表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 及び PT 別発現頻度（PX-171-006）

	Number (%) of Subjects															
	Cohort 1		Cohort 2		Cohort 3		Cohort 4		Total							
System Organ Class	(N=6)		(N=6)		(N=8)		(N=6)		(N=84)							
Preferred Term[1]	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades		Grade 3 or Higher	
Number of Subjects with at Least One TEAE[2]	6 (100.0)	5 (83.3)	6 (100.0)	6 (100.0)	8 (100.0)	8 (100.0)	6 (100.0)	6 (100.0)	84	(100.0)	80	(95.2)
血液およびリンパ系障害	5 (83.3)	4 (66.7)	6 (100.0)	6 (100.0)	7 (87.5)	7 (87.5)	3 (50.0)	2 (33.3)	66	(78.6)	60	(71.4)
好中球減少症	4 (66.7)	2 (33.3)	4 (66.7)	4 (66.7)	4 (50.0)	2 (25.0)	2 (33.3)	2 (33.3)	38	(45.2)	32	(38.1)
リンパ球減少症	1 (16.7)	1 (16.7)	3 (50.0)	3 (50.0)	2 (25.0)	2 (25.0)	1 (16.7)	1 (16.7)	34	(40.5)	32	(38.1)
貧血	2 (33.3)	1 (16.7)	2 (33.3)	0 (0.0)	6 (75.0)	3 (37.5)	2 (33.3)	2 (33.3)	32	(38.1)	16	(19.0)
血小板減少症	3 (50.0)	3 (50.0)	3 (50.0)	3 (50.0)	2 (25.0)	1 (12.5)	2 (33.3)	1 (16.7)	29	(34.5)	21	(25.0)
白血球減少症	0 (0.0)	0 (0.0)	3 (50.0)	3 (50.0)	1 (12.5)	0 (0.0)	1 (16.7)	1 (16.7)	17	(20.2)	11	(13.1)
白血球増加症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3	(3.6)	0	(0.0)
リンパ節症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	2	(2.4)	0	(0.0)
発熱性好中球減少症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)	1 (12.5)	0 (0.0)	0 (0.0)	1	(1.2)	1	(1.2)
溶血性貧血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1	(1.2)	0	(0.0)
リンパ節痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1	(1.2)	0	(0.0)
心臓障害	1 (16.7)	0 (0.0)	1 (16.7)	1 (16.7)	1 (12.5)	0 (0.0)	2 (33.3)	0 (0.0)	21	(25.0)	6	(7.1)
頻脈	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5	(6.0)	1	(1.2)
徐脈	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (33.3)	0 (0.0)	4	(4.8)	1	(1.2)
動悸	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4	(4.8)	0	(0.0)
心房細動	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	2	(2.4)	1	(1.2)
期外収縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2	(2.4)	0	(0.0)
急性心筋梗塞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1	(1.2)	1	(1.2)
うっ血性心不全	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1	(1.2)	0	(0.0)
心拡大	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1	(1.2)	0	(0.0)
冠動脈疾患	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1	(1.2)	1	(1.2)
心筋梗塞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1	(1.2)	1	(1.2)
洞不全症候群	0 (0.0)	0 (0.0)	1 (16.7)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1	(1.2)	1	(1.2)
洞性徐脈	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1	(1.2)	0	(0.0)
心室性期外収縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1	(1.2)	0	(0.0)
心室肥大	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	1	(1.2)	0	(0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).

[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 1）

	Number (%) of Subjects																			
	Cohort 1				Cohort 2				Cohort 3				Cohort 4				Total			
System Organ Class	(N=6)				(N=6)				(N=8)				(N=6)				(N=84)			
Preferred Term[1]	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
耳および迷路障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	6	(7.1)	1	(1.2)
耳垢栓塞	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	2	(2.4)	0	(0.0)
ろう	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	1	(1.2)
耳鳴	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
耳痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
内分泌障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
クッシング様	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
眼障害	1	(16.7)	0	(0.0)	3	(50.0)	1	(16.7)	4	(50.0)	0	(0.0)	2	(33.3)	0	(0.0)	27	(32.1)	1	(1.2)
霧視	1	(16.7)	0	(0.0)	1	(16.7)	1	(16.7)	3	(37.5)	0	(0.0)	1	(16.7)	0	(0.0)	14	(16.7)	1	(1.2)
眼乾燥	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	5	(6.0)	0	(0.0)
白内障	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	3	(3.6)	0	(0.0)
流涙増加	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	3	(3.6)	0	(0.0)
眼充血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	2	(2.4)	0	(0.0)
視力低下	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
眼瞼炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
結膜炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
角膜病変	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
眼脂	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
眼出血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
眼刺激	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
眼痛	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
眼そう痒症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
眼部腫脹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
強膜出血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
視覚の明るさ	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
胃腸障害	3	(50.0)	0	(0.0)	5	(83.3)	0	(0.0)	5	(62.5)	0	(0.0)	5	(83.3)	2	(33.3)	64	(76.2)	9	(10.7)
下痢	3	(50.0)	0	(0.0)	3	(50.0)	0	(0.0)	3	(37.5)	0	(0.0)	4	(66.7)	2	(33.3)	47	(56.0)	5	(6.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 2）

System Organ Class Preferred Term[1]	Number (%) of Subjects Cohort 1 (N=6) All Grades	Grade 3 or Higher	Cohort 2 (N=6) All Grades	Grade 3 or Higher	Cohort 3 (N=8) All Grades	Grade 3 or Higher	Cohort 4 (N=6) All Grades	Grade 3 or Higher	Total (N=84) All Grades	Grade 3 or Higher
悪心	1 (16.7)	0 (0.0)	3 (50.0)	0 (0.0)	1 (12.5)	0 (0.0)	2 (33.3)	0 (0.0)	26 (31.0)	0 (0.0)
便秘	1 (16.7)	0 (0.0)	2 (33.3)	0 (0.0)	2 (25.0)	0 (0.0)	2 (33.3)	0 (0.0)	22 (26.2)	0 (0.0)
嘔吐	0 (0.0)	0 (0.0)	2 (33.3)	0 (0.0)	2 (25.0)	0 (0.0)	2 (33.3)	0 (0.0)	18 (21.4)	2 (2.4)
腹痛	0 (0.0)	0 (0.0)	2 (33.3)	0 (0.0)	1 (12.5)	0 (0.0)	1 (16.7)	0 (0.0)	9 (10.7)	1 (1.2)
腹部膨満	1 (16.7)	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (8.3)	0 (0.0)
歯痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	6 (7.1)	0 (0.0)
腹部不快感	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (4.8)	0 (0.0)
口腔内痛	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (4.8)	0 (0.0)
消化不良	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (3.6)	0 (0.0)
胃腸出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (3.6)	2 (2.4)
胃食道逆流性疾患	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (3.6)	0 (0.0)
歯肉出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	3 (3.6)	0 (0.0)
胃不快感	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	3 (3.6)	0 (0.0)
上腹部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
鼓腸	1 (16.7)	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
痔核	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
口腔内軟組織障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	2 (2.4)	0 (0.0)
口内炎	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
腸雑音異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
結腸狭窄	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
口内乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
嚥下障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
心窩部不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	1 (1.2)	0 (0.0)
便失禁	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
排便回数増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
胃炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
消化管運動過剰	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
消化管粘膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
消化器痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
歯肉痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 3）

	Number (%) of Subjects																			
	Cohort 1				Cohort 2				Cohort 3				Cohort 4				Total			
System Organ Class	(N=6)				(N=6)				(N=8)				(N=6)				(N=84)			
Preferred Term[1]	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
歯肉腫脹	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
歯肉炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
血便排泄	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
口の感覚鈍麻	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
口腔内出血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
嚥下痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
食道不快感	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
口唇障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
小腸閉塞	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	1	(1.2)
埋伏歯	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
全身障害および投与局所様態	5	(83.3)	2	(33.3)	6	(100.0)	1	(16.7)	8	(100.0)	0	(0.0)	5	(83.3)	0	(0.0)	77	(91.7)	12	(14.3)
疲労	3	(50.0)	0	(0.0)	4	(66.7)	0	(0.0)	5	(62.5)	0	(0.0)	3	(50.0)	0	(0.0)	55	(65.5)	6	(7.1)
発熱	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	5	(62.5)	0	(0.0)	3	(50.0)	0	(0.0)	33	(39.3)	0	(0.0)
末梢性浮腫	0	(0.0)	0	(0.0)	4	(66.7)	1	(16.7)	2	(25.0)	0	(0.0)	0	(0.0)	0	(0.0)	28	(33.3)	1	(1.2)
無力症	2	(33.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(37.5)	0	(0.0)	0	(0.0)	0	(0.0)	13	(15.5)	0	(0.0)
疼痛	1	(16.7)	0	(0.0)	1	(16.7)	1	(16.7)	1	(12.5)	0	(0.0)	1	(16.7)	0	(0.0)	10	(11.9)	1	(1.2)
悪寒	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	1	(12.5)	0	(0.0)	2	(33.3)	0	(0.0)	9	(10.7)	0	(0.0)
疾患進行	2	(33.3)	2	(33.3)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	7	(8.3)	3	(3.6)
易刺激性	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	6	(7.1)	0	(0.0)
圧痕浮腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(25.0)	0	(0.0)	1	(16.7)	0	(0.0)	6	(7.1)	0	(0.0)
歩行障害	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(4.8)	0	(0.0)
インフルエンザ様疾患	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(25.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(4.8)	0	(0.0)
胸痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(3.6)	0	(0.0)
顔面浮腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	3	(3.6)	1	(1.2)
倦怠感	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(3.6)	0	(0.0)
カテーテル留置部位浮腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
カテーテル留置部位疼痛	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
胸部不快感	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	2	(2.4)	0	(0.0)
びくびく感	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 4）

	Number (%) of Subjects																			
	Cohort 1				Cohort 2				Cohort 3				Cohort 4				Total			
System Organ Class	(N=6)				(N=6)				(N=8)				(N=6)				(N=84)			
Preferred Term[1]	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
注入に関連した反応	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
注入部位反応	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
注射部位出血	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
注射部位疼痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
局所腫脹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
非心臓性胸痛	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
脱落痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	1	(1.2)	0	(0.0)
カテーテル留置部位内出血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
カテーテル留置部位血腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	1	(1.2)	0	(0.0)
カテーテル留置部位出血	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
蜂窩織	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
死亡	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	1	(1.2)
変形	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
冷感	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
熱感	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
熱感および冷感	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
体温変動感	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
注入部位内出血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
注入部位疼痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
注入部位静脈炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
注入部位発疹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
注射部位内出血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
注射部位不快感	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
注射部位刺激感	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
注射部位反応	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
腫瘤	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
粘膜の炎症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
浮腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
温度変化不耐症	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
血管穿刺部位出血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 5）

System Organ Class Preferred Term[1]	Number (%) of Subjects Cohort 1 (N=6) All Grades	Grade 3 or Higher	Cohort 2 (N=6) All Grades	Grade 3 or Higher	Cohort 3 (N=8) All Grades	Grade 3 or Higher	Cohort 4 (N=6) All Grades	Grade 3 or Higher	Total (N=84) All Grades	Grade 3 or Higher
肝胆道系障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (37.5)	2 (25.0)	0 (0.0)	0 (0.0)	5 (6.0)	2 (2.4)
高ビリルビン血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (37.5)	2 (25.0)	0 (0.0)	0 (0.0)	4 (4.8)	2 (2.4)
胆石症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
免疫系障害	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	4 (4.8)	0 (0.0)
薬物過敏症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
季節性アレルギー	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
感染症および寄生虫症	3 (50.0)	1 (16.7)	3 (50.0)	0 (0.0)	5 (62.5)	1 (12.5)	6 (100.0)	2 (33.3)	57 (67.9)	14 (16.7)
上気道感染	2 (33.3)	0 (0.0)	3 (50.0)	0 (0.0)	5 (62.5)	1 (12.5)	1 (16.7)	0 (0.0)	34 (40.5)	2 (2.4)
鼻咽頭炎	1 (16.7)	0 (0.0)	2 (33.3)	0 (0.0)	1 (12.5)	0 (0.0)	1 (16.7)	0 (0.0)	13 (15.5)	0 (0.0)
肺炎	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	2 (25.0)	0 (0.0)	1 (16.7)	1 (16.7)	13 (15.5)	6 (7.1)
副鼻腔炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (9.5)	0 (0.0)
インフルエンザ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	1 (16.7)	0 (0.0)	6 (7.1)	1 (1.2)
尿路感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (33.3)	1 (16.7)	6 (7.1)	2 (2.4)
蜂巣炎	1 (16.7)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (6.0)	1 (1.2)
気管支炎	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (4.8)	0 (0.0)
単純ヘルペス	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	3 (3.6)	0 (0.0)
鼻炎	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (3.6)	0 (0.0)
毛包炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
ウイルス性胃腸炎	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
口腔カンジダ症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	2 (2.4)	0 (0.0)
ウイルス感染	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	2 (2.4)	0 (0.0)
顎骨骨髄炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
ウイルス性気管支炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
カンジダ症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
カテーテル留置部位蜂巣炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	1 (1.2)	0 (0.0)
サイトメガロウイルス感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
医療用具関連感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 6）

System Organ Class Preferred Term[1]	Number (%) of Subjects Cohort 1 (N=6) All Grades	Grade 3 or Higher	Cohort 2 (N=6) All Grades	Grade 3 or Higher	Cohort 3 (N=8) All Grades	Grade 3 or Higher	Cohort 4 (N=6) All Grades	Grade 3 or Higher	Total (N=84) All Grades	Grade 3 or Higher
眼感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
真菌感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
胃腸炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
大葉性肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
口腔感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
骨髄炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
爪囲炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
肺炎球菌性肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
ＲＳウイルス肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
ＲＳウイルス感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
敗血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)	1 (16.7)	1 (1.2)	1 (1.2)
皮膚カンジダ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
歯髄炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
膣感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
ウイルス性上気道感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
傷害、中毒および処置合併症	0 (0.0)	0 (0.0)	1 (16.7)	1 (16.7)	2 (25.0)	0 (0.0)	1 (16.7)	0 (0.0)	22 (26.2)	2 (2.4)
挫傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	8 (9.5)	0 (0.0)
転倒	0 (0.0)	0 (0.0)	1 (16.7)	1 (16.7)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	3 (3.6)	1 (1.2)
擦過傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
切開部位合併症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
関節捻挫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
皮膚裂傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
歯牙破折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
動物咬傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
圧迫骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
血胸	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
熱性浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
上腕骨骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 7）

	Number (%) of Subjects																	
	Cohort 1		Cohort 2		Cohort 3		Cohort 4		Total									
System Organ Class	(N=6)		(N=6)		(N=8)		(N=6)		(N=84)									
Preferred Term[1]	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades		Grade 3 or Higher							
関節脱臼	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
肺損傷	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
多発性骨折	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
神経根損傷	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
外傷後疼痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
処置による疼痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
肋骨骨折	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
引っかき傷	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	1	(1.2)	0	(0.0)
硬膜下血腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
腱断裂	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	1	(1.2)
熱傷	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
輸血反応	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
臨床検査	1	(16.7)	0	(0.0)	5	(83.3)	3	(50.0)	4	(50.0)	0	(0.0)	3	(50.0)	1	(16.7)	45	(53.6)	18	(21.4)
アラニン・アミノトランスフェラーゼ増加	1	(16.7)	0	(0.0)	1	(16.7)	1	(16.7)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	10	(11.9)	5	(6.0)
アスパラギン酸アミノトランスフェラーゼ増加	1	(16.7)	0	(0.0)	1	(16.7)	1	(16.7)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	9	(10.7)	3	(3.6)
血中クレアチニン増加	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	7	(8.3)	1	(1.2)
ヘモグロビン減少	0	(0.0)	0	(0.0)	1	(16.7)	1	(16.7)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	6	(7.1)	5	(6.0)
体重減少	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	6	(7.1)	0	(0.0)
血中重炭酸塩減少	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	5	(6.0)	1	(1.2)
血中ビリルビン増加	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	4	(4.8)	0	(0.0)
心雑音	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	4	(4.8)	0	(0.0)
体重増加	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	4	(4.8)	0	(0.0)
血中アルカリホスファターゼ増加	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
血中ブドウ糖増加	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	1	(1.2)
ＩＮＲ増加	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(16.7)	1	(16.7)	2	(2.4)	2	(2.4)
血小板数減少	0	(0.0)	0	(0.0)	1	(16.7)	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	1	(1.2)
血中アミラーゼ増加	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	1	(1.2)
血中カルシウム減少	0	(0.0)	0	(0.0)	1	(16.7)	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	1	(1.2)
血中マグネシウム減少	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 8）

	Number (%) of Subjects																	
	Cohort 1			Cohort 2			Cohort 3			Cohort 4			Total					
System Organ Class	(N=6)			(N=6)			(N=8)			(N=6)			(N=84)					
Preferred Term[1]	All Grades		Grade 3 or Higher	All Grades		Grade 3 or Higher	All Grades		Grade 3 or Higher	All Grades		Grade 3 or Higher	All Grades			Grade 3 or Higher		
呼吸音異常	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	1	(1.2)	0	(0.0)		
駆出率減少	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	1	(1.2)	0	(0.0)		
心電図ＱＴ延長	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	1	(1.2)	0	(0.0)		
尿中ブドウ糖陽性	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	1	(1.2)	0	(0.0)		
心拍数不整	0	(0.0)	0 (0.0)	1	(16.7)	1 (16.7)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	1	(1.2)	1	(1.2)		
好中球数減少	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	1	(1.2)	1	(1.2)		
尿色調異常	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	1	(1.2)	0	(0.0)		
代謝および栄養障害	4	(66.7)	2 (33.3)	6	(100.0)	4 (66.7)	5	(62.5)	3 (37.5)	5	(83.3)	3 (50.0)	65	(77.4)	43	(51.2)		
低リン酸血症	0	(0.0)	0 (0.0)	1	(16.7)	1 (16.7)	3	(37.5)	3 (37.5)	0	(0.0)	0 (0.0)	25	(29.8)	18	(21.4)		
高血糖	1	(16.7)	0 (0.0)	2	(33.3)	2 (33.3)	1	(12.5)	0 (0.0)	3	(50.0)	3 (50.0)	23	(27.4)	11	(13.1)		
低カリウム血症	0	(0.0)	0 (0.0)	3	(50.0)	2 (33.3)	3	(37.5)	1 (12.5)	2	(33.3)	0 (0.0)	22	(26.2)	8	(9.5)		
低マグネシウム血症	0	(0.0)	0 (0.0)	2	(33.3)	0 (0.0)	1	(12.5)	0 (0.0)	2	(33.3)	0 (0.0)	17	(20.2)	1	(1.2)		
低ナトリウム血症	0	(0.0)	0 (0.0)	2	(33.3)	2 (33.3)	2	(25.0)	0 (0.0)	1	(16.7)	1 (16.7)	14	(16.7)	9	(10.7)		
食欲不振	0	(0.0)	0 (0.0)	2	(33.3)	0 (0.0)	1	(12.5)	0 (0.0)	1	(16.7)	0 (0.0)	12	(14.3)	0	(0.0)		
食欲減退	1	(16.7)	0 (0.0)	3	(50.0)	0 (0.0)	1	(12.5)	0 (0.0)	1	(16.7)	0 (0.0)	10	(11.9)	0	(0.0)		
低カルシウム血症	0	(0.0)	0 (0.0)	2	(33.3)	0 (0.0)	1	(12.5)	0 (0.0)	0	(0.0)	0 (0.0)	10	(11.9)	1	(1.2)		
脱水	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	2	(33.3)	1 (16.7)	8	(9.5)	1	(1.2)		
低アルブミン血症	1	(16.7)	1 (16.7)	1	(16.7)	1 (16.7)	1	(12.5)	0 (0.0)	0	(0.0)	0 (0.0)	8	(9.5)	4	(4.8)		
高マグネシウム血症	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	1	(12.5)	0 (0.0)	0	(0.0)	0 (0.0)	6	(7.1)	3	(3.6)		
低血糖症	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	1	(12.5)	0 (0.0)	0	(0.0)	0 (0.0)	6	(7.1)	2	(2.4)		
高カルシウム血症	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	4	(4.8)	1	(1.2)		
高尿酸血症	1	(16.7)	1 (16.7)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	4	(4.8)	3	(3.6)		
高リン酸塩血症	1	(16.7)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	3	(3.6)	0	(0.0)		
高カリウム血症	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	1	(1.2)	0	(0.0)		
高ナトリウム血症	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	1	(1.2)	0	(0.0)		
高アルカリホスファターゼ血症	1	(16.7)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	1	(1.2)	0	(0.0)		
食欲亢進	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	1	(1.2)	0	(0.0)		
鉄欠乏	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	1	(1.2)	0	(0.0)		
ラクトース不耐性	0	(0.0)	0 (0.0)	1	(16.7)	0 (0.0)	0	(0.0)	0 (0.0)	0	(0.0)	0 (0.0)	1	(1.2)	0	(0.0)		

