表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
Treatment Randmizen: CRd ; Subject ID: 103809[redacted] ; Randomized Date: 11JUL20[redacted]; First Dose Date: 13JUL20[redacted]; Last Dose Date: 07MAY20[redacted]**								
一般・全身障害および投与部位の状態 発熱 Fever of unknown origin(30)	25MAY20[redacted] (320) *	28MAY20[redacted] (323) *	4	2	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 103809[redacted] ; Randomized Date: 28SEP20[redacted]; First Dose Date: 29SEP20[redacted]; Last Dose Date: 16JUN20[redacted]#								
臨床検査 アラニンアミノトランスフェラーゼ増加 Sgpt increase grade iii(1)	12OCT20[redacted] (15)	25OCT20[redacted] (28)	14	3	Yes/ Yes/ Yes	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	None	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 103809[redacted] ; Randomized Date: 12DEC20[redacted]; First Dose Date: 13DEC20[redacted]; Last Dose Date: 16JUN20[redacted]#								
心臓障害 心房頻脈 Atrial tachycardia(58)	29JAN20[redacted] (780) #	30JAN20[redacted] (781) #	2	2	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required	Not Recovered/ Not Resolved
Treatment Randmizen: CRd ; Subject ID: 103809[redacted] ; Randomized Date: 13DEC20[redacted]; First Dose Date: 15DEC20[redacted]; Last Dose Date: 24APR20[redacted]**								
腎および尿路障害 急性腎不全 Acute renal failure(3)	26JAN20[redacted] (45) *	31JAN20[redacted] (50) *	6	3	Yes/ No/ No	Drug Interrupted/ Dose Reduced/ Drug Interrupted	None	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 103809[redacted] ; Randomized Date: 03JAN20[redacted]; First Dose Date: 04JAN20[redacted]; Last Dose Date: 27MAR20[redacted]*								
感染症および寄生虫症 肺炎 Pneumonia(11)	01APR20[redacted] (90)	09APR20[redacted] (98)	9	3	Yes/ Yes/ Yes	Drug Interrupted/ Dose Reduced/Drug Interrupted/ Dose Reduced/Drug Interrupted	Conmeds/ 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） 結腸癌 Adeno-carcinoma in colon(23)	28MAR20[redacted] (451) *	03APR20[redacted] (457) *	7	2	No/ Yes/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Procedure Required	Recovered/ Resolved
臨床検査 ヘモグロビン減少 Decrease of hemoglobin(24)	28MAR20[redacted] (451) *	03APR20[redacted] (457) *	7	2	No/ Yes/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 103849[redacted] ; Randomized Date: 01AUG20[redacted]; First Dose Date: 02AUG20[redacted]; Last Dose Date: 01MAY20[redacted]*								
心臓障害 心室性頻脈 Idiopathic right ventricular outflow tract tachycardia(20)	16APR20[redacted] (260) *	18APR20[redacted] (262) *	3	2	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 103869[redacted] ; Randomized Date: 26SEP20[redacted]; First Dose Date: 04OCT20[redacted]; Last Dose Date: 14MAR20[redacted]*								

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
#　：「3年後」を意味する

表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 1）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
免疫系障害 薬物過敏症 Allergic reaction against carfizomib(1)	06OCT20[redacted] (11)	18OCT20[redacted] (23)	13	3	Yes/ No/ No	Drug Interrupted/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
神経系障害 失神 Syncope(4)	03FEB20[redacted] (131) *	03FEB20[redacted] (131) *	1	1	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
感染症および寄生虫症 感染 Infection with unknown focus(5)	03APR20[redacted] (191) *	11APR20[redacted] (199) *	9	4	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 103879[redacted] ; Randomized Date: 14MAR20[redacted] ; First Dose Date: 16MAR20[redacted] ; Last Dose Date: 22SEP20[redacted]								
一般・全身障害および投与部位の状態 インフルエンザ様疾患 Flue-like symptoms(1)	17MAR20[redacted] (4)	18MAR20[redacted] (5)	2	2	Yes/ Yes/ Yes	Dose Not Changed/ Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 細菌感染 Bacterial infection(2)	23APR20[redacted] (41)	26APR20[redacted] (44)	4	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Not Recovered/ Not Resolved
Treatment Randmizen: CRd ; Subject ID: 103889[redacted] ; Randomized Date: 08APR20[redacted] ; First Dose Date: 12APR20[redacted] ; Last Dose Date: 31MAY20[redacted]								
胃腸障害 後腹膜血腫 Haematoma retroperitoneal iliac crest(1)	30MAR20[redacted] (-9)	07APR20[redacted] (-1)	9	3	NA/ NA/ NA	NA/ NA/ NA	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 気管支炎 Bronchitis(6)	01JUN20[redacted] (55)	06JUN20[redacted] (60)	6	2	Yes/ Yes/ Yes	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 103889[redacted] ; Randomized Date: 03JUN20[redacted] ; First Dose Date: 06JUN20[redacted] ; Last Dose Date: 23JUL20[redacted]								
感染症および寄生虫症 尿路性敗血症 Urosepsis(2)	23JUN20[redacted] (21)	19JUL20[redacted] (47)	27	3	No/ Yes/ NA	Dose Delayed/Drug Interrupted/ Dose Delayed/Drug Interrupted/ Dose Delayed/Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
心臓障害 心筋梗塞 Myocardial infarction(3)	24JUN20[redacted] (22)	25JUN20[redacted] (23)	2	2	No/ No/ NA	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved With Sequelae
心臓障害 心筋梗塞 Myocaridal infarction(4)	24JUL20[redacted] (52)	24JUL20[redacted] (52)	1	5	No/ No/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	None	Fatal

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 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 2）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
Treatment Randmizen: CRd ; Subject ID: 103889[redacted] ; Randomized Date: 21JUL20[redacted]; First Dose Date: 25JUL20[redacted]; Last Dose Date: 14MAY20[redacted]#								
感染症および寄生虫症 副鼻腔炎 Chronic rhinosinusitis(26)	17SEP20[redacted] (790) **	21SEP20[redacted] (794) **	5	3	NA/ Yes/ No	NA/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
神経系障害 失神 Syncope(32)	07MAY20[redacted] (1022) #	07MAY20[redacted] (1022) #	1	3	No/ Yes/ Yes	NA/ Dose Not Changed/ Dose Not Changed	None	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 103889[redacted] ; Randomized Date: 03FEB20[redacted]; First Dose Date: 06FEB20[redacted]; Last Dose Date: 19AUG20[redacted]*								
呼吸器、胸郭および縦隔障害 肺塞栓症 Bipulmonal pulmonary embolism(34)	30OCT20[redacted] (636) *	[ONGOING] (-)		3	Yes/ Yes/ Yes	Dose Not Changed/ Drug Withdrawn/ Drug Withdrawn	Hospitalization	Not Recovered/ Not Resolved
感染症および寄生虫症 肺炎 Consecutive bipulmonal pneumonia(35)	30OCT20[redacted] (636) *	[ONGOING] (-)		3	Yes/ Yes/ Yes	Dose Not Changed/ Drug Withdrawn/ Drug Withdrawn	Hospitalization	Not Recovered/ Not Resolved
Treatment Randmizen: CRd ; Subject ID: 128539[redacted] ; Randomized Date: 14OCT20[redacted]; First Dose Date: 17OCT20[redacted]; Last Dose Date: 01DEC20[redacted]								
血液およびリンパ系障害 発熱性好中球減少症 Febrile neutropenia(2)	28OCT20[redacted] (15)	05NOV20[redacted] (23)	9	4	Yes/ Yes/ NA	Drug Interrupted/ Drug Interrupted/ NA	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 発熱性好中球減少症 Neutropenia fever(3)	07NOV20[redacted] (25)	10NOV20[redacted] (28)	4	3	Yes/ Yes/ NA	Dose Delayed/ Drug Interrupted/ NA	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 128569[redacted] ; Randomized Date: 15FEB20[redacted]; First Dose Date: 16FEB20[redacted]; Last Dose Date: 13APR20[redacted]								
一般・全身障害および投与部位の状態 疲労 Fatigue(1)	29MAR20[redacted] (44)	05APR20[redacted] (51)	8	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Hospitalization	Recovered/ Resolved
臨床検査 モノクローナル免疫グロブリン陽性 High paraprotein(2)	13APR20[redacted] (59)	22MAY20[redacted] (98)	40	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 128579[redacted] ; Randomized Date: 03OCT20[redacted]; First Dose Date: 04OCT20[redacted]; Last Dose Date: 29JAN20[redacted]**								
筋骨格系および結合組織障害 関節炎 Deteriorative inflammatory arthritis(63)	26JUL20[redacted] (298) *	26JUL20[redacted] (298) *	1	3	No/ No/ No	Dose Delayed/ Dose Delayed/ Dose Delayed	Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 128589[redacted] ; Randomized Date: 20DEC20[redacted]; First Dose Date: 22DEC20[redacted]; Last Dose Date: 22DEC20[redacted]*								

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
#　：「3年後」を意味する

表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 3）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
感染症および寄生虫症 下気道感染 Chest infection(1)	24JAN20[redacted] (36) *	25JAN20[redacted] (37) *	2	2	Yes/ Yes/ Yes	Drug Interrupted/ Dose Not Changed/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 下気道感染 Lower respiratory infection(2)	26JAN20[redacted] (38) *	08FEB20[redacted] (51) *	14	3	Yes/ Yes/ Yes	Drug Interrupted/ Dose Reduced/ Dose Reduced	Conmeds/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 好中球減少症 Neutropenia(20)	08MAR20[redacted] (80) *	15MAR20[redacted] (87) *	8	4	Yes/ Yes/ Yes	Dose Reduced/Dose Delayed/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
感染症および寄生虫症 好中球減少性敗血症 Neutropenic sepsis(32)	23DEC20[redacted] (370) *	23DEC20[redacted] (370) *	1	4	Yes/ Yes/ Yes	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Hospitalization	Recovered/ Resolved
腎および尿路障害 急性腎不全 Acute renal failure(34)	27DEC20[redacted] (374) *	31DEC20[redacted] (378) *	5	3	No/ No/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Hospitalization	Not Recovered/ Not Resolved
心臓障害 心筋梗塞 Myocardial infarction(33)	28DEC20[redacted] (375) *	31DEC20[redacted] (378) *	4	5	No/ No/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Hospitalization	Fatal
Treatment Randmizen: CRd ; Subject ID: 140059[redacted] ; Randomized Date: 12AUG20[redacted]; First Dose Date: 15AUG20[redacted]; Last Dose Date: 30JUL20[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） 扁平上皮癌 Squamous cell carcinoma(18)	08AUG20[redacted] (-4)	16SEP20[redacted] (36)	40	2	NA/ NA/ NA	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required	Recovered/ Resolved
心臓障害 心停止 Cardiac arrest(15)	31JUL20[redacted] (355) *	31JUL20[redacted] (355) *	1	5	Yes/ Yes/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	None	Fatal
Treatment Randmizen: CRd ; Subject ID: 140109[redacted] ; Randomized Date: 08NOV20[redacted]; First Dose Date: 09NOV20[redacted]; Last Dose Date: 03SEP20[redacted]#								
心臓障害 心筋梗塞 Heart attack(67)	25MAY20[redacted] (565) **	30MAY20[redacted] (570) **	6	4	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
臨床検査 心臓負荷試験異常 Cardiac abnormality- abnormal stress test(68)	10JUL20[redacted] (611) **	12JUL20[redacted] (613) **	3	3	Yes/ Yes/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 140109[redacted] ; Randomized Date: 07FEB20[redacted]; First Dose Date: 08FEB20[redacted]; Last Dose Date: 21NOV20[redacted]								

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
#　：「3年後」を意味する

表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 4）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
感染症および寄生虫症 医療機器関連感染 Polymicrobial bacteremia port infection(1)	06APR20[redacted] (59)	13APR20[redacted] (66)	8	3	No/ No/ No	Dose Delayed/ Dose Delayed/ Dose Delayed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 カテーテル留置部位蜂巣炎 Cellulitis at port site(30)	12MAY20[redacted] (95)	17MAY20[redacted] (100)	6	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 菌血症 Gram-negative bacteremia(31)	18MAY20[redacted] (101)	19MAY20[redacted] (102)	2	3	No/ No/ No	Dose Delayed/ Dose Delayed/ Dose Delayed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 菌血症 Gram negative bacteremia(32)	20MAY20[redacted] (103)	23MAY20[redacted] (106)	4	3	No/ No/ No	Dose Delayed/ Dose Delayed/ Dose Delayed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 140109[redacted] ; Randomized Date: 03AUG20[redacted] ; First Dose Date: 03AUG20[redacted] ; Last Dose Date: 21AUG20[redacted] *								
心臓障害 左脚ブロック Left bundle branch block(1)	20JUL20[redacted] (-14)	23JUL20[redacted] (-11)	4	2	NA/ NA/ NA	NA/ NA/ NA	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
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(35)	24NOV20[redacted] (114)	24NOV20[redacted] (114)	1	3	No/ No/ No	Dose Delayed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 上気道感染 Upper respiratory infection(41)	20FEB20[redacted] (202) *	26FEB20[redacted] (208) *	7	3	Yes/ Yes/ Yes	Drug Interrupted/ Dose Reduced/Drug Interrupted/ Dose Reduced/Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 140109[redacted] ; Randomized Date: 19AUG20[redacted] ; First Dose Date: 23AUG20[redacted] ; Last Dose Date: 06NOV20[redacted] *								
一般・全身障害および投与部位の状態 疾患進行 Progressive disease(29)	15NOV20[redacted] (455) *	22NOV20[redacted] (462) *	8	4	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Not Recovered/ Not Resolved
Treatment Randmizen: CRd ; Subject ID: 140109[redacted] ; Randomized Date: 07OCT20[redacted] ; First Dose Date: 11OCT20[redacted] ; Last Dose Date: 07DEC20[redacted]								
呼吸器、胸郭および縦隔障害 肺塞栓症 Acute pulmonary embolism(1)	08NOV20[redacted] (33)	09NOV20[redacted] (34)	2	4	No/ Yes/ Yes	Drug Interrupted/ Dose Reduced/ Dose Reduced/Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved With Sequelae
血液およびリンパ系障害 発熱性好中球減少症 Neutropenic fever(4)	07DEC20[redacted] (62)	09DEC20[redacted] (64)	3	3	Yes/ Yes/ No	Drug Interrupted/ Drug Interrupted/ Dose Not Changed	Conmeds/ 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 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 5）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
Treatment Randmizen: CRd ; Subject ID: 140159[redacted] ; Randomized Date: 06JAN20[redacted]; First Dose Date: 10JAN20[redacted]; Last Dose Date: 06FEB20[redacted] *								
血管障害 深部静脈血栓症 Recurrent left leg deep vein thrombosis(47)	25FEB20[redacted] (416) *	27FEB20[redacted] (418) *	3	3	No/ Yes/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 140159[redacted] ; Randomized Date: 28APR20[redacted]; First Dose Date: 02MAY20[redacted]; Last Dose Date: 30APR20[redacted] **								
一般・全身障害および投与部位の状態 発熱 Fever(28)	26FEB20[redacted] (305) *	28FEB20[redacted] (307) *	3	2	No/ No/ No	Dose Delayed/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺炎 Pneumonia(49)	30JUL20[redacted] (460) *	06AUG20[redacted] (467) *	8	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved With Sequelae
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） 膵腺癌 Adenocarcinoma of the pancreas(53)	08MAY20[redacted] (742) **	[ONGOING] (-)		3	No/ No/ No	Dose Not Changed/ Drug Withdrawn/Drug Interrupted/ Drug Withdrawn/Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Not Recovered/ Not Resolved
Treatment Randmizen: CRd ; Subject ID: 140159[redacted] ; Randomized Date: 28APR20[redacted]; First Dose Date: 02MAY20[redacted]; Last Dose Date: 30NOV20[redacted] *								
胃腸障害 憩室穿孔 Perforated diverticulitis(31)	28NOV20[redacted] (215)	05DEC20[redacted] (222)	8	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 腹部膿瘍 Intra abdominal abscess(39)	28NOV20[redacted] (215)	05DEC20[redacted] (222)	8	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
神経系障害 水頭症 Hydrocephalus(53)	08SEP20[redacted] (500) *	11SEP20[redacted] (503) *	4	3	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
神経系障害 脳嚢胞 Recurent cerebral posterior fossa cyst(55)	17SEP20[redacted] (509) *	29SEP20[redacted] (521) *	13	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 140159[redacted] ; Randomized Date: 07NOV20[redacted]; First Dose Date: 07NOV20[redacted]; Last Dose Date: 02JUL20[redacted] **								
血管障害 血腫 Hematoma of the thigh(1)	29SEP20[redacted] (-39)	04OCT20[redacted] (-34)	6	3	NA/ NA/ NA	NA/ NA/ NA	Conmeds/ Procedure Required	Recovered/ Resolved
感染症および寄生虫症 肺炎 Pneumonia(20)	10JAN20[redacted] (431) **	14JAN20[redacted] (435) **	5	3	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Conmeds/ 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 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 6）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
臨床検査 ＲＳウイルス検査陽性 Respiratory syncytial virus (positive test)(21)	21JAN20[redacted] (442) **	24JAN20[redacted] (445) **	4	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 140199[redacted] ; Randomized Date: 05JUL20[redacted]; First Dose Date: 11JUL20[redacted]; Last Dose Date: 16DEC20[redacted]								
感染症および寄生虫症 肺炎 Pneumonia(1)	14JUL20[redacted] (10)	21JUL20[redacted] (17)	8	3	No/ No/ Yes	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved With Sequelae
心臓障害 うっ血性心不全 Congestive heart failure(2)	10AUG20[redacted] (37)	13AUG20[redacted] (40)	4	3	Yes/ No/ Yes	Dose Reduced/Drug Interrupted/ Drug Interrupted/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved With Sequelae
Treatment Randmizen: CRd ; Subject ID: 140199[redacted] ; Randomized Date: 12SEP20[redacted]; First Dose Date: 16SEP20[redacted]; Last Dose Date: 06MAR20[redacted] *								
感染症および寄生虫症 肺炎 Pneumonia(1)	25SEP20[redacted] (14)	29SEP20[redacted] (18)	5	3	Yes/ No/ Yes	Dose Reduced/Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 慢性Ｃ型肝炎 Chronic hepatitis c(7)	03APR20[redacted] (205) *			3	No/ No/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Procedure Required	Not Recovered/ Not Resolved
Treatment Randmizen: CRd ; Subject ID: 140199[redacted] ; Randomized Date: 30SEP20[redacted]; First Dose Date: 04OCT20[redacted]; Last Dose Date: 10JAN20[redacted]*								
感染症および寄生虫症 クロストリジウム感染 Clostridium difficile infection(1)	17OCT20[redacted] (18)	08NOV20[redacted] (40)	23	3	Yes/ Yes/ Yes	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺炎 Pneumonia(3)	17JAN20[redacted] (110) *	03FEB20[redacted] (127) *	18	3	Yes/ Yes/ Yes	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 140199[redacted] ; Randomized Date: 20SEP20[redacted]; First Dose Date: 22SEP20[redacted]; Last Dose Date: 03FEB20[redacted]**								
胃腸障害 腹痛 Abdominal pain(20)	25JUN20[redacted] (280) *	09JUL20[redacted] (294) *	15	3	Yes/ Yes/ Yes	Drug Interrupted/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
胃腸障害 大腸炎 Colitis(23)	27JUN20[redacted] (282) *	02JUL20[redacted] (287) *	6	3	Yes/ Yes/ Yes	Dose Not Changed/ Dose Not Changed/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
筋骨格系および結合組織障害 四肢痛 Severe pain in left arm(25)	13AUG20[redacted] (329) *	16AUG20[redacted] (332) *	4	3	Yes/ Yes/ No	Drug Interrupted/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved

