表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 50）

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(6)	18FEB20[redacted] (501) **	20FEB20[redacted] (503) **	3	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: 30OCT20[redacted]; First Dose Date: 01NOV20[redacted]; Last Dose Date: 16JUN20[redacted]#								
感染症および寄生虫症 気道感染 Respiratory infection(2)	10FEB20[redacted] (104) *	13FEB20[redacted] (107) *	4	2	No/ Yes/ No	Drug Interrupted/ Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 494269[redacted]; Randomized Date: 30NOV20[redacted]; First Dose Date: 01DEC20[redacted]; Last Dose Date: 03FEB20[redacted]*								
感染症および寄生虫症 下気道感染 Lower respiratory track infection(1)	11DEC20[redacted] (12)	15DEC20[redacted] (16)	5	2	No/ No/ No	Drug Interrupted/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 494269[redacted]; Randomized Date: 05DEC20[redacted]; First Dose Date: 08DEC20[redacted]; Last Dose Date: 16JUN20[redacted]#								
胃腸障害 下部消化管出血 Lower gastrointestinal hemorrhage(12)	30JAN20[redacted] (57) *	01FEB20[redacted] (59) *	3	2	No/ No/ Yes	Dose Delayed/ Dose Reduced/Dose Delayed/ Dose Delayed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 気道感染 Respiratory infection(13)	11FEB20[redacted] (69) *	15FEB20[redacted] (73) *	5	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 494269[redacted]; Randomized Date: 25JAN20[redacted]; First Dose Date: 30JAN20[redacted]; Last Dose Date: 14MAY20[redacted]								
感染症および寄生虫症 気道感染 Respiratory infection(1)	02MAR20[redacted] (38)	06MAR20[redacted] (42)	5	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
心臓障害 心房細動 Atrial fibrilation(2)	04MAR20[redacted] (40)	05MAR20[redacted] (41)	2	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 494269[redacted]; Randomized Date: 06FEB20[redacted]; First Dose Date: 09FEB20[redacted]; Last Dose Date: 30MAY20[redacted]								
感染症および寄生虫症 胃腸炎 Febrile gastrenteritis(6)	03JUN20[redacted] (119)	[ONGOING] (-)		4	No/ No/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Hospitalization	Not Recovered/ Not Resolved
一般・全身障害および投与部位の状態 発熱 Fever up to 38.6 c(8)	06JUN20[redacted] (122)	11JUN20[redacted] (127)	6	1	No/ No/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ 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 51）

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(7)	17JUN20[redacted] (133)	17JUN20[redacted] (133)	1	5	No/ No/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Hospitalization	Fatal
Treatment Randmizen: CRd ; Subject ID: 494269[redacted] ; Randomized Date: 09FEB20[redacted]; First Dose Date: 13FEB20[redacted]; Last Dose Date: 13SEP20[redacted]								
呼吸器、胸郭および縦隔障害 肺水腫 Pulmonary oedema(1)	24FEB20[redacted] (16)	26FEB20[redacted] (18)	3	3	No/ No/ Yes	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
心臓障害 心不全 Cardiac failure(11)	12SEP20[redacted] (217)	17OCT20[redacted] (252)	36	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required	Recovered/ Resolved With Sequelae
Treatment Randmizen: CRd ; Subject ID: 516519[redacted]; Randomized Date: 11JUL20[redacted]; First Dose Date: 12JUL20[redacted]; Last Dose Date: 14JUN20[redacted]*								
血管障害 深部静脈血栓症 Acute thrombosis of deep veins of the left lower extremity(1)	15FEB20[redacted] (220) *	28FEB20[redacted] (233) *	14	3	No/ Yes/ Yes	Drug Interrupted/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Hospitalization	Recovered/ Resolved With Sequelae
Treatment Randmizen: CRd ; Subject ID: 516519[redacted]; Randomized Date: 11JUL20[redacted]; First Dose Date: 12JUL20[redacted]; Last Dose Date: 14NOV20[redacted]*								
血管障害 血栓性静脈炎 Thrombophlebitis of subcutaneous veins of right shank(1)	20SEP20[redacted] (72)	05OCT20[redacted] (87)	16	3	No/ Yes/ Yes	Dose Delayed/Drug Interrupted/ Drug Withdrawn/Drug Interrupted/ Drug Withdrawn/Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved With Sequelae
Treatment Randmizen: CRd ; Subject ID: 516529[redacted]; Randomized Date: 11JUL20[redacted]; First Dose Date: 13JUL20[redacted]; Last Dose Date: 04JUN20[redacted]#								
感染症および寄生虫症 気管支炎 Exacerbation of bronchitis(3)	19FEB20[redacted] (590) **	01MAR20[redacted] (600) **	11	3	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Conmeds	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 516529[redacted]; Randomized Date: 24SEP20[redacted]; First Dose Date: 26SEP20[redacted]; Last Dose Date: 16JUN20[redacted]#								
呼吸器、胸郭および縦隔障害 肺塞栓症 Early signs of pulmonary thromboembolisme(1)	14DEC20[redacted] (82)	17DEC20[redacted] (85)	4	3	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Hospitalization	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 肺塞栓症 Pulmonary thromboembolisme(2)	20DEC20[redacted] (88)	13JAN20[redacted] (112) *	25	3	No/ Yes/ Yes	Dose Delayed/ Dose Reduced/Drug Interrupted/ Dose Reduced/Dose Delayed	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
#　：「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 52）

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 Pulmonary thromboembolisme(7)	10DEC20[redacted] (444) *	26DEC20[redacted] (460) *	17	2	No/ No/ No	Drug Interrupted/ Drug Interrupted/ NA	Conmeds/ Hospitalization	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 肺塞栓症 Pulmonary thromboembolizme(10)	14FEB20[redacted] (875) #	28FEB20[redacted] (889) #	15	2	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved With Sequelae
Treatment Randmizen: CRd ; Subject ID: 516539[redacted] ; Randomized Date: 17JAN20[redacted] ; First Dose Date: 18JAN20[redacted] ; Last Dose Date: 12SEP20[redacted] *								
代謝および栄養障害 腫瘍崩壊症候群 Tumor lysis syndrome(1)	10FEB20[redacted] (25)	15FEB20[redacted] (30)	6	3	Yes/ Yes/ Yes	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 516579[redacted] ; Randomized Date: 14FEB20[redacted] ; First Dose Date: 16FEB20[redacted] ; Last Dose Date: 06MAY20[redacted] *								
感染症および寄生虫症 肺炎 Pneumonia in s2,s6 of right lung(3)	25SEP20[redacted] (225)	03OCT20[redacted] (233)	9	2	No/ No/ No	Dose Not Changed/ Dose Delayed/ Dose Delayed	Conmeds	Recovered/ Resolved With Sequelae
感染症および寄生虫症 ニューモシスティスジロヴェシ肺炎 Pneumocystis pneumonia(4)	18OCT20[redacted] (248)	11NOV20[redacted] (272)	25	2	No/ No/ Yes	Drug Interrupted/ Dose Not Changed/ Drug Interrupted	Conmeds/ Procedure Required	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 516589[redacted] ; Randomized Date: 29AUG20[redacted] ; First Dose Date: 31AUG20[redacted] ; Last Dose Date: 05MAR20[redacted] #								
呼吸器、胸郭および縦隔障害 胞隔炎 Toxic alveolitis(2)	13AUG20[redacted] (716) **	27AUG20[redacted] (730) **	15	3	NA/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 516589[redacted] ; Randomized Date: 05SEP20[redacted] ; First Dose Date: 07SEP20[redacted] ; Last Dose Date: 06MAR20[redacted] *								
感染症および寄生虫症 肺炎 Pneumonia acuta(1)	07MAR20[redacted] (185) *	12MAR20[redacted] (190) *	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） 形質細胞腫 Plasmacytoma(2)	12MAR20[redacted] (190) *			3	No/ No/ No	Drug Interrupted/ Dose Delayed/ Dose Delayed	Conmeds/ Hospitalization	Unknown
Treatment Randmizen: CRd ; Subject ID: 516589[redacted] ; Randomized Date: 25SEP20[redacted] ; First Dose Date: 26SEP20[redacted] ; Last Dose Date: 26MAY20[redacted] #								
胃腸障害 急性膵炎 Pancreatitis acuta(2)	07APR20[redacted] (196) *	16APR20[redacted] (205) *	10	3	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 516589[redacted] ; Randomized Date: 25SEP20[redacted] ; First Dose Date: 28SEP20[redacted] ; Last Dose Date: 22AUG20[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 53）

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 acuta(3)	29AUG20[redacted] (340) *	10SEP20[redacted] (352) *	13	3	No/ No/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 516589[redacted] ; Randomized Date: 11OCT20[redacted] ; First Dose Date: 12OCT20[redacted] ; Last Dose Date: 16JUN20[redacted] #								
感染症および寄生虫症 肺炎 Pneumonia acuta(1)	07FEB20[redacted] (486) **	01MAR20[redacted] (508) **	23	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
肝胆道系障害 中毒性肝炎 Toxic hepatitis(2)	15APR20[redacted] (918) #	23MAY20[redacted] (956) #	39	4	No/ Yes/ Yes	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved With Sequelae
Treatment Randmizen: CRd ; Subject ID: 516589[redacted] ; Randomized Date: 15NOV20[redacted] ; First Dose Date: 16NOV20[redacted] ; Last Dose Date: 29JUL20[redacted] *								
血液およびリンパ系障害 発熱性好中球減少症 Fibrile neutropenia(3)	25JUN20[redacted] (224) *	18JUL20[redacted] (247) *	24	3	No/ Yes/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
神経系障害 頭蓋内出血 Intracranial hemorrhage(5)	30JUL20[redacted] (259) *	30JUL20[redacted] (259) *	1	5	Yes/ Yes/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Conmeds	Fatal
Treatment Randmizen: CRd ; Subject ID: 516589[redacted] ; Randomized Date: 14FEB20[redacted] ; First Dose Date: 15FEB20[redacted] ; Last Dose Date: 28MAY20[redacted] **								
神経系障害 失神 Syncope(1)	01MAR20[redacted] (17)	05MAR20[redacted] (21)	5	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 826019[redacted] ; Randomized Date: 21JAN20[redacted] ; First Dose Date: 24JAN20[redacted] ; Last Dose Date: 31MAR20[redacted]								
胃腸障害 消化性潰瘍 Peptic ulcer(1)	06JAN20[redacted] (-15)	24JAN20[redacted] (4)	19	4	NA/ NA/ NA	NA/ NA/ NA	Conmeds/ Hospitalization	Recovered/ Resolved With Sequelae
代謝および栄養障害 低アルブミン血症 Hypoalbuminemia(10)	14FEB20[redacted] (25)	24FEB20[redacted] (35)	11	3	Yes/ Yes/ Yes	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
胃腸障害 腸閉塞 Intestinal obstruction(2)	08MAR20[redacted] (47)	16MAR20[redacted] (55)	9	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
代謝および栄養障害 低カルシウム血症 Hypocalcemia(4)	21MAR20[redacted] (60)	09APR20[redacted] (79)	20	4	Yes/ Yes/ Yes	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 826029[redacted] ; Randomized Date: 21JUN20[redacted] ; First Dose Date: 23JUN20[redacted] ; Last Dose Date: 03AUG20[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 54）

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
腎および尿路障害 急性腎不全 Acute renal failure(1)	30JUL20[redacted] (406) *	24AUG20[redacted] (431) *	26	3	No/ No/ No	Dose Not Changed/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 826029[redacted] ; Randomized Date: 02JAN20[redacted]; First Dose Date: 04JAN20[redacted]; Last Dose Date: 27MAR20[redacted]*								
感染症および寄生虫症 肺炎 Pneumonia(10)	16OCT20[redacted] (289)	22OCT20[redacted] (295)	7	2	Yes/ No/ Yes	Drug Interrupted/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺炎 Pneumonia(11)	07DEC20[redacted] (341)	16DEC20[redacted] (350)	10	3	Yes/ Yes/ Yes	Drug Interrupted/ Drug Interrupted/ Dose Reduced	Conmeds/ 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 diarrhea with clostridium difficile(12)	11DEC20[redacted] (345)	27DEC20[redacted] (361)	17	3	No/ No/ Yes	Drug Interrupted/ Drug Interrupted/ Dose Reduced	Conmeds/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 血小板減少症 Trombocitopenia(13)	11DEC20[redacted] (345)	08JAN20[redacted] (373) *	29	4	Yes/ Yes/ No	Drug Interrupted/ Drug Withdrawn/Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
心臓障害 心不全 Heart failure(15)	21MAR20[redacted] (445) *	01APR20[redacted] (456) *	12	3	No/ No/ No	Drug Interrupted/ NA/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Not Recovered/ Not Resolved
Treatment Randmizen: CRd ; Subject ID: 826049[redacted] ; Randomized Date: 02JUL20[redacted]; First Dose Date: 05JUL20[redacted]; Last Dose Date: 16JUN20[redacted]#								
感染症および寄生虫症 肺炎 Pneumonia(1)	19FEB20[redacted] (233) *	29FEB20[redacted] (243) *	11	3	No/ No/ No	Drug Interrupted/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 826049[redacted] ; Randomized Date: 05OCT20[redacted]; First Dose Date: 06OCT20[redacted]; Last Dose Date: 12OCT20[redacted]								
感染症および寄生虫症 気管支肺炎 Bronchopneumonia(4)	14OCT20[redacted] (10)	24OCT20[redacted] (20)	11	5	No/ No/ No	Drug Withdrawn/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Hospitalization	Fatal
Treatment Randmizen: CRd ; Subject ID: 896269[redacted] ; Randomized Date: 17OCT20[redacted]; First Dose Date: 20OCT20[redacted]; Last Dose Date: 08MAR20[redacted]**								
感染症および寄生虫症 肺炎 Pleuropneumonia of the left lung(8)	15OCT20[redacted] (365) *	23OCT20[redacted] (373) *	9	3	No/ No/ Yes	Dose Not Changed/ Dose Not Changed/ Dose Delayed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 896279[redacted] ; Randomized Date: 19JUL20[redacted]; First Dose Date: 21JUL20[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 55）

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 慢性閉塞性肺疾患 Chronic obstructive lung disease(8)	13OCT20[redacted] (87)	21OCT20[redacted] (95)	9	2	No/ No/ No	Dose Delayed/ Dose Delayed/ Dose Delayed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺炎 Pneumonia(10)	19FEB20[redacted] (216) *	28FEB20[redacted] (225) *	10	2	No/ No/ No	Drug Interrupted/ Dose Not Changed/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
眼障害 白内障 Cataracta(18)	04APR20[redacted] (626) **	[ONGOING] (-)		4	No/ No/ Yes	NA/ Dose Not Changed/ Drug Withdrawn	None	Not Recovered/ Not Resolved
Treatment Randmizen: CRd ; Subject ID: 896279[redacted] ; Randomized Date: 01NOV20[redacted] ; First Dose Date: 03NOV20[redacted] ; Last Dose Date: 05JUN20[redacted] #								
呼吸器、胸郭および縦隔障害 慢性気管支炎 Exacerbation of chronic obstructive bronchitis(3)	25JAN20[redacted] (86) *	30JAN20[redacted] (91) *	6	2	No/ No/ No	Drug Interrupted/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
眼障害 白内障 Cataracta(16)	18MAR20[redacted] (504) **	[ONGOING] (-)		4	No/ No/ Yes	NA/ Dose Not Changed/ Dose Reduced	Procedure Required/ Hospitalization	Not Recovered/ Not Resolved
Treatment Randmizen: CRd ; Subject ID: 896289[redacted] ; Randomized Date: 28DEC20[redacted] ; First Dose Date: 04JAN20[redacted] ; Last Dose Date: 04JAN20[redacted]								
心臓障害 急性心筋梗塞 Acute myocardial infarction(2)	05JAN20[redacted] (9)	16JAN20[redacted] (20)	12	3	No/ NA/ No	Drug Withdrawn/ NA/ Drug Withdrawn	Hospitalization	Recovered/ Resolved With Sequelae
Treatment Randmizen: CRd ; Subject ID: 896289[redacted] ; Randomized Date: 16FEB20[redacted] ; First Dose Date: 22FEB20[redacted] ; Last Dose Date: 11JUN20[redacted] **								
血管障害 深部静脈血栓症 Deep vein thrombosis(1)	18JUN20[redacted] (124)	22JUN20[redacted] (128)	5	2	No/ Yes/ No	Dose Not Changed/ Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 896299[redacted] ; Randomized Date: 20APR20[redacted] ; First Dose Date: 21APR20[redacted] ; Last Dose Date: 09SEP20[redacted] **								
一般・全身障害および投与部位の状態 疾患進行 Progressive disease(16)	01OCT20[redacted] (896) **	10OCT20[redacted] (905) **	10	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	None	Recovered/ Resolved
Treatment Randmizen: CRd ; Subject ID: 896299[redacted] ; Randomized Date: 09DEC20[redacted] ; First Dose Date: 13DEC20[redacted] ; Last Dose Date: 11MAR20[redacted] #								
呼吸器、胸郭および縦隔障害 肺塞栓症 Pulmonary thromboembolism(5)	30NOV20[redacted] (358) *	17DEC20[redacted] (375) *	18	3	No/ Yes/ No	Drug Interrupted/ Dose Delayed/Drug Withdrawn/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
＊＊　：「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 56）