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 9）

System Organ Class Preferred Term[1]	Number (%) of Subjects Cohort 1 (N=6) All Grades	Grade 3 or Higher	Cohort 2 (N=6) All Grades	Grade 3 or Higher	Cohort 3 (N=8) All Grades	Grade 3 or Higher	Cohort 4 (N=6) All Grades	Grade 3 or Higher	Total (N=84) All Grades	Grade 3 or Higher
筋骨格系および結合組織障害	4 (66.7)	1 (16.7)	5 (83.3)	2 (33.3)	8 (100.0)	0 (0.0)	4 (66.7)	1 (16.7)	66 (78.6)	13 (15.5)
筋痙縮	1 (16.7)	0 (0.0)	4 (66.7)	0 (0.0)	4 (50.0)	0 (0.0)	1 (16.7)	0 (0.0)	31 (36.9)	2 (2.4)
背部痛	2 (33.3)	0 (0.0)	3 (50.0)	1 (16.7)	3 (37.5)	0 (0.0)	1 (16.7)	0 (0.0)	27 (32.1)	2 (2.4)
関節痛	2 (33.3)	0 (0.0)	2 (33.3)	0 (0.0)	3 (37.5)	0 (0.0)	1 (16.7)	0 (0.0)	21 (25.0)	1 (1.2)
四肢痛	1 (16.7)	0 (0.0)	1 (16.7)	0 (0.0)	4 (50.0)	0 (0.0)	1 (16.7)	0 (0.0)	21 (25.0)	0 (0.0)
胸壁痛	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	1 (12.5)	0 (0.0)	2 (33.3)	0 (0.0)	11 (13.1)	0 (0.0)
臀部痛	0 (0.0)	0 (0.0)	1 (16.7)	1 (16.7)	1 (12.5)	0 (0.0)	3 (50.0)	0 (0.0)	11 (13.1)	1 (1.2)
筋痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	8 (9.5)	1 (1.2)
筋力低下	1 (16.7)	0 (0.0)	1 (16.7)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	7 (8.3)	0 (0.0)
病的骨折	1 (16.7)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)	1 (16.7)	7 (8.3)	3 (3.6)
骨痛	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	1 (12.5)	0 (0.0)	1 (16.7)	0 (0.0)	6 (7.1)	1 (1.2)
関節運動範囲減少	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	2 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (6.0)	0 (0.0)
頚部痛	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	2 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (6.0)	0 (0.0)
顎痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (6.0)	0 (0.0)
筋骨格硬直	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (4.8)	0 (0.0)
筋骨格不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (3.6)	0 (0.0)
無菌性骨壊死	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	1 (1.2)
脊柱後弯症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
筋萎縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
殿部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
肢径部痛	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
椎間板突出	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
関節硬直	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
関節腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
筋肉内出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
筋攣縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
骨壊死	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
骨減少症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
腸回旋筋腫板症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 10）

	Number (%) of Subjects																	
	Cohort 1		Cohort 2		Cohort 3		Cohort 4		Total									
System Organ Class	(N=6)		(N=6)		(N=8)		(N=6)		(N=84)									
Preferred Term[1]	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades		Grade 3 or Higher							
仙骨痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	1	(1.2)
顎関節症候群	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
腱炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
腱鞘炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
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）	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	7	(8.3)	2	(2.4)
肺新生物	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
新生物	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
皮膚良性新生物	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	1	(1.2)
乳癌第４期	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	1	(1.2)
脂肪腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
悪性黒色腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	1	(1.2)
形質細胞腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	1	(1.2)	0	(0.0)
脂漏性角化症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
神経系障害	4	(66.7)	0	(0.0)	5	(83.3)	0	(0.0)	5	(62.5)	0	(0.0)	4	(66.7)	0	(0.0)	62	(73.8)	6	(7.1)
錯感覚	2	(33.3)	0	(0.0)	3	(50.0)	0	(0.0)	2	(25.0)	0	(0.0)	0	(0.0)	0	(0.0)	19	(22.6)	0	(0.0)
頭痛	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	1	(12.5)	0	(0.0)	3	(50.0)	0	(0.0)	18	(21.4)	1	(1.2)
感覚減退	1	(16.7)	0	(0.0)	2	(33.3)	0	(0.0)	2	(25.0)	0	(0.0)	1	(16.7)	0	(0.0)	15	(17.9)	0	(0.0)
末梢性ニューロパシー	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	2	(33.3)	0	(0.0)	15	(17.9)	0	(0.0)
浮動性めまい	0	(0.0)	0	(0.0)	2	(33.3)	0	(0.0)	2	(25.0)	0	(0.0)	1	(16.7)	0	(0.0)	14	(16.7)	0	(0.0)
神経障害性疼痛	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	1	(16.7)	0	(0.0)	10	(11.9)	0	(0.0)
味覚異常	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	6	(7.1)	0	(0.0)
反射減弱	2	(33.3)	0	(0.0)	2	(33.3)	0	(0.0)	1	(12.5)	0	(0.0)	1	(16.7)	0	(0.0)	6	(7.1)	0	(0.0)
振戦	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	6	(7.1)	0	(0.0)
記憶障害	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	5	(6.0)	0	(0.0)
傾眠	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	5	(6.0)	0	(0.0)
失語症	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	3	(3.6)	0	(0.0)
知覚過敏	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(3.6)	0	(0.0)
末梢性感覚ニューロパシー	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	3	(3.6)	0	(0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 11）

	Number (%) of Subjects																			
	Cohort 1				Cohort 2				Cohort 3				Cohort 4				Total			
System Organ Class	(N=6)				(N=6)				(N=8)				(N=6)				(N=84)			
Preferred Term[1]	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
反射消失	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
平衡障害	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
灼熱感	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
体位性めまい	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
味覚減退	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
健忘	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
脳梗塞	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	1	(1.2)
脳血管発作	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	1	(1.2)
痙攣	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	1	(1.2)
起立障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
嗜眠	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
精神的機能障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
神経圧迫	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
ニューロパシー	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
口の錯感覚	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
末梢性運動ニューロパシー	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	1	(1.2)
坐骨神経痛	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
失神	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
三叉神経痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	1	(1.2)
精神障害	2	(33.3)	0	(0.0)	3	(50.0)	0	(0.0)	4	(50.0)	0	(0.0)	1	(16.7)	0	(0.0)	39	(46.4)	3	(3.6)
不眠症	1	(16.7)	0	(0.0)	3	(50.0)	0	(0.0)	3	(37.5)	0	(0.0)	0	(0.0)	0	(0.0)	26	(31.0)	0	(0.0)
不安	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	11	(13.1)	2	(2.4)
激越	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	5	(6.0)	0	(0.0)
うつ病	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	5	(6.0)	0	(0.0)
錯乱状態	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(3.6)	0	(0.0)
気分変動	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(3.6)	1	(1.2)
気分動揺	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
ストレス	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
感情不安定	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 12）

	Number (%) of Subjects																			
	Cohort 1				Cohort 2				Cohort 3				Cohort 4				Total			
System Organ Class	(N=6)				(N=6)				(N=8)				(N=6)				(N=84)			
Preferred Term[1]	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
不安障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
失見当識	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
幻覚	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
リビドー減退	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
落ち着きのなさ	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
腎および尿路障害	1	(16.7)	0	(0.0)	3	(50.0)	0	(0.0)	3	(37.5)	0	(0.0)	1	(16.7)	0	(0.0)	22	(26.2)	4	(4.8)
夜間頻尿	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(4.8)	0	(0.0)
腎不全	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	4	(4.8)	1	(1.2)
血尿	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(3.6)	1	(1.2)
急性腎不全	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(3.6)	2	(2.4)
排尿困難	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
尿意切迫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
頻尿	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
尿閉	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	2	(2.4)	0	(0.0)
失禁	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
腎結石症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
多尿	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
蛋白尿	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
排尿躊躇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	1	(1.2)	0	(0.0)
生殖系および乳房障害	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	4	(4.8)	0	(0.0)
骨盤痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
萎縮性外陰膣炎	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
勃起不全	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
女性化乳房	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
閉経後出血	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
精液変色	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
膣出血	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 13）

System Organ Class Preferred Term[1]	Number (%) of Subjects Cohort 1 (N=6) All Grades	Grade 3 or Higher	Cohort 2 (N=6) All Grades	Grade 3 or Higher	Cohort 3 (N=8) All Grades	Grade 3 or Higher	Cohort 4 (N=6) All Grades	Grade 3 or Higher	Total (N=84) All Grades	Grade 3 or Higher
呼吸器、胸郭および縦隔障害	4 (66.7)	0 (0.0)	6 (100.0)	0 (0.0)	6 (75.0)	0 (0.0)	4 (66.7)	2 (33.3)	64 (76.2)	7 (8.3)
咳嗽	1 (16.7)	0 (0.0)	5 (83.3)	0 (0.0)	3 (37.5)	0 (0.0)	2 (33.3)	0 (0.0)	35 (41.7)	1 (1.2)
呼吸困難	0 (0.0)	0 (0.0)	3 (50.0)	0 (0.0)	3 (37.5)	0 (0.0)	2 (33.3)	1 (16.7)	30 (35.7)	1 (1.2)
咽喉頭疼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (37.5)	0 (0.0)	0 (0.0)	0 (0.0)	15 (17.9)	0 (0.0)
鼻出血	1 (16.7)	0 (0.0)	1 (16.7)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	11 (13.1)	0 (0.0)
鼻閉	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (25.0)	0 (0.0)	1 (16.7)	0 (0.0)	11 (13.1)	0 (0.0)
鼻漏	0 (0.0)	0 (0.0)	2 (33.3)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	9 (10.7)	0 (0.0)
発声障害	2 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (9.5)	0 (0.0)
労作性呼吸困難	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	7 (8.3)	1 (1.2)
湿性咳嗽	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (8.3)	0 (0.0)
しゃっくり	2 (33.3)	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (4.8)	0 (0.0)
咽頭紅斑	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	4 (4.8)	0 (0.0)
副鼻腔うっ血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (37.5)	0 (0.0)	0 (0.0)	0 (0.0)	4 (4.8)	0 (0.0)
喘鳴	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (4.8)	0 (0.0)
胸水	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	3 (3.6)	1 (1.2)
無気肺	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
咽喉乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	2 (2.4)	0 (0.0)
喀血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
低酸素症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	1 (1.2)
気道うっ血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	2 (2.4)	0 (0.0)
アレルギー性鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
睡眠時無呼吸症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
咽喉刺激感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
喘息	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
肺ラ音	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
鼻腔内しびれ感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
喉頭腫瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)	1 (16.7)	1 (1.2)	1 (1.2)
肺障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
肺浸潤	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
鼻乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 14）

System Organ Class / Preferred Term[1]	Cohort 1 (N=6)		Cohort 2 (N=6)		Cohort 3 (N=8)		Cohort 4 (N=6)		Total (N=84)	
	Number (%) of Subjects									
	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher
鼻中隔弯曲	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
鼻甲介肥大	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
胸膜痛	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
気胸	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
肺塞栓症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
肺水腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	1 (1.2)	0 (0.0)
ラ音	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
非感染性鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
副鼻腔障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
咽喉絞扼感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
上気道うっ血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
皮膚および皮下組織障害	1 (16.7)	0 (0.0)	4 (66.7)	0 (0.0)	7 (87.5)	1 (12.5)	4 (66.7)	0 (0.0)	52 (61.9)	2 (2.4)
発疹	0 (0.0)	0 (0.0)	2 (33.3)	0 (0.0)	4 (50.0)	1 (12.5)	1 (16.7)	0 (0.0)	19 (22.6)	2 (2.4)
皮膚乾燥	1 (16.7)	0 (0.0)	2 (33.3)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	16 (19.0)	0 (0.0)
そう痒症	0 (0.0)	0 (0.0)	2 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	8 (9.5)	0 (0.0)
寝汗	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	7 (8.3)	0 (0.0)
斑状出血	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	6 (7.1)	0 (0.0)
多汗症	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (7.1)	0 (0.0)
紅斑	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	5 (6.0)	0 (0.0)
全身性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (3.6)	0 (0.0)
斑状皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (3.6)	0 (0.0)
脱毛症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
黄毛症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
挫傷発生の増加傾向	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
爪の障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
爪甲縦裂症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
眼窩周囲浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
そう痒性皮疹	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
皮膚剥脱	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	2 (2.4)	0 (0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 15）

	Number (%) of Subjects																			
	Cohort 1				Cohort 2				Cohort 3				Cohort 4				Total			
System Organ Class	(N=6)				(N=6)				(N=8)				(N=6)				(N=84)			
Preferred Term[1]	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
皮膚出血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
皮膚病変	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
日光性角化症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
接触性皮膚炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
毛髪成長異常	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
爪変色	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
点状出血	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
光線過敏性反応	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
斑状丘疹状皮疹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
丘疹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
皮膚変色	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
皮膚障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
皮膚脆弱性	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
皮膚色素過剰	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
皮膚刺激	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
皮下結節	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	1	(1.2)	0	(0.0)
顔面腫脹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
蕁麻疹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
外科および内科処置	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(16.7)	1	(16.7)	3	(3.6)	2	(2.4)
白内障手術	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	1	(1.2)
膝手術	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
抜歯	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(16.7)	1	(16.7)	1	(1.2)	1	(1.2)
血管障害	1	(16.7)	0	(0.0)	2	(33.3)	0	(0.0)	1	(12.5)	0	(0.0)	1	(16.7)	0	(0.0)	23	(27.4)	4	(4.8)
高血圧	0	(0.0)	0	(0.0)	2	(33.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	7	(8.3)	1	(1.2)
深部静脈血栓症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	6	(7.1)	3	(3.6)
潮紅	1	(16.7)	0	(0.0)	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(4.8)	0	(0.0)
表在性血栓性静脈炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(16.7)	0	(0.0)	3	(3.6)	0	(0.0)
低血圧	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 16）

	Number (%) of Subjects																			
	Cohort 1		Cohort 2		Cohort 3		Cohort 4		Total	
System Organ Class	(N=6)		(N=6)		(N=8)		(N=6)		(N=84)	
Preferred Term[1]	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher
静脈炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
塞栓症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
血腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
ほてり	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
末梢冷感	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
血栓後症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
血栓症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
血管脆弱化	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
大静脈血栓症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 17）

	Number (%) of Subjects															
	Cohort 5				Cohort 6				Cohort 7				Total			
System Organ Class	(N=6)				(N=8)				(N=44)				(N=84)			
Preferred Term[1]	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
Number of Subjects with at Least One TEAE[2]	6	(100.0)	6	(100.0)	8	(100.0)	8	(100.0)	44	(100.0)	41	(93.2)	84	(100.0)	80	(95.2)
血液およびリンパ系障害	5	(83.3)	5	(83.3)	6	(75.0)	5	(62.5)	34	(77.3)	31	(70.5)	66	(78.6)	60	(71.4)
好中球減少症	5	(83.3)	5	(83.3)	3	(37.5)	3	(37.5)	16	(36.4)	14	(31.8)	38	(45.2)	32	(38.1)
リンパ球減少症	0	(0.0)	0	(0.0)	5	(62.5)	4	(50.0)	22	(50.0)	21	(47.7)	34	(40.5)	32	(38.1)
貧血	3	(50.0)	0	(0.0)	3	(37.5)	2	(25.0)	14	(31.8)	8	(18.2)	32	(38.1)	16	(19.0)
血小板減少症	3	(50.0)	3	(50.0)	3	(37.5)	2	(25.0)	13	(29.5)	8	(18.2)	29	(34.5)	21	(25.0)
白血球減少症	1	(16.7)	1	(16.7)	2	(25.0)	1	(12.5)	9	(20.5)	5	(11.4)	17	(20.2)	11	(13.1)
白血球増加症	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	2	(4.5)	0	(0.0)	3	(3.6)	0	(0.0)
リンパ節症	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
発熱性好中球減少症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	1	(1.2)
溶血性貧血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
リンパ節痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
心臓障害	2	(33.3)	2	(33.3)	3	(37.5)	2	(25.0)	11	(25.0)	1	(2.3)	21	(25.0)	6	(7.1)
頻脈	1	(16.7)	1	(16.7)	0	(0.0)	0	(0.0)	4	(9.1)	0	(0.0)	5	(6.0)	1	(1.2)
徐脈	1	(16.7)	1	(16.7)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	4	(4.8)	1	(1.2)
動悸	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.5)	0	(0.0)	4	(4.8)	0	(0.0)
心房細動	0	(0.0)	0	(0.0)	1	(12.5)	1	(12.5)	0	(0.0)	0	(0.0)	2	(2.4)	1	(1.2)
期外収縮	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	1	(2.3)	0	(0.0)	2	(2.4)	0	(0.0)
急性心筋梗塞	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	1	(2.3)	1	(1.2)	1	(1.2)
うっ血性心不全	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
心拡大	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
冠動脈疾患	0	(0.0)	0	(0.0)	1	(12.5)	1	(12.5)	0	(0.0)	0	(0.0)	1	(1.2)	1	(1.2)
心筋梗塞	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	1	(2.3)	1	(1.2)	1	(1.2)
洞不全症候群	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	1	(1.2)
洞性徐脈	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
心室性期外収縮	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
心室肥大	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 18）