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＊　：「翌年」を意味する
＊＊　：「翌々年」を意味する

表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 7）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
筋骨格系および結合組織障害 関節痛 Severe pain left ankle(26)	13AUG20[redacted] (329) *	16AUG20[redacted] (332) *	4	3	Yes/ Yes/ No	Drug Interrupted/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
筋骨格系および結合組織障害 四肢痛 Severe pain left calf(27)	13AUG20[redacted] (329) *	16AUG20[redacted] (332) *	4	3	Yes/ Yes/ No	Drug Interrupted/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 発熱性好中球減少症 Febrile neutropenia(29)	22OCT20[redacted] (399) *	29OCT20[redacted] (406) *	8	2	Yes/ Yes/ No	Drug Interrupted/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 140199[redacted] ; Randomized Date: 23SEP20[redacted] ; First Dose Date: 28SEP20[redacted] ; Last Dose Date: 23APR20[redacted] *								
心臓障害 うっ血性心不全 Congestive heart failure(1)	30SEP20[redacted] (8)	04OCT20[redacted] (12)	5	3	Yes/ No/ Yes	Dose Reduced/Drug Interrupted/ Drug Interrupted/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺炎 Pneumonia(2)	27DEC20[redacted] (96)	17JAN20[redacted] (117) *	22	3	Yes/ Yes/ Yes	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 140199[redacted] ; Randomized Date: 06FEB20[redacted] ; First Dose Date: 09FEB20[redacted] ; Last Dose Date: 30DEC20[redacted] *								
血液およびリンパ系障害 発熱性好中球減少症 Neutropenic fever(1)	10MAR20[redacted] (34)	12MAR20[redacted] (36)	3	2	Yes/ Yes/ Yes	Dose Not Changed/ Dose Delayed/ Dose Delayed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 140209[redacted] ; Randomized Date: 23MAY20[redacted] ; First Dose Date: 25MAY20[redacted] ; Last Dose Date: 01FEB20[redacted] *								
胃腸障害 好中球減少性大腸炎 Neutropenic colitis(19)	29NOV20[redacted] (191)	01DEC20[redacted] (193)	3	3	Yes/ Yes/ No	Dose Reduced/Dose Delayed/ Dose Reduced/Dose Delayed/ Dose Delayed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 140279[redacted] ; Randomized Date: 14FEB20[redacted] ; First Dose Date: 16FEB20[redacted] ; Last Dose Date: 02APR20[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） 基底細胞癌 Basal cell carcinoma lesion of right upper chest(4)	16FEB20[redacted] (3)	22APR20[redacted] (68)	66	2	No/ Yes/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 好酸球性肺炎 Eosinophilic pneumonia(23)	10AUG20[redacted] (178)	20AUG20[redacted] (188)	11	3	Yes/ Yes/ Yes	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved

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マークなし　：「同年」を意味する
＊　：「翌年」を意味する
#　：「3年後」を意味する

表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 8）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
血管障害 深部静脈血栓症 Deep vein thrombosis left leg(34)	28OCT20[redacted] (257)	29OCT20[redacted] (258)	2	2	No/ Yes/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 貧血 Symptomatic anemia(35)	05NOV20[redacted] (265)	06NOV20[redacted] (266)	2	3	No/ Yes/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	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） 基底細胞癌 Basal cell carcinoma lesion of mid-low back(55)	05DEC20[redacted] (1026) **	09JAN20[redacted] (1061) #	36	2	No/ Yes/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 140279[redacted] ; Randomized Date: 16FEB20[redacted]; First Dose Date: 23FEB20[redacted]; Last Dose Date: 07NOV20[redacted]*								
血管障害 深部静脈血栓症 Deep vein thrombosis right leg(9)	27JUN20[redacted] (132)	01JUL20[redacted] (136)	5	3	No/ Yes/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 140279[redacted] ; Randomized Date: 07DEC20[redacted]; First Dose Date: 08DEC20[redacted]; Last Dose Date: 25APR20[redacted]**								
感染症および寄生虫症 副鼻腔炎 Sinusitis(1)	21JAN20[redacted] (46) *	24JAN20[redacted] (49) *	4	1	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
筋骨格系および結合組織障害 筋力低下 Bilateral proximal lower extremity weakness(27)	09JAN20[redacted] (400)**	10JAN20[redacted] (401) **	2	3	No/ No/ Yes	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
臨床検査 A型インフルエンザウイルス検査陽性 Influenza a virus subtype h3n2 positive by pcr(28)	11JAN20[redacted] (402) **	25JAN20[redacted] (416) **	15	3	No/ No/ No	Dose Delayed/Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 140279[redacted] ; Randomized Date: 04JAN20[redacted]; First Dose Date: 05JAN20[redacted]; Last Dose Date: 18MAY20[redacted]								
感染症および寄生虫症 大腸菌性敗血症 Sepsis - e.coli(4)	24MAR20[redacted] (81)	30MAR20[redacted] (87)	7	3	No/ No/ No	Dose Delayed/ Dose Delayed/ Dose Delayed	Conmeds/ 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） 皮膚有棘細胞癌 Squamous cell carcinoma of scalp(12)	08MAY20[redacted] (126)	08MAY20[redacted] (126)	1	1	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required	Recovered/ Resolved

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表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 9）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
心臓障害 心不全 Heart failure(13)	19MAY20[redacted] (137)	07JUN20[redacted] (156)	20	5	No/ No/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Hospitalization	Fatal
Treatment Randmizen: CRd ; Subject ID: 140279[redacted] ; Randomized Date: 27JAN20[redacted]; First Dose Date: 27JAN20[redacted]; Last Dose Date: 06JUN20[redacted] **								
筋骨格系および結合組織障害 腱鞘炎 Long left finger flexor tenosynovitis(24)	29APR20[redacted] (459) *	02MAY20[redacted] (462) *	4	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 大葉性肺炎 Left lobe pneumonia(28)	17JUL20[redacted] (538) *	22JUL20[redacted] (543) *	6	3	No/ Yes/ No	Dose Not Changed/ Drug Interrupted/ Dose Not Changed	Conmeds/ 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） 扁平上皮癌 Squamous cell carcinoma lesions of the head(35)	18OCT20[redacted] (631) *	04FEB20[redacted] (740) **	110	2	No/ Yes/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required	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） 基底細胞癌 Basal cell carcinoma lesion of the head(36)	18OCT20[redacted] (631) *	04FEB20[redacted] (740) **	110	2	No/ Yes/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 140289[redacted] ; Randomized Date: 23FEB20[redacted]; First Dose Date: 24FEB20[redacted]; Last Dose Date: 05SEP20[redacted] *								
神経系障害 脊髄圧迫 Spinal cord compression(18)	17APR20[redacted] (54)	26APR20[redacted] (63)	10	4	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 140289[redacted] ; Randomized Date: 25MAY20[redacted]; First Dose Date: 02JUN20[redacted]; Last Dose Date: 27OCT20[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(1)	29MAY20[redacted] (5)	01JUN20[redacted] (8)	4	4	NA/ NA/ NA	NA/ NA/ NA	Procedure Required/ Hospitalization	Recovered/ Resolved
心臓障害 狭心症 Cardiac chest pain(2)	28JUL20[redacted] (65)	30JUL20[redacted] (67)	3	3	Yes/ No/ No	Drug Interrupted/ Drug Interrupted/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺炎 Pneumonia(3)	12SEP20[redacted] (111)	15SEP20[redacted] (114)	4	3	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Dose Not Changed	Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 140289[redacted] ; Randomized Date: 24FEB20[redacted]; First Dose Date: 27FEB20[redacted]; Last Dose Date: 28OCT20[redacted] *								

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表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 10）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
神経系障害 頭痛 Headache(28)	25FEB20[redacted] (368) *	26FEB20[redacted] (369) *	2	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 140419[redacted] ; Randomized Date: 08SEP20[redacted] ; First Dose Date: 13SEP20[redacted] ; Last Dose Date: 17APR20[redacted]**								
一般・全身障害および投与部位の状態 発熱 Fever(53)	02FEB20[redacted] (148) *	03FEB20[redacted] (149) *	2	1	Yes/ Yes/ Yes	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
肝胆道系障害 急性胆嚢炎 Acute cholecystitis(123)	01FEB20[redacted] (513) **	02FEB20[redacted] (514) **	2	3	NA/ No/ No	NA/ Dose Delayed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 140789[redacted] ; Randomized Date: 10MAY20[redacted] ; First Dose Date: 12MAY20[redacted] ; Last Dose Date: 30JAN20[redacted]#								
胃腸障害 憩室穿孔 Perforated colonic diverticulitis(9)	24MAY20[redacted] (15)	27MAY20[redacted] (18)	4	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
胃腸障害 憩室穿孔 Perforated diverticulitis(11)	20AUG20[redacted] (103)	26AUG20[redacted] (109)	7	3	No/ No/ No	Dose Delayed/ Dose Delayed/ Dose Delayed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 胸膜線維症 Fibrinous pleuritis(41)	25MAR20[redacted] (686) **	28MAR20[redacted] (689) **	4	3	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 ブドウ球菌性菌血症 Staphylococcus aureus bacteremia(56)	11AUG20[redacted] (825) **	20AUG20[redacted] (834) **	10	3	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved With Sequelae
Treatment Randmizen: CRd ; Subject ID: 140789[redacted] ; Randomized Date: 31MAY20[redacted] ; First Dose Date: 01JUN20[redacted] ; Last Dose Date: 10SEP20[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） 扁平上皮癌 Squamous cell carcinoma-left preauricular(28)	09AUG20[redacted] (71)	09AUG20[redacted] (71)	1	1	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required	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） 基底細胞癌 Basal cell carcinoma-mid upper chest(46)	09AUG20[redacted] (71)	09AUG20[redacted] (71)	1	1	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 肺塞栓症 Bilateral pulmonary embolism(9)	17OCT20[redacted] (140)	18OCT20[redacted] (141)	2	3	No/ Yes/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Not Recovered/ Not Resolved

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表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 11）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
感染症および寄生虫症 レンサ球菌性菌血症 Streptococcus pneumoniae bacteremia(20)	23DEC20[redacted] (207)	24DEC20[redacted] (208)	2	3	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Dose Not Changed	Conmeds/ 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） 皮膚有棘細胞癌 Squamous cell carcinoma- right angle of jaw on skin(47)	21MAY20[redacted] (357) *	21MAY20[redacted] (357) *	1	1	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 140789[redacted] ; Randomized Date: 10OCT20[redacted] ; First Dose Date: 12OCT20[redacted] ; Last Dose Date: 03JUN20[redacted] #								
代謝および栄養障害 腫瘍崩壊症候群 Tumor lysis syndrome(1)	13OCT20[redacted] (4)	17OCT20[redacted] (8)	5	3	Yes/ No/ No	Drug Interrupted/ Drug Interrupted/ Dose Not Changed	Conmeds	Recovered/ Resolved
血液およびリンパ系障害 発熱性好中球減少症 Neutropenic fever(7)	29OCT20[redacted] (20)	31OCT20[redacted] (22)	3	3	Yes/ Yes/ No	Dose Delayed/ Dose Delayed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
皮膚および皮下組織障害 発疹 Rash(2)	29OCT20[redacted] (20)	02NOV20[redacted] (24)	5	3	No/ No/ No	Dose Delayed/ Dose Delayed/ Dose Delayed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 蜂巣炎 Right lower extremity cellulitis(13)	04APR20[redacted] (178) *	06APR20[redacted] (180) *	3	3	No/ No/ No	Dose Delayed/ Dose Delayed/ Dose Delayed	Conmeds/ Procedure Required/ Hospitalization	Not Recovered/ Not Resolved
Treatment Randmizen: CRd ; Subject ID: 140789[redacted] ; Randomized Date: 28OCT20[redacted] ; First Dose Date: 31OCT20[redacted] ; Last Dose Date: 25FEB20[redacted] **								
感染症および寄生虫症 肺炎 Pneumonia(2)	17DEC20[redacted] (51)	22DEC20[redacted] (56)	6	3	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 140789[redacted] ; Randomized Date: 03JAN20[redacted] ; First Dose Date: 04JAN20[redacted] ; Last Dose Date: 02JAN20[redacted] *								
呼吸器、胸郭および縦隔障害 肺塞栓症 Bilateral pulmonary emboli(18)	04JAN20[redacted] (368) *	08JAN20[redacted] (372) *	5	3	No/ Yes/ No	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 140789[redacted] ; Randomized Date: 09JAN20[redacted] ; First Dose Date: 10JAN20[redacted] ; Last Dose Date: 03JUN20[redacted] **								
感染症および寄生虫症 肺炎 Pneumonia(22)	29DEC20[redacted] (356)	30DEC20[redacted] (357)	2	3	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
臨床検査 レンサ球菌検査陽性 Streptococcus viridans positive test(39)	04AUG20[redacted] (574) *	10AUG20[redacted] (580) *	7	3	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ 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
#　：「3年後」を意味する

表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 12）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
臨床検査 A型インフルエンザウイルス検査陽性 Infection other- influenza a virus positive(88)	27APR20[redacted] (840) **	30APR20[redacted] (843) **	4	3	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 141109[redacted] ; Randomized Date: 18AUG20[redacted] ; First Dose Date: 19AUG20[redacted] ; Last Dose Date: 04NOV20[redacted]								
精神障害 失見当識 Disorientation(3)	10SEP20[redacted] (24)	13SEP20[redacted] (27)	4	2	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Hospitalization	Not Recovered/ Not Resolved
一般・全身障害および投与部位の状態 無力症 Generalized weakness(4)	10SEP20[redacted] (24)	13SEP20[redacted] (27)	4	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 141129[redacted] ; Randomized Date: 25OCT20[redacted] ; First Dose Date: 28OCT20[redacted] ; Last Dose Date: 31MAY20[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 (related to reflux medical history)(1)	28OCT20[redacted] (4)	29OCT20[redacted] (5)	2	2	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 141149[redacted] ; Randomized Date: 31AUG20[redacted] ; First Dose Date: 01SEP20[redacted] ; Last Dose Date: 16MAY20[redacted] *								
感染症および寄生虫症 肺炎 Bilateral pneumonia(45)	25APR20[redacted] (238) *	09MAY20[redacted] (252) *	15	3	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 急性呼吸窮迫症候群 Acute respiratory distress syndrome(49)	25APR20[redacted] (238) *	09MAY20[redacted] (252) *	15	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 呼吸困難 Shortness of breath(50)	23MAY20[redacted] (266) *	26MAY20[redacted] (269) *	4	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 141149[redacted] ; Randomized Date: 21JAN20[redacted] ; First Dose Date: 24JAN20[redacted] ; Last Dose Date: 10MAR20[redacted] **								
感染症および寄生虫症 副鼻腔炎 Sinusitis(91)	04FEB20[redacted] (15)	08FEB20[redacted] (19)	5	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺炎 Pneumonia(15)	24MAR20[redacted] (63)	29MAR20[redacted] (68)	6	3	No/ No/ No	Drug Interrupted/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 大葉性肺炎 Right lower lobe pneumonia(21)	21JUN20[redacted] (152)	29JUN20[redacted] (160)	9	3	No/ No/ No	Drug Interrupted/ Dose Delayed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved