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 意識消失 Loss of consciousness(11)	01JUL20[redacted] (571) **	04JUL20[redacted] (574) **	4	3	No/ No/ No	Dose Not Changed/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 103809[redacted] ; Randomized Date: 11JUL20[redacted]; First Dose Date: 13JUL20[redacted]; Last Dose Date: 12JAN20[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 Worsening basal cell carcinoma temple right(16)	12DEC20[redacted] (521) *	12DEC20[redacted] (521) *	1	2	NA/ No/ NA	NA/ Dose Not Changed/ NA	Procedure Required	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 103819[redacted] ; Randomized Date: 01SEP20[redacted]; First Dose Date: 05SEP20[redacted]; Last Dose Date: 30JUL20[redacted]*								
感染症および寄生虫症 肺炎 Pneumonia(16)	07DEC20[redacted] (98)	16DEC20[redacted] (107)	10	3	NA/ Yes/ Yes	NA/ Dose Reduced/Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 気管支炎 Acute bronchitis(27)	10JUN20[redacted] (284) *	11JUN20[redacted] (285) *	2	2	NA/ Yes/ Yes	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Not Recovered/ Not Resolved
Treatment Randmizen: Rd ; Subject ID: 103819[redacted] ; Randomized Date: 29SEP20[redacted]; First Dose Date: 05OCT20[redacted]; Last Dose Date: 12JAN20[redacted]*								
一般・全身障害および投与部位の状態 疾患進行 Disease progression(11)	11JAN20[redacted] (105) *	31JAN20[redacted] (125) *	21	5	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Fatal
Treatment Randmizen: Rd ; Subject ID: 103819[redacted] ; Randomized Date: 15NOV20[redacted]; First Dose Date: 16NOV20[redacted]; Last Dose Date: 12NOV20[redacted]*								
神経系障害 痙攣 Seizure(5)	31MAR20[redacted] (138) *	03APR20[redacted] (141) *	4	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 肺障害 Pulmonary diffusing disorder(14)	07NOV20[redacted] (359) *			2	NA/ No/ No	NA/ Dose Not Changed/ Drug Interrupted	Hospitalization	Not Recovered/ Not 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） 形質細胞腫 Soft tissue plasmacytoma orbital cavity right(15)	26NOV20[redacted] (378) *	29NOV20[redacted] (381) *	4	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 103819[redacted] ; Randomized Date: 19DEC20[redacted]; First Dose Date: 20DEC20[redacted]; Last Dose Date: 27DEC20[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 57）

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 齲歯 Carious teeth(9)	05JUN20[redacted] (170) *	11JUN20[redacted] (176) *	7	3	NA/ No/ No	NA/ Dose Delayed/ Dose Delayed	None/ Hospitalization	Recovered/ Resolved
心臓障害 心筋梗塞 Subacute myocardial infarction(19)	20SEP20[redacted] (277) *	24SEP20[redacted] (281) *	5	3	NA/ Yes/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved With Sequelae
一般・全身障害および投与部位の状態 全身健康状態低下 Reduced general condition(31)	27DEC20[redacted] (375) *	04JAN20[redacted] (383) **	9	3	NA/ Yes/ No	NA/ Drug Interrupted/ Drug Interrupted	Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 103849[redacted] ; Randomized Date: 26SEP20[redacted] ; First Dose Date: 27SEP20[redacted] ; Last Dose Date: 16JUL20[redacted] *								
心臓障害 心房細動 Intermittent atrial fibrillation(3)	04NOV20[redacted] (40)	04NOV20[redacted] (40)	1	3	NA/ Yes/ Yes	NA/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 103889[redacted] ; Randomized Date: 14JUN20[redacted] ; First Dose Date: 14JUN20[redacted] ; Last Dose Date: 24AUG20[redacted]								
腎および尿路障害 腎不全 Renal failure(1)	22JUN20[redacted] (9)	27JUN20[redacted] (14)	6	3	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 汎血球減少症 Pancytopenia(3)	22JUN20[redacted] (9)	27JUN20[redacted] (14)	6	2	NA/ Yes/ Yes	NA/ Dose Reduced/Drug Interrupted/ Drug Interrupted	None	Recovered/ Resolved
感染症および寄生虫症 膀胱炎 Cystitis(2)	23JUN20[redacted] (10)	27JUN20[redacted] (14)	5	2	NA/ Yes/ Yes	NA/ Drug Interrupted/ Drug Interrupted	Conmeds	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 103889[redacted] ; Randomized Date: 27JUN20[redacted] ; First Dose Date: 01JUL20[redacted] ; Last Dose Date: 08SEP20[redacted]								
心臓障害 急性心筋梗塞 Non st-elevation myocardial infarction(8)	22SEP20[redacted] (88)	[ONGOING] (-)		4	NA/ Yes/ Yes	NA/ Drug Interrupted/ Dose Not Changed	Hospitalization	Not Recovered/ Not Resolved
感染症および寄生虫症 肺炎 Pneumonia(7)	22SEP20[redacted] (88)	23SEP20[redacted] (89)	2	3	NA/ Yes/ Yes	NA/ Drug Interrupted/ Drug Interrupted	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)	22SEP20[redacted] (88)	07OCT20[redacted] (103)	16	5	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Fatal

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＊＊　：「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 58）

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 脳出血 Bi-occipetal cerebral bleeding(11)	05OCT20[redacted] (101)	07OCT20[redacted] (103)	3	5	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	None	Fatal
Treatment Randmizen: Rd ; Subject ID: 128529[redacted] ; Randomized Date: 05JAN20[redacted]; First Dose Date: 10JAN20[redacted]; Last Dose Date: 20MAY20[redacted]**								
感染症および寄生虫症 ＲＳウイルス感染 Respiratory syncytial virus infection(19)	17FEB20[redacted] (410) *	20FEB20[redacted] (413) *	4	2	NA/ Yes/ Yes	NA/ Dose Delayed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved With Sequelae
神経系障害 神経痛 Neuropathic pain(29)	06JUN20[redacted] (884) **	09JUN20[redacted] (887) **	4	4	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 128539[redacted] ; Randomized Date: 01JUN20[redacted]; First Dose Date: 01JUN20[redacted]; Last Dose Date: 16JUN20[redacted]#								
筋骨格系および結合組織障害 変形性関節症 Osteoarthritis(15)	31AUG20[redacted] (458) *	04SEP20[redacted] (462) *	5	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved With Sequelae
Treatment Randmizen: Rd ; Subject ID: 128539[redacted] ; Randomized Date: 20FEB20[redacted]; First Dose Date: 22FEB20[redacted]; Last Dose Date: 24JAN20[redacted]**								
感染症および寄生虫症 ウイルス性下気道感染 Lower respiratory tract infection influenza(11)	03APR20[redacted] (409) *	10APR20[redacted] (416) *	8	2	NA/ No/ No	NA/ Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 128579[redacted] ; Randomized Date: 12DEC20[redacted]; First Dose Date: 14DEC20[redacted]; Last Dose Date: 24OCT20[redacted]*								
傷害、中毒および処置合併症 腰椎骨折 L3 vertebrae fracture(4)	06JAN20[redacted] (26) *	12JAN20[redacted] (32) *	7	4	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
胃腸障害 下痢 Diarhhoea(8)	17MAR20[redacted] (97) *	22MAR20[redacted] (102) *	6	3	NA/ No/ No	NA/ Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
胃腸障害 嘔吐 Vomiting(9)	17MAR20[redacted] (97) *	22MAR20[redacted] (102) *	6	3	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 下気道感染 Lower respiratory tract infection(15)	16JUN20[redacted] (188) *	24JUN20[redacted] (196) *	9	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved With Sequelae
胃腸障害 下痢 Diarrhoea(17)	07JUL20[redacted] (209) *	08JUL20[redacted] (210) *	2	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	None	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 59）

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: Rd ; Subject ID: 128599[redacted] ; Randomized Date: 20SEP20[redacted]; First Dose Date: 21SEP20[redacted]; Last Dose Date: 28MAY20[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 Recurrence of basal cell carcinoma of right conchal bowl(23)	07NOV20[redacted] (780) **	[ONGOING] (-)		3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Procedure Required	Not Recovered/ Not Resolved
Treatment Randmizen: Rd ; Subject ID: 128599[redacted] ; Randomized Date: 11NOV20[redacted]; First Dose Date: 15NOV20[redacted]; Last Dose Date: 18JUL20[redacted]*								
感染症および寄生虫症 扁桃炎 Tonsilitis(2)	18NOV20[redacted] (8)	30NOV20[redacted] (20)	13	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
筋骨格系および結合組織障害 背部痛 Backpain(3)	09DEC20[redacted] (29)	13DEC20[redacted] (33)	5	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	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 Febrile neutropenia(13)	20MAY20[redacted] (192) *	21MAY20[redacted] (193) *	2	3	NA/ Yes/ Yes	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 140059[redacted] ; Randomized Date: 07MAR20[redacted]; First Dose Date: 07MAR20[redacted]; Last Dose Date: 12JUL20[redacted]*								
血管障害 起立性低血圧 Orthostatic hypotension(1)	21MAR20[redacted] (15)	25MAR20[redacted] (19)	5	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
代謝および栄養障害 低ナトリウム血症 Hyponatremia(2)	03JUN20[redacted] (89)	08JUN20[redacted] (94)	6	3	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Procedure Required/ Hospitalization	Not Recovered/ Not Resolved
Treatment Randmizen: Rd ; Subject ID: 140109[redacted] ; Randomized Date: 13DEC20[redacted]; First Dose Date: 15DEC20[redacted]; Last Dose Date: 12MAY20[redacted]#								
感染症および寄生虫症 肺炎 Pneumonia(45)	29MAR20[redacted] (473) **	02APR20[redacted] (477) **	5	3	NA/ No/ Yes	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 140109[redacted] ; Randomized Date: 07JAN20[redacted]; First Dose Date: 11JAN20[redacted]; Last Dose Date: 05MAR20[redacted]*								
感染症および寄生虫症 ＲＳウイルス肺炎 Rsv pneumonia(3)	04APR20[redacted] (88)	07APR20[redacted] (91)	4	3	NA/ No/ No	NA/ Dose Delayed/ Dose Delayed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
血管障害 低血圧 Hypotension(25)	12JUN20[redacted] (157)	14JUN20[redacted] (159)	3	3	NA/ No/ No	NA/ 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
#　：「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 60）

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(52)	18JAN20[redacted] (377) *	23JAN20[redacted] (382) *	6	3	NA/ Yes/ Yes	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 140109[redacted] ; Randomized Date: 25APR20[redacted]; First Dose Date: 26APR20[redacted]; Last Dose Date: 02APR20[redacted]**								
呼吸器、胸郭および縦隔障害 肺塞栓症 Upper lobe pulmonary embolism(18)	03NOV20[redacted] (193)	07NOV20[redacted] (197)	5	4	NA/ Yes/ No	NA/ Dose Reduced/ Dose Reduced/Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 140159[redacted] ; Randomized Date: 12DEC20[redacted]; First Dose Date: 15DEC20[redacted]; Last Dose Date: 10OCT20[redacted]**								
内分泌障害 甲状腺機能低下症 Uncontrolled hypothyroidsm(18)	08JAN20[redacted] (394) **	17JAN20[redacted] (403) **	10	3	NA/ Yes/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
筋骨格系および結合組織障害 頚部痛 Neck pain(31)	13OCT20[redacted] (672) **	01DEC20[redacted] (721) **	50	2	NA/ No/ No	NA/ Dose Not Changed/ 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） 急性骨髄性白血病 Acute myelogenous leukemia(32)	18OCT20[redacted] (677) **	01DEC20[redacted] (721) **	45	4	NA/ Yes/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Procedure Required	Not Recovered/ Not Resolved
Treatment Randmizen: Rd ; Subject ID: 140159[redacted] ; Randomized Date: 02DEC20[redacted]; First Dose Date: 05DEC20[redacted]; Last Dose Date: 05FEB20[redacted]*								
感染症および寄生虫症 細気管支炎 Bronchiolitis(1)	10JAN20[redacted] (40) *	16JAN20[redacted] (46) *	7	3	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved With Sequelae
胃腸障害 腹痛 Abdominal pain(12)	16FEB20[redacted] (77) *	22FEB20[redacted] (83) *	7	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Hospitalization	Not Recovered/ Not Resolved
血液およびリンパ系障害 貧血 Anemia(13)	16FEB20[redacted] (77) *	22FEB20[redacted] (83) *	7	4	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Not Recovered/ Not Resolved
Treatment Randmizen: Rd ; Subject ID: 140159[redacted] ; Randomized Date: 08DEC20[redacted]; First Dose Date: 12DEC20[redacted]; Last Dose Date: 21MAY20[redacted]**								
一般・全身障害および投与部位の状態 発熱 Fever(7)	25MAR20[redacted] (109) *	27MAR20[redacted] (111) *	3	1	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
筋骨格系および結合組織障害 頚部痛 Neck pain(10)	25MAR20[redacted] (109) *	27MAR20[redacted] (111) *	3	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	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 61）

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: Rd ; Subject ID: 140159[redacted] ; Randomized Date: 14DEC20[redacted] ; First Dose Date: 16DEC20[redacted] ; Last Dose Date: 16JUN20[redacted] #								
傷害、中毒および処置合併症 転倒 Fall(16)	25AUG20[redacted] (621) **	29AUG20[redacted] (625) **	5	3	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	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 right shin(23)	16JAN20[redacted] (765) #	24FEB20[redacted] (804) #	40	2	NA/ Yes/ No	NA/ Dose Not Changed/ Dose Not Changed	Procedure Required	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 140199[redacted] ; Randomized Date: 03JUN20[redacted] ; First Dose Date: 07JUN20[redacted] ; Last Dose Date: 05JUL20[redacted] *								
代謝および栄養障害 高カルシウム血症 Hypercalcemia(12)	17JUL20[redacted] (411) *	20JUL20[redacted] (414) *	4	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 140199[redacted] ; Randomized Date: 29JUL20[redacted] ; First Dose Date: 01AUG20[redacted] ; Last Dose Date: 30APR20[redacted] *								
臨床検査 ウイルス検査陽性 Parainfluenza positive(10)	10DEC20[redacted] (135)	14DEC20[redacted] (139)	5	2	NA/ Yes/ Yes	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 140199[redacted] ; Randomized Date: 09AUG20[redacted] ; First Dose Date: 12AUG20[redacted] ; Last Dose Date: 03NOV20[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） 非小細胞肺癌 Non small cell lung cancer(10)	18NOV20[redacted] (102)	01MAR20[redacted] (206) *	105	3	NA/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Procedure Required	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 140199[redacted] ; Randomized Date: 06SEP20[redacted] ; First Dose Date: 08SEP20[redacted] ; Last Dose Date: 08NOV20[redacted]								
感染症および寄生虫症 肺炎 Pneumonia(1)	10NOV20[redacted] (66)	18NOV20[redacted] (74)	9	3	NA/ Yes/ Yes	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
胃腸障害 悪心 Increased nausea(7)	02JAN20[redacted] (119) *	05JAN20[redacted] (122) *	4	3	NA/ Yes/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 140199[redacted] ; Randomized Date: 04NOV20[redacted] ; First Dose Date: ; Last Dose Date:								
代謝および栄養障害 高カルシウム血症 Hypercalcemia(1)	06NOV20[redacted] (3)	15NOV20[redacted] (12)	10	3	NA/ NA/ NA	NA/ NA/ NA	Conmeds/ Hospitalization	Not Recovered/ Not Resolved
呼吸器、胸郭および縦隔障害 呼吸不全 Respiratory failure(2)	13NOV20[redacted] (10)	15NOV20[redacted] (12)	3	5	NA/ NA/ NA	NA/ NA/ NA	Conmeds/ Hospitalization	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
＊＊　：「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 62）

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: Rd ; Subject ID: 140199[redacted]; Randomized Date: 29NOV20[redacted]; First Dose Date: 02DEC20[redacted]; Last Dose Date: 16JUN20[redacted]#								
精神障害 精神状態変化 Altered mental status(4)	14JAN20[redacted] (413) **	15JAN20[redacted] (414) **	2	3	NA/ No/ No	NA/ Drug Interrupted/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 胸水 Bilateral pleural effusion(16)	19MAY20[redacted] (903) #	21MAY20[redacted] (905) #	3	3	NA/ Yes/ No	NA/ Dose Delayed/ Dose Not Changed	Procedure Required	Not Recovered/ Not Resolved
Treatment Randmizen: Rd ; Subject ID: 140199[redacted]; Randomized Date: 02FEB20[redacted]; First Dose Date: 02MAR20[redacted]; Last Dose Date: 02JAN20[redacted] *								
胃腸障害 腹痛 Increased abdominal pain(1)	14MAR20[redacted] (42)	24MAR20[redacted] (52)	11	3	NA/ Yes/ Yes	NA/ Dose Reduced/ Dose Reduced	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
神経系障害 脳血管発作 Stroke(11)	25JAN20[redacted] (359) *	01FEB20[redacted] (366) *	8	3	NA/ Yes/ NA	NA/ Dose Not Changed/ NA	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved With Sequelae
Treatment Randmizen: Rd ; Subject ID: 140209[redacted]; Randomized Date: 06JUN20[redacted]; First Dose Date: 07JUN20[redacted]; Last Dose Date: 12FEB20[redacted] #								
感染症および寄生虫症 肺炎 Pneumonia(6)	01MAR20[redacted] (270) *	08MAR20[redacted] (277) *	8	3	NA/ Yes/ No	NA/ Dose Reduced/Drug Interrupted/ Dose Not Changed	Conmeds	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 140279[redacted]; Randomized Date: 08JUN20[redacted]; First Dose Date: 08JUN20[redacted]; Last Dose Date: 05FEB20[redacted] **								
傷害、中毒および処置合併症 股関節部骨折 Fracture left hip(1)	29JUN20[redacted] (22)	08AUG20[redacted] (62)	41	3	NA/ No/ No	NA/ Dose Delayed/ Dose Delayed	Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 蜂巣炎 Cellulitis lower extremity(23)	03JUN20[redacted] (362) *	06JUN20[redacted] (365) *	4	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 140279[redacted]; Randomized Date: 06JUL20[redacted]; First Dose Date: 07JUL20[redacted]; Last Dose Date: 28DEC20[redacted]								
感染症および寄生虫症 肺炎 Pneumonia(5)	03DEC20[redacted] (151)	07DEC20[redacted] (155)	5	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 140289[redacted]; Randomized Date: 01MAR20[redacted]; First Dose Date: 04MAR20[redacted]; Last Dose Date: 17JUN20[redacted]								
胃腸障害 下痢 Diarrhea(8)	17JUL20[redacted] (139)	18JUL20[redacted] (140)	2	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 140289[redacted]; Randomized Date: 24MAY20[redacted]; First Dose Date: 25MAY20[redacted]; Last Dose Date: 02AUG20[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 63）

