration(days)]	Severity (NCI Grade)	Study Drug Relationship	Action Taken Regarding Study Drug	Other Action Taken	Outcome
	感染症および寄生虫症 気管支炎 Bronquial Infection (1)	20[redacted]-07-26 (30) to 20[redacted]-08-03 (38) [9]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovering/ Resolving
	心臓障害 心不全 Heart Failure (2)	20[redacted]-07-29 (33) to 20[redacted]-08-03 (38) [6]	2	Not Related	Drug Interrupted	Concomitant Medication, Hospitalization	Recovered/ Resolved
	感染症および寄生虫症 ブドウ球菌性敗血症 Sepsis By S. Aureus Cloxaciline Resistant (6)	20[redacted]-01-17 (205) ＊ to 20[redacted]-01-20 (208) ＊ [4]	5	Not Related	Dose Not Changed	Hospitalization	Fatal
24-721-1[redacted]	一般・全身障害および投与部位の状態 疾患進行 Disease Progression (6)	20[redacted]-09-05 (183) to 20[redacted]-09-06 (184) [2]	5	Not Related	Dose Not Changed	Hospitalization	Fatal
24-722-1[redacted]	胃腸障害 下痢 Diarrhea (4)	20[redacted]-08-29 (76) to 20[redacted]-08-31 (78) [3]	3	Not Related	Dose Not Changed	Hospitalization	Recovering/ Resolving
	心臓障害 心停止 Cardiac Arrest (5)	20[redacted]-09-22 (100) to 20[redacted]-09-22 (100) [1]	5	Not Related	Drug Withdrawn	None	Fatal
24-724-1[redacted]	代謝および栄養障害 高カルシウム血症 Hypercalcemia (8)	20[redacted]-01-19 (30) to 20[redacted]-01-21 (32) [3]	2	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
	腎および尿路障害 腎機能障害 Renal Impairment (11)	20[redacted]-01-19 (30) to 20[redacted]-01-23 (34) [5]	2	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved

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 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 29）

REGIMEN C

Subject ID	System Organ Class PREFERRED TERM Reported Term (AE #)	Date (#Days from First Dose) [Duration(days)]	Severity (NCI Grade)	Study Drug Relationship	Action Taken Regarding Study Drug	Other Action Taken	Outcome
24-724-1[redacted]	感染症および寄生虫症 インフルエンザ Influenza B Virus (7)	20[redacted]-02-15 (57) to 20[redacted]-02-22 (64) [8]	2	Not Related	Dose Not Changed	Hospitalization	Recovered/ Resolved
	感染症および寄生虫症 肺炎球菌性肺炎 Pneumococcal Pneumonia (6)	20[redacted]-02-15 (57) to 20[redacted]-02-22 (64) [8]	2	Not Related	Drug Interrupted	Hospitalization	Recovered/ Resolved
	腎および尿路障害 急性腎不全 Acute Renal Failure (4)	20[redacted]-02-15 (57) to 20[redacted]-02-20 (62) [6]	2	Not Related	Dose Not Changed	None	Recovered/ Resolved
24-724-1[redacted]	傷害、中毒および処置合併症 胸椎骨折 Deterioration Vertebral Fracture (Vertebra Thoracic Number 11) (19)	20[redacted]-03-03 (381) to 20[redacted]-03-24 (402) [22]	3	Not Related	Drug Interrupted	Concomitant Medication, Hospitalization	Recovered/ Resolved
24-724-1[redacted]	感染症および寄生虫症 気道感染 Respiratory Infection (3)	20[redacted]-05-27 (124) to 20[redacted]-05-31 (128) [5]	3	Not Related	Drug Interrupted	Concomitant Medication, Hospitalization	Recovered/ Resolved
	筋骨格系および結合組織障害 背部痛 Dorsal Pain (24)	20[redacted]-06-22 (880) ** to 20[redacted]-06-27 (885) ** [6]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
24-724-1[redacted]	神経系障害 浮動性めまい Dizziness (1)	20[redacted]-03-23 (3) to 20[redacted]-04-17 (28) [26]	3	Related	Drug Interrupted, Drug Interrupted	Concomitant Medication, Hospitalization	Recovered/ Resolved
	腎および尿路障害 急性腎不全 Acute Renal Failure (2)	20[redacted]-04-05 (16) to 20[redacted]-04-06 (17) [2]	2	Related	Drug Interrupted	Concomitant Medication, Hospitalization	Recovered/ Resolved

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
＊＊　：「翌々年」を意味する

表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 30）

REGIMEN C							
Subject ID	**System Organ Class PREFERRED TERM Reported Term (AE #)**	**Date (#Days from First Dose) [Duration(days)]**	**Severity (NCI Grade)**	**Study Drug Relationship**	**Action Taken Regarding Study Drug**	**Other Action Taken**	**Outcome**
	胃腸障害 胃出血 Gastric Bleeding (3)	20[redacted]-04-09 (20) to 20[redacted]-04-10 (21) [2]	3	Related	Drug Interrupted	Concomitant Medication, Hospitalization	Recovered/ Resolved
24-724-1[redacted]	感染症および寄生虫症 レンサ球菌性肺炎 Streptococcal Pneumonia (4)	20[redacted]-11-04 (95) to 20[redacted]-11-15 (106) [12]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
28-227-1[redacted]	筋骨格系および結合組織障害 骨溶解 Impending Arm Fracture Due To Osteolysis (3)	20[redacted]-12-18 (84) to 20[redacted]-12-24 (90) [7]	3	Not Related	Dose Not Changed	Procedure Required, Hospitalization	Recovered/ Resolved
38-276-1[redacted]	一般・全身障害および投与部位の状態 発熱 Fever (2)	20[redacted]-02-09 (17) to 20[redacted]-02-23 (31) [15]	2	Not Related	Dose Not Changed	Hospitalization	Recovered/ Resolved
	感染症および寄生虫症 気管支肺炎 Bronchopneumonia Bilateral (1)	20[redacted]-02-09 (17) to 20[redacted]-02-23 (31) [15]	2	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
	感染症および寄生虫症 気管気管支炎 Acute Tracheobronchitis (10)	20[redacted]-05-24 (121) to 20[redacted]-06-06 (134) [14]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovering/ Resolving
	一般・全身障害および投与部位の状態 疾患進行 Disease Progression (14)	20[redacted]-07-10 (168) to 20[redacted]-07-10 (168) [1]	5	Not Related	Dose Not Changed	None	Fatal
38-276-1[redacted]	感染症および寄生虫症 腎感染 Kidney Infection (1)	20[redacted]-01-23 (127) to 20[redacted]-02-08 (143) [17]	5	Not Related	Drug Withdrawn	Concomitant Medication, Hospitalization	Fatal

表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 31）

REGIMEN C							
Subject ID	**System Organ Class PREFERRED TERM Reported Term (AE #)**	**Date (#Days from First Dose) [Duration(days)]**	**Severity (NCI Grade)**	**Study Drug Relationship**	**Action Taken Regarding Study Drug**	**Other Action Taken**	**Outcome**
38-278-1[redacted]	感染症および寄生虫症 気管支肺炎 Bronchopneumonia (1)	20[redacted]-11-12 (-30) to 20[redacted]-11-26 (-16) [15]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
38-278-1[redacted]	血管障害 静脈血栓症 Flebotrombosis (21)	20[redacted]-11-23 (185) to 20[redacted]-12-01 (193) [9]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
38-278-1[redacted]	感染症および寄生虫症 気管支肺炎 Bronchopneumonia (8)	20[redacted]-05-11 (114) to 20[redacted]-05-16 (119) [6]	3	Not Related	Drug Interrupted	Concomitant Medication, Hospitalization	Recovered/ Resolved
38-278-1[redacted]	筋骨格系および結合組織障害 背部痛 Worsening Of Pain Of Back (1)	20[redacted]-01-20 (-2) to 20[redacted]-02-08 (17) [20]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
	一般・全身障害および投与部位の状態 疾患進行 Disease Progression (10)	20[redacted]-02-13 (22) to 20[redacted]-02-21 (30) [9]	5	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Fatal
38-278-1[redacted]	感染症および寄生虫症 気管支肺炎 Bronchopneumonia (17)	20[redacted]-05-27 (102) to 20[redacted]-06-18 (124) [23]	5	Not Related	Drug Withdrawn, Drug Interrupted	Concomitant Medication, Hospitalization	Fatal
38-279-1[redacted]	感染症および寄生虫症 肺炎 Bilateral Pneumonia (6)	20[redacted]-02-03 (94) to 20[redacted]-02-17 (108) [15]	5	Not Related	Drug Withdrawn	Hospitalization	Fatal
	呼吸器、胸郭および縦隔障害 呼吸不全 Respiratory Insufficiency (7)	20[redacted]-02-03 (94) to Continuing	4	Not Related	Drug Interrupted	Hospitalization	Not Recovered/ Not Resolved