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＊　：「翌年」を意味する
＊＊　：「翌々年」を意味する

表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 13）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
神経系障害 頭痛 Headache(64)	21JUN20[redacted] (152)	29JUN20[redacted] (160)	9	3	No/ No/ No	Dose Not Changed/ Dose Delayed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
心臓障害 急性心筋梗塞 Non st elevated myocardial infarction(65)	21JUN20[redacted] (152)	29JUN20[redacted] (160)	9	3	No/ No/ No	Dose Not Changed/ Dose Delayed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 誤嚥性肺炎 Aspiration pneumonia(39)	07SEP20[redacted] (230)	09SEP20[redacted] (232)	3	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 クロストリジウム感染 Clostridium difficile infection(139)	20MAR20[redacted] (425) *	23MAR20[redacted] (428) *	4	3	No/ No/ No	Drug Interrupted/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
一般・全身障害および投与部位の状態 発熱 Fever(71)	29MAY20[redacted] (495) *	31MAY20[redacted] (497) *	3	2	No/ No/ No	Drug Interrupted/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
胃腸障害 食道憩室 Epiphrenic esophageal diverticula(149)	02APR20[redacted] (803) **	09APR20[redacted] (810) **	8	3	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 141189[redacted] ; Randomized Date: 17JAN20[redacted]; First Dose Date: 17JAN20[redacted]; Last Dose Date: 13MAR20[redacted]								
傷害、中毒および処置合併症 脊椎圧迫骨折 T-9 compression fracture(13)	19MAR20[redacted] (63)	23MAR20[redacted] (67)	5	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 141209[redacted] ; Randomized Date: 25MAY20[redacted]; First Dose Date: 26MAY20[redacted]; Last Dose Date: 01NOV20[redacted]*								
一般・全身障害および投与部位の状態 発熱 Fever(1)	01JUN20[redacted] (8)	02JUN20[redacted] (9)	2	1	Yes/ Yes/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved With Sequelae
血液およびリンパ系障害 白血球減少症 Leukocytopenia(3)	03JUN20[redacted] (10)	06JUN20[redacted] (13)	4	3	Yes/ Yes/ No	Dose Not Changed/ Drug Interrupted/ 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 Thrombocytopenia(2)	04JUN20[redacted] (11)	06JUN20[redacted] (13)	3	3	Yes/ Yes/ No	Dose Not Changed/ Drug Interrupted/ Dose Not Changed	Hospitalization	Not Recovered/ Not Resolved
血液およびリンパ系障害 好中球減少症 Neutropenia(4)	04JUN20[redacted] (11)	06JUN20[redacted] (13)	3	3	Yes/ Yes/ No	Dose Not Changed/ Drug Interrupted/ Dose Not Changed	Hospitalization	Not Recovered/ Not Resolved

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＊　：「翌年」を意味する
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表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 14）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
血液およびリンパ系障害 発熱性好中球減少症 Neutropenic fever(6)	02JUL20[redacted] (39)	03JUL20[redacted] (40)	2	3	Yes/ Yes/ No	Dose Reduced/ Dose Reduced/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 血小板減少症 Thrombocytopenia(7)	02JUL20[redacted] (39)	05JUL20[redacted] (42)	4	4	Yes/ Yes/ No	Dose Reduced/Drug Interrupted/ Dose Reduced/ Dose Not Changed	Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 白血球減少症 Leukocytopenia(8)	02JUL20[redacted] (39)	05JUL20[redacted] (42)	4	3	Yes/ Yes/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺炎 Pneumonia(11)	02JUL20[redacted] (39)	05JUL20[redacted] (42)	4	3	Yes/ Yes/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 好中球減少症 Neutropenia(9)	03JUL20[redacted] (40)	05JUL20[redacted] (42)	3	3	Yes/ Yes/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺炎 Community-acquired pneumonia(29)	01AUG20[redacted] (435) *	04AUG20[redacted] (438) *	4	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved With Sequelae
Treatment Randmizen: CRd ; Subject ID: 141219[redacted] ; Randomized Date: 15MAR20[redacted] ; First Dose Date: 21MAR20[redacted] ; Last Dose Date: 18DEC20[redacted]								
感染症および寄生虫症 肺炎 Pneumonia(1)	04FEB20[redacted] (-40)	06FEB20[redacted] (-38)	3	3	NA/ NA/ NA	NA/ NA/ NA	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
一般・全身障害および投与部位の状態 発熱 Fever of unknown origin(8)	20SEP20[redacted] (190)	25SEP20[redacted] (195)	6	1	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
皮膚および皮下組織障害 発疹 Rash, intermitent(10)	20SEP20[redacted] (190)	25SEP20[redacted] (195)	6	3	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved With Sequelae
Treatment Randmizen: CRd ; Subject ID: 141279[redacted] ; Randomized Date: 03NOV20[redacted] ; First Dose Date: 08NOV20[redacted] ; Last Dose Date: 10OCT20[redacted] *								
呼吸器、胸郭および縦隔障害 呼吸困難 Dyspnea(11)	07MAY20[redacted] (187) *	09MAY20[redacted] (189) *	3	3	Yes/ Yes/ Yes	Dose Delayed/ Dose Delayed/ Dose Delayed	Hospitalization	Recovered/ Resolved
胃腸障害 腹痛 Abdominal pain(36)	14AUG20[redacted] (286) *	15AUG20[redacted] (287) *	2	3	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ 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 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 15）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
Treatment Randmizen: CRd ; Subject ID: 163269[redacted] ; Randomized Date: 03JUN20[redacted] ; First Dose Date: 06JUN20[redacted] ; Last Dose Date: 22AUG20[redacted]								
一般・全身障害および投与部位の状態 発熱 Fever(1)	07JUN20[redacted] (5)	10JUN20[redacted] (8)	4	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
腎および尿路障害 尿閉 Acute urinary retention(3)	29AUG20[redacted] (88)	19SEP20[redacted] (109)	22	3	No/ No/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Procedure Required	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 163299[redacted] ; Randomized Date: 14NOV20[redacted] ; First Dose Date: 15NOV20[redacted] ; Last Dose Date: 09JAN20[redacted] #								
感染症および寄生虫症 敗血症症候群 Septic syndrome(13)	14MAR20[redacted] (122) *	23MAR20[redacted] (131) *	10	2	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	None	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 肺障害 Pneumopathy(32)	29SEP20[redacted] (321) *	02OCT20[redacted] (324) *	4	3	No/ No/ No	Drug Interrupted/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺感染 Pulmonary infection(34)	26NOV20[redacted] (379) *	29NOV20[redacted] (382) *	4	3	No/ No/ No	Drug Interrupted/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 気管支肺症 Bronchopneumopathy(50)	22DEC20[redacted] (770) **	30DEC20[redacted] (778) **	9	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 163299[redacted] ; Randomized Date: 31JAN20[redacted] ; First Dose Date: 02FEB20[redacted] ; Last Dose Date: 10JUN20[redacted]**								
一般・全身障害および投与部位の状態 全身健康状態低下 Impairment of fitness(1)	27JAN20[redacted] (-4)	03FEB20[redacted] (4)	8	2	NA/ NA/ NA	NA/ NA/ NA	Conmeds/ Procedure Required	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 163309[redacted] ; Randomized Date: 25OCT20[redacted] ; First Dose Date: 26OCT20[redacted] ; Last Dose Date: 20MAR20[redacted]**								
胃腸障害 大腸穿孔 Sigmoid colon perforation(17)	21MAR20[redacted] (514) **	03APR20[redacted] (527) **	14	4	No/ Yes/ Yes	Dose Not Changed/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 163329[redacted] ; Randomized Date: 01MAR20[redacted] ; First Dose Date: 03MAR20[redacted] ; Last Dose Date: 11JUN20[redacted] #								
感染症および寄生虫症 気道感染 Respiratory infection(1)	19MAR20[redacted] (19)	25MAR20[redacted] (25)	7	2	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 163329[redacted] ; Randomized Date: 15APR20[redacted] ; First Dose Date: 18APR20[redacted] ; Last Dose Date: 02JUN20[redacted] #								

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＊＊　：「翌々年」を意味する
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表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 16）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
血管障害 深部静脈血栓症 Deep vein thrombosis(8)	02MAY20[redacted] (384) *	04MAY20[redacted] (386) *	3	3	No/ Yes/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 163329[redacted] ; Randomized Date: 19APR20[redacted]; First Dose Date: 21APR20[redacted]; Last Dose Date: 09JUL20[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） 形質細胞腫 Sphenoidal plasmocytoma(11)	13JUL20[redacted] (452) *	06AUG20[redacted] (476) *	25	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 163329[redacted] ; Randomized Date: 27JUN20[redacted]; First Dose Date: 29JUN20[redacted]; Last Dose Date: 22AUG20[redacted] **								
呼吸器、胸郭および縦隔障害 肺水腫 Subacute pulmonary edema(1)	31AUG20[redacted] (66)	01SEP20[redacted] (67)	2	2	No/ No/ Yes	Drug Interrupted/ Drug Interrupted/ Dose Not Changed	None/ Hospitalization	Recovered/ Resolved
精神障害 精神的機能代償不全 Psychiatric decompensation(44)	03AUG20[redacted] (769) **	10AUG20[redacted] (776) **	8	3	No/ No/ Yes	Dose Not Changed/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 163329[redacted] ; Randomized Date: 27SEP20[redacted]; First Dose Date: 29SEP20[redacted]; Last Dose Date: 29MAY20[redacted]#								
血管障害 深部静脈血栓症 Deep vein thrombosis(7)	01MAR20[redacted] (157) *	24MAY20[redacted] (241) *	85	3	No/ Yes/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
感染症および寄生虫症 インフルエンザ Influenza a(12)	10APR20[redacted] (197) *	16APR20[redacted] (203) *	7	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 163329[redacted] ; Randomized Date: 17OCT20[redacted]; First Dose Date: 19OCT20[redacted]; Last Dose Date: 20MAY20[redacted] #								
感染症および寄生虫症 ＲＳウイルス細気管支炎 Infectious bronchiolitis with respiratory syncytial virus(18)	27DEC20[redacted] (438) *	03JAN20[redacted] (445) **	8	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 細気管支炎 Bronchiolitis(24)	10MAR20[redacted] (511) **	17MAR20[redacted] (518) **	8	3	No/ No/ Yes	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺感染 Infectious pneumopathy(39)	29MAY20[redacted] (956) #	02JUN20[redacted] (960) #	5	3	No/ Yes/ Yes	NA/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 163389[redacted] ; Randomized Date: 08AUG20[redacted]; First Dose Date: 10AUG20[redacted]; Last Dose Date: 16JUN20[redacted]#								

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＊＊　：「翌々年」を意味する
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表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 17）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
血管障害 血栓症 Left femoro popliteal thrombosis(8)	22FEB20[redacted] (199) ＊			2	No/ Yes/ Yes	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds	Not Recovered/ Not Resolved
Treatment Randmizen: CRd ; Subject ID: 163389[redacted] ; Randomized Date: 02MAR20[redacted]; First Dose Date: 07MAR20[redacted]; Last Dose Date: 16JUN20[redacted]＊＊								
血管障害 高血圧 Worsening of hypertension(6)	21FEB20[redacted] (-10)	FEB20[redacted] (-)		3	NA/ NA/ NA	NA/ NA/ NA	None	Recovered/ Resolved
筋骨格系および結合組織障害 肩回旋筋腱板症候群 Rupture of rotator cuff(7)	25MAY20[redacted] (85)	06SEP20[redacted] (189)	105	3	Yes/ Yes/ Yes	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
一般・全身障害および投与部位の状態 倦怠感 Malaise after the wash out of study drug infusion(27)	15JAN20[redacted] (320) ＊	18JAN20[redacted] (323) ＊	4	2	No/ No/ No	Dose Not Changed/ Dose Delayed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 184519[redacted] ; Randomized Date: 03MAY20[redacted]; First Dose Date: 04MAY20[redacted]; Last Dose Date: 25MAY20[redacted]								
一般・全身障害および投与部位の状態 発熱 Fever(1)	30MAY20[redacted] (28)	05JUN20[redacted] (34)	7	3	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 上気道感染 Infection of upper respiratory system(2)	10JUN20[redacted] (39)	17JUN20[redacted] (46)	8	1	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 184519[redacted] ; Randomized Date: 08FEB20[redacted]; First Dose Date: 09FEB20[redacted]; Last Dose Date: 16MAY20[redacted]								
呼吸器、胸郭および縦隔障害 間質性肺疾患 Interstitial pneumonitis(1)	17MAY20[redacted] (100)	21MAY20[redacted] (104)	5	3	No/ Yes/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 184539[redacted] ; Randomized Date: 20FEB20[redacted]; First Dose Date: 27FEB20[redacted]; Last Dose Date: 09JUL20[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） 胸膜の悪性新生物 Epithelial malignancy of pleura (suspected mesothelioma)(1)	11JUL20[redacted] (143)	11SEP20[redacted] (205)	63	5	No/ No/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Procedure Required/ Hospitalization	Fatal
Treatment Randmizen: CRd ; Subject ID: 184589[redacted] ; Randomized Date: 13AUG20[redacted]; First Dose Date: 16AUG20[redacted]; Last Dose Date: 10JUN20[redacted]#								
感染症および寄生虫症 気道感染 Respiratory tract infection(7)	04OCT20[redacted] (419) ＊	12OCT20[redacted] (427) ＊	9	3	Yes/ Yes/ Yes	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ 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
#　：「3年後」を意味する

表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 18）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
胃腸障害 急性膵炎 Acute pancreatitis(9)	02NOV20[redacted] (448) *	09NOV20[redacted] (455) *	8	3	Yes/ Yes/ Yes	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds	Recovered/ Resolved With Sequelae
胃腸障害 十二指腸狭窄 Stenosis of major duodenal papilla(10)	04DEC20[redacted] (480) *	06DEC20[redacted] (482) *	3	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ 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 Acute clostridium difficile enteritis(11)	18DEC20[redacted] (494) *	03JAN20[redacted] (510) **	17	3	Yes/ Yes/ Yes	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ 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） 膵新生物 Pancreas tumor(12)	08JAN20[redacted] (515) **	10JAN20[redacted] (517) **	3	3	Yes/ Yes/ Yes	NA/ Dose Reduced/Drug Interrupted/ Drug Interrupted	Procedure Required/ Hospitalization	Recovered/ Resolved
血管障害 大動脈瘤 Aneurysma aortae(14)	22MAY20[redacted] (649) **	26MAY20[redacted] (653) **	5	3	No/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 184589[redacted] ; Randomized Date: 19AUG20[redacted] ; First Dose Date: 22AUG20[redacted] ; Last Dose Date: 16JUN20[redacted] #								
心臓障害 心筋虚血 Ischaemic heart disease(8)	06DEC20[redacted] (476) *	07DEC20[redacted] (477) *	2	1	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 184589[redacted] ; Randomized Date: 03OCT20[redacted] ; First Dose Date: 05OCT20[redacted] ; Last Dose Date: 04JUN20[redacted] #								
感染症および寄生虫症 気道感染 Respiratory tract infection(6)	28JAN20[redacted] (118) *	06FEB20[redacted] (127) *	10	3	Yes/ Yes/ Yes	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 184589[redacted] ; Randomized Date: 03OCT20[redacted] ; First Dose Date: 05OCT20[redacted] ; Last Dose Date: 13JAN20[redacted] #								
血液およびリンパ系障害 溶血性貧血 Hemolytic anemia(1)	16NOV20[redacted] (45)	23NOV20[redacted] (52)	8	3	Yes/ Yes/ No	Drug Withdrawn/Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved With Sequelae
感染症および寄生虫症 肺炎 Pneumonia(2)	10DEC20[redacted] (69)	25JAN20[redacted] (115) *	47	2	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Dose Reduced	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 184589[redacted] ; Randomized Date: 03NOV20[redacted] ; First Dose Date: 07NOV20[redacted] ; Last Dose Date: 09JUN20[redacted] #								
胃腸障害 腹痛 Acute abdominal pain(1)	18NOV20[redacted] (16)	22NOV20[redacted] (20)	5	3	Yes/ Yes/ Yes	Dose Delayed/ Drug Interrupted/ Dose Reduced	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved