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 ウイルス性気管支炎 Viral bronchitis(1)	01JUN20[redacted] (9)	03JUN20[redacted] (11)	3	3	NA/ No/ No	NA/ Dose Not Changed/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 140289[redacted] ; Randomized Date: 29AUG20[redacted] ; First Dose Date: 29AUG20[redacted] ; Last Dose Date: 11SEP20[redacted]								
神経系障害 脊髄圧迫 Acute cord compression t7-t8(1)	23SEP20[redacted] (26)	30SEP20[redacted] (33)	8	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 140419[redacted] ; Randomized Date: 18AUG20[redacted] ; First Dose Date: 23AUG20[redacted] ; Last Dose Date: 28FEB20[redacted] *								
胃腸障害 胃食道逆流性疾患 Gerd(1)	24AUG20[redacted] (7)	25AUG20[redacted] (8)	2	1	NA/ No/ Yes	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 140679[redacted] ; Randomized Date: 27JUL20[redacted] ; First Dose Date: 28JUL20[redacted] ; Last Dose Date: 09JUN20[redacted] **								
胃腸障害 胃腸出血 Gastrointestinal bleed(21)	11JUN20[redacted] (686) **	15JUN20[redacted] (690) **	5	3	NA/ No/ No	NA/ 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） 消化管間質性腫瘍 Gastrointestinal stromal tumor(22)	13JUN20[redacted] (688) **	[ONGOING] (-)		3	NA/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	None	Not Recovered/ Not Resolved
Treatment Randmizen: Rd ; Subject ID: 140759[redacted] ; Randomized Date: 09AUG20[redacted] ; First Dose Date: 12AUG20[redacted] ; Last Dose Date: 16JUN20[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） 皮膚有棘細胞癌 Squamous cell cancer right postauricular area and nape-skin cancer(12)	03FEB20[redacted] (1275) $	09APR20[redacted] (1340) $	66	2	NA/ Yes/ Yes	NA/ 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 skin cancer, left lower chin/lip area(15)	06JUN20[redacted] (1398) $	06JUN20[redacted] (1398) $	1	2	NA/ Yes/ Yes	NA/ Dose Not Changed/ Dose Not Changed	Procedure Required	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 140789[redacted] ; Randomized Date: 07JUN20[redacted] ; First Dose Date: 09JUN20[redacted] ; Last Dose Date: 28JAN20[redacted] **								
感染症および寄生虫症 肺炎 Pneumonia(7)	19JUN20[redacted] (13)	23JUN20[redacted] (17)	5	3	NA/ No/ No	NA/ Dose Delayed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 141049[redacted] ; Randomized Date: 11MAR20[redacted] ; First Dose Date: 14MAR20[redacted] ; Last Dose Date: 23AUG20[redacted]								

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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
$　：「4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 64）

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 筋萎縮性側索硬化症 Amyotrophic lateral sclerosis(28)	29AUG20[redacted] (172)	[ONGOING] (-)		4	NA/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Hospitalization	Not Recovered/ Not Resolved
Treatment Randmizen: Rd ; Subject ID: 141109[redacted] ; Randomized Date: 14JUL20[redacted]; First Dose Date: 14JUL20[redacted]; Last Dose Date: 14MAR20[redacted]**								
神経系障害 脳血管発作 Cerebrovascular accident(21)	12MAR20[redacted] (608) **	18APR20[redacted] (645) **	38	4	NA/ Yes/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Hospitalization	Recovered/ Resolved With Sequelae
Treatment Randmizen: Rd ; Subject ID: 141129[redacted] ; Randomized Date: 06AUG20[redacted]; First Dose Date: 08AUG20[redacted]; Last Dose Date: 22AUG20[redacted]**								
胃腸障害 胃排出不全 Gastroparesis(36)	07NOV20[redacted] (459) *	21NOV20[redacted] (473) *	15	3	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 141209[redacted] ; Randomized Date: 07MAR20[redacted]; First Dose Date: 09MAR20[redacted]; Last Dose Date: 31OCT20[redacted] *								
感染症および寄生虫症 蜂巣炎 Cellulitis of the right lower extremity(13)	23SEP20[redacted] (567) *	25SEP20[redacted] (569) *	3	3	NA/ No/ No	NA/ Dose Delayed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved With Sequelae
Treatment Randmizen: Rd ; Subject ID: 141209[redacted] ; Randomized Date: 12JUL20[redacted]; First Dose Date: 14JUL20[redacted]; Last Dose Date: 07SEP20[redacted]								
胃腸障害 下痢 Diarrhea(2)	01AUG20[redacted] (21)	02AUG20[redacted] (22)	2	2	NA/ No/ No	NA/ Drug Interrupted/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
心臓障害 心房粗動 Atrial flutter(4)	01AUG20[redacted] (21)	02AUG20[redacted] (22)	2	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
胃腸障害 嘔吐 Vomiting(7)	01AUG20[redacted] (21)	02AUG20[redacted] (22)	2	2	NA/ No/ No	NA/ Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
胃腸障害 悪心 Nausea(8)	01AUG20[redacted] (21)	02AUG20[redacted] (22)	2	3	NA/ No/ No	NA/ 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 疾患進行 Disease progression(19)	13SEP20[redacted] (64)	17SEP20[redacted] (68)	5	5	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	None	Fatal
Treatment Randmizen: Rd ; Subject ID: 141219[redacted] ; Randomized Date: 06JAN20[redacted]; First Dose Date: 10JAN20[redacted]; Last Dose Date: 16JUN20[redacted] **								
心臓障害 徐脈 Bradycardia(11)	10NOV20[redacted] (310)	16NOV20[redacted] (316)	7	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	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 65）

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
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(49)	03JUN20[redacted] (880) **	[ONGOING] (-)		1	NA/ Yes/ No	NA/ Drug Withdrawn/ Drug Withdrawn	None	Not Recovered/ Not Resolved
Treatment Randmizen: Rd ; Subject ID: 141259[redacted] ; Randomized Date: 26JAN20[redacted]; First Dose Date: 27JAN20[redacted]; Last Dose Date: 12JUN20[redacted]#								
傷害、中毒および処置合併症 ストレス骨折 Left subcapital femoral stress fracture(24)	29AUG20[redacted] (582) *	30AUG20[redacted] (583) *	2	2	NA/ No/ No	NA/ 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(26)	02OCT20[redacted] (616) *	04OCT20[redacted] (618) *	3	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
胃腸障害 下痢 Diarrhea(32)	25FEB20[redacted] (762) **	27FEB20[redacted] (764) **	3	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 141279[redacted] ; Randomized Date: 29SEP20[redacted]; First Dose Date: 03OCT20[redacted]; Last Dose Date: 25NOV20[redacted]**								
心臓障害 心房細動 Atrial fibrillation(15)	22FEB20[redacted] (147) *	29FEB20[redacted] (154) *	8	3	NA/ Yes/ Yes	NA/ Dose Reduced/Dose Delayed/Drug Interrupted/ Dose Reduced/Dose Delayed/Drug Interrupted	Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 141309[redacted] ; Randomized Date: 08JUN20[redacted]; First Dose Date: 10JUN20[redacted]; Last Dose Date: 13DEC20[redacted] **								
心臓障害 うっ血性心不全 Diastolic heart failure(16)	23JUL20[redacted] (777) **	30JUL20[redacted] (784) **	8	3	NA/ No/ No	NA/ 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(19)	08OCT20[redacted] (854) **	20OCT20[redacted] (866) **	13	3	NA/ Yes/ Yes	NA/ Dose Reduced/Dose Delayed/ Dose Reduced/Dose Delayed	Conmeds/ Hospitalization	Recovered/ Resolved With Sequelae
Treatment Randmizen: Rd ; Subject ID: 163289[redacted] ; Randomized Date: 17OCT20[redacted]; First Dose Date: 18OCT20[redacted]; Last Dose Date: 16JUN20[redacted]#								
呼吸器、胸郭および縦隔障害 肺障害 Pneumopathy(6)	27JAN20[redacted] (103) *	02FEB20[redacted] (109) *	7	3	NA/ No/ Yes	NA/ Drug Interrupted/ Dose Reduced/Drug Interrupted	Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 163299[redacted] ; Randomized Date: 31OCT20[redacted]; First Dose Date: 04NOV20[redacted]; Last Dose Date: 23APR20[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 66）

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 Pulmonary embolism(6)	14MAY20[redacted] (197) *	23MAY20[redacted] (206) *	10	3	NA/ Yes/ Yes	NA/ Dose Not Changed/ Drug Withdrawn	Conmeds	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 肺障害 Pneumopathy(13)	09JAN20[redacted] (437) **	16JAN20[redacted] (444) **	8	2	NA/ No/ NA	NA/ Dose Not Changed/ NA	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 163369[redacted] ; Randomized Date: 17OCT20[redacted]; First Dose Date: 18OCT20[redacted]; Last Dose Date: 24APR20[redacted]**								
耳および迷路障害 回転性めまい Vertigo(17)	08MAY20[redacted] (570) **	13MAY20[redacted] (575) **	6	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 184519[redacted] ; Randomized Date: 05APR20[redacted]; First Dose Date: 06APR20[redacted]; Last Dose Date: 22JUN20[redacted]								
一般・全身障害および投与部位の状態 死亡 Unknown cause of death(1)	26JUN20[redacted] (83)	26JUN20[redacted] (83)	1	5	NA/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	None	Fatal
Treatment Randmizen: Rd ; Subject ID: 184519[redacted] ; Randomized Date: 01NOV20[redacted]; First Dose Date: 01NOV20[redacted]; Last Dose Date: 26OCT20[redacted]*								
血管障害 高血圧 Hypertension(2)	17JAN20[redacted] (78) *	20JAN20[redacted] (81) *	4	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 184519[redacted] ; Randomized Date: 29NOV20[redacted]; First Dose Date: 08DEC20[redacted]; Last Dose Date: 13JAN20[redacted]*								
代謝および栄養障害 高カルシウム血症 Hypercalcemia(1)	23NOV20[redacted] (-6)	07DEC20[redacted] (9)	15	4	NA/ NA/ NA	NA/ NA/ NA	Conmeds/ Hospitalization	Recovered/ Resolved
代謝および栄養障害 高カルシウム血症 Hypercalcemia(2)	15DEC20[redacted] (17)	19DEC20[redacted] (21)	5	4	NA/ No/ No	NA/ 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 Hyponatremia(5)	15DEC20[redacted] (17)	20DEC20[redacted] (22)	6	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺炎 Pneumonia(3)	22DEC20[redacted] (24)	22JAN20[redacted] (55) *	32	5	NA/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Hospitalization	Fatal
Treatment Randmizen: Rd ; Subject ID: 184539[redacted] ; Randomized Date: 25FEB20[redacted]; First Dose Date: 28FEB20[redacted]; Last Dose Date: 26JUN20[redacted]								
感染症および寄生虫症 肺炎 Pneumonia(2)	10MAR20[redacted] (14)	31MAR20[redacted] (35)	22	4	NA/ No/ Yes	NA/ Drug Interrupted/ Dose Reduced	Conmeds/ 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 67）

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: Rd ; Subject ID: 184559[redacted]; Randomized Date: 28DEC20[redacted]; First Dose Date: 29DEC20[redacted]; Last Dose Date: 11MAY20[redacted] *								
血液およびリンパ系障害 貧血 Anaemia(2)	08MAR20[redacted] (72) *			2	NA/ Yes/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Unknown
神経系障害 多発ニューロパチー Polineuropaty(4)	09MAY20[redacted] (134) *			3	NA/ Yes/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Hospitalization	Unknown
Treatment Randmizen: Rd ; Subject ID: 184569[redacted]; Randomized Date: 14NOV20[redacted]; First Dose Date: 15NOV20[redacted]; Last Dose Date: 17FEB20[redacted] #								
感染症および寄生虫症 肺炎 Left lung pneumonia(12)	19AUG20[redacted] (280) *	30AUG20[redacted] (291) *	12	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
感染症および寄生虫症 胃腸炎 Gastroenteritis(17)	02APR20[redacted] (506) **	10APR20[redacted] (514) **	9	2	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
胃腸障害 下痢 Diarrhoea(18)	15MAY20[redacted] (549) **	17MAY20[redacted] (551) **	3	1	NA/ No/ Yes	NA/ Dose Delayed/ Dose Delayed	Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 丹毒 Erysipelas(28)	16JUL20[redacted] (611) **	22JUL20[redacted] (617) **	7	3	NA/ No/ Yes	NA/ Dose Delayed/ Dose Delayed	Hospitalization	Recovered/ Resolved
感染症および寄生虫症 丹毒 Erysipelas(31)	16OCT20[redacted] (703) **	18OCT20[redacted] (705) **	3	2	NA/ No/ Yes	NA/ Dose Delayed/ Dose Delayed	Conmeds	Recovered/ Resolved
傷害、中毒および処置合併症 腰椎骨折 Fracture of vertebra l1(33)	13NOV20[redacted] (731) **	15NOV20[redacted] (733) **	3	2	NA/ No/ No	NA/ Dose Delayed/ Dose Delayed	Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺炎 Pneumonia(36)	20FEB20[redacted] (830) #	07MAR20[redacted] (845) #	16	3	NA/ No/ NA	NA/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 184589[redacted]; Randomized Date: 03OCT20[redacted]; First Dose Date: 05OCT20[redacted]; Last Dose Date: 06JUN20[redacted] *								
血液およびリンパ系障害 貧血 Anemia(4)	14MAR20[redacted] (164) *	15MAR20[redacted] (165) *	2	2	NA/ Yes/ Yes	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 貧血 Anaemia(3)	04APR20[redacted] (185) *	05APR20[redacted] (186) *	2	2	NA/ Yes/ No	NA/ Dose Reduced/ 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，
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 68）

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: Rd ; Subject ID: 184619[redacted] ; Randomized Date: 28NOV20[redacted]; First Dose Date: 29NOV20[redacted]; Last Dose Date: 16JUN20[redacted]#								
血液およびリンパ系障害 好中球減少症 Neutropenia(2)	15APR20[redacted] (870) #	22APR20[redacted] (877) #	8	4	NA/ Yes/ Yes	NA/ Drug Interrupted/ Drug Interrupted	Conmeds	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 184629[redacted] ; Randomized Date: 08JUN20[redacted]; First Dose Date: 10JUN20[redacted]; Last Dose Date: 23SEP20[redacted]								
血液およびリンパ系障害 貧血 Anemia(1)	02JUN20[redacted] (-6)	14JUN20[redacted] (7)	13	2	NA/ NA/ NA	NA/ NA/ NA	Procedure Required/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 白血球減少症 Leukopenia(10)	24JUN20[redacted] (17)	24JUL20[redacted] (47)	31	4	NA/ Yes/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
血液およびリンパ系障害 血小板減少症 Thrombocytopenia(18)	29JUN20[redacted] (22)	19JUL20[redacted] (42)	21	4	NA/ Yes/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved With Sequelae
胃腸障害 胃腸出血 Gastrointestinal bleeding(7)	30JUN20[redacted] (23)	01JUL20[redacted] (24)	2	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
傷害、中毒および処置合併症 挫傷 Contusion of head(21)	27JUL20[redacted] (50)	05AUG20[redacted] (59)	10	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
血管障害 血腫 Spectacled haematoma(26)	27JUL20[redacted] (50)	05AUG20[redacted] (59)	10	3	NA/ No/ No	NA/ 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(15)	16SEP20[redacted] (101)	[ONGOING] (-)		3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Not Recovered/ Not Resolved
血液およびリンパ系障害 血小板減少症 Thrombocytopenia(22)	16SEP20[redacted] (101)	[ONGOING] (-)		4	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Not Recovered/ Not Resolved
感染症および寄生虫症 肺炎 Right-side pneumonia(12)	20SEP20[redacted] (105)	[ONGOING] (-)		3	NA/ No/ No	NA/ 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(23)	20SEP20[redacted] (105)	28SEP20[redacted] (113)	9	4	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 184629[redacted] ; Randomized Date: 30JUN20[redacted]; First Dose Date: 01JUL20[redacted]; Last Dose Date: 27JUL20[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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表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 69）