表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 32）

REGIMEN C							
Subject ID	System Organ Class PREFERRED TERM Reported Term (AE #)	Date (#Days from First Dose) [Duration(days)]	Severity (NCI Grade)	Study Drug Relationship	Action Taken Regarding Study Drug	Other Action Taken	Outcome
38-279-1[redacted]	代謝および栄養障害 高カルシウム血症 Hypercalcemia (1)	20[redacted]-02-28 (15) to 20[redacted]-03-04 (19) [5]	2	Not Related	Dose Not Changed	Concomitant Medication	Recovered/ Resolved
	筋骨格系および結合組織障害 病的骨折 Pathologic Fracture Left Femur (2)	20[redacted]-04-06 (52) to 20[redacted]-05-10 (86) [35]	3	Not Related	Dose Not Changed	Concomitant Medication, Procedure Required, Hospitalization	Recovered/ Resolved
38-279-1[redacted]	神経系障害 脳血管発作 Cerebral Stroke (44)	20[redacted]-02-03 (679) to 20[redacted]-02-15 (691) [13]	3	Not Related	Dose Not Changed	Concomitant Medication, Procedure Required, Hospitalization	Recovered/ Resolved
38-279-1[redacted]	感染症および寄生虫症 気管支肺炎 Bronchopneumonia (1)	20[redacted]-09-18 (91) to 20[redacted]-09-30 (103) [13]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
39-478-1[redacted]	筋骨格系および結合組織障害 筋骨格系胸痛 Musculoskeletal Chest Pain (2)	20[redacted]-08-28 (10) to 20[redacted]-08-30 (12) [3]	2	Not Related	Dose Not Changed	Concomitant Medication, Procedure Required, Hospitalization	Recovering/ Resolving
	感染症および寄生虫症 肺炎 Pneumonia (10)	20[redacted]-04-04 (229) ＊ to 20[redacted]-04-15 (240) ＊ [12]	3	Not Related	Drug Interrupted	Concomitant Medication, Hospitalization	Recovered/ Resolved
	感染症および寄生虫症 肺炎 Bilateral Pneumonia (19)	20[redacted]-02-04 (535) ＊＊ to 20[redacted]-02-13 (544) ＊＊[10]	3	Not Related	Drug Interrupted	Concomitant Medication, Procedure Required, Hospitalization	Recovered/ Resolved
	一般・全身障害および投与部位の状態 疾患進行 Worsening Of Multiple Myeloma Disease (22)	20[redacted]-03-10 (569) ＊＊ to 20[redacted]-03-13 (572) ＊＊ [4]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved

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
＊＊　：「翌々年」を意味する

表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 33）

REGIMEN C							
Subject ID	**System Organ Class PREFERRED TERM Reported Term (AE #)**	**Date (#Days from First Dose) [Duration(days)]**	**Severity (NCI Grade)**	**Study Drug Relationship**	**Action Taken Regarding Study Drug**	**Other Action Taken**	**Outcome**
39-482-1[redacted]	感染症および寄生虫症 髄膜炎 Meningitis (4)	20[redacted]-06-06 (37) to 20[redacted]-06-29 (60) [24]	3	Not Related	Drug Interrupted	Concomitant Medication, Procedure Required, Hospitalization	Recovered/ Resolved
39-482-1[redacted]	傷害、中毒および処置合併症 股関節部骨折 Suspected Right Hip Fracture (2)	20[redacted]-03-28 (254) to Continuing	2	Not Related	Dose Not Changed	Procedure Required, Hospitalization	Not Recovered/ Not Resolved
39-482-1[redacted]	胃腸障害 上部消化管出血 Upper Gastrointestinal Bleeding (1)	20[redacted]-08-21 (21) to 20[redacted]-08-26 (26) [6]	5	Not Related	Drug Withdrawn	Hospitalization	Fatal
	腎および尿路障害 急性腎不全 Acute Renal Failure (2)	20[redacted]-08-22 (22) to 20[redacted]-08-26 (26) [5]	2	Not Related	Dose Not Changed	Hospitalization	Recovering/ Resolving
39-482-1[redacted]	神経系障害 脊髄圧迫 Spinal Cord Compression (1)	20[redacted]-10-09 (13) to 20[redacted]-11-22 (57) [45]	3	Not Related	Dose Not Changed	Procedure Required, Hospitalization	Recovered/ Resolved With Sequelae
39-485-1[redacted]	呼吸器、胸郭および縦隔障害 肺うっ血 Pulmonary Congestion (1)	20[redacted]-10-15 (58) to 20[redacted]-10-18 (61) [4]	4	Related	Drug Interrupted	Concomitant Medication, Hospitalization	Recovered/ Resolved
	一般・全身障害および投与部位の状態 発熱 Febrile Disease. (35)	20[redacted]-01-24 (159) ＊ to 20[redacted]-01-28 (163) ＊ [5]	4	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
	肝胆道系障害 胆道仙痛 Suspected Biliary Colic (44)	20[redacted]-01-24 (159) ＊ to 20[redacted]-01-28 (163) ＊ [5]	4	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved

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 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 34）

REGIMEN C							
Subject ID	System Organ Class PREFERRED TERM Reported Term (AE #)	Date (#Days from First Dose) [Duration(days)]	Severity (NCI Grade)	Study Drug Relationship	Action Taken Regarding Study Drug	Other Action Taken	Outcome
	臨床検査 肝酵素上昇 Elevated Liver Enzymes (62)	20[redacted]-01-24 (159) ＊ to 20[redacted]-01-28 (163) ＊ [5]	4	Not Related	Dose Not Changed	Concomitant Medication	Recovered/ Resolved
40-906-1[redacted]	代謝および栄養障害 高カリウム血症 Hyperkalemia (1)	20[redacted]-10-23 (20) to 20[redacted]-10-24 (21) [2]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
	腎および尿路障害 急性腎不全 Acute Renal Failure (7)	20[redacted]-12-14 (72) to 20[redacted]-12-15 (73) [2]	3	Not Related	Drug Interrupted	Hospitalization	Recovering/ Resolving
40-909-1[redacted]	感染症および寄生虫症 肺炎 Pneumonia (1)	20[redacted]-10-13 (16) to 20[redacted]-10-19 (22) [7]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovering/ Resolving
	腎および尿路障害 急性腎不全 Acute On Chronic Renal Failure (2)	20[redacted]-10-18 (21) to 20[redacted]-10-19 (22) [2]	5	Not Related	Drug Withdrawn	None	Fatal
44-201-1[redacted]	腎および尿路障害 急性腎不全 Acute Renal Failure (1)	20[redacted]-03-26 (6) to 20[redacted]-04-17 (28) [23]	5	Not Related	Drug Withdrawn	Concomitant Medication, Procedure Required, Hospitalization	Fatal
44-201-1[redacted]	一般・全身障害および投与部位の状態 疾患進行 Disease Progression (1)	20[redacted]-06-11 (55) to 20[redacted]-06-11 (55) [1]	5	Not Related	Dose Not Changed	Hospitalization	Fatal
44-202-1[redacted]	筋骨格系および結合組織障害 背部痛 Back Pain (1)	20[redacted]-11-08 (-2) to 20[redacted]-11-23 (13) [16]	3	Not Related	Dose Not Changed	Hospitalization	Recovering/ Resolving

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 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 35）

REGIMEN C							
Subject ID	**System Organ Class PREFERRED TERM Reported Term (AE #)**	**Date (#Days from First Dose) [Duration(days)]**	**Severity (NCI Grade)**	**Study Drug Relationship**	**Action Taken Regarding Study Drug**	**Other Action Taken**	**Outcome**
	代謝および栄養障害 高カルシウム血症 Hypercalcemia (4)	20[redacted]-11-24 (14) to 20[redacted]-11-30 (20) [7]	3	Not Related	Dose Not Changed	Hospitalization	Recovered/ Resolved
	腎および尿路障害 腎不全 Renal Failure (3)	20[redacted]-11-24 (14) to Continuing	4	Not Related	Dose Not Changed	Hospitalization	Not Recovered/ Not Resolved
44-202-1[redacted]	代謝および栄養障害 高カルシウム血症 Hypercalcemia (1)	20[redacted]-10-17 (6) to 20[redacted]-10-17 (6) [1]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
	代謝および栄養障害 高カルシウム血症 Hypercalcemia (2)	20[redacted]-10-25 (14) to Continuing	4	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Not Recovered/ Not Resolved
44-202-1[redacted]	血液およびリンパ系障害 貧血 Anemia (6)	20[redacted]-02-19 (26) to 20[redacted]-02-21 (28) [3]	4	Not Related	Dose Not Changed	Procedure Required, Hospitalization	Recovered/ Resolved
	代謝および栄養障害 高カルシウム血症 Hypercalcemia (7)	20[redacted]-02-19 (26) to 20[redacted]-02-22 (29) [4]	4	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
	血液およびリンパ系障害 貧血 Anemia (16)	20[redacted]-03-19 (55) to Continuing	4	Not Related	Dose Not Changed	Procedure Required, Hospitalization	Not Recovered/ Not Resolved
	代謝および栄養障害 高カルシウム血症 Hypercalcemia (18)	20[redacted]-03-19 (55) to Continuing	4	Not Related	Dose Not Changed	Concomitant Medication	Not Recovered/ Not Resolved