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＊＊　：「翌々年」を意味する
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表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 19）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
感染症および寄生虫症 尿路感染 Infection of urinary tract(4)	15FEB20[redacted] (105) ＊	24FEB20[redacted] (114) ＊	10	3	Yes/ Yes/ Yes	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺炎 Pneumonia(6)	15FEB20[redacted] (105) ＊	24FEB20[redacted] (114) ＊	10	3	Yes/ Yes/ Yes	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required	Recovered/ Resolved
感染症および寄生虫症 肺炎 Bilateral pneumonia(13)	07JAN20[redacted] (432) ＊＊	18JAN20[redacted] (443) ＊＊	12	3	Yes/ Yes/ Yes	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
心臓障害 冠動脈疾患 Coronary heart disease(16)	05SEP20[redacted] (673) ＊＊	09SEP20[redacted] (677) ＊＊	5	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 貧血 Anemia(17)	02DEC20[redacted] (761) ＊＊	02DEC20[redacted] (761) ＊＊	1	2	No/ Yes/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 184619[redacted] ; Randomized Date: 31OCT20[redacted] ; First Dose Date: 02NOV20[redacted] ; Last Dose Date: 12MAR20[redacted] #								
精神障害 人格変化 Personality change(17)	13MAR20[redacted] (865) #			3	No/ No/ No	Dose Not Changed/ Drug Withdrawn/ Drug Withdrawn	None	Unknown
Treatment Randmizen: CRd ; Subject ID: 184629[redacted] ; Randomized Date: 19JUL20[redacted] ; First Dose Date: 20JUL20[redacted] ; Last Dose Date: 23AUG20[redacted]								
血液およびリンパ系障害 貧血 Anemia(1)	29JUN20[redacted] (-20)	11JUL20[redacted] (-8)	13	2	NA/ NA/ NA	NA/ NA/ NA	Conmeds/ Hospitalization	Not Recovered/ Not Resolved
代謝および栄養障害 高カルシウム血症 Hypercalcemia(5)	12JUL20[redacted] (-7)	15JUL20[redacted] (-4)	4	4	NA/ NA/ NA	NA/ NA/ NA	Conmeds/ Hospitalization	Recovered/ Resolved
腎および尿路障害 腎不全 Renal insufficiency(4)	12JUL20[redacted] (-7)	19JUL20[redacted] (1)	8	2	NA/ NA/ NA	NA/ NA/ NA	Conmeds/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 貧血 Anemia(2)	12JUL20[redacted] (-7)	04AUG20[redacted] (17)	24	3	NA/ NA/ NA	NA/ NA/ NA	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 血小板減少症 Thrombocytopenia(3)	12JUL20[redacted] (-7)	04AUG20[redacted] (17)	24	4	NA/ NA/ NA	NA/ NA/ NA	Conmeds	Recovered/ Resolved

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＊＊　：「翌々年」を意味する
#　：「3年後」を意味する

表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 20）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
代謝および栄養障害 腫瘍崩壊症候群 Tumor lysis syndrome(6)	20JUL20[redacted] (2)	29JUL20[redacted] (11)	10	4	Yes/ Yes/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
一般・全身障害および投与部位の状態 疾患進行 Progressive disease(9)	16AUG20[redacted] (29)	25AUG20[redacted] (38)	10	5	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Fatal
血液およびリンパ系障害 貧血 Anemia(20)	16AUG20[redacted] (29)	25AUG20[redacted] (38)	10	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required	Recovered/ Resolved With Sequelae
Treatment Randmizen: CRd ; Subject ID: 184629[redacted] ; Randomized Date: 07JUN20[redacted] ; First Dose Date: 10JUN20[redacted] ; Last Dose Date: 16DEC20[redacted]								
代謝および栄養障害 高カルシウム血症 Hypercalcemia(2)	09JUN20[redacted] (3)	10JUN20[redacted] (4)	2	1	NA/ NA/ NA	NA/ NA/ NA	Conmeds/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 貧血 Anemia(4)	01SEP20[redacted] (87)	03SEP20[redacted] (89)	3	3	Yes/ Yes/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 貧血 Anaemia(10)	29SEP20[redacted] (115)	01OCT20[redacted] (117)	3	3	Yes/ Yes/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 貧血 Anaemia(11)	27OCT20[redacted] (143)	31OCT20[redacted] (147)	5	3	Yes/ Yes/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 貧血 Anaemia(13)	30DEC20[redacted] (207)	03JAN20[redacted] (211) *	5	2	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved With Sequelae
Treatment Randmizen: CRd ; Subject ID: 225269[redacted] ; Randomized Date: 19SEP20[redacted] ; First Dose Date: 21SEP20[redacted] ; Last Dose Date: 04JAN20[redacted]*								
感染症および寄生虫症 医療機器関連感染 Port a cath infection(6)	28OCT20[redacted] (40)	03NOV20[redacted] (46)	7	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
神経系障害 脊髄圧迫 Spinal cord compression(9)	18JAN20[redacted] (122) *	JAN20[redacted] (-) *		3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 225269[redacted] ; Randomized Date: 26OCT20[redacted] ; First Dose Date: 27OCT20[redacted] ; Last Dose Date: 05JUN20[redacted]#								
一般・全身障害および投与部位の状態 全身性炎症反応症候群 Sirs(1)	29OCT20[redacted] (4)	05NOV20[redacted] (11)	8	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved

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＊　：「翌年」を意味する
#　：「3年後」を意味する

表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 21）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
呼吸器、胸郭および縦隔障害 呼吸困難 Dyspnea(2)	29OCT20[redacted] (4)	05NOV20[redacted] (11)	8	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 225269[redacted] ; Randomized Date: 22NOV20[redacted]; First Dose Date: 23NOV20[redacted]; Last Dose Date: 27MAY20[redacted]#								
感染症および寄生虫症 肺炎 Pneumonia(9)	30JUL20[redacted] (252) *	07AUG20[redacted] (260) *	9	3	No/ No/ No	Dose Delayed/ Dose Reduced/Drug Interrupted/ Dose Reduced/Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 肺塞栓症 Massive pulmonary embolism(18)	03NOV20[redacted] (348) *	14NOV20[redacted] (359) *	12	2	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Dose Delayed/Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 225269[redacted] ; Randomized Date: 20JAN20[redacted]; First Dose Date: ; Last Dose Date:								
心臓障害 頻脈 Tachycardia(4)	14JAN20[redacted] (-6)	[ONGOING] (-)		3	NA/ NA/ NA	NA/ NA/ NA	Hospitalization	Not Recovered/ Not Resolved
呼吸器、胸郭および縦隔障害 呼吸不全 Respiratory failure(1)	14JAN20[redacted] (-6)	23JAN20[redacted] (4)	10	5	NA/ NA/ NA	NA/ NA/ NA	Procedure Required/ Hospitalization	Fatal
感染症および寄生虫症 肺炎 Pneumonia(2)	21JAN20[redacted] (2)	[ONGOING] (-)		1	NA/ NA/ NA	NA/ NA/ NA	Conmeds/ Procedure Required/ Hospitalization	Not Recovered/ Not Resolved
感染症および寄生虫症 敗血症性ショック Septic shock(13)	23JAN20[redacted] (4)	23JAN20[redacted] (4)	1	5	NA/ NA/ NA	NA/ NA/ NA	None	Fatal
Treatment Randmizen: CRd ; Subject ID: 225309[redacted] ; Randomized Date: 27NOV20[redacted]; First Dose Date: 30NOV20[redacted]; Last Dose Date: 22AUG20[redacted]*								
呼吸器、胸郭および縦隔障害 肺障害 Acute pneumopathy(1)	25DEC20[redacted] (29)	30DEC20[redacted] (34)	6	3	Yes/ Yes/ No	Dose Delayed/ Dose Delayed/ Dose Delayed	Conmeds/ 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） 急性骨髄性白血病 Acute myeloid leukemia(45)	07SEP20[redacted] (286) *	[ONGOING] (-)		3	Yes/ Yes/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Hospitalization	Not Recovered/ Not Resolved
Treatment Randmizen: CRd ; Subject ID: 225309[redacted] ; Randomized Date: 19DEC20[redacted]; First Dose Date: 21DEC20[redacted]; Last Dose Date: 02JAN20[redacted]*								

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表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 22）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	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 Multiple organ failure(1)	30DEC20[redacted] (12)	06JAN20[redacted] (19) *	8	5	No/ No/ No	Drug Withdrawn/Drug Interrupted/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Procedure Required	Fatal
Treatment Randmizen: CRd ; Subject ID: 225339[redacted] ; Randomized Date: 11SEP20[redacted]; First Dose Date: 13SEP20[redacted]; Last Dose Date: 16JUN20[redacted]#								
心臓障害 心房細動 Atrial fibrillation at high frequency(1)	23SEP20[redacted] (13)	24SEP20[redacted] (14)	2	3	Yes/ Yes/ Yes	Dose Reduced/ Drug Interrupted/ Dose Reduced/Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 225339[redacted] ; Randomized Date: 28NOV20[redacted]; First Dose Date: 28NOV20[redacted]; Last Dose Date: 30JAN20[redacted]#								
感染症および寄生虫症 気管支炎 Bronchitis(18)	14NOV20[redacted] (353) *	19NOV20[redacted] (358) *	6	2	No/ No/ No	Drug Interrupted/ Dose Reduced/Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 慢性閉塞性肺疾患 Exacerbation bronchitica (acute exacerbation of chronic obstructive broncho-pulmonary)(26)	11MAR20[redacted] (470) **	13MAR20[redacted] (472) **	3	3	Yes/ Yes/ No	Dose Delayed/ Dose Delayed/Drug Interrupted/ Dose Delayed/Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
心臓障害 僧帽弁閉鎖不全症 Mitral valve insufficiency(27)	04APR20[redacted] (494) **	19APR20[redacted] (509) **	16	3	No/ No/ No	Dose Delayed/ Dose Delayed/ Dose Delayed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
心臓障害 心嚢液貯留 Pericardian effusion(31)	20APR20[redacted] (510) **	07MAY20[redacted] (527) **	18	4	No/ No/ No	Dose Delayed/ Dose Delayed/ Dose Delayed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 血小板減少症 Thrombocytopenia(32)	30APR20[redacted] (520) **	05MAY20[redacted] (525) **	6	4	No/ No/ No	Dose Delayed/ Dose Delayed/ Dose Delayed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 気管支肺炎 Bronchopneumonia(50)	01SEP20[redacted] (644) **	10SEP20[redacted] (653) **	10	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 247169[redacted] ; Randomized Date: 27APR20[redacted]; First Dose Date: 28APR20[redacted]; Last Dose Date: 21OCT20[redacted]								
一般・全身障害および投与部位の状態 死亡 Death of unknown cause(10)	22OCT20[redacted] (179)	22OCT20[redacted] (179)	1	5	No/ No/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	None	Fatal
Treatment Randmizen: CRd ; Subject ID: 247169[redacted] ; Randomized Date: 10NOV20[redacted]; First Dose Date: 14NOV20[redacted]; Last Dose Date: 15JAN20[redacted]#								

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＊＊　：「翌々年」を意味する
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表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 23）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
感染症および寄生虫症 敗血症 Sepsis(26)	15JAN20[redacted] (798) #	16JAN20[redacted] (799) #	2	5	NA/ Yes/ Yes	NA/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Hospitalization	Fatal
Treatment Randmizen: CRd ; Subject ID: 247169[redacted] ; Randomized Date: 29DEC20[redacted]; First Dose Date: 02JAN20[redacted]; Last Dose Date: 26NOV20[redacted]								
感染症および寄生虫症 上気道感染 Upper respiratory infection(1)	04JAN20[redacted] (7)	10JAN20[redacted] (13)	7	3	No/ No/ Yes	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 247169[redacted] ; Randomized Date: 24FEB20[redacted]; First Dose Date: 28FEB20[redacted]; Last Dose Date: 31AUG20[redacted] *								
感染症および寄生虫症 肺炎 Pneumonia(1)	13FEB20[redacted] (-11)	24FEB20[redacted] (1)	12	3	NA/ NA/ NA	NA/ NA/ NA	Conmeds/ Hospitalization	Recovered/ Resolved
肝胆道系障害 胆石症 Cholelithiasis(5)	08OCT20[redacted] (228)	22OCT20[redacted] (242)	15	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
一般・全身障害および投与部位の状態 死亡 Death (unknown reason)(12)	31AUG20[redacted] (555) *	31AUG20[redacted] (555) *	1	5	No/ No/ No	Dose Not Changed/ Drug Withdrawn/ Drug Withdrawn	None	Fatal
Treatment Randmizen: CRd ; Subject ID: 247199[redacted] ; Randomized Date: 19JAN20[redacted]; First Dose Date: 20JAN20[redacted]; Last Dose Date: 29NOV20[redacted]								
腎および尿路障害 ネフローゼ症候群 Worsering of nephrotic syndrome(1)	08FEB20[redacted] (21)	15FEB20[redacted] (28)	8	2	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved With Sequelae
胃腸障害 下痢 Diarrhea(2)	25APR20[redacted] (97)	04MAY20[redacted] (106)	10	1	Yes/ Yes/ Yes	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Hospitalization	Recovered/ Resolved
心臓障害 狭心症 Angor pectoris(12)	19MAY20[redacted] (121)	20MAY20[redacted] (122)	2	4	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds	Recovered/ Resolved
腎および尿路障害 腎不全 Renal failure(3)	13AUG20[redacted] (207)	17AUG20[redacted] (211)	5	2	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
心臓障害 急性心筋梗塞 Acute myocardial infarction(9)	29NOV20[redacted] (315)	30NOV20[redacted] (316)	2	4	No/ No/ No	Drug Withdrawn/ Dose Not Changed/ Drug Withdrawn	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 247199[redacted] ; Randomized Date: 09FEB20[redacted]; First Dose Date: 10FEB20[redacted]; Last Dose Date: 04SEP20[redacted] *								

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
#　：「3年後」を意味する

表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 24）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
感染症および寄生虫症 気道感染 Respiratory infection(1)	13JUL20[redacted] (155)	26JUL20[redacted] (168)	14	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺炎 Pneumonia(5)	26JUN20[redacted] (504) *	29JUN20[redacted] (507) *	4	2	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 247199[redacted] ; Randomized Date: 15FEB20[redacted] ; First Dose Date: 16FEB20[redacted] ; Last Dose Date: 23MAY20[redacted] **								
腎および尿路障害 急性腎不全 Acute renal failure(8)	29AUG20[redacted] (562) *	03SEP20[redacted] (567) *	6	3	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 247199[redacted] ; Randomized Date: 15JUN20[redacted] ; First Dose Date: 16JUN20[redacted] ; Last Dose Date: 22APR20[redacted] *								
傷害、中毒および処置合併症 大腿骨骨折 Accidental femur fracture(7)	14JAN20[redacted] (214) *	24JAN20[redacted] (224) *	11	1	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Hospitalization	Recovered/ Resolved
代謝および栄養障害 低カルシウム血症 Hypocalcemia(8)	23APR20[redacted] (314) *	02MAY20[redacted] (323) *	10	4	Yes/ Yes/ Yes	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 247199[redacted] ; Randomized Date: 27JUN20[redacted] ; First Dose Date: 27JUN20[redacted] ; Last Dose Date: 05NOV20[redacted] *								
傷害、中毒および処置合併症 外傷性骨折 Traumatic fracture of right femoral neck(3)	29JUN20[redacted] (369) *	04JUL20[redacted] (374) *	6	3	No/ No/ No	Dose Delayed/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 247199[redacted] ; Randomized Date: 30JAN20[redacted] ; First Dose Date: 30JAN20[redacted] ; Last Dose Date: 16JAN20[redacted] **								
代謝および栄養障害 低カリウム血症 Hypopotasemia(9)	08DEC20[redacted] (679) *	04FEB20[redacted] (737) **	59	3	No/ No/ No	Dose Not Changed/ Drug Withdrawn/ Drug Withdrawn	Conmeds	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 247219[redacted] ; Randomized Date: 04JUL20[redacted] ; First Dose Date: 04JUL20[redacted] ; Last Dose Date: 16JUN20[redacted] #								
感染症および寄生虫症 気道感染 Respiratory infection(7)	09JAN20[redacted] (190) *	23JAN20[redacted] (204) *	15	3	Yes/ Yes/ Yes	Dose Delayed/ Dose Delayed/ Dose Delayed	Conmeds/ Hospitalization	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 呼吸不全 Respiratory insufficiency(27)	09JAN20[redacted] (190) *	23JAN20[redacted] (204) *	15	3	Yes/ Yes/ Yes	Dose Delayed/ Dose Delayed/ Dose Delayed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved