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(41)	29JUN20[redacted] (366) *	04JUL20[redacted] (371) *	6	2	NA/ No/ No	NA/ Drug Interrupted/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 貧血 Anemia(45)	24JUL20[redacted] (391) *	10AUG20[redacted] (408) *	18	3	NA/ No/ No	NA/ Drug Withdrawn/ 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） 急性骨髄性白血病 Heamatological malignancy acute myeloid leucamia(39)	24JUL20[redacted] (391) *	20SEP20[redacted] (449) *	59	5	NA/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Procedure Required/ Hospitalization	Fatal
感染症および寄生虫症 肺感染 Lung infection(46)	25JUL20[redacted] (392) *	10AUG20[redacted] (408) *	17	3	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 発熱性好中球減少症 Febrile neutropenia(50)	19AUG20[redacted] (417) *	20AUG20[redacted] (418) *	2	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 184639[redacted] ; Randomized Date: 20APR20[redacted]; First Dose Date: 21APR20[redacted]; Last Dose Date: 16JUN20[redacted]#								
血液およびリンパ系障害 貧血 Anaemia(7)	20OCT20[redacted] (184)	28OCT20[redacted] (192)	9	2	NA/ Yes/ No	NA/ Dose Delayed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 溶血性貧血 Anaemia haemolytica(11)	28OCT20[redacted] (192)	21NOV20[redacted] (216)	25	2	NA/ Yes/ No	NA/ Dose Reduced/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 貧血 Anemia g3(17)	13SEP20[redacted] (513) *	17SEP20[redacted] (517) *	5	3	NA/ Yes/ No	NA/ Dose Reduced/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
筋骨格系および結合組織障害 骨痛 Bones pain(18)	13JUN20[redacted] (786) **	14JUN20[redacted] (787) **	2	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
眼障害 白内障 Cataract(21)	25NOV20[redacted] (951) **	27MAY20[redacted] (1134) #	184	3	NA/ No/ Yes	NA/ Dose Not Changed/ Dose Not Changed	Procedure Required	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 225269[redacted] ; Randomized Date: 28SEP20[redacted]; First Dose Date: 29SEP20[redacted]; Last Dose Date: 06JUL20[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 70）

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(13)	04NOV20[redacted] (38)	22NOV20[redacted] (56)	19	2	NA/ Yes/ Yes	NA/ Drug Interrupted/ Dose Reduced/Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 225269[redacted] ; Randomized Date: 26OCT20[redacted] ; First Dose Date: 27OCT20[redacted] ; Last Dose Date: 09JUL20[redacted] **								
心臓障害 心房細動 Atrial fibrillation(19)	09JUL20[redacted] (258) *	11JUL20[redacted] (260) *	3	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	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 General malaise(39)	12JUL20[redacted] (626) **	13JUL20[redacted] (627) **	2	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 225279[redacted] ; Randomized Date: 13FEB20[redacted] ; First Dose Date: 16FEB20[redacted] ; Last Dose Date: 01FEB20[redacted] *								
血液およびリンパ系障害 発熱性好中球減少症 Febrile neutropenia(7)	14MAY20[redacted] (92)	18MAY20[redacted] (96)	5	3	NA/ Yes/ No	NA/ Dose Delayed/ Dose Delayed	Conmeds/ Hospitalization	Recovered/ Resolved
傷害、中毒および処置合併症 脊椎圧迫骨折 Vertebral collapse(24)	26JUL20[redacted] (165)	07AUG20[redacted] (177)	13	3	NA/ No/ No	NA/ Dose Not Changed/ Drug Interrupted	Procedure Required/ Hospitalization	Recovered/ Resolved
神経系障害 第６脳神経麻痺 Paralysis of sixth cranic nerve left(48)	26FEB20[redacted] (380) *	03APR20[redacted] (416) *	37	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Not Recovered/ Not Resolved
Treatment Randmizen: Rd ; Subject ID: 225309[redacted] ; Randomized Date: 06FEB20[redacted] ; First Dose Date: 15FEB20[redacted] ; Last Dose Date: 06DEC20[redacted]								
一般・全身障害および投与部位の状態 発熱 Fever(1)	29FEB20[redacted] (24)	02MAR20[redacted] (26)	3	2	NA/ Yes/ No	NA/ Dose Delayed/Drug Interrupted/ Dose Delayed/Drug Interrupted	Hospitalization	Recovered/ Resolved
胃腸障害 下痢 Diarrhea(2)	29FEB20[redacted] (24)	07MAR20[redacted] (31)	8	2	NA/ Yes/ No	NA/ Dose Delayed/Drug Interrupted/ Dose Delayed/Drug Interrupted	Conmeds	Recovered/ Resolved
一般・全身障害および投与部位の状態 全身健康状態低下 Worsening of physical conditions(3)	29FEB20[redacted] (24)	12MAR20[redacted] (36)	13	3	NA/ Yes/ No	NA/ Dose Reduced/Dose Delayed/Drug Interrupted/ Dose Delayed/Drug Interrupted	None	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 71）

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: Rd ; Subject ID: 225309[redacted]; Randomized Date: 13FEB20[redacted]; First Dose Date: 15FEB20[redacted]; Last Dose Date: 23MAY20[redacted]**								
肝胆道系障害 胆石症 Cholelithiasis(10)	23SEP20[redacted] (224)	26SEP20[redacted] (227)	4	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 225309[redacted]; Randomized Date: 22FEB20[redacted]; First Dose Date: 23FEB20[redacted]; Last Dose Date: 23MAY20[redacted]*								
神経系障害 失神 Syncope(10)	17MAY20[redacted] (86)	17MAY20[redacted] (86)	1	3	NA/ No/ No	NA/ Dose Delayed/ Dose Delayed	Hospitalization	Recovered/ Resolved
筋骨格系および結合組織障害 脊柱管狭窄症 Spinal stenosis(22)	17MAY20[redacted] (451) *	10JUN20[redacted] (475) *	25	3	NA/ No/ No	NA/ Dose Delayed/ Dose Delayed	Conmeds/ Procedure Required	Recovered/ Resolved With Sequelae
Treatment Randmizen: Rd ; Subject ID: 225339[redacted]; Randomized Date: 11OCT20[redacted]; First Dose Date: 13OCT20[redacted]; Last Dose Date: 03JAN20[redacted]*								
呼吸器、胸郭および縦隔障害 呼吸不全 Pulmunary insufficience(1)	25OCT20[redacted] (15)	03NOV20[redacted] (24)	10	3	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 気管支炎 Bronchitis(8)	30JAN20[redacted] (112) *	09FEB20[redacted] (122) *	11	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 225349[redacted]; Randomized Date: 04NOV20[redacted]; First Dose Date: 07NOV20[redacted]; Last Dose Date: 17APR20[redacted]**								
筋骨格系および結合組織障害 骨壊死 Femoral osteonecrosis(4)	11JUL20[redacted] (251) *	18JUL20[redacted] (258) *	8	3	NA/ No/ Yes	NA/ Dose Delayed/ Drug Withdrawn	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 247169[redacted]; Randomized Date: 27AUG20[redacted]; First Dose Date: 30AUG20[redacted]; Last Dose Date: 05FEB20[redacted]**								
感染症および寄生虫症 気道感染 Respiratory infection(10)	14SEP20[redacted] (385) *	18SEP20[redacted] (389) *	5	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 247179[redacted]; Randomized Date: 25MAY20[redacted]; First Dose Date: 25MAY20[redacted]; Last Dose Date: 05JUL20[redacted]								
感染症および寄生虫症 敗血症性ショック Septic shock(1)	20JUL20[redacted] (57)	24JUL20[redacted] (61)	5	5	NA/ No/ Yes	NA/ Drug Withdrawn/ Drug Withdrawn	Procedure Required/ Hospitalization	Fatal
Treatment Randmizen: Rd ; Subject ID: 247179[redacted]; Randomized Date: 15JUN20[redacted]; First Dose Date: 15JUN20[redacted]; Last Dose Date: 03AUG20[redacted]								
呼吸器、胸郭および縦隔障害 間質性肺疾患 Intersticial bilateral pneumonia(1)	06AUG20[redacted] (53)	26AUG20[redacted] (73)	21	4	NA/ Yes/ Yes	NA/ Dose Not Changed/ Dose Not Changed	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 72）

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: Rd ; Subject ID: 247179[redacted]; Randomized Date: 15JUN20[redacted]; First Dose Date: 16JUN20[redacted]; Last Dose Date: 29DEC20[redacted]								
傷害、中毒および処置合併症 大腿骨骨折 Femur fracture(1)	10JUL20[redacted] (26)	22JUL20[redacted] (38)	13	2	NA/ No/ No	NA/ Dose Delayed/ Dose Delayed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 247179[redacted]; Randomized Date: 12JUL20[redacted]; First Dose Date: 12JUL20[redacted]; Last Dose Date: 17OCT20[redacted]								
精神障害 錯乱状態 Confusional disorder(1)	17OCT20[redacted] (98)	31OCT20[redacted] (112)	15	3	NA/ No/ Yes	NA/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Hospitalization	Recovered/ Resolved With Sequelae
Treatment Randmizen: Rd ; Subject ID: 247179[redacted]; Randomized Date: 28JUL20[redacted]; First Dose Date: 02AUG20[redacted]; Last Dose Date: 27NOV20[redacted]*								
肝胆道系障害 胆嚢炎 Cholecystitis(19)	03JUL20[redacted] (342) *	10JUL20[redacted] (349) *	8	3	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds	Not Recovered/ Not Resolved
Treatment Randmizen: Rd ; Subject ID: 247199[redacted]; Randomized Date: 22DEC20[redacted]; First Dose Date: 22DEC20[redacted]; Last Dose Date: 24OCT20[redacted]*								
感染症および寄生虫症 胃腸炎 Acute gastroenteritis(1)	10JAN20[redacted] (20) *	13JAN20[redacted] (23) *	4	2	NA/ No/ No	NA/ Drug Interrupted/ Dose Not Changed	Hospitalization	Recovered/ Resolved
感染症および寄生虫症 敗血症性ショック Septic shock(2)	27OCT20[redacted] (310) *	29OCT20[redacted] (312) *	3	5	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Fatal
Treatment Randmizen: Rd ; Subject ID: 247199[redacted]; Randomized Date: 22MAR20[redacted]; First Dose Date: 23MAR20[redacted]; Last Dose Date: 05JUN20[redacted]								
感染症および寄生虫症 肺炎 Pneumonia(1)	27MAR20[redacted] (6)	15APR20[redacted] (25)	20	3	NA/ No/ No	NA/ Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 247199[redacted]; Randomized Date: 01AUG20[redacted]; First Dose Date: 02AUG20[redacted]; Last Dose Date: 22JUN20[redacted]*								
心臓障害 狭心症 Angor pectoris(1)	23JUN20[redacted] (328) *	29JUN20[redacted] (334) *	7	2	NA/ Yes/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 247199[redacted]; Randomized Date: 04APR20[redacted]; First Dose Date: 04APR20[redacted]; Last Dose Date: 21JUL20[redacted]								
感染症および寄生虫症 肺炎 Pneumonia(1)	07MAY20[redacted] (34)	16MAY20[redacted] (43)	10	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 247199[redacted]; Randomized Date: 24MAY20[redacted]; First Dose Date: 26MAY20[redacted]; Last Dose Date: 07NOV20[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 73）

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 Ictus (stroke)(4)	29NOV20[redacted] (190)	05DEC20[redacted] (196)	7	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved With Sequelae
Treatment Randmizen: Rd ; Subject ID: 247199[redacted]; Randomized Date: 18JUL20[redacted]; First Dose Date: 18JUL20[redacted]; Last Dose Date: 14AUG20[redacted]**								
感染症および寄生虫症 肺炎 Pneumonia(2)	30APR20[redacted] (288) *	04MAY20[redacted] (292) *	5	3	NA/ No/ No	NA/ Dose Delayed/ Dose Delayed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 247199[redacted]; Randomized Date: 17OCT20[redacted]; First Dose Date: 17OCT20[redacted]; Last Dose Date: 16JUN20[redacted]#								
感染症および寄生虫症 肺炎 Pneumonia(1)	26DEC20[redacted] (71)	30DEC20[redacted] (75)	5	3	NA/ No/ No	NA/ Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 肺塞栓症 Bilateral pulmonary thromboembolism(2)	31DEC20[redacted] (76)	09JAN20[redacted] (85) *	10	3	NA/ No/ No	NA/ Drug Interrupted/ Dose Not Changed	Conmeds	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 247219[redacted]; Randomized Date: 30MAY20[redacted]; First Dose Date: 30MAY20[redacted]; Last Dose Date: 02JUN20[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 Mielodisplasic syndrome(1)	17MAY20[redacted] (-13)	[ONGOING] (-)		3	NA/ NA/ NA	NA/ Drug Withdrawn/ Drug Withdrawn	Conmeds	Not Recovered/ Not Resolved
Treatment Randmizen: Rd ; Subject ID: 247219[redacted]; Randomized Date: 08JUN20[redacted]; First Dose Date: 08JUN20[redacted]; Last Dose Date: 16JUN20[redacted]#								
血液およびリンパ系障害 発熱性好中球減少症 Febrile neutropenia(10)	25JAN20[redacted] (598) **	08FEB20[redacted] (612) **	15	3	NA/ Yes/ Yes	NA/ Dose Delayed/ Dose Delayed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺炎 Bilateral pneumonia(11)	25JAN20[redacted] (598) **	08FEB20[redacted] (612) **	15	3	NA/ Yes/ Yes	NA/ 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(12)	25JAN20[redacted] (598) **	08FEB20[redacted] (612) **	15	3	NA/ Yes/ Yes	NA/ Dose Delayed/ Dose Delayed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 胃腸炎 Accute gastroenteritis(18)	08DEC20[redacted] (915) **	11DEC20[redacted] (918) **	4	3	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
腎および尿路障害 腎前性腎不全 Pre-renal renal insufficiency(19)	08DEC20[redacted] (915) **	11DEC20[redacted] (918) **	4	2	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Hospitalization	Recovered/ Resolved

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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 74）

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: Rd ; Subject ID: 247219[redacted] ; Randomized Date: 22SEP20[redacted]; First Dose Date: ; Last Dose Date:								
代謝および栄養障害 体液貯留 Hydric retention(1)	15SEP20[redacted] (-7)	22SEP20[redacted] (1)	8	3	NA/ NA/ NA	NA/ NA/ NA	Conmeds/ Hospitalization	Recovered/ Resolved With Sequelae
一般・全身障害および投与部位の状態 全身健康状態低下 General deterioration(5)	23SEP20[redacted] (2)	23SEP20[redacted] (2)	1	5	NA/ NA/ NA	NA/ NA/ NA	None	Fatal
Treatment Randmizen: Rd ; Subject ID: 247219[redacted] ; Randomized Date: 28DEC20[redacted]; First Dose Date: 28DEC20[redacted]; Last Dose Date: 26MAY20[redacted] *								
筋骨格系および結合組織障害 骨痛 Bone pain increased(1)	19DEC20[redacted] (-9)	22DEC20[redacted] (-6)	4	3	NA/ NA/ NA	NA/ NA/ NA	Conmeds/ Hospitalization	Recovered/ Resolved
代謝および栄養障害 電解質失調 Hydroelectrolitic alteration(2)	09JAN20[redacted] (13) *	11JAN20[redacted] (15) *	3	3	NA/ No/ Yes	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
内分泌障害 副腎機能不全 Adrenal insufficiency(9)	06FEB20[redacted] (41) *	23FEB20[redacted] (58) *	18	3	NA/ No/ Yes	NA/ Drug Interrupted/ Dose Reduced/Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
心臓障害 不整脈 Arrhythmia(29)	27MAY20[redacted] (152) *	27MAY20[redacted] (152) *	1	5	NA/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	None	Fatal
Treatment Randmizen: Rd ; Subject ID: 247229[redacted] ; Randomized Date: 10FEB20[redacted]; First Dose Date: 14FEB20[redacted]; Last Dose Date: 04JUN20[redacted] **								
感染症および寄生虫症 気道感染 Respiratory infection(19)	03DEC20[redacted] (663) *	09DEC20[redacted] (669) *	7	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 247249[redacted] ; Randomized Date: 24OCT20[redacted]; First Dose Date: 27OCT20[redacted]; Last Dose Date: 07FEB20[redacted]**								
感染症および寄生虫症 肺炎 Right basal pneumonia(1)	18FEB20[redacted] (484) **	22FEB20[redacted] (488) **	5	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 247249[redacted] ; Randomized Date: 27DEC20[redacted]; First Dose Date: 28DEC20[redacted]; Last Dose Date: 20AUG20[redacted]**								
感染症および寄生虫症 憩室炎 Complicated acute diverticulitis(1)	10APR20[redacted] (106) *	19APR20[redacted] (115) *	10	3	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	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 75）

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 気管支痙攣 Bronchospasm(9)	03JAN20[redacted] (374) **	04JAN20[redacted] (375) **	2	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
心臓障害 心房細動 Atrial fibrillation slow(12)	10JUN20[redacted] (532) **	12JUN20[redacted] (534) **	3	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
心臓障害 冠動脈狭窄 Coronary stenosis(13)	01JUL20[redacted] (553) **	02JUL20[redacted] (554) **	2	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 247249[redacted] ; Randomized Date: 10FEB20[redacted]; First Dose Date: 13FEB20[redacted]; Last Dose Date: 15JUN20[redacted]**								
呼吸器、胸郭および縦隔障害 肺塞栓症 Pulmonary thromboembolism(4)	09OCT20[redacted] (243)	18OCT20[redacted] (252)	10	3	NA/ Yes/ Yes	NA/ Dose Reduced/Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 蜂巣炎 Right lower limb cellulitis(92)	01MAR20[redacted] (751) **	03MAR20[redacted] (753) **	3	2	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required	Recovered/ Resolved
感染症および寄生虫症 蜂巣炎 Right lower limb cellulitis(95)	26MAR20[redacted] (776) **	28MAR20[redacted] (778) **	3	2	NA/ No/ No	NA/ Dose Reduced/Dose Delayed/ Drug Withdrawn	Conmeds	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 260089[redacted] ; Randomized Date: 10MAY20[redacted]; First Dose Date: 12MAY20[redacted]; Last Dose Date: 07JUN20[redacted] **								
筋骨格系および結合組織障害 骨折痛 Pain due to rib fracture(41)	19JUL20[redacted] (437) *	[ONGOING] (-)		1	NA/ No/ No	NA/ Drug Interrupted/ Dose Not Changed	Conmeds	Not Recovered/ Not Resolved
傷害、中毒および処置合併症 転倒 Fall(24)	20JUL20[redacted] (438) *	24JUL20[redacted] (442) *	5	1	NA/ No/ No	NA/ Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved With Sequelae
筋骨格系および結合組織障害 関節腫脹 Right wrist swelling(34)	14DEC20[redacted] (585) *	03JAN20[redacted] (605) **	21	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
筋骨格系および結合組織障害 ピロリン酸カルシウム結晶性軟骨石灰化症 Pseudo gout(35)	14DEC20[redacted] (585) *	03JAN20[redacted] (605) **	21	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肝感染 Hepatic infection(45)	06JUL20[redacted] (789) **	07JUL20[redacted] (790) **	2	5	NA/ Yes/ Yes	NA/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Hospitalization	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 76）