System Organ Class / Preferred Term[1]	Number (%) of Subjects															
	Cohort 5 (N=6)				Cohort 6 (N=8)				Cohort 7 (N=44)				Total (N=84)			
	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
耳および迷路障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	5	(11.4)	1	(2.3)	6	(7.1)	1	(1.2)
耳垢栓塞	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	2	(2.4)	0	(0.0)
ろう	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.5)	1	(2.3)	2	(2.4)	1	(1.2)
耳鳴	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.5)	0	(0.0)	2	(2.4)	0	(0.0)
耳痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
内分泌障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.5)	0	(0.0)	2	(2.4)	0	(0.0)
クッシング様	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.5)	0	(0.0)	2	(2.4)	0	(0.0)
眼障害	2	(33.3)	0	(0.0)	1	(12.5)	0	(0.0)	14	(31.8)	0	(0.0)	27	(32.1)	1	(1.2)
霧視	1	(16.7)	0	(0.0)	1	(12.5)	0	(0.0)	6	(13.6)	0	(0.0)	14	(16.7)	1	(1.2)
眼乾燥	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	2	(4.5)	0	(0.0)	5	(6.0)	0	(0.0)
白内障	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.5)	0	(0.0)	3	(3.6)	0	(0.0)
流涙増加	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(3.6)	0	(0.0)
眼充血	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
視力低下	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.5)	0	(0.0)	2	(2.4)	0	(0.0)
眼瞼炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
結膜炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
角膜病変	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
眼脂	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
眼出血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
眼刺激	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
眼痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
眼そう痒症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
眼部腫脹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
強膜出血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
視覚の明るさ	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
胃腸障害	5	(83.3)	1	(16.7)	6	(75.0)	0	(0.0)	35	(79.5)	6	(13.6)	64	(76.2)	9	(10.7)
下痢	4	(66.7)	0	(0.0)	4	(50.0)	0	(0.0)	26	(59.1)	3	(6.8)	47	(56.0)	5	(6.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 19）

System Organ Class / Preferred Term[1]	Cohort 5 (N=6)		Cohort 6 (N=8)		Cohort 7 (N=44)		Total (N=84)	
	Number (%) of Subjects							
	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher
悪心	1 (16.7)	0 (0.0)	2 (25.0)	0 (0.0)	16 (36.4)	0 (0.0)	26 (31.0)	0 (0.0)
便秘	1 (16.7)	0 (0.0)	3 (37.5)	0 (0.0)	11 (25.0)	0 (0.0)	22 (26.2)	0 (0.0)
嘔吐	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	11 (25.0)	2 (4.5)	18 (21.4)	2 (2.4)
腹痛	1 (16.7)	0 (0.0)	1 (12.5)	0 (0.0)	3 (6.8)	1 (2.3)	9 (10.7)	1 (1.2)
腹部膨満	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	4 (9.1)	0 (0.0)	7 (8.3)	0 (0.0)
歯痛	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	4 (9.1)	0 (0.0)	6 (7.1)	0 (0.0)
腹部不快感	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	2 (4.5)	0 (0.0)	4 (4.8)	0 (0.0)
口腔内痛	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	4 (4.8)	0 (0.0)
消化不良	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	3 (3.6)	0 (0.0)
胃腸出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.8)	2 (4.5)	3 (3.6)	2 (2.4)
胃食道逆流性疾患	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	1 (2.3)	0 (0.0)	3 (3.6)	0 (0.0)
歯肉出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	3 (3.6)	0 (0.0)
胃不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	3 (3.6)	0 (0.0)
上腹部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	2 (2.4)	0 (0.0)
鼓腸	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
痔核	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	2 (2.4)	0 (0.0)
口腔内軟組織障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	2 (2.4)	0 (0.0)
口内炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	2 (2.4)	0 (0.0)
腸雑音異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
結腸狭窄	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.3)	1 (1.2)	1 (1.2)
口内乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
嚥下障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
心窩部不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
便失禁	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
排便回数増加	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
胃炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
消化管運動過剰	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
消化管粘膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
消化器痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
歯肉痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 20）

System Organ Class / Preferred Term[1]	Cohort 5 (N=6)		Cohort 6 (N=8)		Cohort 7 (N=44)		Total (N=84)	
	Number (%) of Subjects							
	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher
歯肉腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
歯肉炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
血便排泄	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
口の感覚鈍麻	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
口腔内出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
嚥下痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
食道不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
口唇障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
小腸閉塞	1 (16.7)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
埋伏歯	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
全身障害および投与局所様態	4 (66.7)	0 (0.0)	7 (87.5)	3 (37.5)	42 (95.5)	6 (13.6)	77 (91.7)	12 (14.3)
疲労	4 (66.7)	0 (0.0)	6 (75.0)	3 (37.5)	30 (68.2)	3 (6.8)	55 (65.5)	6 (7.1)
発熱	1 (16.7)	0 (0.0)	4 (50.0)	0 (0.0)	19 (43.2)	0 (0.0)	33 (39.3)	0 (0.0)
末梢性浮腫	3 (50.0)	0 (0.0)	2 (25.0)	0 (0.0)	17 (38.6)	0 (0.0)	28 (33.3)	1 (1.2)
無力症	1 (16.7)	0 (0.0)	2 (25.0)	0 (0.0)	5 (11.4)	0 (0.0)	13 (15.5)	0 (0.0)
疼痛	0 (0.0)	0 (0.0)	2 (25.0)	0 (0.0)	4 (9.1)	0 (0.0)	10 (11.9)	1 (1.2)
悪寒	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (11.4)	0 (0.0)	9 (10.7)	0 (0.0)
疾患進行	1 (16.7)	0 (0.0)	1 (12.5)	0 (0.0)	2 (4.5)	1 (2.3)	7 (8.3)	3 (3.6)
易刺激性	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	4 (9.1)	0 (0.0)	6 (7.1)	0 (0.0)
圧痕浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.8)	0 (0.0)	6 (7.1)	0 (0.0)
歩行障害	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	2 (4.5)	0 (0.0)	4 (4.8)	0 (0.0)
インフルエンザ様疾患	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	4 (4.8)	0 (0.0)
胸痛	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	2 (4.5)	0 (0.0)	3 (3.6)	0 (0.0)
顔面浮腫	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.3)	3 (3.6)	1 (1.2)
倦怠感	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	2 (4.5)	0 (0.0)	3 (3.6)	0 (0.0)
カテーテル留置部位浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	2 (2.4)	0 (0.0)
カテーテル留置部位疼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	2 (2.4)	0 (0.0)
胸部不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	2 (2.4)	0 (0.0)
びくびく感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	2 (2.4)	0 (0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 21）

System Organ Class / Preferred Term[1]	Number (%) of Subjects											
	Cohort 5 (N=6)		Cohort 6 (N=8)		Cohort 7 (N=44)		Total (N=84)	
	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher
注入に関連した反応	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	2 (2.4)	0 (0.0)
注入部位反応	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	2 (2.4)	0 (0.0)
注射部位出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	2 (2.4)	0 (0.0)
注射部位疼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	2 (2.4)	0 (0.0)
局所腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	2 (2.4)	0 (0.0)
非心臓性胸痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	2 (2.4)	0 (0.0)
脱落痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
カテーテル留置部位内出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
カテーテル留置部位血腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
カテーテル留置部位出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
蜂窩織炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
死亡	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.3)	1 (1.2)	1 (1.2)
変形	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
冷感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
熱感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
熱感および冷感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
体温変動感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
注入部位内出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
注入部位疼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
注入部位静脈炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
注入部位発疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
注射部位内出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
注射部位不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
注射部位刺激感	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
注射部位反応	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
腫瘤	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
粘膜の炎症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
浮腫	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
温度変化不耐症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
血管穿刺部位出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 22）

System Organ Class / Preferred Term[1]	Number (%) of Subjects															
	Cohort 5 (N=6)				Cohort 6 (N=8)				Cohort 7 (N=44)				Total (N=84)			
	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
肝胆道系障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.5)	0	(0.0)	5	(6.0)	2	(2.4)
高ビリルビン血症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	4	(4.8)	2	(2.4)
胆石症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
免疫系障害	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	1	(2.3)	0	(0.0)	4	(4.8)	0	(0.0)
薬物過敏症	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	1	(2.3)	0	(0.0)	2	(2.4)	0	(0.0)
季節性アレルギー	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
感染症および寄生虫症	0	(0.0)	0	(0.0)	7	(87.5)	1	(12.5)	33	(75.0)	9	(20.5)	57	(67.9)	14	(16.7)
上気道感染	0	(0.0)	0	(0.0)	4	(50.0)	0	(0.0)	19	(43.2)	1	(2.3)	34	(40.5)	2	(2.4)
鼻咽頭炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	8	(18.2)	0	(0.0)	13	(15.5)	0	(0.0)
肺炎	0	(0.0)	0	(0.0)	3	(37.5)	0	(0.0)	6	(13.6)	5	(11.4)	13	(15.5)	6	(7.1)
副鼻腔炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(9.1)	0	(0.0)	8	(9.5)	0	(0.0)
インフルエンザ	0	(0.0)	0	(0.0)	2	(25.0)	1	(12.5)	2	(4.5)	0	(0.0)	6	(7.1)	1	(1.2)
尿路感染	0	(0.0)	0	(0.0)	1	(12.5)	1	(12.5)	3	(6.8)	0	(0.0)	6	(7.1)	2	(2.4)
蜂巣炎	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	3	(6.8)	0	(0.0)	5	(6.0)	1	(1.2)
気管支炎	0	(0.0)	0	(0.0)	2	(25.0)	0	(0.0)	1	(2.3)	0	(0.0)	4	(4.8)	0	(0.0)
単純ヘルペス	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.5)	0	(0.0)	3	(3.6)	0	(0.0)
鼻炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.5)	0	(0.0)	3	(3.6)	0	(0.0)
毛包炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	2	(2.4)	0	(0.0)
ウイルス性胃腸炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	2	(2.4)	0	(0.0)
口腔カンジダ症	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
ウイルス感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
顎骨炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	1	(2.3)	1	(1.2)	1	(1.2)
ウイルス性気管支炎	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
カンジダ症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
カテーテル留置部位蜂巣炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
サイトメガロウイルス感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
医療用具関連感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 23）

System Organ Class / Preferred Term[1]	Cohort 5 (N=6)		Cohort 6 (N=8)		Cohort 7 (N=44)		Total (N=84)	
	Number (%) of Subjects							
	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher
眼感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
真菌感染	0 (0.0)	0 (0.0)	1 (12.5)	1 (12.5)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
胃腸炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.3)	1 (1.2)	1 (1.2)
大葉性肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
口腔感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
骨髄炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.3)	1 (1.2)	1 (1.2)
爪囲炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
肺炎球菌性肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.3)	1 (1.2)	1 (1.2)
ＲＳウイルス肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.3)	1 (1.2)	1 (1.2)
ＲＳウイルス感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
敗血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
皮膚カンジダ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
歯髄炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
膣感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
ウイルス性上気道感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
傷害、中毒および処置合併症	2 (33.3)	0 (0.0)	1 (12.5)	0 (0.0)	15 (34.1)	1 (2.3)	22 (26.2)	2 (2.4)
挫傷	2 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	5 (11.4)	0 (0.0)	8 (9.5)	0 (0.0)
転倒	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	3 (3.6)	1 (1.2)
擦過傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	2 (2.4)	0 (0.0)
切開部位合併症	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	1 (2.3)	0 (0.0)	2 (2.4)	0 (0.0)
関節捻挫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	2 (2.4)	0 (0.0)
皮膚裂傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	2 (2.4)	0 (0.0)
歯牙破折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	2 (2.4)	0 (0.0)
動物咬傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
圧迫骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
血胸	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
熱性浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
上腕骨骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 24）

System Organ Class / Preferred Term[1]	Cohort 5 (N=6)		Cohort 6 (N=8)		Cohort 7 (N=44)		Total (N=84)	
	Number (%) of Subjects							
	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher
関節脱臼	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
肺損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
多発性骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
神経根損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
外傷後疼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
処置による疼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
肋骨骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
引っかき傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
硬膜下血腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
腱断裂	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.3)	1 (1.2)	1 (1.2)
熱傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
輸血反応	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
臨床検査	2 (33.3)	0 (0.0)	4 (50.0)	1 (12.5)	26 (59.1)	13 (29.5)	45 (53.6)	18 (21.4)
アラニン・アミノトランスフェラーゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (15.9)	4 (9.1)	10 (11.9)	5 (6.0)
アスパラギン酸アミノトランスフェラーゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (13.6)	2 (4.5)	9 (10.7)	3 (3.6)
血中クレアチニン増加	0 (0.0)	0 (0.0)	2 (25.0)	0 (0.0)	4 (9.1)	1 (2.3)	7 (8.3)	1 (1.2)
ヘモグロビン減少	0 (0.0)	0 (0.0)	1 (12.5)	1 (12.5)	3 (6.8)	3 (6.8)	6 (7.1)	5 (6.0)
体重減少	2 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.8)	0 (0.0)	6 (7.1)	0 (0.0)
血中重炭酸塩減少	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	3 (6.8)	1 (2.3)	5 (6.0)	1 (1.2)
血中ビリルビン増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.8)	0 (0.0)	4 (4.8)	0 (0.0)
心雑音	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	1 (2.3)	0 (0.0)	4 (4.8)	0 (0.0)
体重増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	4 (4.8)	0 (0.0)
血中アルカリホスファターゼ増加	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
血中ブドウ糖増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	1 (2.3)	2 (2.4)	1 (1.2)
ＩＮＲ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.3)	2 (2.4)	2 (2.4)
血小板数減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	2 (2.4)	1 (1.2)
血中アミラーゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.3)	1 (1.2)	1 (1.2)
血中カルシウム減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
血中マグネシウム減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 25）

System Organ Class / Preferred Term[1]	Cohort 5 (N=6)		Cohort 6 (N=8)		Cohort 7 (N=44)		Total (N=84)	
	Number (%) of Subjects							
	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher
呼吸音異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
駆出率減少	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
心電図ＱＴ延長	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
尿中ブドウ糖陽性	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
心拍数不整	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
好中球数減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.3)	1 (1.2)	1 (1.2)
尿色調異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
代謝および栄養障害	4 (66.7)	4 (66.7)	7 (87.5)	7 (87.5)	34 (77.3)	20 (45.5)	65 (77.4)	43 (51.2)
低リン酸血症	1 (16.7)	1 (16.7)	4 (50.0)	4 (50.0)	16 (36.4)	9 (20.5)	25 (29.8)	18 (21.4)
高血糖	2 (33.3)	2 (33.3)	3 (37.5)	2 (25.0)	11 (25.0)	2 (4.5)	23 (27.4)	11 (13.1)
低カリウム血症	1 (16.7)	0 (0.0)	1 (12.5)	1 (12.5)	12 (27.3)	4 (9.1)	22 (26.2)	8 (9.5)
低マグネシウム血症	1 (16.7)	0 (0.0)	2 (25.0)	0 (0.0)	9 (20.5)	1 (2.3)	17 (20.2)	1 (1.2)
低ナトリウム血症	1 (16.7)	1 (16.7)	3 (37.5)	2 (25.0)	5 (11.4)	3 (6.8)	14 (16.7)	9 (10.7)
食欲不振	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	7 (15.9)	0 (0.0)	12 (14.3)	0 (0.0)
食欲減退	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (9.1)	0 (0.0)	10 (11.9)	0 (0.0)
低カルシウム血症	0 (0.0)	0 (0.0)	2 (25.0)	0 (0.0)	5 (11.4)	1 (2.3)	10 (11.9)	1 (1.2)
脱水	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	5 (11.4)	0 (0.0)	8 (9.5)	1 (1.2)
低アルブミン血症	1 (16.7)	1 (16.7)	1 (12.5)	0 (0.0)	3 (6.8)	1 (2.3)	8 (9.5)	4 (4.8)
高マグネシウム血症	1 (16.7)	1 (16.7)	2 (25.0)	1 (12.5)	2 (4.5)	1 (2.3)	6 (7.1)	3 (3.6)
低血糖症	0 (0.0)	0 (0.0)	2 (25.0)	2 (25.0)	3 (6.8)	0 (0.0)	6 (7.1)	2 (2.4)
高カルシウム血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (9.1)	1 (2.3)	4 (4.8)	1 (1.2)
高尿酸血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.8)	2 (4.5)	4 (4.8)	3 (3.6)
高リン酸塩血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	3 (3.6)	0 (0.0)
高カリウム血症	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
高ナトリウム血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
高アルカリホスファターゼ血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
食欲亢進	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
鉄欠乏	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
ラクトース不耐性	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 26）

System Organ Class Preferred Term[1]	Number (%) of Subjects Cohort 5 (N=6) All Grades	Grade 3 or Higher	Cohort 6 (N=8) All Grades	Grade 3 or Higher	Cohort 7 (N=44) All Grades	Grade 3 or Higher	Total (N=84) All Grades	Grade 3 or Higher
筋骨格系および結合組織障害	4 (66.7)	0 (0.0)	6 (75.0)	3 (37.5)	35 (79.5)	6 (13.6)	66 (78.6)	13 (15.5)
筋痙縮	1 (16.7)	0 (0.0)	3 (37.5)	1 (12.5)	17 (38.6)	1 (2.3)	31 (36.9)	2 (2.4)
背部痛	2 (33.3)	0 (0.0)	1 (12.5)	0 (0.0)	15 (34.1)	1 (2.3)	27 (32.1)	2 (2.4)
関節痛	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	12 (27.3)	1 (2.3)	21 (25.0)	1 (1.2)
四肢痛	1 (16.7)	0 (0.0)	2 (25.0)	0 (0.0)	11 (25.0)	0 (0.0)	21 (25.0)	0 (0.0)
胸壁痛	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	6 (13.6)	0 (0.0)	11 (13.1)	0 (0.0)
肩部痛	1 (16.7)	0 (0.0)	2 (25.0)	0 (0.0)	3 (6.8)	0 (0.0)	11 (13.1)	1 (1.2)
筋痛	2 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	5 (11.4)	1 (2.3)	8 (9.5)	1 (1.2)
筋力低下	0 (0.0)	0 (0.0)	2 (25.0)	0 (0.0)	2 (4.5)	0 (0.0)	7 (8.3)	0 (0.0)
病的骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (11.4)	1 (2.3)	7 (8.3)	3 (3.6)
骨痛	0 (0.0)	0 (0.0)	1 (12.5)	1 (12.5)	2 (4.5)	0 (0.0)	6 (7.1)	1 (1.2)
関節運動範囲減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	5 (6.0)	0 (0.0)
頚部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	5 (6.0)	0 (0.0)
頚痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (11.4)	0 (0.0)	5 (6.0)	0 (0.0)
筋骨格硬直	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	2 (4.5)	0 (0.0)	4 (4.8)	0 (0.0)
筋骨格不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.8)	0 (0.0)	3 (3.6)	0 (0.0)
無菌性骨壊死	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	1 (2.3)	2 (2.4)	1 (1.2)
脊柱後弯症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	2 (2.4)	0 (0.0)
筋萎縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	2 (2.4)	0 (0.0)
殿部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.3)	1 (1.2)	1 (1.2)
末梢部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
椎間板突出	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
関節硬直	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
関節腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
筋肉内出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
筋攣縮	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
骨壊死	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
骨減少症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
肩回旋筋腱板症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 27）