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＊＊　：「翌々年」を意味する
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表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 25）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
感染症および寄生虫症 敗血症性ショック Septic shock(67)	08AUG20[redacted] (402) *	17AUG20[redacted] (411) *	10	4	Yes/ Yes/ Yes	Dose Delayed/ Dose Delayed/ Dose Delayed/Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺炎 Left pneumonia(68)	31AUG20[redacted] (425) *	07SEP20[redacted] (432) *	8	3	Yes/ Yes/ Yes	Dose Delayed/ Dose Delayed/Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
代謝および栄養障害 電解質失調 Hydroelectrolitic alteration(107)	08OCT20[redacted] (463) *	11OCT20[redacted] (466) *	4	3	Yes/ Yes/ Yes	Drug Interrupted/ Dose Reduced/ Dose Reduced	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 気道感染 Respiratory infection(137)	04APR20[redacted] (1006) #	11APR20[redacted] (1013) #	8	3	No/ No/ No	Dose Not Changed/ Dose Delayed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 247219[redacted] ; Randomized Date: 28NOV20[redacted]; First Dose Date: 28NOV20[redacted]; Last Dose Date: 26FEB20[redacted] **								
感染症および寄生虫症 肺炎 Left basal pneumony(1)	11JAN20[redacted] (45) *	18JAN20[redacted] (52) *	8	3	Yes/ Yes/ Yes	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺炎 Basal right pneumonia(2)	04FEB20[redacted] (69) *	09FEB20[redacted] (74) *	6	3	Yes/ Yes/ Yes	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 247249[redacted] ; Randomized Date: 14JUN20[redacted]; First Dose Date: 16JUN20[redacted]; Last Dose Date: 19JAN20[redacted]*								
一般・全身障害および投与部位の状態 発熱 Fever(1)	17JUN20[redacted] (4)	23JUN20[redacted] (10)	7	2	Yes/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺炎 Left pneumonia(7)	23JAN20[redacted] (224) *	03FEB20[redacted] (235) *	12	3	No/ No/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 247249[redacted] ; Randomized Date: 21JUN20[redacted]; First Dose Date: 22JUN20[redacted]; Last Dose Date: 30OCT20[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） 骨髄異形成症候群 Myelodysplastic syndrome(12)	23OCT20[redacted] (491) *	[ONGOING] (-)		3	Yes/ Yes/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	None	Not Recovered/ Not Resolved
Treatment Randmizen: CRd ; Subject ID: 247249[redacted] ; Randomized Date: 18AUG20[redacted]; First Dose Date: 22AUG20[redacted]; Last Dose Date: 02SEP20[redacted] **								

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
＊＊　：「翌々年」を意味する
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表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 26）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
筋骨格系および結合組織障害 背部痛 Lumbar pain(1)	29SEP20[redacted] (43)	11OCT20[redacted] (55)	13	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 尿路感染 Urinary infection(5)	18FEB20[redacted] (185) *	20FEB20[redacted] (187) *	3	3	No/ No/ No	Dose Delayed/ Dose Delayed/Drug Interrupted/ Dose Delayed/Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
生殖系および乳房障害 良性前立腺肥大症 Prostatic thermal ablation (benign prostate hyperplasia)(199)	30MAY20[redacted] (287) *	03JUN20[redacted] (291) *	5	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	None	Recovered/ Resolved
心臓障害 完全房室ブロック Complete atrioventricular block(9)	18JUN20[redacted] (306) *	27JUN20[redacted] (315) *	10	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 気道感染 Respiratory infection(37)	19JUN20[redacted] (307) *	24JUN20[redacted] (312) *	6	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ 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） 基底細胞癌 Basal cell carcinoma left nasal ala(11)	04JUL20[redacted] (322) *	04JUL20[redacted] (322) *	1	1	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required	Recovered/ Resolved
感染症および寄生虫症 尿路感染 Urinary infection(59)	02SEP20[redacted] (747) **	19SEP20[redacted] (764) **	18	3	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 247249[redacted] ; Randomized Date: 09NOV20[redacted] ; First Dose Date: 10NOV20[redacted] ; Last Dose Date: 23JAN20[redacted]**								
感染症および寄生虫症 気道感染 Respiratory infection(4)	13DEC20[redacted] (401) *	20DEC20[redacted] (408) *	8	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 247249[redacted] ; Randomized Date: 27DEC20[redacted] ; First Dose Date: 28DEC20[redacted] ; Last Dose Date: 23OCT20[redacted]**								
感染症および寄生虫症 気道感染 Respiratory infection(4)	31DEC20[redacted] (371) *	04JAN20[redacted] (375) **	5	2	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds	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） 急性リンパ性白血病 Acute lymphoblastic leukemia(52)	27NOV20[redacted] (702) **	[ONGOING] (-)		3	No/ Yes/ No	Dose Not Changed/ Drug Withdrawn/ Drug Withdrawn	Conmeds	Not Recovered/ Not Resolved

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＊　：「翌年」を意味する
＊＊　：「翌々年」を意味する

表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 27）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
Treatment Randmizen: CRd ; Subject ID: 247249[redacted] ; Randomized Date: 16FEB20[redacted]; First Dose Date: 20FEB20[redacted]; Last Dose Date: 16JUN20[redacted] **								
感染症および寄生虫症 肺炎 Pneumonia(10)	17DEC20[redacted] (306)	24DEC20[redacted] (313)	8	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 247249[redacted] ; Randomized Date: 09FEB20[redacted]; First Dose Date: 13FEB20[redacted]; Last Dose Date: 17OCT20[redacted]								
代謝および栄養障害 糖尿病性ケトアシドーシス Diabetic ketoacidosis(1)	03APR20[redacted] (55)	05APR20[redacted] (57)	3	4	No/ No/ Yes	Dose Delayed/ Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
心臓障害 ストレス心筋症 Tako-tsubo syndrome (transient apical dyskinesia)(18)	07APR20[redacted] (59)	18APR20[redacted] (70)	12	4	No/ No/ No	Dose Delayed/ Dose Reduced/Dose Delayed/ Dose Reduced/Dose Delayed	Conmeds/ Procedure Required	Recovered/ Resolved
感染症および寄生虫症 胃腸炎 Acute gastroenteritis(12)	21JUN20[redacted] (134)	25JUN20[redacted] (138)	5	3	No/ No/ No	Dose Delayed/ Dose Delayed/ Dose Delayed	Conmeds/ Hospitalization	Recovered/ Resolved
傷害、中毒および処置合併症 大腿骨骨折 Femur fracture(14)	16JUL20[redacted] (159)	26JUL20[redacted] (169)	11	3	No/ No/ No	Dose Delayed/Drug Interrupted/ Dose Delayed/Drug Interrupted/ Dose Delayed/Drug Interrupted	Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 260089[redacted] ; Randomized Date: 27JUN20[redacted]; First Dose Date: 29JUN20[redacted]; Last Dose Date: 14MAY20[redacted] #								
感染症および寄生虫症 肺炎 Pneumonia(14)	22SEP20[redacted] (454) *	25SEP20[redacted] (457) *	4	2	No/ Yes/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
肝胆道系障害 急性胆嚢炎 Acute cholecystitis(39)	07MAR20[redacted] (985) #	17MAR20[redacted] (995) #	11	3	NA/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Delayed	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 260139[redacted] ; Randomized Date: 24JUN20[redacted]; First Dose Date: 28JUN20[redacted]; Last Dose Date: 05JUN20[redacted] **								
心臓障害 うっ血性心不全 Congestive heart failure-intermittent(3)	06SEP20[redacted] (75)	07NOV20[redacted] (137)	63	3	No/ No/ No	Dose Reduced/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
心臓障害 心筋梗塞 Anterior myocardial infarct(11)	09FEB20[redacted] (231) *	15FEB20[redacted] (237) *	7	3	No/ No/ No	Dose Delayed/Drug Interrupted/ Dose Delayed/ Dose Delayed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved With Sequelae

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表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 28）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
傷害、中毒および処置合併症 腓骨骨折 Fractured fibula(31)	10OCT20[redacted] (475) *	16NOV20[redacted] (512) *	38	2	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 260499[redacted] ; Randomized Date: 07JUN20[redacted]; First Dose Date: 08JUN20[redacted]; Last Dose Date: 07FEB20[redacted] *								
感染症および寄生虫症 肺炎 Pneumonia(7)	17SEP20[redacted] (103)	28SEP20[redacted] (114)	12	3	No/ No/ No	Dose Not Changed/ Dose Reduced/Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved With Sequelae
感染症および寄生虫症 ＲＳウイルス肺炎 Respiratory synctial virus pneumonia(14)	18JAN20[redacted] (226) *	24JAN20[redacted] (232) *	7	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 260559[redacted] ; Randomized Date: 03OCT20[redacted]; First Dose Date: 05OCT20[redacted]; Last Dose Date: 23JAN20[redacted] *								
血液およびリンパ系障害 発熱性好中球減少症 Febrile neurtropenia(23)	14DEC20[redacted] (73)	16DEC20[redacted] (75)	3	3	No/ Yes/ No	Dose Not Changed/ Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 260559[redacted] ; Randomized Date: 15NOV20[redacted]; First Dose Date: 17NOV20[redacted]; Last Dose Date: 12MAR20[redacted]#								
心臓障害 うっ血性心不全 Worsened congestive heart failure(40)	22JUL20[redacted] (251) *	28JUL20[redacted] (257) *	7	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Drug Interrupted	Procedure Required/ Hospitalization	Recovered/ Resolved
心臓障害 うっ血性心不全 Worsened congestive heart failure(72)	27NOV20[redacted] (379) *	30NOV20[redacted] (382) *	4	3	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
心臓障害 うっ血性心不全 Worsened congestive heart failure(73)	04DEC20[redacted] (386) *	12DEC20[redacted] (394) *	9	3	No/ No/ No	Drug Interrupted/ Dose Delayed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
血管障害 低血圧 Hypotension(74)	17DEC20[redacted] (399) *	18DEC20[redacted] (400) *	2	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
肝胆道系障害 胆管炎 Cholangitis(89)	15SEP20[redacted] (671) **	26SEP20[redacted] (682) **	12	4	No/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
傷害、中毒および処置合併症 胆嚢損傷 Bile duct injury(112)	11FEB20[redacted] (820) #	16FEB20[redacted] (825) #	6	3	No/ No/ No	NA/ Dose Delayed/Drug Interrupted/ Dose Delayed/Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved

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表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 29）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
感染症および寄生虫症 菌血症 Bacteremia(101)	13MAR20[redacted] (850) #	28MAR20[redacted] (865) #	16	3	No/ No/ No	Dose Not Changed/ Dose Delayed/ Dose Delayed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肝膿瘍 Liver abscess(115)	14MAR20[redacted] (851) #	28MAR20[redacted] (865) #	15	2	No/ No/ No	Dose Not Changed/ Dose Delayed/ Dose Delayed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 胸水 Pleural effusion(116)	02APR20[redacted] (870) #	23APR20[redacted] (891) #	22	5	NA/ No/ No	NA/ Dose Delayed/Drug Withdrawn/ Dose Delayed/Drug Withdrawn	Conmeds/ Procedure Required/ Hospitalization	Fatal
Treatment Randmizen: CRd ; Subject ID: 261139[redacted] ; Randomized Date: 10JAN20[redacted] ; First Dose Date: 11JAN20[redacted] ; Last Dose Date: 01APR20[redacted] **								
呼吸器、胸郭および縦隔障害 肺塞栓症 Pulmonary embolism(24)	09NOV20[redacted] (305)	09NOV20[redacted] (305)	1	3	No/ Yes/ Yes	Dose Reduced/Drug Interrupted/ Dose Reduced/ Dose Reduced	None	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 261179[redacted] ; Randomized Date: 16JAN20[redacted] ; First Dose Date: 19JAN20[redacted] ; Last Dose Date: 16JAN20[redacted] **								
感染症および寄生虫症 肺炎 Pneumonia(4)	16JUL20[redacted] (183)	20JUL20[redacted] (187)	5	3	Yes/ Yes/ Yes	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ 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） 形質細胞性白血病 Plasma cell leukemia(25)	23JAN20[redacted] (739) **	22FEB20[redacted] (769) **	31	5	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Hospitalization	Fatal
Treatment Randmizen: CRd ; Subject ID: 261179[redacted] ; Randomized Date: 13FEB20[redacted] ; First Dose Date: 15FEB20[redacted] ; Last Dose Date: 14NOV20[redacted]								
心臓障害 心停止 Cardiac arrest(13)	30NOV20[redacted] (292)	30NOV20[redacted] (292)	1	5	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds	Fatal
Treatment Randmizen: CRd ; Subject ID: 261289[redacted] ; Randomized Date: 26APR20[redacted] ; First Dose Date: 27APR20[redacted] ; Last Dose Date: 03JAN20[redacted] *								
筋骨格系および結合組織障害 骨痛 Discomfort in the left femur(10)	04JAN20[redacted] (254) *	10JAN20[redacted] (260) *	7	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 282269[redacted] ; Randomized Date: 25JUL20[redacted] ; First Dose Date: 26JUL20[redacted] ; Last Dose Date: 16JUN20[redacted] #								
感染症および寄生虫症 インフルエンザ Influenza(72)	20MAR20[redacted] (605) **	25MAR20[redacted] (610) **	6	2	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	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
#　：「3年後」を意味する

表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 30）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
Treatment Randmizen: CRd ; Subject ID: 282309[redacted] ; Randomized Date: 23MAY20[redacted]; First Dose Date: 25MAY20[redacted]; Last Dose Date: 13JUN20[redacted] **								
感染症および寄生虫症 肺炎 Pneumonia(6)	01JUL20[redacted] (40)	08JUL20[redacted] (47)	8	3	No/ Yes/ No	Dose Not Changed/ Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
筋骨格系および結合組織障害 側腹部痛 Pain right flank(19)	13MAY20[redacted] (722) **	28MAY20[redacted] (737) **	16	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 282309[redacted] ; Randomized Date: 23JAN20[redacted]; First Dose Date: 26JAN20[redacted]; Last Dose Date: 16JUN20[redacted] **								
感染症および寄生虫症 肺炎 Pneumonia(7)	25JUN20[redacted] (155)	27JUN20[redacted] (157)	3	3	Yes/ Yes/ Yes	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
代謝および栄養障害 低カリウム血症 Hypokalemia(10)	09JUL20[redacted] (534) *	10JUL20[redacted] (535) *	2	3	No/ Yes/ No	Dose Not Changed/ Dose Reduced/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 282349[redacted] ; Randomized Date: 18JUL20[redacted]; First Dose Date: 19JUL20[redacted]; Last Dose Date: 21NOV20[redacted] *								
感染症および寄生虫症 肺感染 Lung infection(1)	25JUN20[redacted] (-23)	01JUL20[redacted] (-17)	7	3	NA/ NA/ NA	NA/ NA/ NA	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺感染 Lung infection with clinical suspiscion of pneumonia(2)	04SEP20[redacted] (49)	06SEP20[redacted] (51)	3	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
心臓障害 心房細動 Atrial fibrillation(14)	09NOV20[redacted] (115)	10NOV20[redacted] (116)	2	3	Yes/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 呼吸困難 Dyspnea(16)	19NOV20[redacted] (125)	03DEC20[redacted] (139)	15	3	Yes/ No/ No	Drug Interrupted/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required	Recovered/ Resolved
心臓障害 心不全 Heart failure(19)	15DEC20[redacted] (151)	29DEC20[redacted] (165)	15	2	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 282349[redacted] ; Randomized Date: 01SEP20[redacted]; First Dose Date: 05SEP20[redacted]; Last Dose Date: 21APR20[redacted] **								
感染症および寄生虫症 医療機器関連感染 Infection port a cath(12)	30JAN20[redacted] (152) *	01FEB20[redacted] (154) *	3	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ 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 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 31）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
Treatment Randmizen: CRd ; Subject ID: 282349[redacted] ; Randomized Date: 24JAN20[redacted] ; First Dose Date: 25JAN20[redacted] ; Last Dose Date: 24OCT20[redacted] *								
感染症および寄生虫症 肺炎 Pneumonia(2)	03FEB20[redacted] (11)	09FEB20[redacted] (17)	7	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
代謝および栄養障害 低ナトリウム血症 Hyponatriemia(1)	26JUL20[redacted] (185)	27JUL20[redacted] (186)	2	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 348019[redacted] ; Randomized Date: 02SEP20[redacted] ; First Dose Date: 05SEP20[redacted] ; Last Dose Date: 16JAN20[redacted] **								
呼吸器、胸郭および縦隔障害 肺塞栓症 Pulmonary embolism(1)	07SEP20[redacted] (6)	09SEP20[redacted] (8)	3	4	No/ Yes/ Yes	Dose Not Changed/ Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved With Sequelae
感染症および寄生虫症 インフルエンザ Influenza a(10)	14APR20[redacted] (226) *	18APR20[redacted] (230) *	5	3	No/ Yes/ No	Drug Interrupted/ Dose Delayed/ Dose Delayed	Hospitalization	Recovered/ Resolved
心臓障害 心房粗動 Atrial flutter(11)	02MAY20[redacted] (244) *	04MAY20[redacted] (246) *	3	3	NA/ No/ Yes	Drug Interrupted/ Drug Interrupted/ Dose Reduced	Conmeds/ Hospitalization	Not Recovered/ Not Resolved
心臓障害 頻脈 Tachycardia(12)	06MAY20[redacted] (248) *	10MAY20[redacted] (252) *	5	3	No/ No/ Yes	Dose Not Changed/ Dose Not Changed/ Drug Interrupted	Conmeds/ Hospitalization	Not Recovered/ Not Resolved
呼吸器、胸郭および縦隔障害 呼吸困難 Dyspnea(13)	24MAY20[redacted] (266) *	04JUN20[redacted] (277) *	12	3	No/ No/ Yes	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 348029[redacted] ; Randomized Date: 10JUN20[redacted] ; First Dose Date: 13JUN20[redacted] ; Last Dose Date: 11APR20[redacted] *								
呼吸器、胸郭および縦隔障害 肺塞栓症 Pulmonary embolism, bilateral(21)	08DEC20[redacted] (182)	27DEC20[redacted] (201)	20	4	No/ Yes/ Yes	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Not Recovered/ Not Resolved
Treatment Randmizen: CRd ; Subject ID: 348029[redacted] ; Randomized Date: 22AUG20[redacted] ; First Dose Date: 24AUG20[redacted] ; Last Dose Date: 23SEP20[redacted] **								
感染症および寄生虫症 肺炎 Pneumonia(30)	30NOV20[redacted] (467) *	03DEC20[redacted] (470) *	4	2	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Not Recovered/ Not Resolved
Treatment Randmizen: CRd ; Subject ID: 348039[redacted] ; Randomized Date: 12OCT20[redacted] ; First Dose Date: 13OCT20[redacted] ; Last Dose Date: 28FEB20[redacted] **								