表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 36）

REGIMEN C							
Subject ID	**System Organ Class PREFERRED TERM Reported Term (AE #)**	**Date (#Days from First Dose) [Duration(days)]**	**Severity (NCI Grade)**	**Study Drug Relationship**	**Action Taken Regarding Study Drug**	**Other Action Taken**	**Outcome**
44-202-1[redacted]	感染症および寄生虫症 鼻咽頭炎 Rhinopharyngitis (6)	20[redacted]-06-07 (29) to 20[redacted]-06-13 (35) [7]	2	Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
	腎および尿路障害 水腎症 Hydronephrosis (11)	20[redacted]-09-14 (128) to 20[redacted]-09-17 (131) [4]	2	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
44-202-1[redacted]	血液およびリンパ系障害 血小板減少症 Thrombopenia (4)	20[redacted]-10-09 (15) to 20[redacted]-10-15 (21) [7]	4	Related	Drug Interrupted	Procedure Required	Recovered/ Resolved
	代謝および栄養障害 高カルシウム血症 Hypercalcemia (6)	20[redacted]-10-16 (22) to 20[redacted]-10-23 (29) [8]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
	一般・全身障害および投与部位の状態 疾患進行 Disease Progression (8)	20[redacted]-11-14 (51) to 20[redacted]-11-14 (51) [1]	5	Not Related	Dose Not Changed	None	Fatal
44-203-1[redacted]	筋骨格系および結合組織障害 背部痛 Lumbago (1)	20[redacted]-04-16 (12) to 20[redacted]-04-20 (16) [5]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
	血液およびリンパ系障害 白血球減少症 Leucopenia (2)	20[redacted]-04-23 (19) to 20[redacted]-04-27 (23) [5]	4	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
	血液およびリンパ系障害 発熱性好中球減少症 Neutropenic Fever (3)	20[redacted]-05-07 (33) to 20[redacted]-05-10 (36) [4]	3	Related	Dose Not Changed	Hospitalization	Recovered/ Resolved

表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 37）

REGIMEN C

Subject ID	System Organ Class PREFERRED TERM Reported Term (AE #)	Date (#Days from First Dose) [Duration(days)]	Severity (NCI Grade)	Study Drug Relationship	Action Taken Regarding Study Drug	Other Action Taken	Outcome
44-203-1[redacted]	筋骨格系および結合組織障害 背部痛 Lumbago (3)	20[redacted]-10-13 (133) to 20[redacted]-10-14 (134) [2]	2	Not Related	Dose Not Changed	Hospitalization	Recovered/ Resolved With Sequelae
44-203-1[redacted]	筋骨格系および結合組織障害 変形性関節症 Gonarthrose Both Legs (2)	20[redacted]-12-21 (27) to Continuing	2	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Not Recovered/ Not Resolved
	一般・全身障害および投与部位の状態 疼痛 Pain Unknown Origin (1)	20[redacted]-12-30 (36) to 20[redacted]-01-13 (50) ＊ [15]	2	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovering/ Resolving
44-203-1[redacted]	心臓障害 心不全 Cardiovascularfailure (1)	20[redacted]-12-11 (3) to 20[redacted]-12-12 (4) [2]	5	Related	Drug Withdrawn	Hospitalization	Fatal
46-301-1[redacted]	感染症および寄生虫症 尿路感染 Urinary Tract Infection (9)	20[redacted]-12-22 (226) to 20[redacted]-12-30 (234) [9]	3	Not Related	Dose Not Changed	Hospitalization	Recovered/ Resolved
	感染症および寄生虫症 肺炎 Pneumonia (17)	20[redacted]-02-26 (292) ＊ to 20[redacted]-03-07 (302) ＊ [11]	3	Not Related	Dose Not Changed	Hospitalization	Recovered/ Resolved
	血液およびリンパ系障害 貧血 Anaemia (20)	20[redacted]-08-30 (478) ＊ to 20[redacted]-09-07 (486) ＊ [9]	3	Not Related	Dose Not Changed	Hospitalization	Recovered/ Resolved
	血液およびリンパ系障害 貧血 Anemia (25)	20[redacted]-10-24 (533) ＊ to 20[redacted]-10-30 (539) ＊ [7]	3	Not Related	Dose Not Changed	Hospitalization	Recovering/ Resolving

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 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 38）

REGIMEN C

Subject ID	System Organ Class PREFERRED TERM Reported Term (AE #)	Date (#Days from First Dose) [Duration(days)]	Severity (NCI Grade)	Study Drug Relationship	Action Taken Regarding Study Drug	Other Action Taken	Outcome
	心臓障害 急性心不全 Acute Heart Failure (27)	20[redacted]-10-30 (539) * to 20[redacted]-10-30 (539) * [1]	5	Not Related	Drug Withdrawn	None	Fatal
46-303-1[redacted]	一般・全身障害および投与部位の状態 発熱 Fever (48)	20[redacted]-08-06 (311) to 20[redacted]-08-08 (313) [3]	2	Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
46-303-1[redacted]	感染症および寄生虫症 肺炎 Pneumonia (1)	20[redacted]-10-16 (6) to Continuing	3	Not Related	Dose Not Changed	Concomitant Medication, Procedure Required, Hospitalization	Not Recovered/ Not Resolved
	感染症および寄生虫症 敗血症 Sepsis (2)	20[redacted]-10-16 (6) to 20[redacted]-10-27 (17) [12]	5	Not Related	Drug Withdrawn	Concomitant Medication, Hospitalization	Fatal
	神経系障害 昏睡 Coma Iv. (4)	20[redacted]-10-16 (6) to Continuing	4	Not Related	Dose Not Changed	Concomitant Medication, Procedure Required, Hospitalization	Not Recovered/ Not Resolved
	腎および尿路障害 急性腎不全 Acut Renal Failure (3)	20[redacted]-10-18 (8) to Continuing	4	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Not Recovered/ Not Resolved
46-303-1[redacted]	神経系障害 構語障害 Dysarthria (1)	20[redacted]-02-16 (-6) to 20[redacted]-02-17 (-5) [2]	2	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
	筋骨格系および結合組織障害 筋骨格系胸痛 Musculoskeletal Chest Pain (18)	20[redacted]-10-07 (227) to 20[redacted]-10-10 (230) [4]	2	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved

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 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 39）

REGIMEN C							
Subject ID	System Organ Class PREFERRED TERM Reported Term (AE #)	Date (#Days from First Dose) [Duration(days)]	Severity (NCI Grade)	Study Drug Relationship	Action Taken Regarding Study Drug	Other Action Taken	Outcome
46-303-1[redacted]	感染症および寄生虫症 気管支炎 Acute Bronchitis (22)	20[redacted]-05-06 (390) to 20[redacted]-05-14 (398) [9]	2	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
46-303-1[redacted]	代謝および栄養障害 腫瘍崩壊症候群 Tumor Lysis Syndrome Gr Iii (8)	20[redacted]-08-01 (5) to 20[redacted]-08-19 (23) [19]	3	Related	Drug Interrupted	Concomitant Medication, Hospitalization	Recovered/ Resolved
	代謝および栄養障害 腫瘍崩壊症候群 Tumor Lysis Syndrome (2)	20[redacted]-09-26 (61) to 20[redacted]-10-28 (93) [33]	4	Related	Drug Interrupted	Concomitant Medication, Procedure Required, Hospitalization	Recovered/ Resolved
46-303-1[redacted]	一般・全身障害および投与部位の状態 疾患進行 Disease Progression (20)	20[redacted]-07-15 (273) to 20[redacted]-07-16 (274) [2]	5	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Fatal
46-303-1[redacted]	腎および尿路障害 腎不全 Renal Failure (57)	20[redacted]-11-16 (-6) to 20[redacted]-11-18 (-4) [3]	3	Not Related	Dose Not Changed	Hospitalization	Recovered/ Resolved
	呼吸器、胸郭および縦隔障害 鼻出血 Nasal Bleeding (1)	20[redacted]-12-27 (35) to 20[redacted]-12-30 (38) [4]	3	Not Related	Drug Interrupted	Concomitant Medication, Procedure Required, Hospitalization	Recovered/ Resolved
	神経系障害 不全対麻痺 Paraparesis (3)	20[redacted]-01-15 (54) ＊ to 20[redacted]-01-16 (55) ＊ [2]	2	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved With Sequelae
	一般・全身障害および投与部位の状態 疾患進行 Disease Progression (56)	20[redacted]-01-20 (59) ＊ to 20[redacted]-01-29 (68) ＊ [10]	5	Not Related	Dose Not Changed	None	Fatal