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 播種性帯状疱疹 Disseminated zoster(46)	06JUL20[redacted] (789) **	07JUL20[redacted] (790) **	2	5	NA/ Yes/ Yes	NA/ Drug Withdrawn/ Drug Withdrawn	Conmeds	Not Recovered/ Not Resolved
Treatment Randmizen: Rd ; Subject ID: 260089[redacted]; Randomized Date: 13JUN20[redacted]; First Dose Date: 16JUN20[redacted]; Last Dose Date: 14MAY20[redacted] #								
腎および尿路障害 尿閉 Urinary retention post turbt complication(13)	06JUN20[redacted] (360) *	08JUN20[redacted] (362) *	3	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
腎および尿路障害 急性腎不全 Acute on chronic renal failure(18)	31OCT20[redacted] (507) *	02NOV20[redacted] (509) *	3	2	NA/ No/ No	NA/ Dose Delayed/ Dose Delayed	Hospitalization	Recovered/ Resolved
臨床検査 血中クレアチニン増加 Elevated creatinine(32)	31OCT20[redacted] (507) *	02NOV20[redacted] (509) *	3	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
感染症および寄生虫症 肺炎 Pneumonia(48)	24JAN20[redacted] (957) #	04FEB20[redacted] (968) #	12	3	NA/ Yes/ Yes	NA/ Drug Interrupted/ Drug Interrupted	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(49)	14FEB20[redacted] (978) #	16FEB20[redacted] (980) #	3	3	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Procedure Required/ Hospitalization	Recovered/ Resolved
傷害、中毒および処置合併症 大腿骨頚部骨折 Fracture neck of left femur(55)	19APR20[redacted] (1042) #	05MAY20[redacted] (1058) #	17	3	NA/ No/ No	NA/ 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） 直腸癌 Invasive adenocarcinoma of rectum(56)	10MAY20[redacted] (1063) #	[ONGOING] (-)		3	NA/ No/ No	NA/ Dose Delayed/Drug Interrupted/ Dose Delayed/Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Not Recovered/ Not Resolved
Treatment Randmizen: Rd ; Subject ID: 260139[redacted]; Randomized Date: 30SEP20[redacted]; First Dose Date: 03OCT20[redacted]; Last Dose Date: 09AUG20[redacted] *								
感染症および寄生虫症 肺炎 Right lung pneumonia(17)	27AUG20[redacted] (333) *	[ONGOING] (-)		3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	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(19)	27AUG20[redacted] (333) *	[ONGOING] (-)		4	NA/ No/ No	NA/ Dose Not Changed/ NA	Conmeds	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 77）

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 呼吸不全 Respiratory failure(20)	27AUG20[redacted] (333) *	[ONGOING] (-)		4	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Procedure Required	Not Recovered/ Not Resolved
一般・全身障害および投与部位の状態 多臓器不全 Multisystem failure(21)	27AUG20[redacted] (333) *	27AUG20[redacted] (333) *	1	5	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	None	Fatal
Treatment Randmizen: Rd ; Subject ID: 260559[redacted] ; Randomized Date: 08JUL20[redacted]; First Dose Date: 11JUL20[redacted]; Last Dose Date: 22OCT20[redacted] *								
傷害、中毒および処置合併症 股関節部骨折 Hip fracture(23)	02FEB20[redacted] (210) *	20FEB20[redacted] (228) *	19	3	NA/ No/ No	NA/ Dose Delayed/ Drug Interrupted	Hospitalization	Recovered/ Resolved With Sequelae
感染症および寄生虫症 尿路性敗血症 Urosepsis(36)	24OCT20[redacted] (475) *	01NOV20[redacted] (483) *	9	5	NA/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Hospitalization	Fatal
Treatment Randmizen: Rd ; Subject ID: 260559[redacted] ; Randomized Date: 06OCT20[redacted]; First Dose Date: 12OCT20[redacted]; Last Dose Date: 02OCT20[redacted] **								
神経系障害 一過性脳虚血発作 Transient ischemic attack(25)	05AUG20[redacted] (670) **	07AUG20[redacted] (672) **	3	1	NA/ Yes/ No	NA/ Drug Interrupted/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 261139[redacted] ; Randomized Date: 15AUG20[redacted]; First Dose Date: 16AUG20[redacted]; Last Dose Date: 21AUG20[redacted] **								
感染症および寄生虫症 肺炎 Pneumonia(18)	17JUL20[redacted] (338) *	26JUL20[redacted] (347) *	10	3	NA/ No/ No	NA/ Dose Not Changed/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved With Sequelae
感染症および寄生虫症 肺敗血症 Chest infection (pulmonary sepsis)(22)	20NOV20[redacted] (464) *	02DEC20[redacted] (476) *	13	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
肝胆道系障害 胆嚢炎 Cholecystisis(24)	22DEC20[redacted] (496) *	28DEC20[redacted] (502) *	7	3	NA/ No/ No	NA/ Dose Delayed/ Dose Delayed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 大葉性肺炎 Left lower lobe pneumonia(29)	31MAR20[redacted] (595) **	04APR20[redacted] (599) **	5	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 261139[redacted] ; Randomized Date: 15AUG20[redacted]; First Dose Date: 16AUG20[redacted]; Last Dose Date: 23OCT20[redacted] *								
胃腸障害 下痢 Diarrhea(9)	17MAR20[redacted] (216) *	19MAR20[redacted] (218) *	3	3	NA/ Yes/ No	NA/ Dose Reduced/Drug Interrupted/ Drug Interrupted	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 78）

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: Rd ; Subject ID: 261139[redacted]; Randomized Date: 21FEB20[redacted]; First Dose Date: 01MAR20[redacted]; Last Dose Date: 28AUG20[redacted] *								
呼吸器、胸郭および縦隔障害 肺塞栓症 Pulmonary embolis(15)	01OCT20[redacted] (224)	02OCT20[redacted] (225)	2	4	NA/ Yes/ Yes	NA/ Dose Reduced/Drug Interrupted/ Dose Reduced/Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 261179[redacted]; Randomized Date: 30JAN20[redacted]; First Dose Date: 02FEB20[redacted]; Last Dose Date: 11JUN20[redacted] **								
胃腸障害 小腸穿孔 Small bowel perforation(7)	08MAR20[redacted] (39)	09MAR20[redacted] (40)	2	3	NA/ No/ Yes	NA/ Drug Interrupted/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
胃腸障害 上腹部痛 Epigastric abdominal pain(9)	31MAR20[redacted] (62)	03APR20[redacted] (65)	4	3	NA/ No/ No	NA/ Dose Not Changed/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 術後膿瘍 Post op abdominal abscess(8)	03APR20[redacted] (65)	27APR20[redacted] (89)	25	3	NA/ No/ No	NA/ Dose Not Changed/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
胃腸障害 下痢 Diarrhea-worsening(28)	19MAR20[redacted] (415) *	22MAR20[redacted] (418) *	4	3	NA/ Yes/ No	NA/ Dose Not Changed/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
胃腸障害 小腸閉塞 Small bowel obstruction(32)	29APR20[redacted] (456) *	03MAY20[redacted] (460) *	5	3	NA/ Yes/ No	NA/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 261269[redacted]; Randomized Date: 11OCT20[redacted]; First Dose Date: 13OCT20[redacted]; Last Dose Date: 19SEP20[redacted] *								
呼吸器、胸郭および縦隔障害 呼吸困難 Shortness of breath(7)	19APR20[redacted] (192) *	22APR20[redacted] (195) *	4	2	NA/ Yes/ No	NA/ Dose Delayed/ Dose Delayed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺炎 Pneumonia(8)	23APR20[redacted] (196) *	26APR20[redacted] (199) *	4	3	NA/ Yes/ No	NA/ Dose Delayed/ Dose Delayed	Conmeds/ Hospitalization	Recovered/ Resolved
神経系障害 粘液水腫性昏睡 Myxedema coma(64)	17OCT20[redacted] (373) *	25OCT20[redacted] (381) *	9	4	NA/ Yes/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 261269[redacted]; Randomized Date: 16FEB20[redacted]; First Dose Date: 21FEB20[redacted]; Last Dose Date: 05MAR20[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 79）

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 (initially reported as fever)(1)	10JUN20[redacted] (116)	06JUL20[redacted] (142)	27	3	NA/ No/ No	NA/ Dose Delayed/ Dose Delayed/Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
心臓障害 心房細動 Atrial fibrillation(2)	12JUN20[redacted] (118)	12SEP20[redacted] (210)	93	2	NA/ Yes/ No	NA/ Dose Reduced/Dose Delayed/ Dose Reduced/Dose Delayed	Conmeds/ Hospitalization	Recovered/ Resolved
神経系障害 失神 Fall (due to fainting)(14)	13SEP20[redacted] (211)	21SEP20[redacted] (219)	9	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 血小板減少症 Thrombocytopenia (causing extension of hospital stay)(15)	04OCT20[redacted] (232)	17OCT20[redacted] (245)	14	3	NA/ Yes/ No	NA/ Dose Delayed/ Dose Delayed	Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 261289[redacted]; Randomized Date: 03OCT20[redacted]; First Dose Date: 04OCT20[redacted]; Last Dose Date: 10JUN20[redacted]#								
感染症および寄生虫症 細菌性肺炎 Bacterial pneumonia(28)	10JAN20[redacted] (831) #	15JAN20[redacted] (836) #	6	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 医療機器関連感染 Bacteremia due to removal of old blocked port a cath(33)	16JUN20[redacted] (988) #	18JUN20[redacted] (990) #	3	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 282269[redacted]; Randomized Date: 05SEP20[redacted]; First Dose Date: 05SEP20[redacted]; Last Dose Date: 16JUN20[redacted]#								
感染症および寄生虫症 レンサ球菌性菌血症 Blood infection: streptococcus pneumoniae(44)	02NOV20[redacted] (790) **	11NOV20[redacted] (799) **	10	2	NA/ Yes/ Yes	NA/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 282269[redacted]; Randomized Date: 28DEC20[redacted]; First Dose Date: 29DEC20[redacted]; Last Dose Date: 16JUN20[redacted]#								
心臓障害 心房細動 Atrial fibrillation(1)	05MAR20[redacted] (69) *	09MAR20[redacted] (73) *	5	2	NA/ No/ Yes	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 282309[redacted]; Randomized Date: 24MAY20[redacted]; First Dose Date: 31MAY20[redacted]; Last Dose Date: 12MAR20[redacted]*								
筋骨格系および結合組織障害 背部痛 Worsening back pain(8)	16MAY20[redacted] (-8)	31MAY20[redacted] (8)	16	3	NA/ NA/ NA	NA/ NA/ NA	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
#　：「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 80）

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 静脈炎 Flebitis right arm(1)	23MAY20[redacted] (-1)	MAY20[redacted] (-)		3	NA/ NA/ NA	NA/ NA/ NA	Hospitalization	Recovered/ Resolved
感染症および寄生虫症 気道感染 Respiratory infection(2)	12JUL20[redacted] (50)	05AUG20[redacted] (74)	25	3	NA/ Yes/ Yes	NA/ Dose Delayed/Drug Interrupted/ Dose Delayed/Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 282309[redacted] ; Randomized Date: 23AUG20[redacted] ; First Dose Date: 25AUG20[redacted] ; Last Dose Date: 28SEP20[redacted] *								
感染症および寄生虫症 肺炎 Pneumonia(7)	15DEC20[redacted] (115)	19DEC20[redacted] (119)	5	3	NA/ Yes/ Yes	NA/ Dose Delayed/ Dose Delayed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved With Sequelae
腎および尿路障害 急性腎不全 Acute renal insufficiency(11)	01OCT20[redacted] (406) *	10OCT20[redacted] (415) *	10	3	NA/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	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） 腺癌 Adenocarcinoma(16)	16APR20[redacted] (603) **	27MAY20[redacted] (644) **	42	5	NA/ Yes/ No	NA/ Dose Not Changed/ Dose Not Changed	Hospitalization	Fatal
Treatment Randmizen: Rd ; Subject ID: 282349[redacted] ; Randomized Date: 25NOV20[redacted] ; First Dose Date: 28NOV20[redacted] ; Last Dose Date: 01MAR20[redacted] *								
感染症および寄生虫症 肺炎 Pneumonia(1)	27FEB20[redacted] (95) *	01MAR20[redacted] (98) *	4	5	NA/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	None	Fatal
Treatment Randmizen: Rd ; Subject ID: 305769[redacted] ; Randomized Date: 18JAN20[redacted] ; First Dose Date: 18JAN20[redacted] ; Last Dose Date: 20FEB20[redacted] *								
呼吸器、胸郭および縦隔障害 気管支痙攣 Bronchospasm(7)	28MAR20[redacted] (71)	30MAR20[redacted] (73)	3	4	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 気道感染 Airway tract infection(8)	30MAR20[redacted] (73)	04APR20[redacted] (78)	6	3	NA/ No/ No	NA/ Dose Delayed/Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 肺塞栓症 Pulmonary emboli(19)	12MAR20[redacted] (420) *	22MAR20[redacted] (430) *	11	4	NA/ Yes/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 348029[redacted] ; Randomized Date: 13JAN20[redacted] ; First Dose Date: 16JAN20[redacted] ; Last Dose Date: 03FEB20[redacted]								

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＊＊　：「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 81）

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 全身健康状態異常 Poor general condition(1)	19JAN20[redacted] (7)	25JAN20[redacted] (13)	7	2	NA/ Yes/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
臨床検査 全身健康状態異常 Poor general condition(2)	02FEB20[redacted] (21)	10FEB20[redacted] (29)	9	3	NA/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 382769[redacted] ; Randomized Date: 14FEB20[redacted]; First Dose Date: 14FEB20[redacted]; Last Dose Date: 16JUN20[redacted]#								
感染症および寄生虫症 気管支肺炎 Bronchopneumonia(18)	15APR20[redacted] (792) **	23APR20[redacted] (800) **	9	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 382769[redacted] ; Randomized Date: 27JUN20[redacted]; First Dose Date: 27JUN20[redacted]; Last Dose Date: 04JUL20[redacted]								
皮膚および皮下組織障害 発疹 Rash(1)	30JUN20[redacted] (4)	14JUL20[redacted] (18)	15	2	NA/ Yes/ No	NA/ Drug Withdrawn/ Drug Withdrawn	None	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 382769[redacted] ; Randomized Date: 14NOV20[redacted]; First Dose Date: 14NOV20[redacted]; Last Dose Date: 05DEC20[redacted]								
一般・全身障害および投与部位の状態 疾患進行 Disease progression(8)	27DEC20[redacted] (44)	17JAN20[redacted] (65) *	22	5	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Hospitalization	Fatal
Treatment Randmizen: Rd ; Subject ID: 382769[redacted] ; Randomized Date: 05FEB20[redacted]; First Dose Date: 06FEB20[redacted]; Last Dose Date: 06JUL20[redacted]*								
傷害、中毒および処置合併症 硬膜下血腫 Subdural hematoma(5)	05JUL20[redacted] (152)	03AUG20[redacted] (181)	30	2	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 382779[redacted] ; Randomized Date: 21MAR20[redacted]; First Dose Date: 21MAR20[redacted]; Last Dose Date: 06AUG20[redacted]*								
代謝および栄養障害 無機質欠乏 Mineral deficiency(14)	23JUL20[redacted] (125)	28JUL20[redacted] (130)	6	3	NA/ No/ Yes	NA/ Dose Not Changed/ Dose Delayed/Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
血管障害 深部静脈血栓症 Deep vein thrombosis(15)	15AUG20[redacted] (148)	19AUG20[redacted] (152)	5	3	NA/ Yes/ No	NA/ Dose Delayed/Drug Interrupted/ Dose Delayed/Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
肝胆道系障害 急性胆嚢炎 Accute cholecystitis(68)	23FEB20[redacted] (340) *	02MAR20[redacted] (348) *	9	3	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 382779[redacted] ; Randomized Date: 11JUL20[redacted]; First Dose Date: 11JUL20[redacted]; Last Dose Date: 01JAN20[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 82）