System Organ Class / Preferred Term[1]	Cohort 5 (N=6)		Cohort 6 (N=8)		Cohort 7 (N=44)		Total (N=84)	
	Number (%) of Subjects							
	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher
仙骨痛	0 (0.0)	0 (0.0)	1 (12.5)	1 (12.5)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
顎関節症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
腱炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
腱鞘炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
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）	1 (16.7)	1 (16.7)	1 (12.5)	1 (12.5)	4 (9.1)	0 (0.0)	7 (8.3)	2 (2.4)
肺新生物	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	2 (2.4)	0 (0.0)
新生物	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	2 (2.4)	0 (0.0)
皮膚良性新生物	0 (0.0)	0 (0.0)	1 (12.5)	1 (12.5)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
乳癌第４期	1 (16.7)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
脂肪腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
悪性黒色腫	0 (0.0)	0 (0.0)	1 (12.5)	1 (12.5)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
形質細胞腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
脂漏性角化症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
神経系障害	4 (66.7)	0 (0.0)	6 (75.0)	1 (12.5)	34 (77.3)	5 (11.4)	62 (73.8)	6 (7.1)
錯感覚	0 (0.0)	0 (0.0)	3 (37.5)	0 (0.0)	9 (20.5)	0 (0.0)	19 (22.6)	0 (0.0)
頭痛	2 (33.3)	0 (0.0)	0 (0.0)	0 (0.0)	11 (25.0)	1 (2.3)	18 (21.4)	1 (1.2)
感覚減退	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	8 (18.2)	0 (0.0)	15 (17.9)	0 (0.0)
末梢性ニューロパシー	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	12 (27.3)	0 (0.0)	15 (17.9)	0 (0.0)
浮動性めまい	2 (33.3)	0 (0.0)	1 (12.5)	0 (0.0)	6 (13.6)	0 (0.0)	14 (16.7)	0 (0.0)
神経障害性疼痛	0 (0.0)	0 (0.0)	2 (25.0)	0 (0.0)	5 (11.4)	0 (0.0)	10 (11.9)	0 (0.0)
味覚異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (11.4)	0 (0.0)	6 (7.1)	0 (0.0)
反射減弱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (7.1)	0 (0.0)
振戦	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	4 (9.1)	0 (0.0)	6 (7.1)	0 (0.0)
記憶障害	1 (16.7)	0 (0.0)	1 (12.5)	0 (0.0)	1 (2.3)	0 (0.0)	5 (6.0)	0 (0.0)
傾眠	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (9.1)	0 (0.0)	5 (6.0)	0 (0.0)
失語症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	3 (3.6)	0 (0.0)
知覚過敏	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	3 (3.6)	0 (0.0)
末梢性感覚ニューロパシー	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	3 (3.6)	0 (0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 28）

System Organ Class / Preferred Term[1]	Cohort 5 (N=6)		Cohort 6 (N=8)		Cohort 7 (N=44)		Total (N=84)	
	Number (%) of Subjects							
	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher
反射消失	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	2 (2.4)	0 (0.0)
平衡障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	2 (2.4)	0 (0.0)
灼熱感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	2 (2.4)	0 (0.0)
体位性めまい	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	2 (2.4)	0 (0.0)
味覚減退	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	2 (2.4)	0 (0.0)
健忘	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
脳梗塞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.3)	1 (1.2)	1 (1.2)
脳血管発作	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.3)	1 (1.2)	1 (1.2)
痙攣	0 (0.0)	0 (0.0)	1 (12.5)	1 (12.5)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
起立障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
嗜眠	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
精神的機能障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
神経圧迫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
ニューロパシー	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
口の錯感覚	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
末梢性運動ニューロパシー	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.3)	1 (1.2)	1 (1.2)
坐骨神経痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
失神	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
三叉神経痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.3)	1 (1.2)	1 (1.2)
精神障害	3 (50.0)	0 (0.0)	2 (25.0)	0 (0.0)	24 (54.5)	3 (6.8)	39 (46.4)	3 (3.6)
不眠症	1 (16.7)	0 (0.0)	1 (12.5)	0 (0.0)	17 (38.6)	0 (0.0)	26 (31.0)	0 (0.0)
不安	2 (33.3)	0 (0.0)	1 (12.5)	0 (0.0)	7 (15.9)	2 (4.5)	11 (13.1)	2 (2.4)
激越	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.8)	0 (0.0)	5 (6.0)	0 (0.0)
うつ病	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	4 (9.1)	0 (0.0)	5 (6.0)	0 (0.0)
錯乱状態	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	3 (3.6)	0 (0.0)
気分変動	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.8)	1 (2.3)	3 (3.6)	1 (1.2)
気分動揺	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
ストレス	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
感情不安定	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 29）

System Organ Class / Preferred Term[1]	Number (%) of Subjects															
	Cohort 5 (N=6)				Cohort 6 (N=8)				Cohort 7 (N=44)				Total (N=84)			
	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
不安障害	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
失見当識	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
幻覚	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
リビドー減退	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
落ち着きのなさ	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
腎および尿路障害	2	(33.3)	0	(0.0)	3	(37.5)	2	(25.0)	9	(20.5)	2	(4.5)	22	(26.2)	4	(4.8)
夜間頻尿	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.5)	0	(0.0)	4	(4.8)	0	(0.0)
腎不全	0	(0.0)	0	(0.0)	1	(12.5)	1	(12.5)	1	(2.3)	0	(0.0)	4	(4.8)	1	(1.2)
血尿	0	(0.0)	0	(0.0)	1	(12.5)	1	(12.5)	1	(2.3)	0	(0.0)	3	(3.6)	1	(1.2)
急性腎不全	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(6.8)	2	(4.5)	3	(3.6)	2	(2.4)
排尿困難	0	(0.0)	0	(0.0)	1	(12.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
尿意切迫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	2	(2.4)	0	(0.0)
頻尿	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.5)	0	(0.0)	2	(2.4)	0	(0.0)
尿閉	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
失禁	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
腎結石症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
多尿	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
蛋白尿	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
排尿躊躇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
生殖系および乳房障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.5)	0	(0.0)	4	(4.8)	0	(0.0)
骨盤痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	2	(2.4)	0	(0.0)
萎縮性外陰膣炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
勃起不全	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
女性化乳房	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
閉経後出血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
精液変色	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
膣出血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 30）

System Organ Class / Preferred Term[1]	Cohort 5 (N=6)		Cohort 6 (N=8)		Cohort 7 (N=44)		Total (N=84)	
	Number (%) of Subjects							
	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher
呼吸器、胸郭および縦隔障害	4 (66.7)	1 (16.7)	6 (75.0)	1 (12.5)	34 (77.3)	3 (6.8)	64 (76.2)	7 (8.3)
咳嗽	3 (50.0)	0 (0.0)	4 (50.0)	0 (0.0)	17 (38.6)	1 (2.3)	35 (41.7)	1 (1.2)
呼吸困難	3 (50.0)	0 (0.0)	4 (50.0)	0 (0.0)	15 (34.1)	0 (0.0)	30 (35.7)	1 (1.2)
咽喉頭疼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	12 (27.3)	0 (0.0)	15 (17.9)	0 (0.0)
鼻出血	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	7 (15.9)	0 (0.0)	11 (13.1)	0 (0.0)
鼻閉	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	7 (15.9)	0 (0.0)	11 (13.1)	0 (0.0)
鼻漏	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (13.6)	0 (0.0)	9 (10.7)	0 (0.0)
発声障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (13.6)	0 (0.0)	8 (9.5)	0 (0.0)
労作性呼吸困難	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	5 (11.4)	1 (2.3)	7 (8.3)	1 (1.2)
湿性咳嗽	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (15.9)	0 (0.0)	7 (8.3)	0 (0.0)
しゃっくり	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	4 (4.8)	0 (0.0)
咽頭紅斑	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.8)	0 (0.0)	4 (4.8)	0 (0.0)
副鼻腔うっ血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	4 (4.8)	0 (0.0)
喘鳴	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	3 (6.8)	0 (0.0)	4 (4.8)	0 (0.0)
胸水	1 (16.7)	1 (16.7)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	3 (3.6)	1 (1.2)
無気肺	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	2 (2.4)	0 (0.0)
咽喉乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	2 (2.4)	0 (0.0)
咯血	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	1 (2.3)	0 (0.0)	2 (2.4)	0 (0.0)
低酸素症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	1 (2.3)	2 (2.4)	1 (1.2)
気道うっ血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	2 (2.4)	0 (0.0)
アレルギー性鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	2 (2.4)	0 (0.0)
睡眠時無呼吸症候群	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	1 (2.3)	0 (0.0)	2 (2.4)	0 (0.0)
咽喉刺激感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	2 (2.4)	0 (0.0)
喘息	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
肺ラ音	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
鼻腔内しびれ感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
喉頭腫瘤	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
肺障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
肺浸潤	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
鼻乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 31）

System Organ Class / Preferred Term[1]	Cohort 5 (N=6)		Cohort 6 (N=8)		Cohort 7 (N=44)		Total (N=84)	
	Number (%) of Subjects							
	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher
鼻中隔彎曲	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
鼻甲介肥大	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
胸膜痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
気胸	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
肺塞栓症	0 (0.0)	0 (0.0)	1 (12.5)	1 (12.5)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
肺水腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
ラ音	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
季節性鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
副鼻腔障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
咽喉絞扼感	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
上気道うっ血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
皮膚および皮下組織障害	3 (50.0)	0 (0.0)	3 (37.5)	0 (0.0)	30 (68.2)	1 (2.3)	52 (61.9)	2 (2.4)
発疹	2 (33.3)	0 (0.0)	2 (25.0)	0 (0.0)	8 (18.2)	1 (2.3)	19 (22.6)	2 (2.4)
皮膚乾燥	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	11 (25.0)	0 (0.0)	16 (19.0)	0 (0.0)
そう痒症	1 (16.7)	0 (0.0)	1 (12.5)	0 (0.0)	4 (9.1)	0 (0.0)	8 (9.5)	0 (0.0)
寝汗	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	5 (11.4)	0 (0.0)	7 (8.3)	0 (0.0)
斑状出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (9.1)	0 (0.0)	6 (7.1)	0 (0.0)
多汗症	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	4 (9.1)	0 (0.0)	6 (7.1)	0 (0.0)
紅斑	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.8)	0 (0.0)	5 (6.0)	0 (0.0)
全身性皮疹	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	2 (4.5)	0 (0.0)	3 (3.6)	0 (0.0)
斑状皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.8)	0 (0.0)	3 (3.6)	0 (0.0)
脱毛症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	2 (2.4)	0 (0.0)
黄毛症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	2 (2.4)	0 (0.0)
挫傷発生の増加傾向	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	2 (2.4)	0 (0.0)
爪の障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	2 (2.4)	0 (0.0)
爪甲縦裂症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	2 (2.4)	0 (0.0)
眼窩周囲浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	2 (2.4)	0 (0.0)
そう痒性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	2 (2.4)	0 (0.0)
皮膚剥脱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 32）

System Organ Class / Preferred Term[1]	Number (%) of Subjects															
	Cohort 5 (N=6)				Cohort 6 (N=8)				Cohort 7 (N=44)				Total (N=84)			
	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
皮膚出血	1	(16.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	2	(2.4)	0	(0.0)
皮膚病変	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	2	(2.4)	0	(0.0)
日光性角化症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
接触性皮膚炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
毛髪成長異常	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
爪変色	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
点状出血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
光線過敏性反応	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
斑状丘疹状皮疹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
丘疹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
皮膚変色	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
皮膚障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
皮膚脆弱性	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
皮膚色素過剰	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
皮膚刺激	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
皮下結節	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
顔面腫脹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
薬疹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
外科および内科処置	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.5)	1	(2.3)	3	(3.6)	2	(2.4)
白内障手術	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	1	(2.3)	1	(1.2)	1	(1.2)
膝手術	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)
抜歯	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	1	(1.2)
血管障害	1	(16.7)	1	(16.7)	1	(12.5)	0	(0.0)	16	(36.4)	3	(6.8)	23	(27.4)	4	(4.8)
高血圧	1	(16.7)	1	(16.7)	0	(0.0)	0	(0.0)	4	(9.1)	0	(0.0)	7	(8.3)	1	(1.2)
深部静脈血栓症	1	(16.7)	1	(16.7)	0	(0.0)	0	(0.0)	5	(11.4)	2	(4.5)	6	(7.1)	3	(3.6)
潮紅	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.5)	0	(0.0)	4	(4.8)	0	(0.0)
表在性血栓性静脈炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.5)	0	(0.0)	3	(3.6)	0	(0.0)
低血圧	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.5)	0	(0.0)	2	(2.4)	0	(0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 33）

System Organ Class / Preferred Term[1]	Number (%) of Subjects											
	Cohort 5 (N=6)		Cohort 6 (N=8)		Cohort 7 (N=44)		Total (N=84)	
	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher
静脈炎	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	2 (2.4)	0 (0.0)
塞栓症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.3)	1 (1.2)	1 (1.2)
血腫	0 (0.0)	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
ほてり	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.2)	0 (0.0)
末梢冷感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
血栓後症候群	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
血栓症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.3)	1 (1.2)	1 (1.2)
血管脆弱化	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
大静脈血栓症	1 (16.7)	1 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 34）

	Number (%) of Subjects							
	Cohort 6 and 7 (N=52)				Total (N=84)			
System Organ Class Preferred Term[1]	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
Number of Subjects with at Least One TEAE[2]	52	(100.0)	49	(94.2)	84	(100.0)	80	(95.2)
血液およびリンパ系障害	40	(76.9)	36	(69.2)	66	(78.6)	60	(71.4)
好中球減少症	19	(36.5)	17	(32.7)	38	(45.2)	32	(38.1)
リンパ球減少症	27	(51.9)	25	(48.1)	34	(40.5)	32	(38.1)
貧血	17	(32.7)	10	(19.2)	32	(38.1)	16	(19.0)
血小板減少症	16	(30.8)	10	(19.2)	29	(34.5)	21	(25.0)
白血球減少症	11	(21.2)	6	(11.5)	17	(20.2)	11	(13.1)
白血球増加症	3	(5.8)	0	(0.0)	3	(3.6)	0	(0.0)
リンパ節症	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
発熱性好中球減少症	0	(0.0)	0	(0.0)	1	(1.2)	1	(1.2)
溶血性貧血	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
リンパ節痛	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
心臓障害	14	(26.9)	3	(5.8)	21	(25.0)	6	(7.1)
頻脈	4	(7.7)	0	(0.0)	5	(6.0)	1	(1.2)
徐脈	1	(1.9)	0	(0.0)	4	(4.8)	1	(1.2)
動悸	2	(3.8)	0	(0.0)	4	(4.8)	0	(0.0)
心房細動	1	(1.9)	1	(1.9)	2	(2.4)	1	(1.2)
期外収縮	2	(3.8)	0	(0.0)	2	(2.4)	0	(0.0)
急性心筋梗塞	1	(1.9)	1	(1.9)	1	(1.2)	1	(1.2)
うっ血性心不全	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
心拡大	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
冠動脈疾患	1	(1.9)	1	(1.9)	1	(1.2)	1	(1.2)
心筋梗塞	1	(1.9)	1	(1.9)	1	(1.2)	1	(1.2)
洞不全症候群	0	(0.0)	0	(0.0)	1	(1.2)	1	(1.2)
洞性徐脈	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
心室性期外収縮	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
心室肥大	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).

[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 35）

System Organ Class Preferred Term[1]	Number (%) of Subjects Cohort 6 and 7 (N=52) All Grades		Grade 3 or Higher		Total (N=84) All Grades		Grade 3 or Higher	
耳および迷路障害	5	(9.6)	1	(1.9)	6	(7.1)	1	(1.2)
耳垢栓塞	1	(1.9)	0	(0.0)	2	(2.4)	0	(0.0)
ろう	2	(3.8)	1	(1.9)	2	(2.4)	1	(1.2)
耳鳴	2	(3.8)	0	(0.0)	2	(2.4)	0	(0.0)
耳痛	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
内分泌障害	2	(3.8)	0	(0.0)	2	(2.4)	0	(0.0)
クッシング様	2	(3.8)	0	(0.0)	2	(2.4)	0	(0.0)
眼障害	15	(28.8)	0	(0.0)	27	(32.1)	1	(1.2)
霧視	7	(13.5)	0	(0.0)	14	(16.7)	1	(1.2)
眼乾燥	3	(5.8)	0	(0.0)	5	(6.0)	0	(0.0)
白内障	2	(3.8)	0	(0.0)	3	(3.6)	0	(0.0)
流涙増加	0	(0.0)	0	(0.0)	3	(3.6)	0	(0.0)
眼充血	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
視力低下	2	(3.8)	0	(0.0)	2	(2.4)	0	(0.0)
眼瞼炎	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
結膜炎	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
角膜病変	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
眼脂	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
眼出血	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
眼刺激	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
眼痛	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
眼そう痒症	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
眼部膨脹	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
強膜出血	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
視覚の明るさ	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
胃腸障害	41	(78.8)	6	(11.5)	64	(76.2)	9	(10.7)
下痢	30	(57.7)	3	(5.8)	47	(56.0)	5	(6.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).

[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 36）

System Organ Class Preferred Term[1]	Number (%) of Subjects Cohort 6 and 7 (N=52) All Grades		Grade 3 or Higher		Total (N=84) All Grades		Grade 3 or Higher	
悪心	18	(34.6)	0	(0.0)	26	(31.0)	0	(0.0)
便秘	14	(26.9)	0	(0.0)	22	(26.2)	0	(0.0)
嘔吐	12	(23.1)	2	(3.8)	18	(21.4)	2	(2.4)
腹痛	4	(7.7)	1	(1.9)	9	(10.7)	1	(1.2)
腹部膨満	4	(7.7)	0	(0.0)	7	(8.3)	0	(0.0)
歯痛	5	(9.6)	0	(0.0)	6	(7.1)	0	(0.0)
腹部不快感	3	(5.8)	0	(0.0)	4	(4.8)	0	(0.0)
口腔内痛	2	(3.8)	0	(0.0)	4	(4.8)	0	(0.0)
消化不良	2	(3.8)	0	(0.0)	3	(3.6)	0	(0.0)
胃腸出血	3	(5.8)	2	(3.8)	3	(3.6)	2	(2.4)
胃食道逆流性疾患	2	(3.8)	0	(0.0)	3	(3.6)	0	(0.0)
歯肉出血	2	(3.8)	0	(0.0)	3	(3.6)	0	(0.0)
胃不快感	1	(1.9)	0	(0.0)	3	(3.6)	0	(0.0)
上腹部痛	1	(1.9)	0	(0.0)	2	(2.4)	0	(0.0)
鼓腸	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
痔核	2	(3.8)	0	(0.0)	2	(2.4)	0	(0.0)
口腔内軟組織障害	1	(1.9)	0	(0.0)	2	(2.4)	0	(0.0)
口内炎	1	(1.9)	0	(0.0)	2	(2.4)	0	(0.0)
腸雑音異常	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
結腸狭窄	1	(1.9)	1	(1.9)	1	(1.2)	1	(1.2)
口内乾燥	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
嚥下障害	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
心窩部不快感	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
便失禁	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
排便回数増加	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
胃炎	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
消化管運動過剰	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
消化管粘膜炎	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
消化器痛	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
歯肉痛	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 37）

System Organ Class Preferred Term[1]	Number (%) of Subjects Cohort 6 and 7 (N=52) All Grades	Grade 3 or Higher	Total (N=84) All Grades	Grade 3 or Higher
歯肉腫脹	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
歯肉炎	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
血便排泄	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
口の感覚鈍麻	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
口腔内出血	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
嚥下痛	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
食道不快感	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
口蓋障害	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
小腸閉塞	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
埋伏歯	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
全身障害および投与局所様態	49 (94.2)	9 (17.3)	77 (91.7)	12 (14.3)
疲労	36 (69.2)	6 (11.5)	55 (65.5)	6 (7.1)
発熱	23 (44.2)	0 (0.0)	33 (39.3)	0 (0.0)
末梢性浮腫	19 (36.5)	0 (0.0)	28 (33.3)	1 (1.2)
無力症	7 (13.5)	0 (0.0)	13 (15.5)	0 (0.0)
疼痛	6 (11.5)	0 (0.0)	10 (11.9)	1 (1.2)
悪寒	5 (9.6)	0 (0.0)	9 (10.7)	0 (0.0)
疾患進行	3 (5.8)	1 (1.9)	7 (8.3)	3 (3.6)
易刺激性	4 (7.7)	0 (0.0)	6 (7.1)	0 (0.0)
圧痕浮腫	3 (5.8)	0 (0.0)	6 (7.1)	0 (0.0)
歩行障害	3 (5.8)	0 (0.0)	4 (4.8)	0 (0.0)
インフルエンザ様疾患	2 (3.8)	0 (0.0)	4 (4.8)	0 (0.0)
胸痛	3 (5.8)	0 (0.0)	3 (3.6)	0 (0.0)
顔面浮腫	1 (1.9)	1 (1.9)	3 (3.6)	1 (1.2)
倦怠感	3 (5.8)	0 (0.0)	3 (3.6)	0 (0.0)
カテーテル留置部位浮腫	2 (3.8)	0 (0.0)	2 (2.4)	0 (0.0)
カテーテル留置部位疼痛	1 (1.9)	0 (0.0)	2 (2.4)	0 (0.0)
胸部不快感	1 (1.9)	0 (0.0)	2 (2.4)	0 (0.0)
びくびく感	1 (1.9)	0 (0.0)	2 (2.4)	0 (0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).