被験者識別コード，年齢以外のマスキングにおいて，
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表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 40）

REGIMEN C							
Subject ID	System Organ Class PREFERRED TERM Reported Term (AE #)	Date (#Days from First Dose) [Duration(days)]	Severity (NCI Grade)	Study Drug Relationship	Action Taken Regarding Study Drug	Other Action Taken	Outcome
	呼吸器、胸郭および縦隔障害 鼻出血 Nasal Bleeding (2)	20[redacted]-01-26 (65) ＊ to Continuing	2	Not Related	Dose Not Changed	Concomitant Medication, Procedure Required, Hospitalization	Not Recovered/ Not Resolved
46-303-1[redacted]	代謝および栄養障害 腫瘍崩壊症候群 Tumor Lysis Syndrome (6)	20[redacted]-09-25 (7) to Continuing	3	Related	Dose Not Changed	Concomitant Medication	Not Recovered/ Not Resolved
	筋骨格系および結合組織障害 病的骨折 Pathological Fracture Of 2nd Cervical Vertebra (10)	20[redacted]-10-06 (18) to 20[redacted]-10-08 (20) [3]	3	Not Related	Dose Not Changed	Concomitant Medication, Procedure Required, Hospitalization	Recovering/ Resolving
	一般・全身障害および投与部位の状態 疾患進行 Disease Progression (14)	20[redacted]-11-12 (55) to 20[redacted]-11-29 (72) [18]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovering/ Resolving
	神経系障害 脊髄圧迫 Myeloncompression At Level Of Th Vi-Vii (13)	20[redacted]-11-12 (55) to 20[redacted]-11-29 (72) [18]	3	Not Related	Dose Not Changed	Concomitant Medication, Procedure Required, Hospitalization	Recovering/ Resolving
46-303-1[redacted]	感染症および寄生虫症 気管支肺炎 Bronchopneumonia Gr Iii (2)	20[redacted]-11-05 (43) to 20[redacted]-11-10 (48) [6]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
	感染症および寄生虫症 気管支炎 Acute Bronchitis Gr Iii (26)	20[redacted]-01-08 (107) ＊ to 20[redacted]-01-13 (112) ＊ [6]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
	傷害、中毒および処置合併症 大腿骨骨折 Pertrochanter Fracture Of Right Femur (30)	20[redacted]-02-09 (139) ＊ to 20[redacted]-02-22 (152) ＊ [14]	2	Not Related	Dose Not Changed	Procedure Required, Hospitalization	Recovered/ Resolved
	感染症および寄生虫症 肺炎 Pneumonia (Left Lung) (43)	20[redacted]-12-07 (440) ＊ to 20[redacted]-12-11 (444) ＊ [5]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved

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 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 41）

REGIMEN C

Subject ID	System Organ Class PREFERRED TERM Reported Term (AE #)	Date (#Days from First Dose) [Duration(days)]	Severity (NCI Grade)	Study Drug Relationship	Action Taken Regarding Study Drug	Other Action Taken	Outcome
	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 Enterocolitis (44)	20[redacted]-12-28 (461) * to 20[redacted]-12-31 (464) * [4]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
	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 Enterocolitis (45)	20[redacted]-01-02 (466) ** to 20[redacted]-01-15 (479) ** [14]	2	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovering/ Resolving
	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 Enterocolitis (63)	20[redacted]-05-16 (600) ** to 20[redacted]-05-23 (607) ** [8]	3	Not Related	Drug Interrupted	Concomitant Medication, Procedure Required, Hospitalization	Recovered/ Resolved
46-304-1[redacted]	心臓障害 心不全 Cardiac Failure (6)	20[redacted]-03-12 (143) to 20[redacted]-03-22 (153) [11]	3	Not Related	Drug Interrupted	Hospitalization	Recovered/ Resolved
	感染症および寄生虫症 肺炎 Pneumonia (7)	20[redacted]-03-12 (143) to 20[redacted]-03-22 (153) [11]	3	Not Related	Drug Interrupted	Concomitant Medication, Hospitalization	Recovered/ Resolved
46-307-1[redacted]	呼吸器、胸郭および縦隔障害 肺水腫 Pulmonary Oedema (29)	20[redacted]-01-24 (113) to 20[redacted]-02-06 (126) [14]	5	Not Related	Drug Withdrawn	Concomitant Medication, Hospitalization	Fatal
46-308-1[redacted]	感染症および寄生虫症 敗血症 Septicaemia (1)	20[redacted]-04-14 (34) to 20[redacted]-04-27 (47) [14]	4	Not Related	Dose Not Changed	Concomitant Medication, Procedure Required, Hospitalization	Recovered/ Resolved
49-426-1[redacted]	血液およびリンパ系障害 貧血 Anemia (4)	20[redacted]-06-29 (37) to 20[redacted]-07-03 (41) [5]	4	Not Related	Dose Not Changed	Hospitalization	Recovered/ Resolved With Sequelae

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
＊＊　：「翌々年」を意味する

表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 42）

REGIMEN C							
Subject ID	System Organ Class PREFERRED TERM Reported Term (AE #)	Date (#Days from First Dose) [Duration(days)]	Severity (NCI Grade)	Study Drug Relationship	Action Taken Regarding Study Drug	Other Action Taken	Outcome
	腎および尿路障害 急性腎不全 Acute Renal Failure (26)	20[redacted]06-29 (37) to 20[redacted]10-14 (144) [108]	4	Not Related	Drug Withdrawn	Procedure Required, Hospitalization	Not Recovered/ Not Resolved
	腎および尿路障害 急性腎不全 Acute Renal Failure (3)	20[redacted]10-15 (145) to 20[redacted]10-15 (145) [1]	5	Not Related	Dose Not Changed	Procedure Required, Hospitalization	Fatal
49-426-1[redacted]	一般・全身障害および投与部位の状態 疾患進行 Progression Disease (14)	20[redacted]12-23 (123) to 20[redacted]01-08 (139) ＊ [17]	5	Not Related	Dose Not Changed	Hospitalization	Fatal
49-426-1[redacted]	腎および尿路障害 急性腎不全 Acute Renal Failure (2)	20[redacted]09-10 (13) to 20[redacted]10-14 (47) [35]	4	Not Related	Drug Withdrawn	Concomitant Medication, Hospitalization	Recovered/ Resolved
	腎および尿路障害 急性腎不全 Acute Kidney Injury (9)	20[redacted]10-15 (48) to 20[redacted]11-17 (81) [34]	5	Not Related	Dose Not Changed	Hospitalization	Fatal
49-428-1[redacted]	一般・全身障害および投与部位の状態 発熱 Fever (1)	20[redacted]03-29 (-10) to 20[redacted]03-29 (-10) [1]	1	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
	感染症および寄生虫症 カンジダ症 Candida Parapsilosis (2)	20[redacted]04-01 (-7) to 20[redacted]04-08 (0) [8]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
	呼吸器、胸郭および縦隔障害 呼吸困難 Dyspnea (3)	20[redacted]04-03 (-5) to Continuing	2	Not Related	Dose Not Changed	Hospitalization	Not Recovered/ Not Resolved

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 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 43）