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 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 32）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
神経系障害 脳血管発作 Stroke(3)	13MAR20[redacted] (154) *	05APR20[redacted] (177) *	24	4	No/ Yes/ No	Dose Delayed/Drug Interrupted/ Drug Withdrawn/ Drug Interrupted	Hospitalization	Recovered/ Resolved With Sequelae
腎および尿路障害 血尿 Hematuria(8)	06DEC20[redacted] (422) *	07DEC20[redacted] (423) *	2	2	No/ NA/ No	Drug Interrupted/ NA/ Drug Interrupted	Hospitalization	Recovered/ Resolved
一般・全身障害および投与部位の状態 突然死 Sudden death(12)	07MAR20[redacted] (513) **	07MAR20[redacted] (513) **	1	5	No/ NA/ No	Drug Withdrawn/ NA/ Drug Withdrawn	None	Fatal
Treatment Randmizen: CRd ; Subject ID: 382769[redacted] ; Randomized Date: 14JAN20[redacted]; First Dose Date: 17JAN20[redacted]; Last Dose Date: 17APR20[redacted]								
感染症および寄生虫症 気管気管支炎 Acute tracheobronchitis(1)	18FEB20[redacted] (36)	03MAR20[redacted] (49)	14	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 382769[redacted] ; Randomized Date: 14FEB20[redacted]; First Dose Date: 14FEB20[redacted]; Last Dose Date: 23JAN20[redacted] **								
血管障害 塞栓症 Thromboembolic event(9)	05DEC20[redacted] (295)	09DEC20[redacted] (299)	5	2	No/ Yes/ No	Drug Interrupted/ Dose Reduced/Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 382769[redacted] ; Randomized Date: 21FEB20[redacted]; First Dose Date: 21FEB20[redacted]; Last Dose Date: 17SEP20[redacted]*								
感染症および寄生虫症 尿路感染 Urinary tract infection(8)	26MAR20[redacted] (400) *	16APR20[redacted] (421) *	22	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 細菌性喉頭炎 Larynx infection of stenotrofomonas origin(16)	09JUL20[redacted] (505) *	16JUL20[redacted] (512) *	8	2	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Drug Interrupted	Conmeds	Recovered/ Resolved
感染症および寄生虫症 大腸菌性尿路感染 Uroinfection of e.coli origin(18)	22SEP20[redacted] (580) *	26SEP20[redacted] (584) *	5	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 382769[redacted] ; Randomized Date: 22AUG20[redacted]; First Dose Date: 22AUG20[redacted]; Last Dose Date: 18MAR20[redacted]**								
感染症および寄生虫症 細菌性腸炎 Enterocolitis of clostridium difficile origin(26)	18MAR20[redacted] (575) **	23MAR20[redacted] (580) **	6	3	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ 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 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 33）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
精神障害 錯乱状態 Confusion of unknown etiology(35)	15APR20[redacted] (603) **	25APR20[redacted] (613) **	11	3	NA/ Yes/ Yes	NA/ Drug Withdrawn/Drug Interrupted/ Drug Withdrawn/Drug Interrupted	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 382769[redacted] ; Randomized Date: 25OCT20[redacted]; First Dose Date: 25OCT20[redacted]; Last Dose Date: 15MAY20[redacted]#								
一般・全身障害および投与部位の状態 発熱 High fever(1)	27OCT20[redacted] (3)	01NOV20[redacted] (8)	6	3	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺炎 Bilateral pneumonia(37)	20SEP20[redacted] (332) *	29SEP20[redacted] (341) *	10	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 382769[redacted] ; Randomized Date: 05FEB20[redacted]; First Dose Date: 06FEB20[redacted]; Last Dose Date: 16JUN20[redacted]**								
血管障害 塞栓症 Thromboembolic event(8)	11JUN20[redacted] (128)	15JUN20[redacted] (132)	5	2	No/ Yes/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds	Recovered/ Resolved
感染症および寄生虫症 気道感染 Respiratory infection(31)	09JAN20[redacted] (705) **	15JAN20[redacted] (711) **	7	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 382779[redacted] ; Randomized Date: 02MAY20[redacted]; First Dose Date: 02MAY20[redacted]; Last Dose Date: 15JUN20[redacted]#								
精神障害 失見当識 Short-term disorientation(41)	02OCT20[redacted] (520) *	08OCT20[redacted] (526) *	7	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 382779[redacted] ; Randomized Date: 27JUN20[redacted]; First Dose Date: 27JUN20[redacted]; Last Dose Date: 16JUN20[redacted]#								
呼吸器、胸郭および縦隔障害 肺塞栓症 Pulmonary embolism(2)	05JUL20[redacted] (9)	11JUL20[redacted] (15)	7	4	No/ Yes/ No	Dose Delayed/ Dose Delayed/ Dose Delayed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
筋骨格系および結合組織障害 椎間板圧迫 Compression th7,th8, th9, th10, l1, l2.(38)	27MAY20[redacted] (1066) #	30MAY20[redacted] (1069) #	4	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 382779[redacted] ; Randomized Date: 10AUG20[redacted]; First Dose Date: 10AUG20[redacted]; Last Dose Date: 14AUG20[redacted]**								
腎および尿路障害 急性腎不全 Accute renal failure(26)	09AUG20[redacted] (731) **	14AUG20[redacted] (736) **	6	3	NA/ No/ No	NA/ Drug Interrupted/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 382779[redacted] ; Randomized Date: 08AUG20[redacted]; First Dose Date: 08AUG20[redacted]; Last Dose Date: 25JUN20[redacted]**								

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
#　：「3年後」を意味する

表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 34）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
感染症および寄生虫症 肺炎 Pneumonia(31)	26JUN20[redacted] (689) **	04JUL20[redacted] (697) **	9	5	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Procedure Required/ Hospitalization	Fatal
Treatment Randmizen: CRd ; Subject ID: 382779[redacted] ; Randomized Date: 03OCT20[redacted] ; First Dose Date: 03OCT20[redacted] ; Last Dose Date: 17JUL20[redacted] *								
血管障害 低血圧 Hypotension(25)	31MAY20[redacted] (242) *	04JUN20[redacted] (246) *	5	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 382779[redacted] ; Randomized Date: 31OCT20[redacted] ; First Dose Date: 31OCT20[redacted] ; Last Dose Date: 16JUN20[redacted] #								
傷害、中毒および処置合併症 脳振盪 Comotio cerebri(21)	07AUG20[redacted] (647) **	09AUG20[redacted] (649) **	3	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 382779[redacted] ; Randomized Date: 03FEB20[redacted] ; First Dose Date: 06FEB20[redacted] ; Last Dose Date: 14JAN20[redacted] **								
感染症および寄生虫症 憩室炎 Diverticulitis(8)	02NOV20[redacted] (274)	13NOV20[redacted] (285)	12	4	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 382779[redacted] ; Randomized Date: 06FEB20[redacted] ; First Dose Date: 08FEB20[redacted] ; Last Dose Date: 10APR20[redacted] *								
心臓障害 急性心筋梗塞 Accute myocardial infarct(24)	06SEP20[redacted] (214)	11SEP20[redacted] (219)	6	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
心臓障害 冠動脈閉塞 Obstruction of arteria coronary dexter(27)	03OCT20[redacted] (241)	04OCT20[redacted] (242)	2	3	No/ No/ No	Drug Interrupted/ Dose Not Changed/ Drug Interrupted	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 382779[redacted] ; Randomized Date: 08FEB20[redacted] ; First Dose Date: 08FEB20[redacted] ; Last Dose Date: 21MAY20[redacted] **								
筋骨格系および結合組織障害 顎骨壊死 Jaw osteonecrosis(26)	30JUL20[redacted] (539) *	01AUG20[redacted] (541) *	3	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 382789[redacted] ; Randomized Date: 04FEB20[redacted] ; First Dose Date: 07FEB20[redacted] ; Last Dose Date: 02JAN20[redacted] *								
胃腸障害 下痢 Diarhoea of unknown origin(13)	31AUG20[redacted] (209)	05SEP20[redacted] (214)	6	2	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds	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） 急性骨髄性白血病 Acute myeloid leukaemia(47)	16JAN20[redacted] (347) *	05APR20[redacted] (427) *	81	5	Yes/ Yes/ No	Drug Withdrawn/ Dose Not Changed/ Drug Withdrawn	Conmeds	Fatal
Treatment Randmizen: CRd ; Subject ID: 382789[redacted] ; Randomized Date: 14FEB20[redacted] ; First Dose Date: 15FEB20[redacted] ; Last Dose Date: 16JUN20[redacted] #								

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
#　：「3年後」を意味する

表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 35）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
感染症および寄生虫症 気管支肺炎 Bronchopneumonia(48)	27MAR20[redacted] (773) **	03APR20[redacted] (780) **	8	2	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds	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 Enterocolitis post antibiotics(55)	02APR20[redacted] (1144) #	09APR20[redacted] (1151) #	8	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 382789[redacted] ; Randomized Date: 22MAY20[redacted] ; First Dose Date: 23MAY20[redacted] ; Last Dose Date: 13MAY20[redacted] #								
神経系障害 意識変容状態 Impairment of consciousness unclear causes(31)	14FEB20[redacted] (269) *	23FEB20[redacted] (278) *	10	2	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	None	Recovered/ Resolved
血管障害 深部静脈血栓症 Deep vein thrombosis of right leg(56)	13MAR20[redacted] (297) *	19MAR20[redacted] (303) *	7	2	No/ Yes/ Yes	Drug Interrupted/ Dose Reduced/Drug Interrupted/ Dose Reduced/Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
血管障害 血栓症 Thrombosis of right leg(60)	09MAY20[redacted] (354) *	16MAY20[redacted] (361) *	8	2	No/ Yes/ Yes	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
筋骨格系および結合組織障害 顎骨壊死 Osteonecrosis mandible(90)	01JUL20[redacted] (772) **	09JUL20[redacted] (780) **	9	3	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 382789[redacted] ; Randomized Date: 10JUN20[redacted] ; First Dose Date: 13JUN20[redacted] ; Last Dose Date: 23MAY20[redacted] *								
感染症および寄生虫症 肺炎 Pneumonia(3)	18JUL20[redacted] (39)	26JUL20[redacted] (47)	9	3	No/ No/ No	Dose Delayed/Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 382789[redacted] ; Randomized Date: 21JUN20[redacted] ; First Dose Date: 23JUN20[redacted] ; Last Dose Date: 03NOV20[redacted]								
心臓障害 心筋梗塞 Heart attack(10)	09NOV20[redacted] (142)	09NOV20[redacted] (142)	1	5	No/ No/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	None	Fatal
Treatment Randmizen: CRd ; Subject ID: 382789009 ; Randomized Date: 02AUG20[redacted] ; First Dose Date: 04AUG20[redacted] ; Last Dose Date: 10JUN20[redacted] #								
一般・全身障害および投与部位の状態 疾患進行 Disease progresion(39)	11JUN20[redacted] (1045) #	04JUL20[redacted] (1068) #	24	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	None	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 382789[redacted] ; Randomized Date: 13DEC20[redacted] ; First Dose Date: 15DEC20[redacted] ; Last Dose Date: 16JUN20[redacted] #								

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＊＊　：「翌々年」を意味する
#　：「3年後」を意味する

表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 36）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
胃腸障害 下痢 Diarrhoea(31)	18NOV20[redacted] (342) *	20NOV20[redacted] (344) *	3	2	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 382789[redacted] ; Randomized Date: 16DEC20[redacted]; First Dose Date: 19DEC20[redacted]; Last Dose Date: 15JUL20[redacted]*								
感染症および寄生虫症 歯肉炎 Gingivitis(17)	10APR20[redacted] (117) *	16APR20[redacted] (123) *	7	2	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 382799[redacted] ; Randomized Date: 04FEB20[redacted]; First Dose Date: 07FEB20[redacted]; Last Dose Date: 09SEP20[redacted]**								
筋骨格系および結合組織障害 筋骨格痛 Vertebral algical syndrome worsening(13)	23SEP20[redacted] (963) **	30SEP20[redacted] (970) **	8	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 肺塞栓症 Pulmonary embolism(14)	25SEP20[redacted] (965) **	30SEP20[redacted] (970) **	6	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 382799[redacted] ; Randomized Date: 17OCT20[redacted]; First Dose Date: 17OCT20[redacted]; Last Dose Date: 02DEC20[redacted]**								
感染症および寄生虫症 肺炎 Pneumonia(31)	13JUL20[redacted] (271) *	18JUL20[redacted] (276) *	6	3	No/ Yes/ No	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 貧血 Anemia(57)	07DEC20[redacted] (783) **	10DEC20[redacted] (786) **	4	4	No/ Yes/ No	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Not Recovered/ Not Resolved
傷害、中毒および処置合併症 腰椎骨折 Fractures of the lumbar vertebrae(75)	07FEB20[redacted] (845) #	13FEB20[redacted] (851) #	7	3	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Procedure Required/ Hospitalization	Recovered/ Resolved With Sequelae
呼吸器、胸郭および縦隔障害 急性呼吸不全 Acute respiratory failure(84)	17APR20[redacted] (914) #	25APR20[redacted] (922) #	9	5	No/ No/ No	Dose Not Changed/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Procedure Required/ Hospitalization	Fatal
Treatment Randmizen: CRd ; Subject ID: 382799[redacted] ; Randomized Date: 21NOV20[redacted]; First Dose Date: 21NOV20[redacted]; Last Dose Date: 12MAY20[redacted]#								
皮膚および皮下組織障害 発疹 Skin rash(2)	30JAN20[redacted] (71) *	01FEB20[redacted] (73) *	3	2	Yes/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	None	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 382799[redacted] ; Randomized Date: 12DEC20[redacted]; First Dose Date: 12DEC20[redacted]; Last Dose Date: 16JUN20[redacted]#								

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
＊＊　：「翌々年」を意味する
#　：「3年後」を意味する

表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 37）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
感染症および寄生虫症 気管支肺炎 Bronchopneumonia(6)	24JUN20[redacted] (196) *	10JUL20[redacted] (212) *	17	4	No/ Yes/ No	Drug Interrupted/ Dose Reduced/Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 敗血症 Septikemia(7)	24JUN20[redacted] (196) *	10JUL20[redacted] (212) *	17	4	No/ Yes/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 382809[redacted] ; Randomized Date: 15AUG20[redacted]; First Dose Date: 17AUG20[redacted]; Last Dose Date: 19MAR20[redacted]**								
血管障害 血栓症 Thrombosis(17)	19MAR20[redacted] (583) **	21MAR20[redacted] (585) **	3	3	No/ Yes/ Yes	Dose Not Changed/ Dose Not Changed/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 382809[redacted] ; Randomized Date: 18NOV20[redacted]; First Dose Date: 21NOV20[redacted]; Last Dose Date: 01APR20[redacted]**								
胃腸障害 閉塞を伴う腹部ヘルニア Gastrocele with incarceration(23)	08APR20[redacted] (508) **			4	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Procedure Required/ Hospitalization	Not Recovered/ Not Resolved
感染症および寄生虫症 腹膜炎 Peritonitis acuta(26)	08APR20[redacted] (508) **			4	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Not Recovered/ Not Resolved
感染症および寄生虫症 敗血症 Sepsis(27)	26APR20[redacted] (526) **	27APR20[redacted] (527) **	2	5	No/ No/ No	Dose Not Changed/ Drug Withdrawn/ Drug Withdrawn	Conmeds	Fatal
一般・全身障害および投与部位の状態 多臓器不全 Multiorgan failure(28)	26APR20[redacted] (526) **	27APR20[redacted] (527) **	2	4	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds	Not Recovered/ Not Resolved
Treatment Randmizen: CRd ; Subject ID: 382809[redacted] ; Randomized Date: 02JAN20[redacted]; First Dose Date: 04JAN20[redacted]; Last Dose Date: 20MAR20[redacted]*								
感染症および寄生虫症 胃腸炎 Suspected gastroenteritis(8)	20JUN20[redacted] (171)	27JUN20[redacted] (178)	8	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
神経系障害 認知障害 Alteration of cognition(15)	11DEC20[redacted] (345)	23DEC20[redacted] (357)	13	2	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 気管気管支炎 Acute tracheobronchitis(16)	07FEB20[redacted] (403) *	15FEB20[redacted] (411) *	9	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved

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表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 38）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
感染症および寄生虫症 胃腸炎 Gastroenteritis acuta(19)	21MAR20[redacted] (445) *	06APR20[redacted] (461) *	17	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Not Recovered/ Not Resolved
感染症および寄生虫症 気管支肺炎 Bronchial infection - bronchopneumonia(20)	03APR20[redacted] (458) *	06APR20[redacted] (461) *	4	5	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required	Fatal
Treatment Randmizen: CRd ; Subject ID: 394779[redacted] ; Randomized Date: 04JUL20[redacted] ; First Dose Date: 05JUL20[redacted] ; Last Dose Date: 12JUL20[redacted]								
感染症および寄生虫症 肺炎 Pneumonia(1)	12JUL20[redacted] (9)	15JUL20[redacted] (12)	4	5	No/ No/ Yes	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Procedure Required/ Hospitalization	Fatal
Treatment Randmizen: CRd ; Subject ID: 394779[redacted] ; Randomized Date: 26SEP20[redacted] ; First Dose Date: 27SEP20[redacted] ; Last Dose Date: 04SEP20[redacted] **								
感染症および寄生虫症 肺炎 Pneumonia(25)	10JUN20[redacted] (624) **	13JUN20[redacted] (627) **	4	3	No/ No/ No	NA/ Dose Delayed/Drug Interrupted/ Dose Not Changed	Conmeds/ 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） 転移性膵癌 Pancreatic cancer with liver metastases(29)	17SEP20[redacted] (723) **	20NOV20[redacted] (787) **	65	5	No/ Yes/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Procedure Required	Fatal
Treatment Randmizen: CRd ; Subject ID: 394789[redacted] ; Randomized Date: 24JUL20[redacted] ; First Dose Date: 25JUL20[redacted] ; Last Dose Date: 16JUN20[redacted] #								
感染症および寄生虫症 肺炎 Pneumonia(12)	28NOV20[redacted] (494) *	02DEC20[redacted] (498) *	5	3	No/ No/ No	Dose Delayed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 394789[redacted] ; Randomized Date: 08AUG20[redacted] ; First Dose Date: 08AUG20[redacted] ; Last Dose Date: 08APR20[redacted] #								
感染症および寄生虫症 肺炎 Pneumonia(10)	24SEP20[redacted] (48)	02OCT20[redacted] (56)	9	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺炎 Pneumonia(21)	21JAN20[redacted] (167) *	26JAN20[redacted] (172) *	6	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 気管支炎 Bronchitis(30)	23MAY20[redacted] (290) *	25MAY20[redacted] (292) *	3	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 気管支炎 Bronchitis(38)	09SEP20[redacted] (399) *	12SEP20[redacted] (402) *	4	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ 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，
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＊＊　：「翌々年」を意味する
#　：「3年後」を意味する

表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 39）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
感染症および寄生虫症 気管支炎 Acute bronchitis(41)	08NOV20[redacted] (459) *	17NOV20[redacted] (468) *	10	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 慢性閉塞性肺疾患 Chronic obstructive pulmonary disease(52)	10MAR20[redacted] (581) **	12MAR20[redacted] (583) **	3	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 気管支炎 Acute bronchitis(56)	29JUN20[redacted] (692) **	02JUL20[redacted] (695) **	4	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 慢性閉塞性肺疾患 Copd(62)	07NOV20[redacted] (823) **	10NOV20[redacted] (826) **	4	2	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
心臓障害 うっ血性心不全 Congestive heart failure(65)	13APR20[redacted] (980) #	17APR20[redacted] (984) #	5	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
胃腸障害 下痢 Diarrhea(67)	17APR20[redacted] (984) #	22APR20[redacted] (989) #	6	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 394829[redacted] ; Randomized Date: 16JAN20[redacted] ; First Dose Date: 18JAN20[redacted] ; Last Dose Date: 13FEB20[redacted] *								
肝胆道系障害 胆管結石 Choledocholithiasis(7)	19NOV20[redacted] (309)	23NOV20[redacted] (313)	5	3	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 394859[redacted] ; Randomized Date: 30OCT20[redacted] ; First Dose Date: 30OCT20[redacted] ; Last Dose Date: 03JUN20[redacted] #								
感染症および寄生虫症 肺炎 Pneumonia(1)	02NOV20[redacted] (4)	13NOV20[redacted] (15)	12	3	No/ No/ No	Dose Delayed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺炎 Pneumonia(38)	30MAR20[redacted] (153) *	01APR20[redacted] (155) *	3	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 394859[redacted] ; Randomized Date: 13DEC20[redacted] ; First Dose Date: 13DEC20[redacted] ; Last Dose Date: 28JAN20[redacted] #								
感染症および寄生虫症 肺炎 Pneumonia(11)	25MAR20[redacted] (104) *	29MAR20[redacted] (108) *	5	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 394869[redacted] ; Randomized Date: 08AUG20[redacted] ; First Dose Date: 09AUG20[redacted] ; Last Dose Date: 03JUN20[redacted] *								

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表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 40）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
代謝および栄養障害 水分過負荷 Volume overload(3)	10AUG20[redacted] (3)	16AUG20[redacted] (9)	7	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
一般・全身障害および投与部位の状態 胸痛 Chest pain(2)	20AUG20[redacted] (13)	24AUG20[redacted] (17)	5	2	No/ No/ No	Drug Interrupted/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 412529[redacted] ; Randomized Date: 03JUN20[redacted] ; First Dose Date: 06JUN20[redacted] ; Last Dose Date: 01DEC20[redacted]								
血液およびリンパ系障害 好中球減少症 Neutropenia(1)	18JUL20[redacted] (46)	19JUL20[redacted] (47)	2	4	Yes/ No/ No	Drug Interrupted/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
血液およびリンパ系障害 好中球減少症 Neutropenia(10)	10OCT20[redacted] (130)	17OCT20[redacted] (137)	8	4	Yes/ Yes/ No	Dose Reduced/ Drug Interrupted/ Dose Not Changed	Conmeds	Recovered/ Resolved
血液およびリンパ系障害 血小板減少症 Thrombocytopenia gr.4(11)	10OCT20[redacted] (130)	17OCT20[redacted] (137)	8	4	Yes/ Yes/ No	Dose Reduced/ Drug Interrupted/ Dose Not Changed	Conmeds/ Procedure Required	Recovered/ Resolved
血液およびリンパ系障害 貧血 Anemia(12)	10OCT20[redacted] (130)	17OCT20[redacted] (137)	8	4	Yes/ Yes/ No	Dose Reduced/ Drug Interrupted/ Dose Not Changed	Procedure Required	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 412529[redacted] ; Randomized Date: 07NOV20[redacted] ; First Dose Date: 09NOV20[redacted] ; Last Dose Date: 16JUN20[redacted] #								
心臓障害 左室機能不全 Acute lv dysfunction(1)	02OCT20[redacted] (331) *	08OCT20[redacted] (337) *	7	4	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 412529[redacted] ; Randomized Date: 23DEC20[redacted] ; First Dose Date: 27DEC20[redacted] ; Last Dose Date: 12MAR20[redacted] **								
心臓障害 心房細動 Atrial fibrillation(1)	15MAR20[redacted] (449) **	[ONGOING] (-)		3	No/ No/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Hospitalization	Not Recovered/ Not Resolved
心臓障害 左室機能不全 Left ventricular systolic disfunction(4)	21MAR20[redacted] (455) **	23MAR20[redacted] (457) **	3	5	No/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Hospitalization	Fatal
Treatment Randmizen: CRd ; Subject ID: 412539[redacted] ; Randomized Date: 28DEC20[redacted] ; First Dose Date: 02JAN20[redacted] ; Last Dose Date: 02JAN20[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） 結腸直腸癌 Colorectal carcinoma(2)	04JAN20[redacted] (8) *	12MAY20[redacted] (137) *	130	5	No/ No/ No	Drug Interrupted*/ Drug Interrupted/ Drug Interrupted	Hospitalization *	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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＊　：「翌年」を意味する
＊＊　：「翌々年」を意味する
#　：「3年後」を意味する

表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 41）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
筋骨格系および結合組織障害 病的骨折 Pathologic fracture of the neck of the femur.(3)	05JAN20[redacted] (9)	05FEB20[redacted] (40)	32	3	No/ No/ No	Drug Withdrawn/Drug Interrupted/ Drug Withdrawn/ Drug Withdrawn	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 412549[redacted] ; Randomized Date: 29NOV20[redacted]; First Dose Date: 30NOV20[redacted]; Last Dose Date: 16JUN20[redacted]#								
感染症および寄生虫症 肺炎 Pleuropneumonia sinistra(5)	02JUL20[redacted] (582) **	07AUG20[redacted] (618) **	37	3	NA/ Yes/ Yes	NA/ Dose Reduced/Drug Interrupted/ Dose Reduced/Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 412559[redacted] ; Randomized Date: 13MAY20[redacted]; First Dose Date: 16MAY20[redacted]; Last Dose Date: 16JUN20[redacted]#								
心臓障害 心房細動 Paroxysmal atrium fibrillation(1)	11JAN20[redacted] (244) *	12JAN20[redacted] (245) *	2	3	No/ No/ No	Dose Reduced/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 412559[redacted] ; Randomized Date: 14DEC20[redacted]; First Dose Date: 19DEC20[redacted]; Last Dose Date: 12MAR20[redacted]*								
感染症および寄生虫症 肺炎 Pneumonia(1)	07FEB20[redacted] (56) *	15FEB20[redacted] (64) *	9	3	No/ No/ No	Dose Delayed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
血管障害 循環虚脱 Acute cardiovascular failure(2)	05APR20[redacted] (114) *	07APR20[redacted] (116) *	3	5	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Fatal
Treatment Randmizen: CRd ; Subject ID: 412569[redacted] ; Randomized Date: 26MAR20[redacted]; First Dose Date: 28MAR20[redacted]; Last Dose Date: 02OCT20[redacted]*								
感染症および寄生虫症 肺炎 Pneumonia bilateralis(2)	03MAY20[redacted] (39)	09MAY20[redacted] (45)	7	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
神経系障害 馬尾症候群 Lumbo - sacral syndrom(10)	13SEP20[redacted] (538) *	26SEP20[redacted] (551) *	14	2	No/ Yes/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 貧血 Anemia(12)	27SEP20[redacted] (552) *	03OCT20[redacted] (558) *	7	2	No/ Yes/ No	Dose Not Changed/ Drug Interrupted/ Dose Not Changed	Procedure Required/ Hospitalization	Not Recovered/ Not Resolved
神経系障害 不全対麻痺 Lower paraparesis(11)	27SEP20[redacted] (552) *	01NOV20[redacted] (587) *	36	3	No/ Yes/ No	Dose Not Changed/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Procedure Required/ Hospitalization	Not Recovered/ Not Resolved
Treatment Randmizen: CRd ; Subject ID: 412569[redacted] ; Randomized Date: 25JUL20[redacted]; First Dose Date: 27JUL20[redacted]; Last Dose Date: 30JAN20[redacted]**								

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＊　：「翌年」を意味する
＊＊　：「翌々年」を意味する
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表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 42）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
血液およびリンパ系障害 貧血 Anemia(1)	10AUG20[redacted] (17)	15AUG20[redacted] (22)	6	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 442029[redacted] ; Randomized Date: 17JUN20[redacted]; First Dose Date: 20JUN20[redacted]; Last Dose Date: 24DEC20[redacted] **								
感染症および寄生虫症 肺炎 Pneumonia(25)	24MAR20[redacted] (647) **	02APR20[redacted] (656) **	10	3	No/ Yes/ Yes	Dose Not Changed/ Drug Interrupted/ Dose Reduced/Drug Interrupted	Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 442029[redacted] ; Randomized Date: 14JUL20[redacted]; First Dose Date: 14JUL20[redacted]; Last Dose Date: 15MAR20[redacted] *								
代謝および栄養障害 高血糖 Hyperglycemia(6)	09DEC20[redacted] (149)	16DEC20[redacted] (156)	8	4	No/ No/ Yes	Drug Interrupted/ Dose Not Changed/ Dose Reduced	Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 442029[redacted] ; Randomized Date: 08AUG20[redacted]; First Dose Date: 09AUG20[redacted]; Last Dose Date: 05FEB20[redacted] **								
一般・全身障害および投与部位の状態 発熱 Fever(1)	11AUG20[redacted] (4)	13AUG20[redacted] (6)	3	1	No/ Yes/ No	Dose Not Changed/ Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
心臓障害 心室性不整脈 Ventricular arrhythmia(2)	11AUG20[redacted] (4)	18AUG20[redacted] (11)	8	1	No/ Yes/ No	Dose Not Changed/ Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
一般・全身障害および投与部位の状態 無力症 Weakness(5)	06SEP20[redacted] (30)	13SEP20[redacted] (37)	8	3	No/ Yes/ No	Dose Not Changed/ Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
臨床検査 体重減少 Weight loss(14)	18OCT20[redacted] (72)	21OCT20[redacted] (75)	4	2	Yes/ Yes/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 好中球減少症 Neutropenia(15)	20OCT20[redacted] (74)	21OCT20[redacted] (75)	2	4	No/ Yes/ No	Dose Not Changed/ Dose Reduced/Drug Interrupted/ Dose Not Changed	Hospitalization	Recovered/ Resolved With Sequelae
胃腸障害 イレウス Ileus(17)	26NOV20[redacted] (111)	02DEC20[redacted] (117)	7	4	No/ No/ No	Dose Not Changed/ Dose Delayed/ Dose Delayed	Hospitalization	Recovered/ Resolved
一般・全身障害および投与部位の状態 発熱 Status febrilis(26)	08MAY20[redacted] (275) *	14MAY20[redacted] (281) *	7	2	Yes/ No/ No	Dose Not Changed/ Dose Reduced/Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved

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表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 43）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
血液およびリンパ系障害 血小板減少症 Thrombocytopenia(28)	08MAY20[redacted] (275) *	14MAY20[redacted] (281) *	7	4	No/ Yes/ No	Dose Not Changed/ Dose Reduced/Drug Interrupted/ Dose Not Changed	Hospitalization	Recovered/ Resolved
傷害、中毒および処置合併症 外傷性骨折 Traumatic fracture(31)	06SEP20[redacted] (396) *	14SEP20[redacted] (404) *	9	4	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Dose Not Changed	Hospitalization	Recovered/ Resolved
胃腸障害 イレウス Ileus(34)	30NOV20[redacted] (481) *	15DEC20[redacted] (496) *	16	4	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Hospitalization	Recovered/ Resolved
傷害、中毒および処置合併症 大腿骨骨折 Femoral fracture(36)	16JAN20[redacted] (528) **	02FEB20[redacted] (545) **	18	4	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 442029[redacted] ; Randomized Date: 03NOV20[redacted]; First Dose Date: 07NOV20[redacted]; Last Dose Date: 10JUN20[redacted]#								
代謝および栄養障害 高血糖 Hyperglycemia(2)	13FEB20[redacted] (103) *	28FEB20[redacted] (118) *	16	4	No/ No/ Yes	Drug Interrupted/ Drug Interrupted/ Dose Reduced	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 463019[redacted] ; Randomized Date: 06NOV20[redacted]; First Dose Date: 09NOV20[redacted]; Last Dose Date: 11JUN20[redacted]#								
臨床検査 眼圧上昇 Elevated intraocular pressure(3)	14AUG20[redacted] (283) *	15AUG20[redacted] (284) *	2	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
感染症および寄生虫症 胃腸炎 Acute gastroenteritis(4)	06AUG20[redacted] (640) **	12AUG20[redacted] (646) **	7	2	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
胃腸障害 腹痛 Abdominal pain(7)	17MAR20[redacted] (863) #	21MAR20[redacted] (867) #	5	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 463029[redacted] ; Randomized Date: 28FEB20[redacted]; First Dose Date: 01MAR20[redacted]; Last Dose Date: 20NOV20[redacted]*								
傷害、中毒および処置合併症 交通事故 Motorcycle crash accident(4)	28SEP20[redacted] (213)	03OCT20[redacted] (218)	6	1	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	None	Recovered/ Resolved
一般・全身障害および投与部位の状態 発熱 Fever of unknown origin(5)	22DEC20[redacted] (298)	30DEC20[redacted] (306)	9	2	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ 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，
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表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 44）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
一般・全身障害および投与部位の状態 発熱 Fever of unknown origin(6)	18FEB20[redacted] (356) *	02MAR20[redacted] (369) *	14	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ 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 of unknown origin(7)	11MAR20[redacted] (378) *	14MAR20[redacted] (381) *	4	2	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 化膿性胆管炎 Cholangiosepsis(8)	21MAY20[redacted] (449) *	01JUN20[redacted] (460) *	12	2	No/ No/ No	Dose Delayed/ Dose Delayed/ Dose Delayed	Conmeds/ Hospitalization	Recovered/ Resolved
肝胆道系障害 胆管炎 Cholangitis(9)	20OCT20[redacted] (601) *	29OCT20[redacted] (610) *	10	2	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 心内膜炎 Endocarditis(10)	07NOV20[redacted] (619) *	20NOV20[redacted] (632) *	14	5	No/ No/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Hospitalization	Fatal
Treatment Randmizen: CRd ; Subject ID: 463029[redacted] ; Randomized Date: 04MAR20[redacted]; First Dose Date: 07MAR20[redacted]; Last Dose Date: 10MAR20[redacted]								
感染症および寄生虫症 上気道感染 Upper airway tract infection(1)	09MAR20[redacted] (6)	11MAR20[redacted] (8)	3	5	No/ No/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Hospitalization	Fatal
Treatment Randmizen: CRd ; Subject ID: 463029[redacted] ; Randomized Date: 04MAR20[redacted]; First Dose Date: 07MAR20[redacted]; Last Dose Date: 14FEB20[redacted] *								
感染症および寄生虫症 肺炎 Pneumonia(2)	05DEC20[redacted] (277)	23DEC20[redacted] (295)	19	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 463029[redacted] ; Randomized Date: 05DEC20[redacted]; First Dose Date: 06DEC20[redacted]; Last Dose Date: 10JUN20[redacted] #								
感染症および寄生虫症 気管支炎 Acute bronchitis(1)	15DEC20[redacted] (11)	22DEC20[redacted] (18)	8	2	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺炎 Pneumonia(2)	25SEP20[redacted] (296) *	03OCT20[redacted] (304) *	9	2	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 463039[redacted] ; Randomized Date: 30MAR20[redacted]; First Dose Date: 31MAR20[redacted]; Last Dose Date: 05SEP20[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） 基底細胞癌 Basocellular cancer of the skin of the face(9)	28NOV20[redacted] (244)	28NOV20[redacted] (244)	1	1	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required	Recovered/ Resolved