[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 38）

System Organ Class Preferred Term[1]	Number (%) of Subjects Cohort 6 and 7 (N=52) All Grades		Grade 3 or Higher		Total (N=84) All Grades		Grade 3 or Higher	
注入に関連した反応	2	(3.8)	0	(0.0)	2	(2.4)	0	(0.0)
注入部位反応	1	(1.9)	0	(0.0)	2	(2.4)	0	(0.0)
注射部位出血	1	(1.9)	0	(0.0)	2	(2.4)	0	(0.0)
注射部位疼痛	2	(3.8)	0	(0.0)	2	(2.4)	0	(0.0)
局所腫脹	2	(3.8)	0	(0.0)	2	(2.4)	0	(0.0)
非心臓性胸痛	1	(1.9)	0	(0.0)	2	(2.4)	0	(0.0)
腋窩痛	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
カテーテル留置部位内出血	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
カテーテル留置部位血腫	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
カテーテル留置部位出血	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
嚢胞	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
死亡	1	(1.9)	1	(1.9)	1	(1.2)	1	(1.2)
変形	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
冷感	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
熱感	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
熱感および冷感	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
体温変動感	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
注入部位内出血	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
注入部位疼痛	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
注入部位静脈炎	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
注入部位発疹	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
注射部位内出血	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
注射部位不快感	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
注射部位刺激感	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
注射部位反応	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
腫瘤	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
粘膜の炎症	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
浮腫	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
温度変化不耐症	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
血管穿刺部位出血	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).

[2] Subjects were counted only once for each system organ class and each preferred term.

System Organ Class Preferred Term[1]	Number (%) of Subjects Cohort 6 and 7 (N=52) All Grades		Grade 3 or Higher		Total (N=84) All Grades		Grade 3 or Higher	
肝胆道系障害	2	(3.8)	0	(0.0)	5	(6.0)	2	(2.4)
高ビリルビン血症	1	(1.9)	0	(0.0)	4	(4.8)	2	(2.4)
胆石症	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
免疫系障害	2	(3.8)	0	(0.0)	4	(4.8)	0	(0.0)
薬物過敏症	2	(3.8)	0	(0.0)	2	(2.4)	0	(0.0)
季節性アレルギー	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
感染症および寄生虫症	40	(76.9)	10	(19.2)	57	(67.9)	14	(16.7)
上気道感染	23	(44.2)	1	(1.9)	34	(40.5)	2	(2.4)
鼻咽頭炎	8	(15.4)	0	(0.0)	13	(15.5)	0	(0.0)
肺炎	9	(17.3)	5	(9.6)	13	(15.5)	6	(7.1)
副鼻腔炎	4	(7.7)	0	(0.0)	8	(9.5)	0	(0.0)
インフルエンザ	4	(7.7)	1	(1.9)	6	(7.1)	1	(1.2)
尿路感染	4	(7.7)	1	(1.9)	6	(7.1)	2	(2.4)
蜂巣炎	4	(7.7)	0	(0.0)	5	(6.0)	1	(1.2)
気管支炎	3	(5.8)	0	(0.0)	4	(4.8)	0	(0.0)
単純ヘルペス	2	(3.8)	0	(0.0)	3	(3.6)	0	(0.0)
鼻炎	2	(3.8)	0	(0.0)	3	(3.6)	0	(0.0)
毛包炎	1	(1.9)	0	(0.0)	2	(2.4)	0	(0.0)
ウイルス性胃腸炎	1	(1.9)	0	(0.0)	2	(2.4)	0	(0.0)
口腔カンジダ症	1	(1.9)	0	(0.0)	2	(2.4)	0	(0.0)
ウイルス感染	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
顎膿瘍	1	(1.9)	1	(1.9)	1	(1.2)	1	(1.2)
ウイルス性気管支炎	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
カンジダ症	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
カテーテル留置部位蜂巣炎	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
サイトメガロウイルス感染	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
医療用具関連感染	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).

[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 40）

System Organ Class Preferred Term[1]	Number (%) of Subjects Cohort 6 and 7 (N=52) All Grades	 Grade 3 or Higher	 Total (N=84) All Grades	 Grade 3 or Higher
眼感染	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
真菌感染	1 (1.9)	1 (1.9)	1 (1.2)	1 (1.2)
胃腸炎	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
感染	1 (1.9)	1 (1.9)	1 (1.2)	1 (1.2)
大葉性肺炎	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
口腔感染	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
骨髄炎	1 (1.9)	1 (1.9)	1 (1.2)	1 (1.2)
爪囲炎	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
肺炎球菌性肺炎	1 (1.9)	1 (1.9)	1 (1.2)	1 (1.2)
ＲＳウイルス肺炎	1 (1.9)	1 (1.9)	1 (1.2)	1 (1.2)
ＲＳウイルス感染	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
敗血症	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
皮膚カンジダ	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
歯膿瘍	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
膣感染	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
ウイルス性上気道感染	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
傷害、中毒および処置合併症	16 (30.8)	1 (1.9)	22 (26.2)	2 (2.4)
挫傷	5 (9.6)	0 (0.0)	8 (9.5)	0 (0.0)
転倒	1 (1.9)	0 (0.0)	3 (3.6)	1 (1.2)
擦過傷	2 (3.8)	0 (0.0)	2 (2.4)	0 (0.0)
切開部位合併症	2 (3.8)	0 (0.0)	2 (2.4)	0 (0.0)
関節捻挫	2 (3.8)	0 (0.0)	2 (2.4)	0 (0.0)
皮膚裂傷	1 (1.9)	0 (0.0)	2 (2.4)	0 (0.0)
歯牙破折	2 (3.8)	0 (0.0)	2 (2.4)	0 (0.0)
動物咬傷	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
圧迫骨折	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
血胸	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
熱性浮腫	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
上腕骨骨折	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).

[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 41）

System Organ Class Preferred Term[1]	Number (%) of Subjects Cohort 6 and 7 (N=52) All Grades	 Grade 3 or Higher	 Total (N=84) All Grades	 Grade 3 or Higher
関節脱臼	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
肺損傷	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
多発性骨折	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
神経根損傷	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
外傷後疼痛	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
処置による疼痛	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
肋骨骨折	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
引っかき傷	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
硬膜下血腫	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
腱断裂	1 (1.9)	1 (1.9)	1 (1.2)	1 (1.2)
熱傷	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
輸血反応	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
臨床検査	30 (57.7)	14 (26.9)	45 (53.6)	18 (21.4)
アラニン・アミノトランスフェラーゼ増加	7 (13.5)	4 (7.7)	10 (11.9)	5 (6.0)
アスパラギン酸アミノトランスフェラーゼ増加	6 (11.5)	2 (3.8)	9 (10.7)	3 (3.6)
血中クレアチニン増加	6 (11.5)	1 (1.9)	7 (8.3)	1 (1.2)
ヘモグロビン減少	4 (7.7)	4 (7.7)	6 (7.1)	5 (6.0)
体重減少	3 (5.8)	0 (0.0)	6 (7.1)	0 (0.0)
血中重炭酸塩減少	4 (7.7)	1 (1.9)	5 (6.0)	1 (1.2)
血中ビリルビン増加	3 (5.8)	0 (0.0)	4 (4.8)	0 (0.0)
心雑音	2 (3.8)	0 (0.0)	4 (4.8)	0 (0.0)
体重増加	2 (3.8)	0 (0.0)	4 (4.8)	0 (0.0)
血中アルカリホスファターゼ増加	1 (1.9)	0 (0.0)	2 (2.4)	0 (0.0)
血中ブドウ糖増加	2 (3.8)	1 (1.9)	2 (2.4)	1 (1.2)
ＩＮＲ増加	1 (1.9)	1 (1.9)	2 (2.4)	2 (2.4)
血小板数減少	1 (1.9)	0 (0.0)	2 (2.4)	1 (1.2)
血中アミラーゼ増加	1 (1.9)	1 (1.9)	1 (1.2)	1 (1.2)
血中カルシウム減少	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
血中マグネシウム減少	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).

[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 42）

System Organ Class Preferred Term[1]	Number (%) of Subjects Cohort 6 and 7 (N=52) All Grades	Grade 3 or Higher	Total (N=84) All Grades	Grade 3 or Higher
呼吸音異常	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
駆出率減少	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
心電図ＱＴ延長	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
尿中ブドウ糖陽性	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
心拍数不整	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
好中球数減少	1 (1.9)	1 (1.9)	1 (1.2)	1 (1.2)
尿色調異常	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
代謝および栄養障害	41 (78.8)	27 (51.9)	65 (77.4)	43 (51.2)
低リン酸血症	20 (38.5)	13 (25.0)	25 (29.8)	18 (21.4)
高血糖	14 (26.9)	4 (7.7)	23 (27.4)	11 (13.1)
低カリウム血症	13 (25.0)	5 (9.6)	22 (26.2)	8 (9.5)
低マグネシウム血症	11 (21.2)	1 (1.9)	17 (20.2)	1 (1.2)
低ナトリウム血症	8 (15.4)	5 (9.6)	14 (16.7)	9 (10.7)
食欲不振	7 (13.5)	0 (0.0)	12 (14.3)	0 (0.0)
食欲減退	4 (7.7)	0 (0.0)	10 (11.9)	0 (0.0)
低カルシウム血症	7 (13.5)	1 (1.9)	10 (11.9)	1 (1.2)
脱水	5 (9.6)	0 (0.0)	8 (9.5)	1 (1.2)
低アルブミン血症	4 (7.7)	1 (1.9)	8 (9.5)	4 (4.8)
高マグネシウム血症	4 (7.7)	2 (3.8)	6 (7.1)	3 (3.6)
低血糖症	5 (9.6)	2 (3.8)	6 (7.1)	2 (2.4)
高カルシウム血症	4 (7.7)	1 (1.9)	4 (4.8)	1 (1.2)
高尿酸血症	3 (5.8)	2 (3.8)	4 (4.8)	3 (3.6)
高リン酸塩血症	2 (3.8)	0 (0.0)	3 (3.6)	0 (0.0)
高カリウム血症	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
高ナトリウム血症	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
高アルカリホスファターゼ血症	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
食欲亢進	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
鉄欠乏	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
ラクトース不耐性	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).

[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 43）

System Organ Class Preferred Term[1]	Number (%) of Subjects Cohort 6 and 7 (N=52) All Grades		Grade 3 or Higher		Total (N=84) All Grades		Grade 3 or Higher	
筋骨格系および結合組織障害	41	(78.8)	9	(17.3)	66	(78.6)	13	(15.5)
筋痙縮	20	(38.5)	2	(3.8)	31	(36.9)	2	(2.4)
背部痛	16	(30.8)	1	(1.9)	27	(32.1)	2	(2.4)
関節痛	13	(25.0)	1	(1.9)	21	(25.0)	1	(1.2)
四肢痛	13	(25.0)	0	(0.0)	21	(25.0)	0	(0.0)
胸壁痛	6	(11.5)	0	(0.0)	11	(13.1)	0	(0.0)
肩部痛	5	(9.6)	0	(0.0)	11	(13.1)	1	(1.2)
筋痛	5	(9.6)	1	(1.9)	8	(9.5)	1	(1.2)
筋力低下	4	(7.7)	0	(0.0)	7	(8.3)	0	(0.0)
病的骨折	5	(9.6)	1	(1.9)	7	(8.3)	3	(3.6)
骨痛	3	(5.8)	1	(1.9)	6	(7.1)	1	(1.2)
関節運動範囲減少	2	(3.8)	0	(0.0)	5	(6.0)	0	(0.0)
頸部痛	2	(3.8)	0	(0.0)	5	(6.0)	0	(0.0)
顎痛	5	(9.6)	0	(0.0)	5	(6.0)	0	(0.0)
筋骨格硬直	3	(5.8)	0	(0.0)	4	(4.8)	0	(0.0)
筋骨格不快感	3	(5.8)	0	(0.0)	3	(3.6)	0	(0.0)
無腐性骨壊死	2	(3.8)	1	(1.9)	2	(2.4)	1	(1.2)
脊柱後弯症	2	(3.8)	0	(0.0)	2	(2.4)	0	(0.0)
筋萎縮	2	(3.8)	0	(0.0)	2	(2.4)	0	(0.0)
殿部痛	1	(1.9)	1	(1.9)	1	(1.2)	1	(1.2)
尺骨部痛	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
椎間板突出	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
関節硬直	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
関節腫脹	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
筋肉内出血	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
筋攣縮	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
骨壊死	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
骨減少症	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
肩回旋筋腱板症候群	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).

[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 44）

System Organ Class Preferred Term[1]	Number (%) of Subjects Cohort 6 and 7 (N=52) All Grades	 Grade 3 or Higher	 Total (N=84) All Grades	 Grade 3 or Higher
仙骨痛	1 (1.9)	1 (1.9)	1 (1.2)	1 (1.2)
顎関節症候群	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
腱炎	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
腱鞘炎	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
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）	5 (9.6)	1 (1.9)	7 (8.3)	2 (2.4)
肺新生物	1 (1.9)	0 (0.0)	2 (2.4)	0 (0.0)
新生物	2 (3.8)	0 (0.0)	2 (2.4)	0 (0.0)
皮膚良性新生物	1 (1.9)	1 (1.9)	1 (1.2)	1 (1.2)
乳癌第４期	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
脂肪腫	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
悪性黒色腫	1 (1.9)	1 (1.9)	1 (1.2)	1 (1.2)
形質細胞腫	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
脂漏性角化症	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
神経系障害	40 (76.9)	6 (11.5)	62 (73.8)	6 (7.1)
錯感覚	12 (23.1)	0 (0.0)	19 (22.6)	0 (0.0)
頭痛	11 (21.2)	1 (1.9)	18 (21.4)	1 (1.2)
感覚減退	9 (17.3)	0 (0.0)	15 (17.9)	0 (0.0)
末梢性ニューロパシー	12 (23.1)	0 (0.0)	15 (17.9)	0 (0.0)
浮動性めまい	7 (13.5)	0 (0.0)	14 (16.7)	0 (0.0)
神経障害性疼痛	7 (13.5)	0 (0.0)	10 (11.9)	0 (0.0)
味覚異常	5 (9.6)	0 (0.0)	6 (7.1)	0 (0.0)
反射減弱	0 (0.0)	0 (0.0)	6 (7.1)	0 (0.0)
振戦	4 (7.7)	0 (0.0)	6 (7.1)	0 (0.0)
記憶障害	2 (3.8)	0 (0.0)	5 (6.0)	0 (0.0)
傾眠	4 (7.7)	0 (0.0)	5 (6.0)	0 (0.0)
失語症	1 (1.9)	0 (0.0)	3 (3.6)	0 (0.0)
知覚過敏	2 (3.8)	0 (0.0)	3 (3.6)	0 (0.0)
末梢性感覚ニューロパシー	2 (3.8)	0 (0.0)	3 (3.6)	0 (0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).

[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 45）

System Organ Class Preferred Term[1]	Number (%) of Subjects Cohort 6 and 7 (N=52) All Grades		Grade 3 or Higher		Total (N=84) All Grades		Grade 3 or Higher	
反射消失	1	(1.9)	0	(0.0)	2	(2.4)	0	(0.0)
平衡障害	1	(1.9)	0	(0.0)	2	(2.4)	0	(0.0)
灼熱感	2	(3.8)	0	(0.0)	2	(2.4)	0	(0.0)
体位性めまい	2	(3.8)	0	(0.0)	2	(2.4)	0	(0.0)
味覚減退	2	(3.8)	0	(0.0)	2	(2.4)	0	(0.0)
健忘	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
脳腫瘤	1	(1.9)	1	(1.9)	1	(1.2)	1	(1.2)
脳血管発作	1	(1.9)	1	(1.9)	1	(1.2)	1	(1.2)
痙攣	1	(1.9)	1	(1.9)	1	(1.2)	1	(1.2)
起立障害	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
嗜眠	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
精神的機能障害	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
神経圧迫	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
ニューロパシー	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
口の錯感覚	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
末梢性運動ニューロパシー	1	(1.9)	1	(1.9)	1	(1.2)	1	(1.2)
坐骨神経痛	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
失神	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
三叉神経痛	1	(1.9)	1	(1.9)	1	(1.2)	1	(1.2)
精神障害	26	(50.0)	3	(5.8)	39	(46.4)	3	(3.6)
不眠症	18	(34.6)	0	(0.0)	26	(31.0)	0	(0.0)
不安	8	(15.4)	2	(3.8)	11	(13.1)	2	(2.4)
激越	3	(5.8)	0	(0.0)	5	(6.0)	0	(0.0)
うつ病	5	(9.6)	0	(0.0)	5	(6.0)	0	(0.0)
錯乱状態	2	(3.8)	0	(0.0)	3	(3.6)	0	(0.0)
気分変動	3	(5.8)	1	(1.9)	3	(3.6)	1	(1.2)
気分動揺	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)
ストレス	1	(1.9)	0	(0.0)	2	(2.4)	0	(0.0)
感情不安定	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).

[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 46）

System Organ Class Preferred Term[1]	Number (%) of Subjects Cohort 6 and 7 (N=52) All Grades	 Grade 3 or Higher	 Total (N=84) All Grades	 Grade 3 or Higher
不安障害	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
失見当識	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
幻覚	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
リビドー減退	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
落ち着きのなさ	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
腎および尿路障害	12 (23.1)	4 (7.7)	22 (26.2)	4 (4.8)
夜間頻尿	2 (3.8)	0 (0.0)	4 (4.8)	0 (0.0)
腎不全	2 (3.8)	1 (1.9)	4 (4.8)	1 (1.2)
血尿	2 (3.8)	1 (1.9)	3 (3.6)	1 (1.2)
急性腎不全	3 (5.8)	2 (3.8)	3 (3.6)	2 (2.4)
排尿困難	1 (1.9)	0 (0.0)	2 (2.4)	0 (0.0)
尿意切迫	1 (1.9)	0 (0.0)	2 (2.4)	0 (0.0)
頻尿	2 (3.8)	0 (0.0)	2 (2.4)	0 (0.0)
尿閉	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
失禁	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
腎結石症	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
多尿	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
蛋白尿	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
排尿躊躇	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
生殖系および乳房障害	2 (3.8)	0 (0.0)	4 (4.8)	0 (0.0)
骨盤痛	1 (1.9)	0 (0.0)	2 (2.4)	0 (0.0)
萎縮性外陰膣炎	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
勃起不全	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
女性化乳房	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
閉経後出血	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
精液変色	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
膣出血	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).