REGIMEN C							
Subject ID	**System Organ Class PREFERRED TERM Reported Term (AE #)**	**Date (#Days from First Dose) [Duration(days)]**	**Severity (NCI Grade)**	**Study Drug Relationship**	**Action Taken Regarding Study Drug**	**Other Action Taken**	**Outcome**
	腎および尿路障害 乏尿 Oliguria (7)	20[redacted]-04-09 (1) to 20[redacted]-04-09 (1) [1]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
	血管障害 低血圧 Hypotension (4)	20[redacted]-04-09 (1) to 20[redacted]-04-09 (1) [1]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
	呼吸器、胸郭および縦隔障害 鼻出血 Epistaxis (5)	20[redacted]-04-16 (8) to 20[redacted]-04-16 (8) [1]	4	Not Related	Dose Not Changed	Procedure Required	Recovered/ Resolved
	一般・全身障害および投与部位の状態 疾患進行 Disease Worsening (6)	20[redacted]-05-04 (26) to 20[redacted]-05-04 (26) [1]	5	Not Related	Dose Not Changed	None	Fatal
	一般・全身障害および投与部位の状態 多臓器不全 Multi Organ Failure (11)	20[redacted]-05-04 (26) to 20[redacted]-05-04 (26) [1]	5	Not Related	Drug Withdrawn	None	Fatal
49-428-1[redacted]	一般・全身障害および投与部位の状態 発熱 Fever (1)	20[redacted]-09-26 (3) to 20[redacted]-09-29 (6) [4]	1	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
	感染症および寄生虫症 尿路感染 Urine Tract Infection (2)	20[redacted]-09-26 (3) to 20[redacted]-10-04 (11) [9]	3	Not Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved
	心臓障害 うっ血性心不全 Congestive Heart Failure (6)	20[redacted]-12-17 (85) to 20[redacted]-12-24 (92) [8]	3	Related	Drug Withdrawn	Hospitalization	Recovering/ Resolving
51-653-1[redacted]	筋骨格系および結合組織障害 顎骨壊死 Bisphosphonate-Associated Osteonecrosis Of The Jaw (8)	20[redacted]-02-16 (303) to 20[redacted]-02-24 (311) [9]	2	Not Related	Drug Interrupted	Hospitalization	Recovering/ Resolving

表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 44）

REGIMEN C							
Subject ID	System Organ Class PREFERRED TERM Reported Term (AE #)	Date (#Days from First Dose) [Duration(days)]	Severity (NCI Grade)	Study Drug Relationship	Action Taken Regarding Study Drug	Other Action Taken	Outcome
51-655-1[redacted]	呼吸器、胸郭および縦隔障害 肺水腫 Pulmonary Oedema (1)	20[redacted]-03-10 (2) to 20[redacted]-03-18 (10) [9]	4	Not Related	Drug Withdrawn	Concomitant Medication	Recovered/ Resolved
52-640-1[redacted]	筋骨格系および結合組織障害 骨粗鬆症 Worsening Of Osteoporosis (2)	20[redacted]-10-04 (30) to 20[redacted]-10-09 (35) [6]	2	Not Related	Dose Not Changed	Hospitalization	Recovering/ Resolving
56-927-1[redacted]	一般・全身障害および投与部位の状態 発熱 Fever (3)	20[redacted]-10-18 (31) to 20[redacted]-10-19 (32) [2]	2	Related	Dose Not Changed	Hospitalization	Recovered/ Resolved
	一般・全身障害および投与部位の状態 発熱 Fever (4)	20[redacted]-10-25 (38) to 20[redacted]-10-26 (39) [2]	1	Related	Dose Not Changed	Concomitant Medication, Hospitalization	Recovered/ Resolved

出典［総括報告書5.3.5.1-2（PX-171-011），Listing 16.2.7.2］

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）

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
14-003-0[redacted]	呼吸器、胸郭および縦隔障害/ 呼吸困難/ Shortness of Breath	Yes	17FEB20[redacted] (2)/	Grade 3 Severe/ Related	Unchanged/ Dose interrupted	Yes/ Inpatient hospitalization
	神経系障害/ 脳出血/ Brain hemorrhage	Yes	22FEB20[redacted] (7)/ 22FEB20[redacted] (7)	Grade 5 Fatal/ Not Related/ Other: Believed patient fell and hit her head	Death/ Discontinued permanently	Yes/ Results in death
14-003-0[redacted]	心臓障害/ 狭心症/ right sided cardiac chest pain	Yes	10MAR20[redacted] (26)/ 13MAR20[redacted] (29)	Grade 3 Severe/ Not Related/ Other: cardiac	Resolved/ None	Yes/ Inpatient hospitalization
	呼吸器、胸郭および縦隔障害/ 胸水/ Bilateral Pleural effusions	Yes	20MAR20[redacted] (36)/ 25MAR20[redacted] (41)	Grade 4 Life threatening/ Not Related/ Other: Possible infection	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 1）

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
14-003-0[redacted] (Cont'd.)	一般・全身障害および投与部位の状態/ 死亡/ Death Cause unknown	Yes	26MAR20[redacted] (42)/ 26MAR20[redacted] (42)	Grade 5 Fatal/ Not Related/ Underlying disease	Death/ Discontinued permanently	Yes/ Results in death
14-003-0[redacted]	感染症および寄生虫症/ 肺炎/ Pneumonia	Yes	17MAY20[redacted] (87)/ 21MAY20[redacted] (91)	Grade 3 Severe/ Related	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	傷害、中毒および処置合併症/ 鎖骨骨折/ Clavicle fracture	Yes	05JUN20[redacted] (106)/ 07JUN20[redacted] (108)	Grade 2 Moderate/ 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	22JUN20[redacted] (123)/ 04JUL20[redacted] (135)	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 2）

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
14-003-0[redacted]	一般・全身障害および投与部位の状態/ 発熱/ Fever	Yes	21JUN20[redacted](4)/ 26JUN20[redacted](9)	Grade 2 Moderate/ Related	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	血管障害/ 低血圧/ Hypotension	Yes	21JUN20[redacted](4)/ 26JUN20[redacted](9)	Grade 2 Moderate/ Related	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	感染症および寄生虫症/ インフルエンザ/ influenza	Yes	21JUL20[redacted](34)/ 25JUL20[redacted](38)	Grade 1 Mild/ Not Related/ Other: influenza	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	感染症および寄生虫症/ 肺炎/ pneumonia	Yes	21JUL20[redacted](34)/ 25JUL20[redacted](38)	Grade 1 Mild/ Not Related/ Other: pneumonia	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 3）

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
14-003-0[redacted]	肝胆道系障害/ 黄疸/ myeloma infiltration of liver and obstructive jaundice	Yes	23JUL20[redacted] (36)/ 26JUL20[redacted] (39)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ Dose interrupted	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	10AUG20[redacted] (54)/ 10AUG20[redacted] (54)	Grade 5 Fatal/ Not Related/ Underlying disease	Death/ None	Yes/ Results in death
14-005-0[redacted]	呼吸器、胸郭および縦隔障害/ 呼吸困難/ Dyspnea	Yes	21DEC20[redacted] (22)/ 22DEC20[redacted] (23)	Grade 3 Severe/ Not Related/ Concomitant drug	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 4）

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
14-005-0[redacted] (Cont'd.)	感染症および寄生虫症/ ＲＳウイルス感染/ Upper Respiratory Infection: Positive Respiratory Syncytial Virus	Yes	05FEB20[redacted]*(68)/ 13FEB20[redacted]*(76)	Grade 3 Severe/ Not Related/ Other: Patient had sick contact with grandaughter that also was positive for RSV infection.	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
14-005-0[redacted]	呼吸器、胸郭および縦隔障害/ 胸水/ Pleural effusion	Yes	24JAN20[redacted](49)/ 27JAN20[redacted](52)	Grade 3 Severe/ Related	Improved/ Discontinued permanently	Yes/ Inpatient hospitalization
14-005-0[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）/	Yes	13DEC20[redacted](6)/	Grade 5 Fatal/	Death/	Yes/
	多発性骨髄腫/ Multiple Myeloma Progression		13DEC20[redacted](6)	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 5）

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
14-005-0[redacted]	感染症および寄生虫症/ 敗血症性ショック/ Septic shock	Yes	04FEB20[redacted] (61)/ 09FEB20[redacted] (66)	Grade 4 Life threatening/ Not Related/ Intercurrent disease	Resolved/ Dose interrupted	Yes/ Life-threatening,Inpatient hospitalization
14-005-0[redacted]	精神障害/ 精神状態変化/ Altered mental status	Yes	07JAN20[redacted] (31)/ 18JAN20[redacted] (42)	Grade 3 Severe/ Not Related/ Other: Related to infection of unknown source	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	血液およびリンパ系障害/ 血小板減少症/ Thrombocytopenia	Yes	09JAN20[redacted] (33)/ 15JAN20[redacted] (39)	Grade 4 Life threatening/ Related	Resolved/ Dose interrupted	Yes/ Life-threatening
14-005-0[redacted]	精神障害/ 自殺念慮/ Psych Disorder-suicidal ideation with no specific plan or intent	Yes	07JUN20[redacted] (169)/ 21JUN20[redacted] (183)	Grade 2 Moderate/ Not Related/ Concomitant drug	Resolved/ Dose interrupted	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 6）