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(4)	10SEP20[redacted] (62)	22SEP20[redacted] (74)	13	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
腎および尿路障害 急性腎不全 Acute renal insufficience(5)	15SEP20[redacted] (67)	22SEP20[redacted] (74)	8	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
感染症および寄生虫症 ウイルス性肺炎 Pneumonia (h1n1 positive)(16)	02JAN20[redacted] (542) **	14JAN20[redacted] (554) **	13	5	NA/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Hospitalization	Fatal
Treatment Randmizen: Rd ; Subject ID: 382779[redacted]; Randomized Date: 08AUG20[redacted]; First Dose Date: 08AUG20[redacted]; Last Dose Date: 30JAN20[redacted] *								
感染症および寄生虫症 肺炎 Pneumonia(18)	22DEC20[redacted] (137)	27DEC20[redacted] (142)	6	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
感染症および寄生虫症 気管支肺炎 Bronchopneumonia(36)	13JAN20[redacted] (159) *	26FEB20[redacted] (203) *	45	5	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Hospitalization	Fatal
Treatment Randmizen: Rd ; Subject ID: 382779[redacted]; Randomized Date: 10OCT20[redacted]; First Dose Date: 10OCT20[redacted]; Last Dose Date: 23JAN20[redacted] **								
神経系障害 脊髄圧迫 Accute compression of spinal cord(20)	04JAN20[redacted] (453) **	11JAN20[redacted] (460) **	8	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 382779[redacted]; Randomized Date: 02NOV20[redacted]; First Dose Date: 02NOV20[redacted]; Last Dose Date: 14MAR20[redacted] *								
感染症および寄生虫症 肺炎 Pneumonia(5)	21JAN20[redacted] (81) *	26JAN20[redacted] (86) *	6	3	NA/ No/ No	NA/ Dose Delayed/ Dose Delayed	Hospitalization	Recovered/ Resolved
感染症および寄生虫症 気管支肺炎 Bronchopneumonia(15)	09APR20[redacted] (160) *	17APR20[redacted] (168) *	9	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 382789[redacted]; Randomized Date: 17APR20[redacted]; First Dose Date: 18APR20[redacted]; Last Dose Date: 11JUL20[redacted]								
一般・全身障害および投与部位の状態 粘膜の炎症 Infection -mucositis(2)	30MAY20[redacted] (44)	10JUN20[redacted] (55)	12	3	NA/ Yes/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
一般・全身障害および投与部位の状態 全身健康状態低下 Deterioration of general health condition(6)	11JUL20[redacted] (86)	24JUL20[redacted] (99)	14	4	NA/ Yes/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	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 83）

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
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） 消化器新生物 Gastrointestinal tumor(8)	24JUL20[redacted] (99)	[ONGOING] (-)		1	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	None	Not Recovered/ Not Resolved
心臓障害 心不全 Cardiac failure(7)	24JUL20[redacted] (99)	24JUL20[redacted] (99)	1	5	NA/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	None	Fatal
Treatment Randmizen: Rd ; Subject ID: 382789[redacted]; Randomized Date: 08NOV20[redacted]; First Dose Date: 08NOV20[redacted]; Last Dose Date: 10JUN20[redacted]#								
感染症および寄生虫症 感染 Infection of unknown origin(1)	29NOV20[redacted] (22)	12DEC20[redacted] (35)	14	2	NA/ No/ No	NA/ Dose Not Changed/ Drug Interrupted	Conmeds/ Procedure Required	Recovered/ Resolved
筋骨格系および結合組織障害 関節痛 Pain of the hip of left lower leg of unknown origin(41)	08JUL20[redacted] (609)**	15JUL20[redacted] (616) **	8	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 382789[redacted]; Randomized Date: 22NOV20[redacted]; First Dose Date: 23NOV20[redacted]; Last Dose Date: 04DEC20[redacted]								
一般・全身障害および投与部位の状態 突然死 Sudden death(2)	04DEC20[redacted] (13)	04DEC20[redacted] (13)	1	5	NA/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	None	Fatal
Treatment Randmizen: Rd ; Subject ID: 382789[redacted]; Randomized Date: 06JAN20[redacted]; First Dose Date: 09JAN20[redacted]; Last Dose Date: 15APR20[redacted]								
呼吸器、胸郭および縦隔障害 慢性閉塞性肺疾患 Exacerbation of chronic obstructive pulmonary disease(2)	01FEB20[redacted] (27)	07FEB20[redacted] (33)	7	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 慢性閉塞性肺疾患 Exacerbation of chronic obstructive pulmonary disease(14)	06APR20[redacted] (92)	13APR20[redacted] (99)	8	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
呼吸器、胸郭および縦隔障害 呼吸困難 Dyspnoea(15)	13APR20[redacted] (99)	06JUN20[redacted] (153)	55	3	NA/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Hospitalization	Not Recovered/ Not Resolved
Treatment Randmizen: Rd ; Subject ID: 382789[redacted]; Randomized Date: 30DEC20[redacted]; First Dose Date: 02JAN20[redacted]; Last Dose Date: 09JUN20[redacted] **								
呼吸器、胸郭および縦隔障害 肺臓炎 Pneumonitis(14)	21JAN20[redacted] (389) *	20MAR20[redacted] (447) *	59	4	NA/ Yes/ Yes	NA/ Dose Reduced/Drug Interrupted/ Drug Withdrawn	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 84）

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 筋力低下 General muscle weakness(23)	20MAR20[redacted] (447) *	14MAY20[redacted] (502) *	56	3	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	None	Recovered/ Resolved With Sequelae
感染症および寄生虫症 気管支肺炎 Bronchopneumonia(29)	13DEC20[redacted] (715) *	17DEC20[redacted] (719) *	5	3	NA/ No/ NA	NA/ Drug Interrupted/ NA	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 382789[redacted] ; Randomized Date: 07FEB20[redacted]; First Dose Date: 07FEB20[redacted]; Last Dose Date: 16JUN20[redacted] **								
筋骨格系および結合組織障害 顎骨壊死 Osteonecrosis mandibule(36)	26AUG20[redacted] (567) *	31AUG20[redacted] (572) *	6	2	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 382799[redacted]; Randomized Date: 17AUG20[redacted]; First Dose Date: 18AUG20[redacted]; Last Dose Date: 31OCT20[redacted]								
感染症および寄生虫症 肺炎 Pneumonia(1)	21AUG20[redacted] (5)	26AUG20[redacted] (10)	6	3	NA/ Yes/ No	NA/ Dose Reduced/Drug Interrupted/ Dose Reduced/Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 気管支肺炎 Bronchopneumonia(4)	29OCT20[redacted] (74)	04NOV20[redacted] (80)	7	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds	Recovered/ Resolved
感染症および寄生虫症 気管支肺炎 Bronchopneumonia relapsed(6)	21NOV20[redacted] (97)	19JUL20[redacted] (338) *	242	3	NA/ No/ No	NA/ Drug Withdrawn/Drug Interrupted/ Drug Withdrawn/Drug Interrupted	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 382799[redacted]; Randomized Date: 05SEP20[redacted]; First Dose Date: 05SEP20[redacted]; Last Dose Date: 05NOV20[redacted]**								
感染症および寄生虫症 リステリア性敗血症 Listeria sepsis(3)	12APR20[redacted] (221) *	24APR20[redacted] (233) *	13	3	NA/ Yes/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
神経系障害 脳血管発作 Cerebral stroke(11)	18MAY20[redacted] (257) *	24MAY20[redacted] (263) *	7	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
神経系障害 脳血管発作 Cerebral stroke(44)	12JUN20[redacted] (647) **	18JUN20[redacted] (653) **	7	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 382799[redacted]; Randomized Date: 17OCT20[redacted]; First Dose Date: 17OCT20[redacted]; Last Dose Date: 18JUN20[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 85）

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 Cerebral stroke(7)	29APR20[redacted] (196) *	03MAY20[redacted] (200) *	5	3	NA/ No/ Yes	NA/ Drug Interrupted/ Dose Reduced/Drug Interrupted	None/ Procedure Required/ Hospitalization	Recovered/ Resolved
肝胆道系障害 急性胆嚢炎 Acute cholecystitis(8)	29APR20[redacted] (196) *	03MAY20[redacted] (200) *	5	3	NA/ No/ No	NA/ 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 疾患進行 Disease progression(16)	02JUL20[redacted] (260) *	03JUL20[redacted] (261) *	2	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	None/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 382799[redacted]; Randomized Date: 17OCT20[redacted]; First Dose Date: 17OCT20[redacted]; Last Dose Date: 18JUN20[redacted]*								
一般・全身障害および投与部位の状態 疾患進行 Disease progression(17)	18JUN20[redacted] (246) *	22JUN20[redacted] (250) *	5	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
感染症および寄生虫症 尿路性敗血症 Urosepsis(18)	11JUL20[redacted] (269) *	18JUL20[redacted] (276) *	8	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 382799[redacted]; Randomized Date: 12DEC20[redacted]; First Dose Date: 12DEC20[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 syndrom(19)	01OCT20[redacted] (295) *	05OCT20[redacted] (299) *	5	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
筋骨格系および結合組織障害 筋骨格痛 Vertebral algical syndrom(32)	27MAY20[redacted] (533) **	31MAY20[redacted] (537) **	5	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
筋骨格系および結合組織障害 筋骨格痛 Vertebral algical syndrome worsening(42)	16SEP20[redacted] (645) **	02OCT20[redacted] (661) **	17	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 382799[redacted]; Randomized Date: 19DEC20[redacted]; First Dose Date: 19DEC20[redacted]; Last Dose Date: 08AUG20[redacted]**								
感染症および寄生虫症 気道感染 Respiratory infection(15)	29SEP20[redacted] (286) *	04NOV20[redacted] (322) *	37	3	NA/ Yes/ Yes	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 気管支肺炎 Bronchopneumonia(19)	21APR20[redacted] (490) **	26APR20[redacted] (495) **	6	3	NA/ No/ No	NA/ 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，
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 86）

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 便秘 Obstipation(23)	25MAY20[redacted] (524) **	27MAY20[redacted] (526) **	3	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
一般・全身障害および投与部位の状態 全身健康状態低下 General physical health deterioration(25)	31MAY20[redacted] (530) **	18JUN20[redacted] (548) **	19	3	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 気管支肺炎 Bronchopneumonia(22)	22JUN20[redacted] (552) **	02JUL20[redacted] (562) **	11	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
胃腸障害 便秘 Obstipation(29)	09AUG20[redacted] (600) **	13AUG20[redacted] (604) **	5	3	NA/ No/ No	NA/ 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 全身健康状態低下 General physical health deterioration(30)	30AUG20[redacted] (621) **	25SEP20[redacted] (647) **	27	5	NA/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Hospitalization	Fatal
Treatment Randmizen: Rd ; Subject ID: 394779[redacted] ; Randomized Date: 27APR20[redacted]; First Dose Date: 27APR20[redacted]; Last Dose Date: 12JUL20[redacted] *								
感染症および寄生虫症 副鼻腔炎 Sinusitis(1)	31MAY20[redacted] (35)	01JUN20[redacted] (36)	2	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
代謝および栄養障害 ２型糖尿病 Diabettes mellitus - type 2(2)	29SEP20[redacted] (156)	02OCT20[redacted] (159)	4	4	NA/ No/ Yes	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
神経系障害 脊髄圧迫 Spinal cord compression(11)	12JUL20[redacted] (443) *	19JUL20[redacted] (450) *	8	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 394779[redacted] ; Randomized Date: 23MAY20[redacted]; First Dose Date: 24MAY20[redacted]; Last Dose Date: 16JUN20[redacted] #								
筋骨格系および結合組織障害 背部痛 Worsening of back pains(25)	11MAY20[redacted] (1085) #	14MAY20[redacted] (1088) #	4	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 394779[redacted]; Randomized Date: 26JUN20[redacted]; First Dose Date: 27JUN20[redacted]; Last Dose Date: 11JUN20[redacted] #								
感染症および寄生虫症 インフルエンザ Influenza virus type a(12)	13FEB20[redacted] (599) **	18FEB20[redacted] (604) **	6	3	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
胃腸障害 小腸炎 Intestinal inflammation(23)	21MAR20[redacted] (1000) #	25MAR20[redacted] (1004) #	5	3	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	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 87）

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(24)	21MAR20[redacted] (1000) #	25MAR20[redacted] (1004) #	5	3	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
血管障害 深部静脈血栓症 Acute deep venous thrombosis of calf(27)	01MAY20[redacted] (1041) #	02MAY20[redacted] (1042) #	2	3	NA/ Yes/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Not Recovered/ Not Resolved
傷害、中毒および処置合併症 顎の骨折 Open fracture of body of mandibula -right(31)	10JUN20[redacted] (1081)#	16JUN20[redacted] (1087) #	7	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 394779[redacted]; Randomized Date: 18JUL20[redacted]; First Dose Date: 20JUL20[redacted]; Last Dose Date: 18MAR20[redacted] #								
筋骨格系および結合組織障害 腰部脊柱管狭窄症 Spinal stenosis of lumbar region(8)	10JAN20[redacted] (177) *	25JAN20[redacted] (192) *	16	3	NA/ No/ No	NA/ Dose Delayed/ Dose Delayed	Procedure Required	Recovered/ Resolved
神経系障害 脳血管発作 Cerebrovascular accident (cva)(20)	17MAR20[redacted] (609) **	14APR20[redacted] (637) **	29	3	NA/ Yes/ No	NA/ Dose Reduced/Drug Interrupted/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 394789[redacted]; Randomized Date: 10NOV20[redacted]; First Dose Date: 13NOV20[redacted]; Last Dose Date: 25JUN20[redacted] *								
胃腸障害 腹痛 Abdominal pain(7)	20MAY20[redacted] (193) *	22MAY20[redacted] (195) *	3	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
一般・全身障害および投与部位の状態 疾患進行 Progressive disease(10)	26JUN20[redacted] (230) *	10JUL20[redacted] (244) *	15	5	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Fatal
感染症および寄生虫症 肺炎 Pneumonia(13)	01JUL20[redacted] (235) *	[ONGOING] (-)		4	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required	Not Recovered/ Not Resolved
Treatment Randmizen: Rd ; Subject ID: 394789[redacted]; Randomized Date: 10JAN20[redacted]; First Dose Date: 12JAN20[redacted]; Last Dose Date: 01MAR20[redacted]								
感染症および寄生虫症 上気道感染 Upper respiratory infection(1)	04JAN20[redacted] (-6)	08JAN20[redacted] (-2)	5	1	NA/ NA/ NA	NA/ NA/ NA	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 気管支炎 Acute bronchitis(2)	05FEB20[redacted] (27)	09FEB20[redacted] (31)	5	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	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 88）

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 呼吸障害 Respiratory abnormality(3)	20FEB20[redacted] (42)	23FEB20[redacted] (45)	4	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 394789[redacted]; Randomized Date: 29JAN20[redacted]; First Dose Date: 31JAN20[redacted]; Last Dose Date: 15MAY20[redacted]								
一般・全身障害および投与部位の状態 胸痛 Uncpecified chest pain(2)	02FEB20[redacted] (5)	06FEB20[redacted] (9)	5	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 394799[redacted] ; Randomized Date: 01JUN20[redacted]; First Dose Date: 02JUN20[redacted]; Last Dose Date: 28DEC20[redacted]								
皮膚および皮下組織障害 急性汎発性発疹性膿疱症 Acute generalized exanthematous pustulosis(1)	13JUN20[redacted] (13)	19JUN20[redacted] (19)	7	3	NA/ Yes/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Not Recovered/ Not Resolved
Treatment Randmizen: Rd ; Subject ID: 394799[redacted] ; Randomized Date: 22SEP20[redacted]; First Dose Date: 25SEP20[redacted]; Last Dose Date: 20JUN20[redacted] **								
一般・全身障害および投与部位の状態 発熱 Fever(1)	27SEP20[redacted] (6)	30SEP20[redacted] (9)	4	1	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
心臓障害 うっ血性心不全 Congestive heart(9)	03JAN20[redacted] (104) *	05JAN20[redacted] (106) *	3	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
眼障害 網膜静脈閉塞 Central retinal vein occlusion - left(33)	20JUN20[redacted] (638) **	[ONGOING] (-)		3	NA/ Yes/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Procedure Required	Not Recovered/ Not Resolved
Treatment Randmizen: Rd ; Subject ID: 394799[redacted] ; Randomized Date: 09FEB20[redacted]; First Dose Date: 15FEB20[redacted]; Last Dose Date: 28MAY20[redacted]								
肝胆道系障害 肝毒性 Liver toxicity event(9)	28MAY20[redacted] (110)	14JUN20[redacted] (127)	18	3	NA/ Yes/ No	NA/ Drug Withdrawn/ Drug Withdrawn	None	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 394829[redacted] ; Randomized Date: 20JUL20[redacted]; First Dose Date: 20JUL20[redacted]; Last Dose Date: 14SEP20[redacted] **								
感染症および寄生虫症 肺炎 Pneumonia(7)	21JAN20[redacted] (552) **	23JAN20[redacted] (554) **	3	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
心臓障害 狭心症 Stable angina pectoris(15)	17JUL20[redacted] (729) **	18JUL20[redacted] (730) **	2	1	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 394829[redacted] ; Randomized Date: 01NOV20[redacted]; First Dose Date: 02NOV20[redacted]; Last Dose Date: 10FEB20[redacted] *								

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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 89）