[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 47）

System Organ Class Preferred Term[1]	Number (%) of Subjects Cohort 6 and 7 (N=52) All Grades		Grade 3 or Higher		Total (N=84) All Grades		Grade 3 or Higher	
呼吸器、胸郭および縦隔障害	40	(76.9)	4	(7.7)	64	(76.2)	7	(8.3)
咳嗽	21	(40.4)	1	(1.9)	35	(41.7)	1	(1.2)
呼吸困難	19	(36.5)	0	(0.0)	30	(35.7)	1	(1.2)
咽喉頭疼痛	12	(23.1)	0	(0.0)	15	(17.9)	0	(0.0)
鼻出血	7	(13.5)	0	(0.0)	11	(13.1)	0	(0.0)
鼻閉	8	(15.4)	0	(0.0)	11	(13.1)	0	(0.0)
鼻漏	6	(11.5)	0	(0.0)	9	(10.7)	0	(0.0)
発声障害	6	(11.5)	0	(0.0)	8	(9.5)	0	(0.0)
労作性呼吸困難	6	(11.5)	1	(1.9)	7	(8.3)	1	(1.2)
湿性咳嗽	7	(13.5)	0	(0.0)	7	(8.3)	0	(0.0)
しゃっくり	1	(1.9)	0	(0.0)	4	(4.8)	0	(0.0)
咽頭紅斑	3	(5.8)	0	(0.0)	4	(4.8)	0	(0.0)
副鼻腔うっ血	1	(1.9)	0	(0.0)	4	(4.8)	0	(0.0)
喘鳴	4	(7.7)	0	(0.0)	4	(4.8)	0	(0.0)
胸水	1	(1.9)	0	(0.0)	3	(3.6)	1	(1.2)
無気肺	2	(3.8)	0	(0.0)	2	(2.4)	0	(0.0)
咽喉乾燥	1	(1.9)	0	(0.0)	2	(2.4)	0	(0.0)
喀血	2	(3.8)	0	(0.0)	2	(2.4)	0	(0.0)
低酸素症	2	(3.8)	1	(1.9)	2	(2.4)	1	(1.2)
気道うっ血	1	(1.9)	0	(0.0)	2	(2.4)	0	(0.0)
アレルギー性鼻炎	2	(3.8)	0	(0.0)	2	(2.4)	0	(0.0)
睡眠時無呼吸症候群	2	(3.8)	0	(0.0)	2	(2.4)	0	(0.0)
咽喉刺激感	1	(1.9)	0	(0.0)	2	(2.4)	0	(0.0)
喘息	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
肺ラ音	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
鼻腔内しびれ感	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
喉頭腫瘤	0	(0.0)	0	(0.0)	1	(1.2)	1	(1.2)
肺障害	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
肺浸潤	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
鼻乾燥	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).

[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 48）

System Organ Class Preferred Term[1]	Number (%) of Subjects Cohort 6 and 7 (N=52) All Grades	 Grade 3 or Higher	 Total (N=84) All Grades	 Grade 3 or Higher
鼻中隔弯曲	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
鼻甲介肥大	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
胸膜痛	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
気胸	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
肺塞栓症	1 (1.9)	1 (1.9)	1 (1.2)	1 (1.2)
肺水腫	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
ラ音	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
季節性鼻炎	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
副鼻腔障害	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
咽喉絞扼感	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
上気道うっ血	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
皮膚および皮下組織障害	33 (63.5)	1 (1.9)	52 (61.9)	2 (2.4)
発疹	10 (19.2)	1 (1.9)	19 (22.6)	2 (2.4)
皮膚乾燥	11 (21.2)	0 (0.0)	16 (19.0)	0 (0.0)
そう痒症	5 (9.6)	0 (0.0)	8 (9.5)	0 (0.0)
寝汗	6 (11.5)	0 (0.0)	7 (8.3)	0 (0.0)
斑状出血	4 (7.7)	0 (0.0)	6 (7.1)	0 (0.0)
多汗症	5 (9.6)	0 (0.0)	6 (7.1)	0 (0.0)
紅斑	3 (5.8)	0 (0.0)	5 (6.0)	0 (0.0)
全身性皮疹	3 (5.8)	0 (0.0)	3 (3.6)	0 (0.0)
斑状皮疹	3 (5.8)	0 (0.0)	3 (3.6)	0 (0.0)
脱毛症	2 (3.8)	0 (0.0)	2 (2.4)	0 (0.0)
貧毛症	2 (3.8)	0 (0.0)	2 (2.4)	0 (0.0)
挫傷発生の増加傾向	1 (1.9)	0 (0.0)	2 (2.4)	0 (0.0)
爪の障害	1 (1.9)	0 (0.0)	2 (2.4)	0 (0.0)
爪甲縦裂症	2 (3.8)	0 (0.0)	2 (2.4)	0 (0.0)
眼窩周囲浮腫	2 (3.8)	0 (0.0)	2 (2.4)	0 (0.0)
そう痒性皮疹	1 (1.9)	0 (0.0)	2 (2.4)	0 (0.0)
皮膚剥脱	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).

[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 49）

System Organ Class Preferred Term[1]	Number (%) of Subjects Cohort 6 and 7 (N=52) All Grades		Grade 3 or Higher		Total (N=84) All Grades		Grade 3 or Higher	
皮膚出血	1	(1.9)	0	(0.0)	2	(2.4)	0	(0.0)
皮膚病変	1	(1.9)	0	(0.0)	2	(2.4)	0	(0.0)
日光性角化症	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
接触性皮膚炎	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
毛髪成長異常	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
爪変色	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
点状出血	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
光線過敏性反応	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
斑状丘疹状皮疹	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
丘疹	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
皮膚変色	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
皮膚障害	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
皮膚脆弱性	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
皮膚色素過剰	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
皮膚刺激	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
皮下結節	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
顔面腫脹	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)
蕁麻疹	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
外科および内科処置	2	(3.8)	1	(1.9)	3	(3.6)	2	(2.4)
白内障手術	1	(1.9)	1	(1.9)	1	(1.2)	1	(1.2)
膝手術	1	(1.9)	0	(0.0)	1	(1.2)	0	(0.0)
抜歯	0	(0.0)	0	(0.0)	1	(1.2)	1	(1.2)
血管障害	17	(32.7)	3	(5.8)	23	(27.4)	4	(4.8)
高血圧	4	(7.7)	0	(0.0)	7	(8.3)	1	(1.2)
深部静脈血栓症	5	(9.6)	2	(3.8)	6	(7.1)	3	(3.6)
潮紅	2	(3.8)	0	(0.0)	4	(4.8)	0	(0.0)
表在性血栓性静脈炎	2	(3.8)	0	(0.0)	3	(3.6)	0	(0.0)
低血圧	2	(3.8)	0	(0.0)	2	(2.4)	0	(0.0)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).

[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-14　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-006）（続き 50）

System Organ Class Preferred Term[1]	Number (%) of Subjects Cohort 6 and 7 (N=52) All Grades	Grade 3 or Higher	Total (N=84) All Grades	Grade 3 or Higher
静脈炎	1 (1.9)	0 (0.0)	2 (2.4)	0 (0.0)
塞栓症	1 (1.9)	1 (1.9)	1 (1.2)	1 (1.2)
血腫	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
ほてり	1 (1.9)	0 (0.0)	1 (1.2)	0 (0.0)
末梢冷感	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
血栓後症候群	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
血栓症	1 (1.9)	1 (1.9)	1 (1.2)	1 (1.2)
血管脆弱化	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
大静脈血栓症	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)

[1] Investigator reported adverse event terms were coded using MedDRA dictionary (version 8.1).
[2] Subjects were counted only once for each system organ class and each preferred term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 及び PT 別発現頻度（PX-171-009）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
Number of Subjects with at Least One TEAE	380	(96.9%)	328	(83.7%)	378	(97.2%)	314	(80.7%)
血液およびリンパ系障害	243	(62.0%)	167	(42.6%)	232	(59.6%)	162	(41.6%)
貧血	167	(42.6%)	70	(17.9%)	155	(39.8%)	67	(17.2%)
好中球減少症	148	(37.8%)	116	(29.6%)	131	(33.7%)	103	(26.5%)
血小板減少症	114	(29.1%)	65	(16.6%)	88	(22.6%)	48	(12.3%)
白血球減少症	31	(7.9%)	12	(3.1%)	22	(5.7%)	16	(4.1%)
発熱性好中球減少症	13	(3.3%)	10	(2.6%)	5	(1.3%)	4	(1.0%)
リンパ球減少症	12	(3.1%)	11	(2.8%)	14	(3.6%)	8	(2.1%)
リンパ節症	2	(0.5%)	0		2	(0.5%)	0	
汎血球減少症	2	(0.5%)	2	(0.5%)	5	(1.3%)	1	(0.3%)
自己免疫性溶血性貧血	1	(0.3%)	1	(0.3%)	0		0	
大球性貧血	1	(0.3%)	0		0		0	
溶血	1	(0.3%)	0		0		0	
溶血性貧血	1	(0.3%)	1	(0.3%)	1	(0.3%)	0	
白血球増加症	1	(0.3%)	0		0		0	
小球性貧血	1	(0.3%)	0		0		0	
単球増加症	1	(0.3%)	0		0		0	
好中球増加症	1	(0.3%)	0		0		0	
血小板増加症	1	(0.3%)	0		0		0	
骨髄機能不全	0		0		1	(0.3%)	1	(0.3%)
好酸球増加症	0		0		1	(0.3%)	1	(0.3%)
出血性貧血	0		0		1	(0.3%)	1	(0.3%)
過粘稠度症候群	0		0		1	(0.3%)	0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 1）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
鉄欠乏性貧血	0		0		2	(0.5%)	0	
血小板障害	0		0		1	(0.3%)	0	
心臓障害	84	(21.4%)	38	(9.7%)	72	(18.5%)	24	(6.2%)
動悸	14	(3.6%)	1	(0.3%)	9	(2.3%)	0	
心房細動	12	(3.1%)	5	(1.3%)	18	(4.6%)	7	(1.8%)
心不全	11	(2.8%)	4	(1.0%)	7	(1.8%)	4	(1.0%)
狭心症	9	(2.3%)	3	(0.8%)	8	(2.1%)	2	(0.5%)
うっ血性心不全	8	(2.0%)	5	(1.3%)	6	(1.5%)	1	(0.3%)
頻脈	8	(2.0%)	1	(0.3%)	7	(1.8%)	0	
心筋梗塞	7	(1.8%)	6	(1.5%)	2	(0.5%)	2	(0.5%)
洞性徐脈	7	(1.8%)	0		2	(0.5%)	1	(0.3%)
徐脈	5	(1.3%)	2	(0.5%)	10	(2.6%)	0	
急性心筋梗塞	4	(1.0%)	4	(1.0%)	1	(0.3%)	1	(0.3%)
上室性期外収縮	4	(1.0%)	1	(0.3%)	2	(0.5%)	0	
左室機能不全	3	(0.8%)	2	(0.5%)	0		0	
大動脈弁閉鎖不全症	2	(0.5%)	1	(0.3%)	0		0	
不整脈	2	(0.5%)	0		1	(0.3%)	1	(0.3%)
心房粗動	2	(0.5%)	2	(0.5%)	1	(0.3%)	0	
心停止	2	(0.5%)	2	(0.5%)	0		0	
冠動脈疾患	2	(0.5%)	0		1	(0.3%)	0	
僧帽弁閉鎖不全症	2	(0.5%)	2	(0.5%)	0		0	
洞性不整脈	2	(0.5%)	0		0		0	
上室性頻脈	2	(0.5%)	0		0		0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 2）

System Organ Class	CRd (N=392)		Rd (N=389)	
Preferred Term	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher
大動脈弁石灰化	1 (0.3%)	0	0	0
大動脈弁硬化症	1 (0.3%)	0	0	0
心房頻脈	1 (0.3%)	0	0	0
完全房室ブロック	1 (0.3%)	1 (0.3%)	0	0
第二度房室ブロック	1 (0.3%)	0	0	0
二束ブロック	1 (0.3%)	0	0	0
徐脈性不整脈	1 (0.3%)	0	0	0
右脚ブロック	1 (0.3%)	0	1 (0.3%)	0
心アミロイドーシス	1 (0.3%)	0	1 (0.3%)	0
急性心不全	1 (0.3%)	1 (0.3%)	0	0
心肥大	1 (0.3%)	0	0	0
心拡大	1 (0.3%)	0	0	0
心筋症	1 (0.3%)	0	0	0
心肺不全	1 (0.3%)	1 (0.3%)	1 (0.3%)	1 (0.3%)
冠動脈閉塞	1 (0.3%)	1 (0.3%)	0	0
拡張機能障害	1 (0.3%)	0	0	0
期外収縮	1 (0.3%)	0	1 (0.3%)	0
心臓内血栓	1 (0.3%)	0	0	0
左房拡張	1 (0.3%)	0	0	0
左室肥大	1 (0.3%)	0	0	0
心筋虚血	1 (0.3%)	0	2 (0.5%)	0
心嚢液貯留	1 (0.3%)	1 (0.3%)	1 (0.3%)	0
心嚢内出血	1 (0.3%)	0	0	0
右室不全	1 (0.3%)	1 (0.3%)	0	0

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 3）

System Organ Class	CRd (N=392)		Rd (N=389)	
Preferred Term	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher
洞性頻脈	1 (0.3%)	0	3 (0.8%)	1 (0.3%)
ストレス心筋症	1 (0.3%)	1 (0.3%)	0	0
心室性不整脈	1 (0.3%)	0	0	0
心室性期外収縮	1 (0.3%)	0	3 (0.8%)	0
心室壁運動低下	1 (0.3%)	0	0	0
心室性頻脈	1 (0.3%)	0	0	0
急性冠動脈症候群	0	0	1 (0.3%)	1 (0.3%)
不安定狭心症	0	0	1 (0.3%)	1 (0.3%)
大動脈弁疾患	0	0	1 (0.3%)	1 (0.3%)
左脚ブロック	0	0	1 (0.3%)	1 (0.3%)
心障害	0	0	1 (0.3%)	0
心血管不全	0	0	1 (0.3%)	0
伝導障害	0	0	1 (0.3%)	0
冠動脈狭窄	0	0	1 (0.3%)	1 (0.3%)
僧帽弁逸脱	0	0	1 (0.3%)	1 (0.3%)
発作性不整脈	0	0	1 (0.3%)	0
肺動脈弁閉鎖不全症	0	0	1 (0.3%)	0
洞不全症候群	0	0	1 (0.3%)	1 (0.3%)
先天性、家族性および遺伝性障害	1 (0.3%)	0	1 (0.3%)	0
先天性凝固亢進	1 (0.3%)	0	0	0
包茎	0	0	1 (0.3%)	0
耳および迷路障害	32 (8.2%)	0	24 (6.2%)	2 (0.5%)

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 4）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
回転性めまい	17	(4.3%)	0		13	(3.3%)	2	(0.5%)
耳鳴	4	(1.0%)	0		1	(0.3%)	0	
難聴	3	(0.8%)	0		1	(0.3%)	0	
耳痛	3	(0.8%)	0		3	(0.8%)	0	
両耳難聴	2	(0.5%)	0		0		0	
耳不快感	2	(0.5%)	0		0		0	
聴力低下	2	(0.5%)	0		0		0	
頭位性回転性めまい	2	(0.5%)	0		0		0	
感音性難聴	1	(0.3%)	0		0		0	
耳管機能障害	1	(0.3%)	0		0		0	
耳管炎	1	(0.3%)	0		0		0	
鼓膜穿孔	1	(0.3%)	0		1	(0.3%)	0	
耳垢栓塞	0		0		1	(0.3%)	0	
片耳難聴	0		0		1	(0.3%)	0	
耳出血	0		0		1	(0.3%)	0	
聴覚障害	0		0		2	(0.5%)	0	
内分泌障害	14	(3.6%)	2	(0.5%)	13	(3.3%)	4	(1.0%)
クッシング様	4	(1.0%)	2	(0.5%)	2	(0.5%)	1	(0.3%)
副腎機能不全	3	(0.8%)	0		2	(0.5%)	2	(0.5%)
甲状腺機能低下症	3	(0.8%)	0		5	(1.3%)	1	(0.3%)
クッシング症候群	2	(0.5%)	0		0		0	
アジソン病	1	(0.3%)	0		0		0	
甲状腺嚢腫	1	(0.3%)	0		1	(0.3%)	0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 5）

System Organ Class	CRd (N=392)		Rd (N=389)	
Preferred Term	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher
甲状腺障害	1 (0.3%)	0	0	0
甲状腺腫	0	0	1 (0.3%)	0
甲状腺機能亢進症	0	0	1 (0.3%)	0
ステロイド離脱症候群	0	0	2 (0.5%)	0
眼障害	103 (26.3%)	16 (4.1%)	70 (18.0%)	15 (3.9%)
白内障	34 (8.7%)	15 (3.8%)	26 (6.7%)	10 (2.6%)
霧視	22 (5.6%)	0	15 (3.9%)	1 (0.3%)
結膜炎	15 (3.8%)	0	5 (1.3%)	0
眼乾燥	11 (2.8%)	0	8 (2.1%)	0
視力障害	8 (2.0%)	0	4 (1.0%)	0
眼刺激	4 (1.0%)	0	0	0
眼瞼浮腫	4 (1.0%)	0	4 (1.0%)	0
眼充血	4 (1.0%)	0	3 (0.8%)	0
緑内障	3 (0.8%)	0	2 (0.5%)	0
流涙増加	3 (0.8%)	0	2 (0.5%)	0
硝子体浮遊物	3 (0.8%)	1 (0.3%)	0	0
失明	2 (0.5%)	0	0	0
複視	2 (0.5%)	0	2 (0.5%)	0
眼出血	2 (0.5%)	0	3 (0.8%)	0
眼痛	2 (0.5%)	0	3 (0.8%)	0
眼部腫脹	2 (0.5%)	0	2 (0.5%)	0
眼窩浮腫	2 (0.5%)	0	0	0
視力低下	2 (0.5%)	0	4 (1.0%)	0

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 6）

System Organ Class	CRd (N=392)		Rd (N=389)	
Preferred Term	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher
硝子体剥離	2 (0.5%)	0	1 (0.3%)	0
眼の異常感	1 (0.3%)	0	1 (0.3%)	0
眼精疲労	1 (0.3%)	0	0	0
眼瞼炎	1 (0.3%)	0	0	0
片側失明	1 (0.3%)	0	0	0
結膜出血	1 (0.3%)	0	2 (0.5%)	0
眼の炎症	1 (0.3%)	0	0	0
眼球浮腫	1 (0.3%)	0	0	0
眼そう痒症	1 (0.3%)	0	1 (0.3%)	0
角膜炎	1 (0.3%)	0	0	0
夜盲	1 (0.3%)	0	0	0
視神経乳頭浮腫	1 (0.3%)	0	0	0
光視症	1 (0.3%)	0	0	0
瞳孔不同	1 (0.3%)	0	0	0
網膜剥離	1 (0.3%)	0	1 (0.3%)	1 (0.3%)
暗点	1 (0.3%)	0	0	0
眼瞼痙攣	0	0	1 (0.3%)	0
核性白内障	0	0	1 (0.3%)	1 (0.3%)
嚢下白内障	0	0	1 (0.3%)	1 (0.3%)
結膜充血	0	0	1 (0.3%)	0
眼瞼下垂	0	0	1 (0.3%)	0
眼の異物感	0	0	1 (0.3%)	0
水晶体混濁	0	0	1 (0.3%)	0
黄斑変性	0	0	1 (0.3%)	0