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
14-005-0[redacted] (Cont'd.)	心臓障害/ 左室機能不全/ Cardiac disorder: ventricular systolic dysfunction	Yes	05JUL20[redacted] (197)/ 11OCT20[redacted] (295)	Grade 3 Severe/ Related	Improved/ Discontinued permanently	Yes/ Important medical event
14-005-0[redacted]	一般・全身障害および投与部位の状態/ 疾患進行/ Progressive disease	Yes	20MAR20[redacted] (57)/ 23MAR20[redacted] (60)	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 Kidney Injury	Yes	20MAR20[redacted] (57)/ 23MAR20[redacted] (60)	Grade 3 Severe/ Not Related/ Underlying disease	Improved/ None	Yes/ Inpatient hospitalization
14-005-0[redacted]	感染症および寄生虫症/ 敗血症/ Sepsis	Yes	01MAR20[redacted] (30)/ 06MAR20[redacted] (35)	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 7）

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
14-005-0[redacted] (Cont'd.)	一般・全身障害および投与部位の状態/ 疾患進行/ Multiple Myeloma DiseaseProgression	Yes	24MAR20[redacted] (53)/ 24MAR20[redacted] (53)	Grade 5 Fatal/ Not Related/ Underlying disease	Death/ None	Yes/ Results in death
14-005-0[redacted]	感染症および寄生虫症/ 肺炎/ Pneumonia	Yes	16JUN20[redacted] (123)/ 25JUN20[redacted] (132)	Grade 3 Severe/ Related	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
14-006-0[redacted]	血管障害/ 深部静脈血栓症/ Deep Vein Thrombosis	Yes	10APR20[redacted] (210)/ 16APR20[redacted] (216)	Grade 2 Moderate/ Not Related/ Other: Recent Hip surgery	Resolved/ None	Yes/ Inpatient hospitalization
14-006-0[redacted]	一般・全身障害および投与部位の状態/ 発熱/ Fever	No	21SEP20[redacted] (-77)/ 21SEP20[redacted] (-77)	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.

表 2.7.4.7-44　重篤な有害事象の一覧表（2011-002）（続き 8）

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
14-006-0[redacted] (Cont'd.)	代謝および栄養障害/ 脱水/ Dehydration	No	21SEP20[redacted](-77)/ 21SEP20[redacted](-77)	Grade 1 Mild/ Not Related/ Concomitant disease	Resolved/ None	Yes/ Inpatient hospitalization
	心臓障害/ 心筋梗塞/ NSTEMI	No	27SEP20[redacted](-71)/ 28SEP20[redacted](-70)	Grade 3 Severe/ Not Related/ Concomitant disease	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	09DEC20[redacted](3)/ 12DEC20[redacted](6)	Grade 3 Severe/ Not Related/ Concomitant disease	Resolved/ None	Yes/ Inpatient hospitalization
	心臓障害/ うっ血性心不全/ DECOMPENSATED CHF	Yes	10DEC20[redacted](4)/ 20DEC20[redacted](14)	Grade 4 Life threatening/ Related	Improved/ None	Yes/ Life-threatening,Inpatient hospitalization
	心臓障害/ 心筋梗塞/ NSTEMI	Yes	10DEC20[redacted](4)/ 20DEC20[redacted](14)	Grade 4 Life threatening/ Related	Improved/ 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 9）

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
14-006-0[redacted] (Cont'd.)	呼吸器、胸郭および縦隔障害/ 肺水腫/ Pulmonary edema	Yes	10DEC20[redacted](4)/ 17DEC20[redacted](11)	Grade 4 Life threatening/ Not Related/ Related to study procedure	Resolved/ None	Yes/ Life-threatening,Inpatient hospitalization
	心臓障害/ 心房細動/ ATRIAL FIBRILLATION WITH RVR	Yes	12DEC20[redacted](6)/ 19DEC20[redacted](13)	Grade 3 Severe/ Not Related/ Intercurrent 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	28DEC20[redacted](22)/ 03JAN20[redacted](28) *	Grade 5 Fatal/ Not Related/ Underlying disease	Death/ None	Yes/ Results in death
14-006-0[redacted]	一般・全身障害および投与部位の状態/ 無力症/ Weakness	Yes	20OCT20[redacted](16)/ 22OCT20[redacted](18)	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 10）

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
14-006-0[redacted] (Cont'd.)	腎および尿路障害/ 急性腎不全/ ACUTE KIDNEY INJURY	Yes	20OCT20[redacted] (16)/ 23OCT20[redacted] (19)	Grade 3 Severe/ Not Related/ Underlying disease	Improved/ None	Yes/ Inpatient hospitalization
	心臓障害/ 心不全/ HEART FAILURE	Yes	24OCT20[redacted] (20)/ 20NOV20[redacted] (47)	Grade 4 Life threatening/ Not Related/ Concomitant disease	Improved/ Discontinued permanently	Yes/ Life-threatening
	心臓障害/ 心筋梗塞/ MYOCARDIAL INFARCTION	Yes	24OCT20[redacted] (20)/ 08NOV20[redacted] (35)	Grade 4 Life threatening/ Not Related/ Concomitant disease	Improved/ None	Yes/ Life-threatening
	呼吸器、胸郭および縦隔障害/ 呼吸困難/ DYSPNEA	Yes	24OCT20[redacted] (20)/ 28OCT20[redacted] (24)	Grade 4 Life threatening/ Not Related/ Concomitant disease	Resolved/ None	Yes/ Life-threatening
14-006-0[redacted]	腎および尿路障害/ 急性腎不全/ ACUTE KIDNEY INJURY	No	25SEP20[redacted] (-3)/ 04OCT20[redacted] (7)	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 11）

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
14-006-0[redacted]	血液およびリンパ系障害/ 発熱性好中球減少症/ NEUTROPENIC FEVER	Yes	30SEP20[redacted](3)/ 02OCT20[redacted](5)	Grade 3 Severe/ Not Related/ Intercurrent disease	Resolved/ None	Yes/ Inpatient hospitalization
	感染症および寄生虫症/ 肺炎/ PNEUMONIA	Yes	30SEP20[redacted](3)/ 02OCT20[redacted](5)	Grade 2 Moderate/ Not Related/ Concomitant disease	Resolved/ None	Yes/ Inpatient hospitalization
	精神障害/ 精神状態変化/ decline in mental status	Yes	03DEC20[redacted](67)/ 12DEC20[redacted](76)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ Discontinued permanently	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	12DEC20[redacted](76)/ 12DEC20[redacted](76)	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 12）

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
14-006-0[redacted]	感染症および寄生虫症/ 敗血症/ SEPSIS	Yes	17NOV20[redacted](18)/ 28NOV20[redacted](29)	Grade 3 Severe/ Not Related/ Concomitant disease	Resolved/ None	Yes/ Inpatient hospitalization
	臨床検査/ 血小板数減少/ PLATELET COUNT DECREASED	Yes	18NOV20[redacted](19)/ 22NOV20[redacted](23)	Grade 3 Severe/ Not Related/ Concomitant 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	17JAN20[redacted](79)/ *	Grade 3 Severe/ Not Related/ Underlying disease	Unchanged/ 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	22JAN20[redacted](84)/ *	Grade 3 Severe/	Resolved/	Yes/
	形質細胞腫/ NEW PLASMACYTOMA		27JAN20[redacted](89) *	Not Related/ Underlying disease	None	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 13）

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
14-006-0[redacted]	呼吸器、胸郭および縦隔障害/ 肺水腫/ IATROGENIC PULMONARY EDEMA	Yes	05NOV20[redacted] (3)/ 07NOV20[redacted] (5)	Grade 3 Severe/ Not Related/ Intercurrent disease	Resolved/ None	Yes/ Inpatient hospitalization
14-006-0[redacted]	血液およびリンパ系障害/ 血小板減少症/ Thrombocytopenia	Yes	01DEC20[redacted] (15)/ 14DEC20[redacted] (28)	Grade 4 Life threatening/ Not Related/ Underlying disease	Improved/ None	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	16DEC20[redacted] (30)/ 24DEC20[redacted] (38)	Grade 5 Fatal/ Not Related/ Underlying disease	Death/ None	Yes/ Results in death
14-006-0[redacted]	一般・全身障害および投与部位の状態/ 疾患進行/ Progressive disease.	Yes	21NOV20[redacted] (6)/ 29NOV20[redacted] (14)	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 14）

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
14-006-0[redacted]	呼吸器、胸郭および縦隔障害/ 呼吸困難/ Shortness of breath	Yes	28NOV20[redacted] (1)/ 15DEC20[redacted] (18)	Grade 2 Moderate/ Not Related/ Other: related to study procedure, underlying disease, and concomitant disease	Improved/ Dose interrupted	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	19DEC20[redacted] (22)/ 19DEC20[redacted] (22)	Grade 5 Fatal/ Not Related/ Underlying disease	Death/ None	Yes/ Results in death
14-006-0[redacted]	感染症および寄生虫症/ 敗血症/ SEPSIS	Yes	24JUL20[redacted] (19)/ 26JUL20[redacted] (21)	Grade 3 Severe/ Not Related/ Intercurrent disease	Resolved/ None	Yes/ Inpatient hospitalization
14-007-0[redacted]	代謝および栄養障害/ 高カルシウム血症/ worsening hypercalcemia	Yes	28MAR20[redacted] (37)/ 29MAR20[redacted] (38)	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 15）