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 Pulmonary embolism(1)	11FEB20[redacted] (103) *	11FEB20[redacted] (103) *	1	5	NA/ Yes/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Procedure Required	Fatal
Treatment Randmizen: Rd ; Subject ID: 394829[redacted] ; Randomized Date: 08FEB20[redacted] ; First Dose Date: 09FEB20[redacted] ; Last Dose Date: 25APR20[redacted] *								
筋骨格系および結合組織障害 四肢痛 Pain in limb(9)	20MAY20[redacted] (468) *	26MAY20[redacted] (474) *	7	3	NA/ No/ No	NA/ NA/ NA	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 394829[redacted] ; Randomized Date: 15FEB20[redacted] ; First Dose Date: 19FEB20[redacted] ; Last Dose Date: 11MAR20[redacted]								
感染症および寄生虫症 肺炎 Pneumonia(1)	01MAR20[redacted] (16)	07MAR20[redacted] (22)	7	3	NA/ No/ No	NA/ Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Not Recovered/ Not Resolved
Treatment Randmizen: Rd ; Subject ID: 394859[redacted] ; Randomized Date: 24JUL20[redacted] ; First Dose Date: 24JUL20[redacted] ; Last Dose Date: 04NOV20[redacted]								
感染症および寄生虫症 肺炎 Pneumonia(14)	23OCT20[redacted] (92)	26OCT20[redacted] (95)	4	3	NA/ Yes/ No	NA/ Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 気管支炎 Acute bronchitis(15)	05NOV20[redacted] (105)	08NOV20[redacted] (108)	4	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 394859[redacted] ; Randomized Date: 26SEP20[redacted] ; First Dose Date: 27SEP20[redacted] ; Last Dose Date: 29MAY20[redacted] *								
一般・全身障害および投与部位の状態 発熱 Fever(23)	22MAY20[redacted] (240) *	24MAY20[redacted] (242) *	3	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 412519[redacted] ; Randomized Date: 29OCT20[redacted] ; First Dose Date: 31OCT20[redacted] ; Last Dose Date: 16JUN20[redacted] #								
傷害、中毒および処置合併症 大腿骨骨折 Intertrochanteric hip fracture of right leg(2)	17OCT20[redacted] (720) **	21OCT20[redacted] (724) **	5	4	NA/ No/ Yes	NA/ Dose Not Changed/ Dose Delayed	Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 412529[redacted] ; Randomized Date: 06OCT20[redacted] ; First Dose Date: 07OCT20[redacted] ; Last Dose Date: 25JUL20[redacted] **								
血管障害 低血圧 Hypotension, grade 4(1)	21OCT20[redacted] (16)	22OCT20[redacted] (17)	2	4	NA/ No/ No	NA/ 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 死亡 Unspecified cause of death(9)	26JUL20[redacted] (660) **	26JUL20[redacted] (660) **	1	5	NA/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	None	Fatal
Treatment Randmizen: Rd ; Subject ID: 412539[redacted] ; Randomized Date: 14MAY20[redacted] ; First Dose Date: 16MAY20[redacted] ; Last Dose Date: 11OCT20[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 90）

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 Febrile temperature(14)	26SEP20[redacted] (502) *	28OCT20[redacted] (534) *	33	2	NA/ Yes/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
内分泌障害 副腎機能不全 Acute iatrogenic adrenal failure(13)	27SEP20[redacted] (503) *	28OCT20[redacted] (534) *	32	4	NA/ No/ Yes	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
腎および尿路障害 腎症 Myeloma nephropathy(15)	27SEP20[redacted] (503) *	28OCT20[redacted] (534) *	32	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	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） 多発性骨髄腫 Multiple myeloma progression(17)	27SEP20[redacted] (503) *	28OCT20[redacted] (534) *	32	5	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	None	Fatal
Treatment Randmizen: Rd ; Subject ID: 412539[redacted]; Randomized Date: 26AUG20[redacted]; First Dose Date: 29AUG20[redacted]; Last Dose Date: 25JUN20[redacted] *								
腎および尿路障害 急性腎不全 Acute renal failure(9)	26JUN20[redacted] (306) *	06JUL20[redacted] (316) *	11	5	NA/ Yes/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Procedure Required/ Hospitalization	Fatal
Treatment Randmizen: Rd ; Subject ID: 412549[redacted]; Randomized Date: 02APR20[redacted]; First Dose Date: 04APR20[redacted]; Last Dose Date: 09JAN20[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 Bicytopenia probably due to secondary mds(5)	12DEC20[redacted] (621) *	30JAN20[redacted] (670) **	50	5	NA/ Yes/ No	NA/ Drug Withdrawn/Drug Interrupted/ Drug Withdrawn/Drug Interrupted	Procedure Required/ Hospitalization	Fatal
Treatment Randmizen: Rd ; Subject ID: 412549[redacted]; Randomized Date: 19JUN20[redacted]; First Dose Date: 21JUN20[redacted]; Last Dose Date: 05MAY20[redacted] *								
神経系障害 昏睡 Coma nos(3)	07MAY20[redacted] (324) *	08MAY20[redacted] (325) *	2	5	NA/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Hospitalization	Fatal
Treatment Randmizen: Rd ; Subject ID: 412549[redacted]; Randomized Date: 25SEP20[redacted]; First Dose Date: 27SEP20[redacted]; Last Dose Date: 19FEB20[redacted] **								
筋骨格系および結合組織障害 病的骨折 Open reduction and internal fixation-pathological fracture of femur(11)	22DEC20[redacted] (455) *	[ONGOING] (-)		4	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Hospitalization	Not Recovered/ Not Resolved
Treatment Randmizen: Rd ; Subject ID: 412549[redacted]; Randomized Date: 25DEC20[redacted]; First Dose Date: 27DEC20[redacted]; Last Dose Date: 08MAY20[redacted] *								
血液およびリンパ系障害 貧血 Anemia(1)	10JAN20[redacted] (17) *	16JAN20[redacted] (23) *	7	4	NA/ Yes/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ 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 91）

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 好中球減少症 Neutropenia(11)	02MAY20[redacted] (130) *	07MAY20[redacted] (135) *	6	4	NA/ Yes/ No	NA/ Dose Reduced/Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 412569[redacted]; Randomized Date: 30JAN20[redacted]; First Dose Date: 02FEB20[redacted]; Last Dose Date: 02AUG20[redacted]								
血液およびリンパ系障害 貧血 Secondary anemia(4)	26JUL20[redacted] (178)	28JUL20[redacted] (180)	3	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
一般・全身障害および投与部位の状態 疾患進行 Progressive disease(3)	15AUG20[redacted] (198)	15AUG20[redacted] (198)	1	5	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	None	Fatal
Treatment Randmizen: Rd ; Subject ID: 412569[redacted]; Randomized Date: 12FEB20[redacted]; First Dose Date: 15FEB20[redacted]; Last Dose Date: 03MAY20[redacted]								
血液およびリンパ系障害 貧血 Anaemia(1)	26APR20[redacted] (74)	17MAY20[redacted] (95)	22	3	NA/ Yes/ No	NA/ Drug Interrupted/ Drug Interrupted	Procedure Required/ Hospitalization	Not Recovered/ Not Resolved
腎および尿路障害 腎機能障害 Renal dysfunction(2)	26APR20[redacted] (74)	17MAY20[redacted] (95)	22	2	NA/ Yes/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 412569[redacted]; Randomized Date: 14FEB20[redacted]; First Dose Date: 16FEB20[redacted]; Last Dose Date: 06DEC20[redacted]								
感染症および寄生虫症 細菌性肺炎 Bacterial pneumonia in the right lung(2)	10JUL20[redacted] (148)	18JUL20[redacted] (156)	9	2	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 442019[redacted]; Randomized Date: 04JUL20[redacted]; First Dose Date: 05JUL20[redacted]; Last Dose Date: 16JUN20[redacted] #								
一般・全身障害および投与部位の状態 発熱 Fever(5)	28AUG20[redacted] (56)	29SEP20[redacted] (88)	33	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 インフルエンザ Influenza(11)	26FEB20[redacted] (604) **	26FEB20[redacted] (604) **	1	3	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 442019[redacted]; Randomized Date: 20NOV20[redacted]; First Dose Date: 22NOV20[redacted]; Last Dose Date: 20FEB20[redacted] **								
感染症および寄生虫症 泌尿生殖器感染 Urogenital infection(10)	20FEB20[redacted] (459) **	04MAR20[redacted] (471) **	13	3	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 442019[redacted]; Randomized Date: 23JAN20[redacted]; First Dose Date: 25JAN20[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 92）

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 Bronchitis(3)	25FEB20[redacted] (400) *	02MAR20[redacted] (405) *	6	3	NA/ Yes/ Yes	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 442029[redacted] ; Randomized Date: 07APR20[redacted]; First Dose Date: 07APR20[redacted]; Last Dose Date: 12OCT20[redacted]								
血液およびリンパ系障害 好中球減少症 Neutropenia(5)	19MAY20[redacted] (43)	31MAY20[redacted] (55)	13	4	NA/ Yes/ No	NA/ Dose Reduced/Drug Interrupted/ Dose Not Changed	None	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 442029[redacted] ; Randomized Date: 02SEP20[redacted]; First Dose Date: 05SEP20[redacted]; Last Dose Date: 06FEB20[redacted] *								
感染症および寄生虫症 尿路感染 Urinary tract infection(3)	01OCT20[redacted] (30)	03OCT20[redacted] (32)	3	2	NA/ Yes/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 好中球減少症 Neutropenia(10)	02OCT20[redacted] (31)	02OCT20[redacted] (31)	1	4	NA/ Yes/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 442029[redacted] ; Randomized Date: 14OCT20[redacted]; First Dose Date: 17OCT20[redacted]; Last Dose Date: 27MAY20[redacted]#								
感染症および寄生虫症 肺炎 Pneumonia left side(5)	31JAN20[redacted] (476) **	05FEB20[redacted] (481) **	6	2	NA/ No/ No	NA/ 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(8)	02NOV20[redacted] (751) **	08NOV20[redacted] (757) **	7	3	NA/ No/ Yes	NA/ Drug Interrupted/ Dose Reduced/Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 463029[redacted] ; Randomized Date: 12APR20[redacted]; First Dose Date: 13APR20[redacted]; Last Dose Date: 16JUN20[redacted]#								
血管障害 深部静脈血栓症 Deep vein thrombosis(1)	30JUL20[redacted] (476) *	07AUG20[redacted] (484) *	9	2	NA/ Yes/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 463029[redacted] ; Randomized Date: 12JUN20[redacted]; First Dose Date: 14JUN20[redacted]; Last Dose Date: 03JUN20[redacted]**								
代謝および栄養障害 高カルシウム血症 Hypercalcaemia(1)	27MAY20[redacted] (716) **	10JUN20[redacted] (730) **	15	4	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 463029[redacted] ; Randomized Date: 17SEP20[redacted]; First Dose Date: 19SEP20[redacted]; Last Dose Date: 07NOV20[redacted]								
心臓障害 心不全 Cardiac decompensation(1)	12NOV20[redacted] (57)	12NOV20[redacted] (57)	1	5	NA/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	None	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 93）

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: Rd ; Subject ID: 463039[redacted] ; Randomized Date: 17JAN20[redacted]; First Dose Date: 19JAN20[redacted]; Last Dose Date: 11APR20[redacted]								
感染症および寄生虫症 気管支肺アスペルギルス症 Pulmonary aspergillosis(1)	01MAR20[redacted] (44)	25MAR20[redacted] (68)	25	3	NA/ No/ No	NA/ Dose Not Changed/ 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） 多発性骨髄腫 Fever due to myeloma(2)	05APR20[redacted] (79)	14APR20[redacted] (88)	10	3	NA/ No/ No	NA/ Dose Not Changed/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 463039[redacted] ; Randomized Date: 02MAR20[redacted]; First Dose Date: 02MAR20[redacted]; Last Dose Date: 18MAY20[redacted]								
胃腸障害 下痢 Diarrhoea(1)	06MAY20[redacted] (66)	12MAY20[redacted] (72)	7	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 463039[redacted] ; Randomized Date: 08APR20[redacted]; First Dose Date: 11APR20[redacted]; Last Dose Date: 02JAN20[redacted] **								
感染症および寄生虫症 肺炎 Pneumonia(1)	17APR20[redacted] (10)	27APR20[redacted] (20)	11	3	NA/ No/ No	NA/ Dose Not Changed/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 463039[redacted] ; Randomized Date: 06MAY20[redacted]; First Dose Date: 09MAY20[redacted]; Last Dose Date: 01MAY20[redacted] *								
神経系障害 痙攣 Convulsion(1)	19SEP20[redacted] (137)	19SEP20[redacted] (137)	1	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 463039[redacted] ; Randomized Date: 19JUN20[redacted]; First Dose Date: 21JUN20[redacted]; Last Dose Date: 12JUN20[redacted] **								
感染症および寄生虫症 気管支炎 Bronchitis(17)	24FEB20[redacted] (617) **	05MAR20[redacted] (626) **	10	2	NA/ Yes/ Yes	NA/ Dose Not Changed/ Dose Reduced/Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 463039[redacted] ; Randomized Date: 30JUN20[redacted]; First Dose Date: 01JUL20[redacted]; Last Dose Date: 26MAY20[redacted] #								
心臓障害 うっ血性心不全 Congestive heart failure(3)	21SEP20[redacted] (84)	24SEP20[redacted] (87)	4	2	NA/ No/ Yes	NA/ Dose Not Changed/ Dose Reduced/Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 463039[redacted] ; Randomized Date: 03AUG20[redacted]; First Dose Date: 04AUG20[redacted]; Last Dose Date: 08NOV20[redacted]								
感染症および寄生虫症 敗血症 Sepsis(3)	11NOV20[redacted] (101)	13NOV20[redacted] (103)	3	5	NA/ Yes/ Yes	NA/ Dose Not Changed/ Dose Not Changed	Conmeds	Fatal
Treatment Randmizen: Rd ; Subject ID: 463039[redacted] ; Randomized Date: 03AUG20[redacted]; First Dose Date: 04AUG20[redacted]; Last Dose Date: 25JUL20[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 94）

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 ウイルス性気道感染 Viral infection of respiratory tract(1)	09OCT20[redacted] (68)	13OCT20[redacted] (72)	5	2	NA/ Yes/ Yes	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 463039[redacted]; Randomized Date: 06JAN20[redacted]; First Dose Date: 10JAN20[redacted]; Last Dose Date: 04DEC20[redacted]								
傷害、中毒および処置合併症 関節脱臼 Luxation of the scaphoid bone gr ii(16)	04JUL20[redacted] (181)	05JUL20[redacted] (182)	2	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 463049[redacted]; Randomized Date: 20SEP20[redacted]; First Dose Date: 22SEP20[redacted]; Last Dose Date: 16JUN20[redacted]#								
感染症および寄生虫症 肺炎 Pneumonia(1)	11JAN20[redacted] (114) *	25JAN20[redacted] (128) *	15	3	NA/ No/ No	NA/ Dose Delayed/ Dose Delayed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 463069[redacted]; Randomized Date: 22FEB20[redacted]; First Dose Date: 24FEB20[redacted]; Last Dose Date: 14MAR20[redacted]*								
呼吸器、胸郭および縦隔障害 呼吸不全 Respiratory insufficiency (information from the husband)(9)	15MAR20[redacted] (388) *	19MAR20[redacted] (392) *	5	5	NA/ No/ Yes	NA/ Drug Withdrawn/ Drug Withdrawn	None	Fatal
Treatment Randmizen: Rd ; Subject ID: 463069[redacted]; Randomized Date: 25OCT20[redacted]; First Dose Date: 27OCT20[redacted]; Last Dose Date: 19SEP20[redacted]*								
心臓障害 不安定狭心症 Instabil angina pectoris(2)	10AUG20[redacted] (291) *	13AUG20[redacted] (294) *	4	3	NA/ No/ Yes	NA/ Dose Not Changed/ Dose Reduced	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 463079[redacted]; Randomized Date: 22FEB20[redacted]; First Dose Date: 22FEB20[redacted]; Last Dose Date: 02JUL20[redacted]*								
血管障害 深部静脈血栓症 Deep vein thrombosis on the left lower limb(12)	12MAR20[redacted] (385) *	17APR20[redacted] (421) *	37	3	NA/ Yes/ No	NA/ Drug Interrupted/ Dose Not Changed	Conmeds	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 463079[redacted]; Randomized Date: 08SEP20[redacted]; First Dose Date: 13SEP20[redacted]; Last Dose Date: 12JUN20[redacted]#								
感染症および寄生虫症 細菌性肺炎 Bacterial pneumonia(9)	19APR20[redacted] (590) **	30APR20[redacted] (601) **	12	3	NA/ No/ No	NA/ Drug Interrupted/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 463089[redacted]; Randomized Date: 20OCT20[redacted]; First Dose Date: 24OCT20[redacted]; Last Dose Date: 02SEP20[redacted]**								
血管障害 深部静脈血栓症 Deep vein thrombosis(7)	21JUN20[redacted] (246) *	26JUN20[redacted] (251) *	6	3	NA/ Yes/ Yes	NA/ Dose Not Changed/ Dose Not Changed	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 95）