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 7）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
黄斑円孔	0		0		1	(0.3%)	1	(0.3%)
近視	0		0		1	(0.3%)	0	
開放隅角緑内障	0		0		2	(0.5%)	0	
眼窩周囲浮腫	0		0		2	(0.5%)	0	
網膜血管障害	0		0		1	(0.3%)	0	
網膜静脈閉塞	0		0		1	(0.3%)	1	(0.3%)
胃腸障害	260	(66.3%)	42	(10.7%)	220	(56.6%)	40	(10.3%)
下痢	166	(42.3%)	15	(3.8%)	131	(33.7%)	16	(4.1%)
便秘	79	(20.2%)	1	(0.3%)	67	(17.2%)	2	(0.5%)
悪心	78	(19.9%)	2	(0.5%)	55	(14.1%)	4	(1.0%)
嘔吐	47	(12.0%)	0		32	(8.2%)	2	(0.5%)
腹痛	34	(8.7%)	7	(1.8%)	27	(6.9%)	4	(1.0%)
上腹部痛	25	(6.4%)	0		11	(2.8%)	1	(0.3%)
消化不良	23	(5.9%)	0		20	(5.1%)	1	(0.3%)
歯痛	18	(4.6%)	1	(0.3%)	11	(2.8%)	0	
痔核	15	(3.8%)	0		8	(2.1%)	0	
口内炎	13	(3.3%)	0		5	(1.3%)	0	
腹部不快感	12	(3.1%)	2	(0.5%)	8	(2.1%)	3	(0.8%)
腹部膨満	10	(2.6%)	0		8	(2.1%)	0	
胃炎	9	(2.3%)	0		6	(1.5%)	0	
口内乾燥	8	(2.0%)	0		7	(1.8%)	1	(0.3%)
鼓腸	8	(2.0%)	0		5	(1.3%)	0	
胃食道逆流性疾患	7	(1.8%)	0		11	(2.8%)	0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 8）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
嚥下障害	6	(1.5%)	2	(0.5%)	4	(1.0%)	0	
口腔内潰瘍形成	6	(1.5%)	0		3	(0.8%)	0	
アフタ性口内炎	5	(1.3%)	0		0		0	
齲歯	5	(1.3%)	1	(0.3%)	3	(0.8%)	2	(0.5%)
直腸出血	5	(1.3%)	0		1	(0.3%)	0	
胃腸障害	4	(1.0%)	1	(0.3%)	1	(0.3%)	1	(0.3%)
歯肉痛	4	(1.0%)	0		2	(0.5%)	0	
痔出血	3	(0.8%)	0		2	(0.5%)	0	
口腔内不快感	3	(0.8%)	0		0		0	
臍ヘルニア	3	(0.8%)	0		0		0	
下腹部痛	2	(0.5%)	0		3	(0.8%)	1	(0.3%)
腹部圧痛	2	(0.5%)	0		1	(0.3%)	0	
肛門出血	2	(0.5%)	0		0		0	
口唇炎	2	(0.5%)	0		0		0	
血性下痢	2	(0.5%)	0		1	(0.3%)	0	
鼓室穿孔	2	(0.5%)	2	(0.5%)	0		0	
心窩部不快感	2	(0.5%)	0		3	(0.8%)	0	
食中毒	2	(0.5%)	0		1	(0.3%)	0	
胃腸毒性	2	(0.5%)	1	(0.3%)	1	(0.3%)	1	(0.3%)
歯肉出血	2	(0.5%)	0		2	(0.5%)	0	
舌痛	2	(0.5%)	0		1	(0.3%)	0	
血便排泄	2	(0.5%)	0		2	(0.5%)	0	
胃排出不全	2	(0.5%)	0		1	(0.3%)	1	(0.3%)
鼠径ヘルニア	2	(0.5%)	1	(0.3%)	1	(0.3%)	1	(0.3%)

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 9）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
食道炎	2	(0.5%)	1	(0.3%)	0		0	
急性膵炎	2	(0.5%)	2	(0.5%)	0		0	
慢性膵炎	2	(0.5%)	0		0		0	
歯の知覚過敏	2	(0.5%)	0		2	(0.5%)	0	
舌腫脹	2	(0.5%)	0		0		0	
閉塞を伴う腹部ヘルニア	1	(0.3%)	1	(0.3%)	0		0	
空気嚥下	1	(0.3%)	0		1	(0.3%)	0	
裂肛	1	(0.3%)	0		1	(0.3%)	0	
便習慣変化	1	(0.3%)	0		0		0	
大腸炎	1	(0.3%)	1	(0.3%)	0		0	
結腸ポリープ	1	(0.3%)	0		2	(0.5%)	0	
憩室	1	(0.3%)	0		2	(0.5%)	0	
腸憩室	1	(0.3%)	0		1	(0.3%)	0	
食道憩室	1	(0.3%)	1	(0.3%)	0		0	
十二指腸狭窄	1	(0.3%)	1	(0.3%)	0		0	
小腸炎	1	(0.3%)	0		1	(0.3%)	1	(0.3%)
おくび	1	(0.3%)	0		0		0	
便失禁	1	(0.3%)	1	(0.3%)	2	(0.5%)	0	
変色便	1	(0.3%)	0		2	(0.5%)	0	
排便回数増加	1	(0.3%)	0		1	(0.3%)	0	
歯肉の炎症	1	(0.3%)	0		1	(0.3%)	0	
歯肉腫脹	1	(0.3%)	0		0		0	
歯肉潰瘍	1	(0.3%)	0		0		0	
イレウス	1	(0.3%)	1	(0.3%)	0		0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 10）

System Organ Class	CRd (N=392)		Rd (N=389)	
Preferred Term	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher
排便回数減少	1 (0.3%)	0	0	0
腸閉塞	1 (0.3%)	1 (0.3%)	0	0
大腸穿孔	1 (0.3%)	1 (0.3%)	0	0
口唇変色	1 (0.3%)	0	0	0
口唇乾燥	1 (0.3%)	0	0	0
口唇腫脹	1 (0.3%)	0	1 (0.3%)	0
下部消化管出血	1 (0.3%)	0	1 (0.3%)	0
メレナ	1 (0.3%)	0	0	0
口腔内出血	1 (0.3%)	0	1 (0.3%)	0
好中球減少性大腸炎	1 (0.3%)	1 (0.3%)	0	0
嚥下痛	1 (0.3%)	0	0	0
食道痛	1 (0.3%)	0	0	0
口腔障害	1 (0.3%)	0	1 (0.3%)	0
口腔粘膜びらん	1 (0.3%)	0	0	0
口腔粘膜水疱形成	1 (0.3%)	0	1 (0.3%)	0
口の錯感覚	1 (0.3%)	0	1 (0.3%)	1 (0.3%)
耳下腺管閉塞	1 (0.3%)	0	0	0
肛門周囲痛	1 (0.3%)	0	0	0
歯根嚢胞	1 (0.3%)	0	0	0
直腸ポリープ	1 (0.3%)	0	0	0
吐き戻し	1 (0.3%)	0	0	0
舌変色	1 (0.3%)	0	0	0
舌障害	1 (0.3%)	0	0	0
変色歯	1 (0.3%)	0	0	0

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 11）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
歯の障害	1	(0.3%)	0		0		0	
腹部ヘルニア	0		0		2	(0.5%)	0	
キライディティ症候群	0		0		1	(0.3%)	0	
胃出血	0		0		1	(0.3%)	0	
胃腸出血	0		0		5	(1.3%)	3	(0.8%)
消化器痛	0		0		1	(0.3%)	0	
歯肉嚢胞	0		0		1	(0.3%)	0	
吐血	0		0		2	(0.5%)	0	
口の感覚鈍麻	0		0		1	(0.3%)	0	
腸管ポリープ	0		0		1	(0.3%)	0	
口唇水疱	0		0		1	(0.3%)	0	
弛緩歯	0		0		1	(0.3%)	0	
口腔潰瘍	0		0		1	(0.3%)	0	
口腔内痛	0		0		2	(0.5%)	0	
膵炎	0		0		1	(0.3%)	0	
歯周病	0		0		3	(0.8%)	0	
直腸炎	0		0		1	(0.3%)	0	
小腸閉塞	0		0		1	(0.3%)	1	(0.3%)
小腸穿孔	0		0		1	(0.3%)	1	(0.3%)
舌苔	0		0		1	(0.3%)	0	
舌潰瘍	0		0		2	(0.5%)	0	
歯の脱落	0		0		2	(0.5%)	0	
一般・全身障害および投与部位の状態	267	(68.1%)	68	(17.3%)	242	(62.2%)	52	(13.4%)

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 12）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
疲労	129	(32.9%)	30	(7.7%)	119	(30.6%)	25	(6.4%)
発熱	112	(28.6%)	7	(1.8%)	81	(20.8%)	2	(0.5%)
末梢性浮腫	85	(21.7%)	5	(1.3%)	75	(19.3%)	2	(0.5%)
無力症	70	(17.9%)	14	(3.6%)	56	(14.4%)	8	(2.1%)
悪寒	25	(6.4%)	0		9	(2.3%)	0	
浮腫	17	(4.3%)	1	(0.3%)	19	(4.9%)	1	(0.3%)
疼痛	16	(4.1%)	0		14	(3.6%)	0	
インフルエンザ様疾患	15	(3.8%)	0		10	(2.6%)	1	(0.3%)
胸痛	14	(3.6%)	2	(0.5%)	16	(4.1%)	1	(0.3%)
倦怠感	10	(2.6%)	0		5	(1.3%)	0	
非心臓性胸痛	10	(2.6%)	3	(0.8%)	7	(1.8%)	0	
易刺激性	9	(2.3%)	2	(0.5%)	5	(1.3%)	0	
粘膜の炎症	9	(2.3%)	1	(0.3%)	5	(1.3%)	1	(0.3%)
胸部不快感	8	(2.0%)	0		2	(0.5%)	0	
脊椎痛	7	(1.8%)	0		5	(1.3%)	0	
歩行障害	6	(1.5%)	1	(0.3%)	8	(2.1%)	1	(0.3%)
注入部位疼痛	6	(1.5%)	0		0		0	
疾患進行	4	(1.0%)	4	(1.0%)	8	(2.1%)	8	(2.1%)
顔面浮腫	4	(1.0%)	1	(0.3%)	6	(1.5%)	1	(0.3%)
カテーテル留置部位疼痛	3	(0.8%)	0		0		0	
全身性浮腫	3	(0.8%)	1	(0.3%)	2	(0.5%)	1	(0.3%)
死亡	2	(0.5%)	2	(0.5%)	2	(0.5%)	2	(0.5%)
医療機器閉塞	2	(0.5%)	0		1	(0.3%)	0	
早期満腹	2	(0.5%)	0		0		0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 13）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
冷感	2	(0.5%)	0		1	(0.3%)	0	
全身健康状態低下	2	(0.5%)	1	(0.3%)	6	(1.5%)	5	(1.3%)
多臓器不全	2	(0.5%)	2	(0.5%)	1	(0.3%)	1	(0.3%)
医療機器関連の血栓症	2	(0.5%)	1	(0.3%)	0		0	
医薬品副作用	1	(0.3%)	0		2	(0.5%)	0	
腋窩痛	1	(0.3%)	0		1	(0.3%)	0	
突出痛	1	(0.3%)	1	(0.3%)	0		0	
カテーテル留置部位紅斑	1	(0.3%)	0		0		0	
カテーテル留置部位出血	1	(0.3%)	1	(0.3%)	0		0	
カテーテル留置部位炎症	1	(0.3%)	0		0		0	
嚢胞	1	(0.3%)	0		0		0	
異常感	1	(0.3%)	0		1	(0.3%)	0	
熱感	1	(0.3%)	0		0		0	
びくびく感	1	(0.3%)	0		1	(0.3%)	0	
ヘルニア	1	(0.3%)	0		0		0	
高熱	1	(0.3%)	0		0		0	
治癒不良	1	(0.3%)	0		1	(0.3%)	0	
硬結	1	(0.3%)	0		1	(0.3%)	0	
炎症	1	(0.3%)	0		1	(0.3%)	0	
注入部位血管外漏出	1	(0.3%)	0		1	(0.3%)	0	
注入部位硬結	1	(0.3%)	0		0		0	
注入部位炎症	1	(0.3%)	0		0		0	
注入部位刺激感	1	(0.3%)	0		0		0	
注入部位反応	1	(0.3%)	0		0		0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 14）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
注入部位腫脹	1	(0.3%)	0		0		0	
注入部位小水疱	1	(0.3%)	0		0		0	
注射部位硬結	1	(0.3%)	0		0		0	
注射部位反応	1	(0.3%)	0		0		0	
局所腫脹	1	(0.3%)	0		1	(0.3%)	0	
限局性浮腫	1	(0.3%)	0		0		0	
腫瘤	1	(0.3%)	0		1	(0.3%)	0	
医療機器合併症	1	(0.3%)	0		0		0	
小結節	1	(0.3%)	0		0		0	
突然死	1	(0.3%)	1	(0.3%)	1	(0.3%)	1	(0.3%)
全身性炎症反応症候群	1	(0.3%)	1	(0.3%)	0		0	
圧痛	1	(0.3%)	0		1	(0.3%)	0	
血管穿刺部位血腫	1	(0.3%)	0		0		0	
顔面痛	0		0		1	(0.3%)	0	
注射部位分泌物	0		0		1	(0.3%)	0	
注射部位静脈炎	0		0		1	(0.3%)	0	
粘膜乾燥	0		0		1	(0.3%)	1	(0.3%)
活動状態低下	0		0		1	(0.3%)	0	
肝胆道系障害	37	(9.4%)	12	(3.1%)	19	(4.9%)	7	(1.8%)
高ビリルビン血症	15	(3.8%)	5	(1.3%)	3	(0.8%)	1	(0.3%)
胆石症	4	(1.0%)	1	(0.3%)	4	(1.0%)	0	
中毒性肝炎	4	(1.0%)	1	(0.3%)	1	(0.3%)	0	
急性胆嚢炎	3	(0.8%)	2	(0.5%)	2	(0.5%)	2	(0.5%)

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 15）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
肝細胞損傷	3	(0.8%)	0		0		0	
肝障害	3	(0.8%)	0		0		0	
胆管炎	2	(0.5%)	1	(0.3%)	0		0	
肝臓うっ血	2	(0.5%)	2	(0.5%)	0		0	
肝毒性	2	(0.5%)	2	(0.5%)	1	(0.3%)	1	(0.3%)
胆管結石	1	(0.3%)	1	(0.3%)	0		0	
胆嚢炎	1	(0.3%)	0		3	(0.8%)	3	(0.8%)
慢性胆嚢炎	1	(0.3%)	0		0		0	
慢性肝炎	1	(0.3%)	0		0		0	
肝腫大	1	(0.3%)	0		1	(0.3%)	0	
胆道仙痛	0		0		1	(0.3%)	0	
胆汁うっ滞	0		0		2	(0.5%)	1	(0.3%)
胆嚢痛	0		0		1	(0.3%)	0	
肝嚢胞	0		0		1	(0.3%)	0	
胆汁うっ滞性肝炎	0		0		1	(0.3%)	0	
水腫性胆嚢炎	0		0		1	(0.3%)	0	
肝損傷	0		0		1	(0.3%)	0	
免疫系障害	15	(3.8%)	3	(0.8%)	12	(3.1%)	0	
薬物過敏症	5	(1.3%)	1	(0.3%)	2	(0.5%)	0	
低γグロブリン血症	5	(1.3%)	1	(0.3%)	0		0	
季節性アレルギー	2	(0.5%)	0		4	(1.0%)	0	
アナフィラキシー反応	1	(0.3%)	0		0		0	
サイトカイン放出症候群	1	(0.3%)	1	(0.3%)	1	(0.3%)	0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 16）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
過敏症	1	(0.3%)	0		3	(0.8%)	0	
アレルギー性浮腫	0		0		1	(0.3%)	0	
食物アレルギー	0		0		1	(0.3%)	0	
感染症および寄生虫症	310	(79.1%)	114	(29.1%)	270	(69.4%)	93	(23.9%)
上気道感染	112	(28.6%)	7	(1.8%)	75	(19.3%)	4	(1.0%)
鼻咽頭炎	84	(21.4%)	1	(0.3%)	63	(16.2%)	0	
気管支炎	74	(18.9%)	7	(1.8%)	54	(13.9%)	7	(1.8%)
肺炎	68	(17.3%)	49	(12.5%)	56	(14.4%)	41	(10.5%)
気道感染	43	(11.0%)	16	(4.1%)	39	(10.0%)	8	(2.1%)
尿路感染	34	(8.7%)	4	(1.0%)	21	(5.4%)	1	(0.3%)
インフルエンザ	26	(6.6%)	2	(0.5%)	12	(3.1%)	2	(0.5%)
ウイルス感染	24	(6.1%)	0		10	(2.6%)	0	
副鼻腔炎	22	(5.6%)	2	(0.5%)	16	(4.1%)	0	
鼻炎	19	(4.8%)	0		8	(2.1%)	0	
胃腸炎	17	(4.3%)	3	(0.8%)	12	(3.1%)	1	(0.3%)
気管支肺炎	15	(3.8%)	7	(1.8%)	9	(2.3%)	7	(1.8%)
蜂巣炎	14	(3.6%)	1	(0.3%)	11	(2.8%)	1	(0.3%)
咽頭炎	13	(3.3%)	0		7	(1.8%)	0	
膀胱炎	8	(2.0%)	0		5	(1.3%)	0	
ウイルス性気道感染	8	(2.0%)	0		7	(1.8%)	0	
感染	7	(1.8%)	2	(0.5%)	5	(1.3%)	2	(0.5%)
下気道感染	7	(1.8%)	2	(0.5%)	8	(2.1%)	3	(0.8%)
クロストリジウム・ディフィシレ大腸炎	6	(1.5%)	3	(0.8%)	2	(0.5%)	0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 17）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
耳感染	6	(1.5%)	0		4	(1.0%)	0	
丹毒	6	(1.5%)	0		3	(0.8%)	1	(0.3%)
帯状疱疹	6	(1.5%)	0		9	(2.3%)	0	
限局性感染	6	(1.5%)	0		3	(0.8%)	0	
口腔カンジダ症	6	(1.5%)	1	(0.3%)	6	(1.5%)	0	
口腔ヘルペス	6	(1.5%)	0		5	(1.3%)	0	
歯膿瘍	6	(1.5%)	0		3	(0.8%)	2	(0.5%)
肺感染	5	(1.3%)	3	(0.8%)	3	(0.8%)	1	(0.3%)
敗血症	5	(1.3%)	4	(1.0%)	5	(1.3%)	4	(1.0%)
急性副鼻腔炎	4	(1.0%)	0		6	(1.5%)	0	
カンジダ症	4	(1.0%)	0		2	(0.5%)	0	
クロストリジウム感染	4	(1.0%)	2	(0.5%)	0		0	
医療機器関連感染	4	(1.0%)	3	(0.8%)	1	(0.3%)	1	(0.3%)
眼感染	4	(1.0%)	0		3	(0.8%)	0	
せつ	4	(1.0%)	0		5	(1.3%)	0	
口腔真菌感染	4	(1.0%)	0		4	(1.0%)	0	
気管気管支炎	4	(1.0%)	2	(0.5%)	0		0	
ウイルス性上気道感染	4	(1.0%)	0		4	(1.0%)	0	
菌血症	3	(0.8%)	2	(0.5%)	0		0	
ウイルス性胃腸炎	3	(0.8%)	0		2	(0.5%)	1	(0.3%)
ウイルス性消化管感染	3	(0.8%)	0		0		0	
歯肉炎	3	(0.8%)	0		1	(0.3%)	0	
骨髄炎	3	(0.8%)	0		2	(0.5%)	0	
中耳炎	3	(0.8%)	0		2	(0.5%)	0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 18）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
急性中耳炎	3	(0.8%)	0		1	(0.3%)	0	
敗血症性ショック	3	(0.8%)	3	(0.8%)	3	(0.8%)	3	(0.8%)
歯感染	3	(0.8%)	1	(0.3%)	2	(0.5%)	0	
腹部膿瘍	2	(0.5%)	1	(0.3%)	0		0	
細菌感染	2	(0.5%)	1	(0.3%)	0		0	
細気管支炎	2	(0.5%)	1	(0.3%)	1	(0.3%)	1	(0.3%)
サイトメガロウイルス感染	2	(0.5%)	2	(0.5%)	0		0	
憩室炎	2	(0.5%)	1	(0.3%)	3	(0.8%)	1	(0.3%)
心内膜炎	2	(0.5%)	2	(0.5%)	0		0	
毛包炎	2	(0.5%)	0		7	(1.8%)	0	
単純ヘルペス	2	(0.5%)	0		3	(0.8%)	0	
喉頭炎	2	(0.5%)	0		3	(0.8%)	2	(0.5%)
大葉性肺炎	2	(0.5%)	2	(0.5%)	1	(0.3%)	1	(0.3%)
口腔感染	2	(0.5%)	0		0		0	
パラインフルエンザウイルス感染	2	(0.5%)	0		0		0	
歯周炎	2	(0.5%)	0		2	(0.5%)	0	
皮膚感染	2	(0.5%)	0		2	(0.5%)	0	
ブドウ球菌性菌血症	2	(0.5%)	2	(0.5%)	0		0	
気管炎	2	(0.5%)	0		1	(0.3%)	0	
細菌性上気道感染	2	(0.5%)	0		1	(0.3%)	0	
創傷感染	2	(0.5%)	0		1	(0.3%)	0	
アデノウイルス感染	1	(0.3%)	0		0		0	
細菌性関節炎	1	(0.3%)	0		0		0	
感染性関節炎	1	(0.3%)	0		0		0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 19）