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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＊＊　：「翌々年」を意味する
#　：「3年後」を意味する

表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 45）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
Treatment Randmizen: CRd ; Subject ID: 463039[redacted] ; Randomized Date: 29JUL20[redacted]; First Dose Date: 01AUG20[redacted]; Last Dose Date: 30MAR20[redacted]#								
胃腸障害 下痢 Diarrhoea(45)	09SEP20[redacted] (409) *	13SEP20[redacted] (413) *	5	2	No/ No/ Yes	Dose Not Changed/ Drug Interrupted/ Dose Delayed	Conmeds	Recovered/ Resolved
感染症および寄生虫症 サルモネラ性敗血症 Salmonella sepsis(77)	30APR20[redacted] (642) **	10MAY20[redacted] (652) **	11	3	No/ NA/ Yes	NA/ Dose Delayed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
腎および尿路障害 腎機能障害 Worsening of renal function(103)	02JAN20[redacted] (889) #	09JAN20[redacted] (896) #	8	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 インフルエンザ性肺炎 Pneumonia caused by influenza a virus(108)	31MAR20[redacted] (977) #	06APR20[redacted] (983) #	7	4	NA/ Yes/ Yes	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Not Recovered/ Not Resolved
呼吸器、胸郭および縦隔障害 急性呼吸窮迫症候群 Acute respiratory distress syndrome(109)	06APR20[redacted] (983) #	06APR20[redacted] (983) #	1	5	No/ No/ No	Dose Not Changed/ Drug Withdrawn/ Drug Withdrawn	None	Fatal
Treatment Randmizen: CRd ; Subject ID: 463039[redacted] ; Randomized Date: 29JUL20[redacted]; First Dose Date: 01AUG20[redacted]; Last Dose Date: 26MAY20[redacted]#								
一般・全身障害および投与部位の状態 発熱 Fever(1)	17AUG20[redacted] (20)	19AUG20[redacted] (22)	3	2	Yes/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
血管障害 深部静脈血栓症 Deep venous thrombosis of the right lower extremity(9)	01JUN20[redacted] (309) *	19JUN20[redacted] (327) *	19	3	No/ Yes/ Yes	Dose Delayed/Drug Interrupted/ Dose Delayed/Drug Interrupted/ Dose Delayed/Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved With Sequelae
感染症および寄生虫症 気管支炎 Acut bronchitis(23)	05JAN20[redacted] (527) **	11JAN20[redacted] (533) **	7	2	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 463039[redacted] ; Randomized Date: 26OCT20[redacted]; First Dose Date: 27OCT20[redacted]; Last Dose Date: 10JAN20[redacted] *								
感染症および寄生虫症 敗血症性ショック Septic shock(1)	11JAN20[redacted] (78) *	19JAN20[redacted] (86) *	9	4	No/ No/ Yes	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Procedure Required/ Hospitalization	Not Recovered/ Not Resolved
心臓障害 急性心不全 Acute heart failure(4)	17JAN20[redacted] (84) *	19JAN20[redacted] (86) *	3	5	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required	Fatal

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表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 46）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
Treatment Randmizen: CRd ; Subject ID: 463039[redacted] ; Randomized Date: 26OCT20[redacted] ; First Dose Date: 26OCT20[redacted] ; Last Dose Date: 27SEP20[redacted] *								
肝胆道系障害 急性胆嚢炎 Cholecystitis acuta calculosa(8)	31MAR20[redacted] (158) *	06APR20[redacted] (164) *	7	2	No/ No/ Yes	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Not Recovered/ Not Resolved
Treatment Randmizen: CRd ; Subject ID: 463039[redacted] ; Randomized Date: 23NOV20[redacted] ; First Dose Date: 24NOV20[redacted] ; Last Dose Date: 28MAY20[redacted] #								
腎および尿路障害 急性腎不全 Acute renal failure(38)	13MAR20[redacted] (842) #	17MAR20[redacted] (846) #	5	3	No/ Yes/ Yes	Dose Not Changed/ Dose Delayed/ Dose Delayed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 463049[redacted] ; Randomized Date: 30MAR20[redacted] ; First Dose Date: 31MAR20[redacted] ; Last Dose Date: 05OCT20[redacted]								
感染症および寄生虫症 術後膿瘍 Peristomal abscess(5)	06OCT20[redacted] (191)	19OCT20[redacted] (204)	14	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Procedure Required/ Hospitalization	Recovered/ Resolved With Sequelae
Treatment Randmizen: CRd ; Subject ID: 463049[redacted] ; Randomized Date: 01NOV20[redacted] ; First Dose Date: 03NOV20[redacted] ; Last Dose Date: 05JUN20[redacted] #								
胃腸障害 下痢 Diarrhoea(12)	13NOV20[redacted] (379) *	22NOV20[redacted] (388) *	10	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
心臓障害 心筋梗塞 Myocardial infarction(13)	29NOV20[redacted] (395) *	06DEC20[redacted] (402) *	8	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved With Sequelae
Treatment Randmizen: CRd ; Subject ID: 463049[redacted] ; Randomized Date: 07FEB20[redacted] ; First Dose Date: 08FEB20[redacted] ; Last Dose Date: 21MAR20[redacted]								
感染症および寄生虫症 気管支炎 Bronchitis(2)	20MAR20[redacted] (43)	27MAR20[redacted] (50)	8	3	No/ No/ No	Drug Interrupted/ Dose Not Changed/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 463069[redacted] ; Randomized Date: 28MAR20[redacted] ; First Dose Date: 31MAR20[redacted] ; Last Dose Date: 29DEC20[redacted]								
精神障害 自殺既遂 Committed suicide(11)	03JAN20[redacted] (282) *	03JAN20[redacted] (282) *	1	5	No/ No/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	None	Fatal
Treatment Randmizen: CRd ; Subject ID: 463069[redacted] ; Randomized Date: 07DEC20[redacted] ; First Dose Date: 12DEC20[redacted] ; Last Dose Date: 19MAY20[redacted] #								
感染症および寄生虫症 肺炎 Pneumonia(12)	26SEP20[redacted] (295) *	08OCT20[redacted] (307) *	13	3	No/ Yes/ Yes	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 463069[redacted] ; Randomized Date: 10FEB20[redacted] ; First Dose Date: 15FEB20[redacted] ; Last Dose Date: 26JUN20[redacted] *								

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
#　：「3年後」を意味する

表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 47）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
呼吸器、胸郭および縦隔障害 肺塞栓症 Embolia pulmonum(4)	19OCT20[redacted] (253)	31OCT20[redacted] (265)	13	4	Yes/ Yes/ Yes	Drug Interrupted/ Dose Delayed/ Drug Interrupted	Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 463069[redacted] ; Randomized Date: 10FEB20[redacted] ; First Dose Date: 15FEB20[redacted] ; Last Dose Date: 03OCT20[redacted]								
傷害、中毒および処置合併症 硬膜下血腫 Subdural haematoma(3)	04OCT20[redacted] (238)	10OCT20[redacted] (244)	7	5	No/ No/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Procedure Required/ Hospitalization	Fatal
Treatment Randmizen: CRd ; Subject ID: 463079[redacted] ; Randomized Date: 18JUL20[redacted] ; First Dose Date: 20JUL20[redacted] ; Last Dose Date: 06OCT20[redacted]								
皮膚および皮下組織障害 発疹 Skin rash(1)	31JUL20[redacted] (14)	09AUG20[redacted] (23)	10	2	No/ Yes/ No	Dose Not Changed/ Dose Reduced/Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved With Sequelae
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） 結腸癌 Colon cancer(6)	14OCT20[redacted] (89)			4	No/ No/ No	Drug Withdrawn/Drug Interrupted/ Drug Withdrawn/Drug Interrupted/ Drug Withdrawn/Drug Interrupted	Procedure Required/ Hospitalization	Not Recovered/ Not Resolved
神経系障害 脳血管発作 Stroke(7)	29OCT20[redacted] (104)	11NOV20[redacted] (117)	14	4	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved With Sequelae
Treatment Randmizen: CRd ; Subject ID: 463079[redacted] ; Randomized Date: 03SEP20[redacted] ; First Dose Date: 13SEP20[redacted] ; Last Dose Date: 29MAY20[redacted]**								
呼吸器、胸郭および縦隔障害 誤嚥性肺炎 Aspiration pneumonia(2)	06JAN20[redacted] (126) *	11JAN20[redacted] (131) *	6	2	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 気管支炎 Bronchitis(7)	07MAR20[redacted] (187) *	19MAR20[redacted] (199) *	13	2	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 気管支炎 Bronchitis acuta(9)	04MAY20[redacted] (245) *	17MAY20[redacted] (258) *	14	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 463079[redacted] ; Randomized Date: 24NOV20[redacted] ; First Dose Date: 28NOV20[redacted] ; Last Dose Date: 21AUG20[redacted]*								
感染症および寄生虫症 肺炎 Pneumonia(8)	30MAY20[redacted] (189) *	01JUN20[redacted] (191) *	3	1	No/ Yes/ No	Drug Interrupted/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required	Recovered/ Resolved

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表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 48）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
感染症および寄生虫症 敗血症 Sepsis(12)	01SEP20[redacted] (283) *	02SEP20[redacted] (284) *	2	5	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds	Fatal
Treatment Randmizen: CRd ; Subject ID: 463079[redacted] ; Randomized Date: 11JAN20[redacted] ; First Dose Date: 13JAN20[redacted] ; Last Dose Date: 04MAY20[redacted] *								
呼吸器、胸郭および縦隔障害 肺臓炎 Pneumonitis(11)	31OCT20[redacted] (295)	07NOV20[redacted] (302)	8	3	No/ Yes/ No	Dose Not Changed/ Drug Withdrawn/ Dose Not Changed	Conmeds/ Procedure Required	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 463089[redacted] ; Randomized Date: 01DEC20[redacted] ; First Dose Date: 05DEC20[redacted] ; Last Dose Date: 07DEC20[redacted]								
心臓障害 心肺不全 Cardiorespiratoric insufficiency(4)	07DEC20[redacted] (7)	08DEC20[redacted] (8)	2	5	No/ No/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Procedure Required/ Hospitalization	Fatal
Treatment Randmizen: CRd ; Subject ID: 463099[redacted] ; Randomized Date: 19OCT20[redacted] ; First Dose Date: 24OCT20[redacted] ; Last Dose Date: 27MAY20[redacted] #								
生殖系および乳房障害 精巣上体炎 Epididymitis(4)	01NOV20[redacted] (380) *	19NOV20[redacted] (398) *	19	3	No/ No/ No	Drug Interrupted/ Dose Not Changed/ Drug Interrupted	Conmeds/ Procedure Required	Recovered/ Resolved
感染症および寄生虫症 精巣膿瘍 Abscessus of testis(5)	03DEC20[redacted] (412) *	06DEC20[redacted] (415) *	4	3	No/ No/ No	Drug Interrupted/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved With Sequelae
感染症および寄生虫症 切開部位感染 Suppuration in surgical region(6)	22DEC20[redacted] (431) *	04JAN20[redacted] (444) **	14	3	No/ No/ No	Drug Interrupted/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved With Sequelae
感染症および寄生虫症 肺炎 Pneumonia(16)	17APR20[redacted] (912) #	25APR20[redacted] (920) #	9	3	NA/ Yes/ Yes	NA/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 463099[redacted] ; Randomized Date: 27NOV20[redacted] ; First Dose Date: ; Last Dose Date:								
血液およびリンパ系障害 貧血 Anaemia(1)	08NOV20[redacted] (-19)	14NOV20[redacted] (-13)	7	2	NA/ NA/ NA	NA/ NA/ NA	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 494269[redacted] ; Randomized Date: 21JAN20[redacted] ; First Dose Date: 24JAN20[redacted] ; Last Dose Date: 26NOV20[redacted] *								
傷害、中毒および処置合併症 大腿骨骨折 Intertrochanderic hip fracture(1)	21MAR20[redacted] (60)	05APR20[redacted] (75)	16	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 気道感染 Respiratory track infection(36)	14SEP20[redacted] (603) *	01OCT20[redacted] (620) *	18	3	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved With Sequelae

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表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 49）

System Organ Class PERFFERED TERM Reported Term (AE #)	Start Date (#Days from First Dose)	End Date (#Days from First Dose)	Duration (days)	CTCAE Grade	Related to C/R/d	Action Taken with C/R/d	Other Action Taken	Outcome
Treatment Randmizen: CRd ; Subject ID: 494269[redacted] ; Randomized Date: 13MAY20[redacted]; First Dose Date: 16MAY20[redacted]; Last Dose Date: 04NOV20[redacted] **								
呼吸器、胸郭および縦隔障害 肺水腫 Pulmonary oedema(4)	04JAN20[redacted] (237) *	10JAN20[redacted] (243) *	7	3	No/ No/ Yes	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
一般・全身障害および投与部位の状態 疲労 Fatigue(19)	06DEC20[redacted] (939) **	12DEC20[redacted] (945) **	7	3	NA/ No/ No	NA/ Dose Delayed/ Dose Delayed	Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 494269[redacted] ; Randomized Date: 03JUN20[redacted]; First Dose Date: 06JUN20[redacted]; Last Dose Date: 19AUG20[redacted] **								
感染症および寄生虫症 気道感染 Respiratory track infection(1)	10OCT20[redacted] (130)	19OCT20[redacted] (139)	10	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 494269[redacted] ; Randomized Date: 26JUL20[redacted]; First Dose Date: 27JUL20[redacted]; Last Dose Date: 13MAR20[redacted] **								
傷害、中毒および処置合併症 股関節部骨折 Left hip bone fracture(26)	14AUG20[redacted] (386) *	01SEP20[redacted] (404) *	19	4	No/ No/ No	Dose Delayed/Drug Interrupted/ Dose Delayed/Drug Interrupted/ Dose Delayed/Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 気道感染 Respiratory track infection(39)	15APR20[redacted] (630) **	22AUG20[redacted] (759) **	130	5	No/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Hospitalization	Fatal
Treatment Randmizen: CRd ; Subject ID: 494269[redacted] ; Randomized Date: 03OCT20[redacted]; First Dose Date: 04OCT20[redacted]; Last Dose Date: 27MAR20[redacted] *								
呼吸器、胸郭および縦隔障害 肺水腫 Pulmonary oedema(1)	16NOV20[redacted] (45)	19NOV20[redacted] (48)	4	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
心臓障害 心房細動 Paroxysmal atrial fibrilation(2)	17NOV20[redacted] (46)	18NOV20[redacted] (47)	2	2	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺炎 Pneumonia(21)	19FEB20[redacted] (140) *	05MAR20[redacted] (155) *	16	2	No/ No/ No	Dose Delayed/ Dose Delayed/ Dose Delayed	Conmeds/ Hospitalization	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 急性呼吸窮迫症候群 Acute respiratory distress syndrome(25)	30MAR20[redacted] (180) *	02APR20[redacted] (183) *	4	5	No/ No/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Hospitalization	Fatal
Treatment Randmizen: CRd ; Subject ID: 494269[redacted] ; Randomized Date: 07OCT20[redacted]; First Dose Date: 10OCT20[redacted]; Last Dose Date: 17FEB20[redacted] **								

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