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(9)	02SEP20[redacted] (684) **	09SEP20[redacted] (691) **	8	3	NA/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved With Sequelae
Treatment Randmizen: Rd ; Subject ID: 463089[redacted]; Randomized Date: 19JAN20[redacted]; First Dose Date: 23JAN20[redacted]; Last Dose Date: 23MAY20[redacted]								
感染症および寄生虫症 敗血症 Septicaemia(1)	30JAN20[redacted] (12)	06FEB20[redacted] (19)	8	4	NA/ No/ No	NA/ Dose Not Changed/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 敗血症 Septicaemia(4)	18MAY20[redacted] (121)	01JUN20[redacted] (135)	15	4	NA/ No/ Yes	NA/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 463099[redacted]; Randomized Date: 18FEB20[redacted]; First Dose Date: 21FEB20[redacted]; Last Dose Date: 03JUN20[redacted] #								
感染症および寄生虫症 気管支肺炎 Bronchopneumonia(6)	28FEB20[redacted] (376) *	03MAR20[redacted] (380) *	5	3	NA/ Yes/ No	NA/ Dose Delayed/ Dose Delayed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 463099[redacted]; Randomized Date: 07FEB20[redacted]; First Dose Date: 09FEB20[redacted]; Last Dose Date: 01MAR20[redacted]								
一般・全身障害および投与部位の状態 発熱 Fever of unknown origine(2)	08MAR20[redacted] (31)	25MAR20[redacted] (48)	18	1	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 好中球減少症 Chemotherapy induced neutropenia(4)	19MAR20[redacted] (42)	25MAR20[redacted] (48)	7	4	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Not Recovered/ Not Resolved
感染症および寄生虫症 敗血症 Chemotherapy induced sepsis(3)	24MAR20[redacted] (47)	25MAR20[redacted] (48)	2	5	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Fatal
Treatment Randmizen: Rd ; Subject ID: 494269[redacted]; Randomized Date: 27JAN20[redacted]; First Dose Date: 31JAN20[redacted]; Last Dose Date: 13JUN20[redacted] #								
心臓障害 狭心症 Cardiac chest pain(13)	23JUN20[redacted] (148)	27JUN20[redacted] (152)	5	3	NA/ Yes/ No	NA/ Drug Interrupted/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
心臓障害 狭心症 Cardiac chest pain(42)	15JUL20[redacted] (536) *	19JUL20[redacted] (540) *	5	3	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 尿路感染 Urinary track infection(43)	30JUL20[redacted] (551) *	09AUG20[redacted] (561) *	11	3	NA/ No/ No	NA/ Dose Delayed/ Dose Delayed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 494269[redacted]; Randomized Date: 13MAY20[redacted]; First Dose Date: 16MAY20[redacted]; Last Dose Date: 17JUN20[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 96）

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 Lower respiratory infection - pneumonia(1)	18MAY20[redacted] (6)	25MAY20[redacted] (13)	8	3	NA/ No/ No	NA/ Drug Interrupted/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 494269[redacted]; Randomized Date: 27MAY20[redacted]; First Dose Date: 30MAY20[redacted]; Last Dose Date: 11OCT20[redacted]								
感染症および寄生虫症 下気道感染 Lower respiratory tract infection(1)	18OCT20[redacted] (145)	04NOV20[redacted] (162)	18	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 494269[redacted]; Randomized Date: 10SEP20[redacted]; First Dose Date: 13SEP20[redacted]; Last Dose Date: 13JUN20[redacted]#								
感染症および寄生虫症 下気道感染 Infection of lower respiratory(1)	23SEP20[redacted] (14)	05OCT20[redacted] (26)	13	3	NA/ No/ No	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 494269[redacted]; Randomized Date: 04OCT20[redacted]; First Dose Date: 06OCT20[redacted]; Last Dose Date: 03JAN20[redacted]**								
腎および尿路障害 急性腎不全 Acute renal failure(22)	17FEB20[redacted] (503) **	28FEB20[redacted] (514) **	12	5	NA/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Conmeds/ Hospitalization	Fatal
Treatment Randmizen: Rd ; Subject ID: 494269[redacted]; Randomized Date: 06NOV20[redacted]; First Dose Date: 07NOV20[redacted]; Last Dose Date: 16JUN20[redacted]#								
心臓障害 狭心症 Chest angina(10)	08MAY20[redacted] (185) *	12MAY20[redacted] (189) *	5	3	No/ No/ No	NA/ Drug Interrupted/ Dose Reduced	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 494269[redacted]; Randomized Date: 21NOV20[redacted]; First Dose Date: 21NOV20[redacted]; Last Dose Date: 26SEP20[redacted]**								
傷害、中毒および処置合併症 股関節部骨折 Hip fracture(3)	16JAN20[redacted] (57) *	28JAN20[redacted] (69) *	13	3	NA/ No/ No	NA/ Dose Delayed/ Dose Delayed	None/ Procedure Required/ Hospitalization	Recovered/ Resolved
血液およびリンパ系障害 貧血 Anemia(11)	16NOV20[redacted] (362) *	21NOV20[redacted] (367) *	6	4	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved With Sequelae
Treatment Randmizen: Rd ; Subject ID: 494269[redacted]; Randomized Date: 04FEB20[redacted]; First Dose Date: 08FEB20[redacted]; Last Dose Date: 16JUN20[redacted]**								
感染症および寄生虫症 気道感染 Respiratory infection(2)	18MAR20[redacted] (44)	21MAR20[redacted] (47)	4	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
血管障害 低血圧 Hypotension(3)	18MAR20[redacted] (44)	21MAR20[redacted] (47)	4	3	NA/ No/ Yes	NA/ Drug Interrupted/ Drug Interrupted	None/ Hospitalization	Recovered/ Resolved

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：「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 97）

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 Pulmonary embolism(8)	19AUG20[redacted] (198)	31AUG20[redacted] (210)	13	4	NA/ Yes/ No	NA/ Dose Delayed/ Dose Delayed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved With Sequelae
感染症および寄生虫症 気道感染 Respiratory infection(19)	06OCT20[redacted] (246)	15OCT20[redacted] (255)	10	3	NA/ No/ No	NA/ Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
心臓障害 心房細動 Paroxysmal atrial fibrilation(23)	28OCT20[redacted] (268)	31OCT20[redacted] (271)	4	3	NA/ No/ No	NA/ Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 気道感染 Respiratory infection(24)	07NOV20[redacted] (278)	16NOV20[redacted] (287)	10	3	NA/ No/ Yes	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
代謝および栄養障害 脱水 Dehydration(27)	09JAN20[redacted] (341) *	14JAN20[redacted] (346) *	6	3	NA/ No/ No	NA/ Dose Reduced/Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 516519[redacted]; Randomized Date: 01FEB20[redacted]; First Dose Date: 02FEB20[redacted]; Last Dose Date: 20JAN20[redacted]*								
心臓障害 心不全 Cardio decompensation(5)	08FEB20[redacted] (374) *	11FEB20[redacted] (377) *	4	5	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Fatal
呼吸器、胸郭および縦隔障害 肺障害 Pulmonary function impairment(6)	08FEB20[redacted] (374) *	11FEB20[redacted] (377) *	4	5	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Fatal
Treatment Randmizen: Rd ; Subject ID: 516529[redacted]; Randomized Date: 19JUL20[redacted]; First Dose Date: 20JUL20[redacted]; Last Dose Date: 20JAN20[redacted]#								
傷害、中毒および処置合併症 多発骨折 Multiple bones fractures(19)	08FEB20[redacted] (936) #	[ONGOING] (-)		4	NA/ No/ No	NA/ NA/ NA	Conmeds/ Procedure Required/ Hospitalization	Not Recovered/ Not Resolved
傷害、中毒および処置合併症 脾臓損傷 Injury of spleen(20)	08FEB20[redacted] (936) #	[ONGOING] (-)		4	NA/ No/ No	NA/ NA/ NA	Conmeds/ Hospitalization	Not Recovered/ Not Resolved
Treatment Randmizen: Rd ; Subject ID: 516539[redacted]; Randomized Date: 09AUG20[redacted]; First Dose Date: 09AUG20[redacted]; Last Dose Date: 13SEP20[redacted]								
心臓障害 心筋梗塞 Cardiac infarction(1)	20SEP20[redacted] (43)	20SEP20[redacted] (43)	1	5	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds	Fatal
Treatment Randmizen: Rd ; Subject ID: 516549[redacted]; Randomized Date: 20DEC20[redacted]; First Dose Date: 21DEC20[redacted]; Last Dose Date: 31MAY20[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 98）

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 Acute thrombosis of deep veins of left lower extremity(4)	06JUN20[redacted] (170) *	28JUN20[redacted] (192) *	23	2	NA/ Yes/ Yes	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved With Sequelae
Treatment Randmizen: Rd ; Subject ID: 516559[redacted] ; Randomized Date: 31JAN20[redacted]; First Dose Date: 01FEB20[redacted]; Last Dose Date: 16JUN20[redacted] **								
感染症および寄生虫症 肺炎 Lower lobe bilateral pneumonia(30)	26DEC20[redacted] (331)	16JAN20[redacted] (352) *	22	2	NA/ Yes/ Yes	NA/ Drug Interrupted/ Dose Delayed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 516579[redacted] ; Randomized Date: 26JUL20[redacted]; First Dose Date: 28JUL20[redacted]; Last Dose Date: 16JUN20[redacted] #								
筋骨格系および結合組織障害 顎骨壊死 Biphosphonate osteonecrosis of the low jaw(1)	17DEC20[redacted] (511) *	27DEC20[redacted] (521) *	11	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 516589[redacted] ; Randomized Date: 15JUL20[redacted]; First Dose Date: 18JUL20[redacted]; Last Dose Date: 10JUN20[redacted] #								
血管障害 静脈血栓症 Left-side low phlebothrombosis(2)	20MAY20[redacted] (676) **	04JUN20[redacted] (691) **	16	2	NA/ Yes/ Yes	NA/ Drug Interrupted/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺炎 Pneumonia acuta(3)	06MAY20[redacted] (1027) #	23MAY20[redacted] (1044) #	18	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 516589[redacted] ; Randomized Date: 09SEP20[redacted]; First Dose Date: 12SEP20[redacted]; Last Dose Date: 10JUL20[redacted] *								
心臓障害 急性冠動脈症候群 Acute coronary syndrome(1)	03JUL20[redacted] (299) *	24JUL20[redacted] (320) *	22	5	NA/ Yes/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Fatal
Treatment Randmizen: Rd ; Subject ID: 516589[redacted] ; Randomized Date: 19OCT20[redacted]; First Dose Date: 24OCT20[redacted]; Last Dose Date: 05MAR20[redacted] *								
血液およびリンパ系障害 血小板減少症 Thrombocytopenia(3)	13MAR20[redacted] (147) *	05APR20[redacted] (170) *	24	4	NA/ No/ No	NA/ Drug Interrupted/ Dose Not Changed	Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 516589[redacted] ; Randomized Date: 18NOV20[redacted]; First Dose Date: 22NOV20[redacted]; Last Dose Date: 16JUN20[redacted] #								
筋骨格系および結合組織障害 痛風性関節炎 Gout arthritis exacerbation of the right first metatarsophalangeal joint(1)	26JAN20[redacted] (70) *	10FEB20[redacted] (85) *	16	2	NA/ No/ No	NA/ 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 99）

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 血小板障害 Thrombocytopathya(2)	21FEB20[redacted] (96) *	24FEB20[redacted] (99) *	4	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
血管障害 血管炎 Vasculitis(3)	24FEB20[redacted] (99) *	07MAR20[redacted] (111) *	13	3	NA/ Yes/ No	NA/ Dose Delayed/ Dose Delayed	Conmeds/ Hospitalization	Recovered/ Resolved With Sequelae
感染症および寄生虫症 ウイルス性気道感染 Acute respiratory viral infection(4)	15MAR20[redacted] (119) *	29MAR20[redacted] (133) *	15	2	NA/ Yes/ No	NA/ Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
血管障害 血管炎 Vasculitis(6)	29MAR20[redacted] (133) *	22APR20[redacted] (157) *	25	1	NA/ Yes/ No	NA/ Dose Reduced/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
腎および尿路障害 慢性腎不全 Chronic kidney disease(7)	17MAY20[redacted] (182) *	15JUN20[redacted] (211) *	30	2	NA/ Yes/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
代謝および栄養障害 糖尿病 Diabetes(9)	04SEP20[redacted] (292) *	18SEP20[redacted] (306) *	15	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
代謝および栄養障害 痛風 Podagra(10)	26MAY20[redacted] (921) #	03JUN20[redacted] (929) #	9	2	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 516599[redacted]; Randomized Date: 14DEC20[redacted]; First Dose Date: 19DEC20[redacted]; Last Dose Date: 06FEB20[redacted] *								
感染症および寄生虫症 副鼻腔炎 Both side antritis (sinus)(1)	16JAN20[redacted] (34) *	20FEB20[redacted] (69) *	36	1	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	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） 骨髄異形成症候群 Myelodisplastic syndrome(3)	06FEB20[redacted] (55) *	27FEB20[redacted] (76) *	22	5	NA/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Hospitalization	Fatal
Treatment Randmizen: Rd ; Subject ID: 826019[redacted]; Randomized Date: 16MAY20[redacted]; First Dose Date: 18MAY20[redacted]; Last Dose Date: 03JUN20[redacted]#								
眼障害 核性白内障 Posterior nuclear cataract of the right eye(5)	14JAN20[redacted] (975) #	15JAN20[redacted] (976) #	2	3	NA/ No/ No	NA/ 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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表 2.7.4.7-34　重篤な有害事象の一覧表（PX-171-009）（続き 100）

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
眼障害 嚢下白内障 Posterior subcapsular cataract of the right eye(7)	14JAN20[redacted] (975) #	15JAN20[redacted] (976) #	2	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 826019[redacted]; Randomized Date: 23JAN20[redacted]; First Dose Date: 25JAN20[redacted]; Last Dose Date: 02JUN20[redacted] **								
呼吸器、胸郭および縦隔障害 鼻出血 Epistaxis(1)	20JAN20[redacted] (-3)	23JAN20[redacted] (1)	4	4	NA/ NA/ NA	NA/ NA/ NA	Hospitalization	Recovered/ Resolved
感染症および寄生虫症 肺炎 Pneumonia(3)	13FEB20[redacted] (22)	23FEB20[redacted] (32)	11	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
感染症および寄生虫症 結核 Tuberculosis(5)	21MAR20[redacted] (59)	16MAY20[redacted] (115)	57	4	NA/ No/ No	NA/ Dose Not Changed/ Drug Withdrawn	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 826029[redacted]; Randomized Date: 09JAN20[redacted]; First Dose Date: 10JAN20[redacted]; Last Dose Date: 02NOV20[redacted]								
感染症および寄生虫症 急性腎盂腎炎 Acute pyelonephritis(1)	27JUN20[redacted] (171)	03JUL20[redacted] (177)	7	3	NA/ No/ No	NA/ Dose Delayed/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 発熱 Febrile syndrome(2)	06AUG20[redacted] (211)	16AUG20[redacted] (221)	11	3	NA/ No/ No	NA/ Dose Reduced/Drug Interrupted/ Dose Not Changed	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） 肝の悪性新生物 Liver adenocarcinoma(3)	29OCT20[redacted] (295)	[ONGOING] (-)		4	NA/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	None	Not Recovered/ Not Resolved
Treatment Randmizen: Rd ; Subject ID: 896279[redacted]; Randomized Date: 11NOV20[redacted]; First Dose Date: 14NOV20[redacted]; Last Dose Date: 16JUN20[redacted]#								
感染症および寄生虫症 歯膿瘍 Periapical abscess(4)	09JUL20[redacted] (607) **	22JUL20[redacted] (620) **	14	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Procedure Required	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 896289[redacted]; Randomized Date: 07JUL20[redacted]; First Dose Date: 11JUL20[redacted]; Last Dose Date: 09APR20[redacted] *								
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） 悪性黒色腫 Superficial melanoma(10)	27MAR20[redacted] (265) *	27MAR20[redacted] (265) *	1	3	NA/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	Procedure Required	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 101）

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: Rd ; Subject ID: 896289[redacted] ; Randomized Date: 19JUL20[redacted]; First Dose Date: 21JUL20[redacted]; Last Dose Date: 24AUG20[redacted]								
一般・全身障害および投与部位の状態 発熱 Fever(3)	27JUL20[redacted] (9)	03AUG20[redacted] (16)	8	1	NA/ Yes/ No	NA/ Dose Reduced/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
一般・全身障害および投与部位の状態 発熱 Fever over 40 c(2)	25AUG20[redacted] (38)	09SEP20[redacted] (53)	16	3	NA/ Yes/ No	NA/ Drug Withdrawn/ Drug Interrupted	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 896289[redacted] ; Randomized Date: 10NOV20[redacted]; First Dose Date: 14NOV20[redacted]; Last Dose Date: 08JUN20[redacted]*								
免疫系障害 サイトカイン放出症候群 Cytokine release syndrome(1)	18NOV20[redacted] (9)	25NOV20[redacted] (16)	8	2	NA/ Yes/ No	NA/ Drug Interrupted/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 896289[redacted] ; Randomized Date: 16JAN20[redacted]; First Dose Date: 18JAN20[redacted]; Last Dose Date: 12MAY20[redacted]								
神経系障害 一過性脳虚血発作 Transitory ischemic attack(4)	13MAY20[redacted] (119)	13MAY20[redacted] (119)	1	2	NA/ Yes/ Yes	NA/ Drug Withdrawn/ Drug Withdrawn	None	Recovered/ Resolved
Treatment Randmizen: Rd ; Subject ID: 896309[redacted] ; Randomized Date: 26SEP20[redacted]; First Dose Date: 28SEP20[redacted]; Last Dose Date: 14DEC20[redacted]								
感染症および寄生虫症 肺炎 Pneumonia(2)	01OCT20[redacted] (6)	12OCT20[redacted] (17)	12	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	Conmeds/ Hospitalization	Recovered/ Resolved With Sequelae
血液およびリンパ系障害 骨髄機能不全 Myelosuppression(3)	09NOV20[redacted] (45)	22DEC20[redacted] (88)	44	3	NA/ No/ No	NA/ Dose Not Changed/ Dose Not Changed	None	Recovered/ Resolved
心臓障害 心肺不全 Cardiopulmonary failure(4)	22DEC20[redacted] (88)	22DEC20[redacted] (88)	1	5	NA/ No/ No	NA/ Drug Withdrawn/ Drug Withdrawn	None	Fatal

出典［総括報告書5.3.5.1-1（PX-171-009），Listing 16.2.21］

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