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
14-007-0[redacted] (Cont'd.)	筋骨格系および結合組織障害/ 顎痛/ worsening right mandibular pain	Yes	17APR20[redacted] (57)/ 20APR20[redacted] (60)	Grade 3 Severe/ Not Related/ Concomitant disease	Improved/ None	Yes/ Inpatient hospitalization
14-007-0[redacted]	心臓障害/ うっ血性心不全/ Congestive heart failure exacerbation	Yes	04APR20[redacted] (45)/ 06APR20[redacted] (47)	Grade 2 Moderate/ Related	Resolved/ Dose reduced	Yes/ Inpatient hospitalization,Important medical event
	心臓障害/ うっ血性心不全/ congestive heart failure exacerbation	Yes	13JUN20[redacted] (115)/ 17JUN20[redacted] (119)	Grade 3 Severe/ Related	Resolved/ Discontinued permanently	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 16）

Patient ID	MedDRA SOC / MedDRA PT / Verbatim Term	Treatmen 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
14-007-0[redacted]	呼吸器、胸郭および縦隔障害/ 急性呼吸不全/ Acute respiratory decompensation	Yes	21FEB20[redacted](2)/ 25FEB20[redacted](6)	Grade 4 Life threatening/ Related	Resolved/ Dose interrupted	Yes/ Life-threatening,Inpatient hospitalization
14-007-0[redacted]	感染症および寄生虫症/ 上気道感染/ upper respiratory infection	Yes	03JUL20[redacted](21)/ 05JUL20[redacted](23)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization
14-007-0[redacted]	一般・全身障害および投与部位の状態/ 発熱/ fever	Yes	25JUN20[redacted](8)/ 28JUN20[redacted](11)	Grade 1 Mild/ Not Related/ Underlying disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	精神障害/ 精神状態変化/ altered mental status	Yes	25JUN20[redacted](8)/ 28JUN20[redacted](11)	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 17）

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
14-007-0[redacted] (Cont'd.)	一般・全身障害および投与部位の状態/ 発熱/ fever	Yes	08JUL20[redacted] (21)/ 08JUL20[redacted] (21)	Grade 1 Mild/ Not Related/ Concomitant disease	Resolved/ None	Yes/ Inpatient hospitalization
	精神障害/ 精神状態変化/ altered mental status	Yes	08JUL20[redacted] (21)/	Grade 2 Moderate/ Not Related/ Concomitant disease	Unchanged/ 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	Yes	12JUL20[redacted] (25)/ 12JUL20[redacted] (25)	Grade 5 Fatal/ Not Related/ Underlying disease	Death/ None	Yes/ Results in death
14-011-0[redacted]	筋骨格系および結合組織障害/ 背部痛/ back pain	Yes	08DEC20[redacted] (23)/ 30DEC20[redacted] (45)	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 18）

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
14-011-0[redacted] (Cont'd.)	腎および尿路障害/ 尿閉/ urinary retention	Yes	08DEC20[redacted] (23)/ 15DEC20[redacted] (30)	Grade 2 Moderate/ Not Related/ Intercurrent disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	感染症および寄生虫症/ 尿路感染/ urinary tract infection	Yes	13DEC20[redacted] (28)/ 20DEC20[redacted] (35)	Grade 4 Life threatening/ Not Related/ Intercurrent disease	Resolved/ Dose interrupted	Yes/ Life-threatening,Inpatient hospitalization
	血管障害/ 血腫/ hematoma	Yes	16DEC20[redacted] (31)/ 23DEC20[redacted] (38)	Grade 4 Life threatening/ Not Related/ Other: d/c of R axillary A line	Resolved/ Dose interrupted	Yes/ Life-threatening,Inpatient hospitalization
	血管障害/ 高血圧/ hypertension	Yes	21DEC20[redacted] (36)/ 22DEC20[redacted] (37)	Grade 4 Life threatening/ Related	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 19）

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
14-011-0[redacted] (Cont'd.)	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.Diff	Yes	04FEB20[redacted]*(81)/ 07FEB20[redacted]*(84)	Grade 3 Severe/ Not Related/ Intercurrent disease	Resolved/ None	Yes/ Inpatient hospitalization
	呼吸器、胸郭および縦隔障害/ 慢性呼吸不全/ chronic respiratory failure	Yes	16FEB20[redacted]*(93)/ 19MAR20[redacted]*(125)	Grade 3 Severe/ Not Related/ Concomitant disease	Resolved/ None	Yes/ Inpatient hospitalization
14-011-0[redacted]	代謝および栄養障害/ 高カルシウム血症/ hypercalcemia	Yes	06JAN20[redacted](30)/ 07JAN20[redacted](31)	Grade 2 Moderate/ 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	02FEB20[redacted](57)/ 08FEB20[redacted](63)	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 20）

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
14-011-0[redacted]	腎および尿路障害/ 急性腎不全/ acute renal failure	Yes	13DEC20[redacted](14)/ 20DEC20[redacted](21)	Grade 3 Severe/ Related	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization,Important medical event
14-011-0[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）/	Yes	29FEB20[redacted](93)/	Grade 5 Fatal/	Death/	Yes/
	急性骨髄性白血病/ Acute myeloid leukemia		25MAR20[redacted](118)	Not Related/ Intercurrent disease	Discontinued permanently	Results in death,Inpatient hospitalization,Important medical event
14-011-0[redacted]	感染症および寄生虫症/ 肺炎/ pneumonia	Yes	02JUL20[redacted](209)/ 10JUL20[redacted](217)	Grade 2 Moderate/ Not Related/ Concomitant disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	感染症および寄生虫症/ 蜂巣炎/ right index finger cellulitis	Yes	22AUG20[redacted](260)/ 26AUG20[redacted](264)	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 21）

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
14-011-0[redacted]	感染症および寄生虫症/ 肺炎/ Pneumonia	Yes	21DEC20[redacted](9)/ 10JAN20[redacted](29) *	Grade 3 Severe/ Not Related/ Intercurrent disease	Resolved/ None	Yes/ Inpatient hospitalization
14-011-0[redacted]	心臓障害/ うっ血性心不全/ Congestive Heart Failure	Yes	29DEC20[redacted](17)/ 02JAN20[redacted](21) *	Grade 3 Severe/ Related	Resolved/ Dose reduced	Yes/ Inpatient hospitalization
	感染症および寄生虫症/ 肺炎/ pneumonia	Yes	29DEC20[redacted](17)/ 02JAN20[redacted](21) *	Grade 3 Severe/ Related	Resolved/ None	Yes/ Inpatient hospitalization
	腎および尿路障害/ 急性腎不全/ acute kidney injury	Yes	29DEC20[redacted](17)/ 02JAN20[redacted](21) *	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.

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 22）

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
14-011-0[redacted] (Cont'd.)	呼吸器、胸郭および縦隔障害/ 呼吸困難/ Shortness of breath	Yes	29JAN20[redacted]*(48)/ 03FEB20[redacted]*(53)	Grade 3 Severe/ Related	Resolved/ Discontinued permanently	Yes/ Inpatient hospitalization
	血管障害/ 高血圧/ Hypertension	Yes	29JAN20[redacted]*(48)/ 03FEB20[redacted]*(53)	Grade 3 Severe/ Related	Resolved/ None	Yes/ Inpatient hospitalization
14-011-0[redacted]	筋骨格系および結合組織障害/ 背部痛/ Back Pain	Yes	07APR20[redacted](111)/ 10APR20[redacted](114)	Grade 3 Severe/ Not Related/ Concomitant disease	Resolved/ None	Yes/ Inpatient hospitalization
14-011-0[redacted]	呼吸器、胸郭および縦隔障害/ 呼吸困難/ Shortness of breath	Yes	24MAR20[redacted](38)/ 25MAR20[redacted](39)	Grade 3 Severe/ Not Related/ Concomitant disease	Resolved/ None	Yes/ Inpatient hospitalization
	心臓障害/ うっ血性心不全/ Congestive Heart Failure	Yes	28MAR20[redacted](42)/ 02APR20[redacted](47)	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.

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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 23）

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
14-011-0[redacted]	筋骨格系および結合組織障害/ 筋力低下/ leg weakness	Yes	10MAR20[redacted] (25)/	Grade 3 Severe/ Not Related/ Underlying disease	Unchanged/ 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	30MAR20[redacted] (45)/	Grade 5 Fatal/	Death/	Yes/
	多発性骨髄腫/ Multiple Myeloma progression		30MAR20[redacted] (45)	Not Related/ Underlying disease	None	Results in death
14-012-0[redacted]	感染症および寄生虫症/ 肺炎/ Pneumonia	Yes	11MAY20[redacted] (99)/ 15MAY20[redacted] (103)	Grade 3 Severe/ Related	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
14-012-0[redacted]	感染症および寄生虫症/ 処置後敗血症/ Sepsis d/t Gallbladder	Yes	13MAR20[redacted] (40)/ 23MAR20[redacted] (50)	Grade 4 Life threatening/ Related	Resolved/ Discontinued permanently	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 24）

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
14-012-0[redacted] (Cont'd.)	感染症および寄生虫症/ 腹部感染/ Intra-abdominal infection	Yes	26MAR20[redacted] (53)/ 03APR20[redacted] (61)	Grade 3 Severe/ Not Related/ Other: Postoperative abscess per scan findings	Resolved/ None	Yes/ Inpatient hospitalization
14-012-0[redacted]	呼吸器、胸郭および縦隔障害/ 非心原性肺水腫/ non-cardiogenic pulmonary edema	Yes	19FEB20[redacted] (3)/ 23FEB20[redacted] (7)	Grade 3 Severe/ Related	Improved/ Dose interrupted	Yes/ Inpatient hospitalization
14-012-0[redacted]	血液およびリンパ系障害/ 血小板減少症/ Thrombocytopenia	No	17FEB20[redacted] (-7)/ 17FEB20[redacted] (-7)	Grade 4 Life threatening/ Not Related/ Intercurrent disease	Improved/ None	Yes/ Life-threatening
	血液およびリンパ系障害/ 血小板減少症/ Thrombocytopenia	Yes	24FEB20[redacted] (1)/ 24FEB20[redacted] (1)	Grade 4 Life threatening/ Not Related/ Intercurrent disease	Improved/ None	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 25）

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
14-012-0[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 progression	Yes	25FEB20[redacted] (2)/ 25FEB20[redacted] (2)	Grade 5 Fatal/ Not Related/ Underlying disease	Death/ None	Yes/ Results in death
14-015-0[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	05DEC20[redacted] (47)/ 05DEC20[redacted] (47)	Grade 5 Fatal/ Not Related/ Underlying disease	Death/ None	Yes/ Results in death
14-015-0[redacted]	感染症および寄生虫症/ 肺炎/ pneumonia	Yes	19DEC20[redacted] (56)/ 22DEC20[redacted] (59)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization
	感染症および寄生虫症/ 肺炎/ pneumonia	Yes	26DEC20[redacted] (63)/ 30DEC20[redacted] (67)	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 26）

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
14-015-0[redacted]	呼吸器、胸郭および縦隔障害/ 気管支拡張症/ bronchiectasis	Yes	05FEB20[redacted] (90)/ 10FEB20[redacted] (95)	Grade 2 Moderate/ Not Related/ Concomitant disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
14-015-0[redacted]	血液およびリンパ系障害/ 発熱性好中球減少症/ Febrile neutropenia	Yes	02FEB20[redacted] (36)/ 06FEB20[redacted] (40)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	胃腸障害/ 胃腸出血/ GI bleed	Yes	14FEB20[redacted] (48)/ 22FEB20[redacted] (56)	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	04MAR20[redacted] (67)/ 04MAR20[redacted] (67)	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 27）

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
14-015-0[redacted]	一般・全身障害および投与部位の状態/ 胸痛/ chest pain	Yes	06JUL20[redacted](101)/ 09JUL20[redacted](104)	Grade 2 Moderate/ Not Related/ Concomitant disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
14-015-0[redacted]	感染症および寄生虫症/ 肺炎/ pneumonia	Yes	24JUN20[redacted](4)/ 30JUN20[redacted](10)	Grade 3 Severe/ Not Related/ Intercurrent disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	呼吸器、胸郭および縦隔障害/ 肺浸潤/ pulmonary infiltrates	Yes	04JUL20[redacted](14)/ 16JUL20[redacted](26)	Grade 3 Severe/ Related	Improved/ Discontinued permanently	Yes/ Inpatient hospitalization
14-016-0[redacted]	一般・全身障害および投与部位の状態/ 無力症/ Weakness	Yes	19DEC20[redacted](7)/ 21DEC20[redacted](9)	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 28）

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
14-016-0[redacted] (Cont'd.)	神経系障害/ 頭蓋内出血/ Intracranial Hemorrhage	Yes	24DEC20[redacted] (12)/ 25DEC20[redacted] (13)	Grade 5 Fatal/ Not Related/ Other: Accidental fall	Death/ Discontinued permanently	Yes/ Results in death,Inpatient hospitalization
14-016-0[redacted]	一般・全身障害および投与部位の状態/ 非心臓性胸痛/ Non-cardiac Chest Pain	Yes	05JAN20[redacted] (16)/ 06JAN20[redacted] (17)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
	筋骨格系および結合組織障害/ 関節痛/ Increasing right hip pain	Yes	22FEB20[redacted] (64)/ 24FEB20[redacted] (66)	Grade 2 Moderate/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization
	呼吸器、胸郭および縦隔障害/ 喘息/ Asthma Exacerbation	Yes	12MAR20[redacted] (83)/ 22MAR20[redacted] (93)	Grade 3 Severe/ Not Related/ Other: unknown	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 29）

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
14-016-0[redacted]	一般・全身障害および投与部位の状態/ 発熱/ Fever	Yes	06JAN20[redacted](17)/ 08JAN20[redacted](19)	Grade 2 Moderate/ Related	Resolved/ Dose interrupted	Yes/ Inpatient hospitalization
14-016-0[redacted]	筋骨格系および結合組織障害/ 筋力低下/ Upper Extremity Weakness	Yes	02FEB20[redacted](8)/ 10FEB20[redacted](16)	Grade 2 Moderate/ Not Related/ Underlying disease	Improved/ Dose interrupted	Yes/ Inpatient hospitalization
	代謝および栄養障害/ 高カルシウム血症/ Hypercalcemia	Yes	21MAR20[redacted](56)/ 27MAR20[redacted](62)	Grade 3 Severe/ Not Related/ Underlying disease	Resolved/ None	Yes/ Inpatient hospitalization
14-017-0[redacted]	精神障害/ 錯乱状態/ Confusion	Yes	22FEB20[redacted](107)/ 28FEB20[redacted](113)	Grade 3 Severe/ Not Related/ Intercurrent disease	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 30）

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]	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, non-pulmonary)	Yes	23FEB20[redacted] (85)/ 24FEB20[redacted] (86)	Grade 2 Moderate/ Not Related/ Other: unknown etiology	Improved/ Dose interrupted	Yes/ Inpatient hospitalization
	血管障害/ 高血圧/ Hypertension	Yes	23FEB20[redacted] (85)/ 23FEB20[redacted] (85)	Grade 3 Severe/ Not Related/ Intercurrent disease	Improved/ Dose interrupted	Yes/ Inpatient hospitalization
14-017-0[redacted]	代謝および栄養障害/ 脱水/ Dehydration	Yes	19DEC20[redacted] (19)/ 21DEC20[redacted] (21)	Grade 3 Severe/ Not Related/ Other: secondary to poor oral intake	Resolved/ None	Yes/ Inpatient hospitalization
	代謝および栄養障害/ 高カリウム血症/ Hyperkalemia	Yes	19DEC20[redacted] (19)/ 21DEC20[redacted] (21)	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 31）

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.)	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	26JAN20[redacted] (57)/ * 31JAN20[redacted] (62) *	Grade 4 Life threatening/ Not Related/ Underlying disease	Improved/ None	Yes/ Life-threatening,Inpatient hospitalization
14-017-0[redacted]	代謝および栄養障害/ 低ナトリウム血症/ Hyponatremia	No	15DEC20[redacted] (-5)/ 18DEC20[redacted] (-2)	Grade 3 Severe/ Not Related/ Other: possible due to renal failure or excessive hydration	Resolved/ None	Yes/ Inpatient hospitalization
	腎および尿路障害/ 急性腎不全/ acute renal failure	No	15DEC20[redacted] (-5)/ 21DEC20[redacted] (2)	Grade 3 Severe/ Not Related/ Intercurrent disease	Improved/ None	Yes/ Inpatient hospitalization
	神経系障害/ 代謝性脳症/ Metabolic encephalopathy	Yes	03JAN20[redacted] (15)/ * 09JAN20[redacted] (21) *	Grade 1 Mild/ 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.

被験者識別コード，年齢以外のマスキングにおいて，
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＊　：「翌年」を意味する