System Organ Class	CRd (N=392)		Rd (N=389)	
Preferred Term	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher
節足動物寄生	1 (0.3%)	0	0	0
細菌性腎盂腎炎	1 (0.3%)	1 (0.3%)	0	0
カンピロバクター感染	1 (0.3%)	0	0	0
カテーテル留置部位蜂巣炎	1 (0.3%)	1 (0.3%)	0	0
化膿性胆管炎	1 (0.3%)	0	0	0
慢性Ｃ型肝炎	1 (0.3%)	1 (0.3%)	0	0
慢性副鼻腔炎	1 (0.3%)	0	2 (0.5%)	0
感染性結膜炎	1 (0.3%)	0	0	0
ウイルス性結膜炎	1 (0.3%)	0	0	0
エンテロバクター性敗血症	1 (0.3%)	0	0	0
細菌性腸炎	1 (0.3%)	1 (0.3%)	0	0
大腸菌性菌血症	1 (0.3%)	1 (0.3%)	0	0
大腸菌性敗血症	1 (0.3%)	1 (0.3%)	0	0
大腸菌性尿路感染	1 (0.3%)	1 (0.3%)	2 (0.5%)	0
皮膚真菌感染	1 (0.3%)	0	5 (1.3%)	0
消化管感染	1 (0.3%)	0	2 (0.5%)	0
歯肉感染	1 (0.3%)	0	0	0
鼠径部膿瘍	1 (0.3%)	0	0	0
Ｈ１Ｎ１インフルエンザ	1 (0.3%)	1 (0.3%)	0	0
切開部位感染	1 (0.3%)	1 (0.3%)	0	0
咬傷感染	1 (0.3%)	0	0	0
感染性嚢腫	1 (0.3%)	0	0	0
感染性皮膚嚢腫	1 (0.3%)	0	0	0
迷路炎	1 (0.3%)	0	1 (0.3%)	0

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 20）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
細菌性喉頭炎	1	(0.3%)	0		0		0	
潜伏結核	1	(0.3%)	0		0		0	
肝膿瘍	1	(0.3%)	0		0		0	
ウイルス性下気道感染	1	(0.3%)	0		1	(0.3%)	0	
好中球減少性敗血症	1	(0.3%)	1	(0.3%)	0		0	
食道カンジダ症	1	(0.3%)	0		0		0	
爪真菌症	1	(0.3%)	0		2	(0.5%)	0	
精巣炎	1	(0.3%)	0		0		0	
細菌性中耳炎	1	(0.3%)	0		0		0	
直腸周囲膿瘍	1	(0.3%)	0		0		0	
腹膜炎	1	(0.3%)	1	(0.3%)	0		0	
細菌性咽頭炎	1	(0.3%)	0		0		0	
レンサ球菌性咽頭炎	1	(0.3%)	1	(0.3%)	0		0	
ニューモシスティスジロヴェシ肺炎	1	(0.3%)	0		1	(0.3%)	0	
インフルエンザ性肺炎	1	(0.3%)	1	(0.3%)	0		0	
ＲＳウイルス肺炎	1	(0.3%)	1	(0.3%)	1	(0.3%)	1	(0.3%)
術後膿瘍	1	(0.3%)	1	(0.3%)	1	(0.3%)	1	(0.3%)
術後創感染	1	(0.3%)	0		0		0	
進行性多巣性白質脳症	1	(0.3%)	0		0		0	
腎盂腎炎	1	(0.3%)	0		0		0	
慢性腎盂腎炎	1	(0.3%)	0		0		0	
膿疱性皮疹	1	(0.3%)	0		0		0	
呼吸器モニリア症	1	(0.3%)	0		0		0	
ＲＳウイルス細気管支炎	1	(0.3%)	1	(0.3%)	0		0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 21）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
ＲＳウイルス感染	1	(0.3%)	0		1	(0.3%)	0	
サルモネラ性敗血症	1	(0.3%)	1	(0.3%)	0		0	
サルモネラ症	1	(0.3%)	0		0		0	
敗血症症候群	1	(0.3%)	0		0		0	
軟部組織感染	1	(0.3%)	0		0		0	
膿性痰	1	(0.3%)	0		0		0	
ブドウ球菌感染	1	(0.3%)	0		0		0	
レンサ球菌性菌血症	1	(0.3%)	1	(0.3%)	1	(0.3%)	0	
皮下組織膿瘍	1	(0.3%)	0		0		0	
精巣膿瘍	1	(0.3%)	1	(0.3%)	0		0	
白癬感染	1	(0.3%)	0		0		0	
足部白癬	1	(0.3%)	0		2	(0.5%)	0	
細菌性扁桃炎	1	(0.3%)	0		0		0	
細菌性尿路感染	1	(0.3%)	0		0		0	
尿路性敗血症	1	(0.3%)	1	(0.3%)	2	(0.5%)	2	(0.5%)
腟感染	1	(0.3%)	0		0		0	
ウイルス性咽頭炎	1	(0.3%)	0		0		0	
外陰部腟カンジダ症	1	(0.3%)	0		0		0	
四肢膿瘍	0		0		2	(0.5%)	0	
肛門カンジダ症	0		0		1	(0.3%)	0	
体部白癬	0		0		1	(0.3%)	0	
ボレリア感染	0		0		1	(0.3%)	0	
ウイルス性気管支炎	0		0		1	(0.3%)	1	(0.3%)
気管支肺アスペルギルス症	0		0		1	(0.3%)	1	(0.3%)

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 22）

System Organ Class	CRd (N=392)		Rd (N=389)	
Preferred Term	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher
カンピロバクター胃腸炎	0	0	1 (0.3%)	0
カテーテル留置部位感染	0	0	1 (0.3%)	0
赤痢	0	0	1 (0.3%)	0
細菌性眼感染	0	0	1 (0.3%)	0
真菌感染	0	0	2 (0.5%)	0
性器カンジダ症	0	0	1 (0.3%)	0
陰部ヘルペス	0	0	1 (0.3%)	0
泌尿生殖器感染	0	0	1 (0.3%)	1 (0.3%)
肝感染	0	0	1 (0.3%)	1 (0.3%)
ヘルペスウイルス感染	0	0	2 (0.5%)	0
播種性帯状疱疹	0	0	1 (0.3%)	1 (0.3%)
口唇感染	0	0	2 (0.5%)	0
リステリア性敗血症	0	0	1 (0.3%)	1 (0.3%)
粘膜感染	0	0	1 (0.3%)	0
ムンプス	0	0	1 (0.3%)	0
爪感染	0	0	1 (0.3%)	0
中咽頭カンジダ症	0	0	1 (0.3%)	0
爪囲炎	0	0	1 (0.3%)	0
百日咳	0	0	1 (0.3%)	0
咽頭扁桃炎	0	0	1 (0.3%)	0
細菌性肺炎	0	0	3 (0.8%)	2 (0.5%)
ウイルス性肺炎	0	0	1 (0.3%)	1 (0.3%)
肺敗血症	0	0	1 (0.3%)	1 (0.3%)
歯髄炎	0	0	1 (0.3%)	0

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 23）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
急性腎盂腎炎	0		0		1	(0.3%)	1	(0.3%)
陰嚢感染	0		0		1	(0.3%)	0	
扁桃炎	0		0		2	(0.5%)	1	(0.3%)
結核	0		0		1	(0.3%)	1	(0.3%)
腸球菌性尿路感染	0		0		1	(0.3%)	0	
外陰腟真菌感染	0		0		1	(0.3%)	0	
傷害、中毒および処置合併症	77	(19.6%)	11	(2.8%)	65	(16.7%)	13	(3.3%)
挫傷	12	(3.1%)	0		16	(4.1%)	1	(0.3%)
転倒	11	(2.8%)	0		13	(3.3%)	2	(0.5%)
歯牙破折	6	(1.5%)	0		7	(1.8%)	1	(0.3%)
大腿骨骨折	5	(1.3%)	3	(0.8%)	2	(0.5%)	1	(0.3%)
処置による疼痛	4	(1.0%)	0		6	(1.5%)	0	
創傷	4	(1.0%)	0		1	(0.3%)	0	
注入に伴う反応	3	(0.8%)	0		1	(0.3%)	0	
靭帯捻挫	3	(0.8%)	0		0		0	
四肢損傷	3	(0.8%)	0		0		0	
節足動物咬傷	2	(0.5%)	0		3	(0.8%)	0	
顔面骨骨折	2	(0.5%)	1	(0.3%)	0		0	
腓骨骨折	2	(0.5%)	0		0		0	
足骨折	2	(0.5%)	0		0		0	
眼窩周囲出血	2	(0.5%)	0		0		0	
肋骨骨折	2	(0.5%)	0		1	(0.3%)	0	
交通事故	2	(0.5%)	0		0		0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 24）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
脊椎圧迫骨折	2	(0.5%)	1	(0.3%)	4	(1.0%)	1	(0.3%)
外傷性骨折	2	(0.5%)	2	(0.5%)	0		0	
創合併症	2	(0.5%)	0		0		0	
免疫後有害事象	1	(0.3%)	0		0		0	
背部損傷	1	(0.3%)	0		0		0	
粉砕骨折	1	(0.3%)	1	(0.3%)	0		0	
脳振盪	1	(0.3%)	1	(0.3%)	0		0	
角膜擦過傷	1	(0.3%)	0		0		0	
焼痂	1	(0.3%)	0		0		0	
擦過傷	1	(0.3%)	0		2	(0.5%)	0	
眼外傷	1	(0.3%)	0		0		0	
胆嚢損傷	1	(0.3%)	1	(0.3%)	0		0	
消化管ストーマ合併症	1	(0.3%)	0		0		0	
頭部損傷	1	(0.3%)	0		0		0	
股関節部骨折	1	(0.3%)	1	(0.3%)	3	(0.8%)	3	(0.8%)
上腕骨骨折	1	(0.3%)	0		1	(0.3%)	0	
切開部位合併症	1	(0.3%)	0		0		0	
切開部位痛	1	(0.3%)	0		0		0	
損傷	1	(0.3%)	0		0		0	
裂傷	1	(0.3%)	0		3	(0.8%)	0	
口唇損傷	1	(0.3%)	0		0		0	
下肢骨折	1	(0.3%)	0		0		0	
肉離れ	1	(0.3%)	0		1	(0.3%)	0	
過量投与	1	(0.3%)	0		0		0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 25）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
膝蓋骨骨折	1	(0.3%)	0		0		0	
外傷後疼痛	1	(0.3%)	0		0		0	
術後創合併症	1	(0.3%)	0		0		0	
放射線関連痛	1	(0.3%)	0		0		0	
橈骨骨折	1	(0.3%)	0		0		0	
骨格損傷	1	(0.3%)	0		0		0	
刺創	1	(0.3%)	0		0		0	
皮下血腫	1	(0.3%)	0		0		0	
硬膜下血腫	1	(0.3%)	1	(0.3%)	1	(0.3%)	0	
血管確保合併症	1	(0.3%)	0		0		0	
創し開	1	(0.3%)	0		0		0	
鎖骨骨折	0		0		2	(0.5%)	0	
大腿骨頸部骨折	0		0		1	(0.3%)	1	(0.3%)
顎の骨折	0		0		1	(0.3%)	1	(0.3%)
関節脱臼	0		0		1	(0.3%)	0	
腰椎骨折	0		0		2	(0.5%)	1	(0.3%)
半月板障害	0		0		1	(0.3%)	0	
多発骨折	0		0		1	(0.3%)	1	(0.3%)
筋断裂	0		0		1	(0.3%)	0	
骨盤骨折	0		0		1	(0.3%)	0	
中毒	0		0		1	(0.3%)	0	
処置後血腫	0		0		1	(0.3%)	0	
皮膚損傷	0		0		1	(0.3%)	0	
脾臓損傷	0		0		1	(0.3%)	1	(0.3%)

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 26）

System Organ Class	CRd (N=392)		Rd (N=389)	
Preferred Term	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher
ストレス骨折	0	0	1 (0.3%)	0
腱断裂	0	0	1 (0.3%)	0
熱傷	0	0	1 (0.3%)	0
上肢骨折	0	0	1 (0.3%)	0
手首関節骨折	0	0	1 (0.3%)	0
臨床検査	144 (36.7%)	55 (14.0%)	132 (33.9%)	40 (10.3%)
血中クレアチニン増加	26 (6.6%)	4 (1.0%)	18 (4.6%)	1 (0.3%)
アラニンアミノトランスフェラーゼ増加	20 (5.1%)	9 (2.3%)	15 (3.9%)	3 (0.8%)
好中球数減少	20 (5.1%)	12 (3.1%)	22 (5.7%)	11 (2.8%)
血小板数減少	18 (4.6%)	12 (3.1%)	13 (3.3%)	9 (2.3%)
Ｃ－反応性蛋白増加	16 (4.1%)	0	7 (1.8%)	2 (0.5%)
血中ビリルビン増加	12 (3.1%)	4 (1.0%)	5 (1.3%)	0
体重減少	12 (3.1%)	3 (0.8%)	15 (3.9%)	2 (0.5%)
腎クレアチニン・クリアランス減少	11 (2.8%)	1 (0.3%)	9 (2.3%)	2 (0.5%)
アスパラギン酸アミノトランスフェラーゼ増加	8 (2.0%)	5 (1.3%)	7 (1.8%)	1 (0.3%)
血中乳酸脱水素酵素増加	8 (2.0%)	0	4 (1.0%)	0
血中アルカリホスファターゼ増加	7 (1.8%)	0	5 (1.3%)	1 (0.3%)
血中ブドウ糖増加	6 (1.5%)	1 (0.3%)	4 (1.0%)	1 (0.3%)
γ－グルタミルトランスフェラーゼ増加	6 (1.5%)	2 (0.5%)	10 (2.6%)	2 (0.5%)
ヘモグロビン減少	6 (1.5%)	3 (0.8%)	2 (0.5%)	1 (0.3%)
血中カリウム減少	5 (1.3%)	0	4 (1.0%)	0
血中尿酸増加	5 (1.3%)	0	1 (0.3%)	0
国際標準比増加	5 (1.3%)	3 (0.8%)	8 (2.1%)	7 (1.8%)

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 27）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
血中リン減少	4	(1.0%)	3	(0.8%)	4	(1.0%)	2	(0.5%)
白血球数減少	4	(1.0%)	3	(0.8%)	6	(1.5%)	3	(0.8%)
血中クレアチンホスホキナーゼ増加	3	(0.8%)	0		0		0	
血圧上昇	3	(0.8%)	1	(0.3%)	3	(0.8%)	0	
血中尿素増加	3	(0.8%)	0		1	(0.3%)	0	
眼圧上昇	3	(0.8%)	1	(0.3%)	3	(0.8%)	0	
体重増加	3	(0.8%)	0		0		0	
血中クロール増加	2	(0.5%)	0		0		0	
血中マグネシウム減少	2	(0.5%)	0		3	(0.8%)	0	
心電図ＱＴ延長	2	(0.5%)	0		1	(0.3%)	0	
肝酵素上昇	2	(0.5%)	1	(0.3%)	1	(0.3%)	0	
Ａ型インフルエンザウイルス検査陽性	2	(0.5%)	2	(0.5%)	0		0	
前立腺特異性抗原増加	2	(0.5%)	0		1	(0.3%)	0	
ＲＳウイルス検査陽性	2	(0.5%)	1	(0.3%)	0		0	
抱合ビリルビン増加	1	(0.3%)	1	(0.3%)	0		0	
血中ビリルビン異常	1	(0.3%)	0		0		0	
血中カルシウム減少	1	(0.3%)	0		1	(0.3%)	0	
血中カルシウム増加	1	(0.3%)	0		0		0	
血中コレステロール増加	1	(0.3%)	0		0		0	
血中クレアチン増加	1	(0.3%)	0		0		0	
血中鉄減少	1	(0.3%)	0		0		0	
血中乳酸脱水素酵素減少	1	(0.3%)	0		0		0	
血中カリウム増加	1	(0.3%)	0		1	(0.3%)	0	
血中テストステロン減少	1	(0.3%)	0		0		0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 28）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
血中尿素減少	1	(0.3%)	0		0		0	
カンピロバクター検査陽性	1	(0.3%)	0		0		0	
カンジダ検査陽性	1	(0.3%)	0		0		0	
二酸化炭素減少	1	(0.3%)	0		0		0	
心雑音	1	(0.3%)	0		1	(0.3%)	0	
心臓負荷試験異常	1	(0.3%)	1	(0.3%)	0		0	
全身健康状態異常	1	(0.3%)	0		1	(0.3%)	1	(0.3%)
糸球体濾過率減少	1	(0.3%)	0		1	(0.3%)	0	
グリコヘモグロビン増加	1	(0.3%)	0		0		0	
ヘマトクリット減少	1	(0.3%)	1	(0.3%)	0		0	
心拍数不整	1	(0.3%)	0		0		0	
打聴診音減弱	1	(0.3%)	0		0		0	
Ｂ型インフルエンザウイルス検査陽性	1	(0.3%)	0		0		0	
眼圧検査	1	(0.3%)	0		0		0	
肝機能検査異常	1	(0.3%)	0		3	(0.8%)	0	
平均赤血球容積増加	1	(0.3%)	0		1	(0.3%)	0	
モノクローナル免疫グロブリン陽性	1	(0.3%)	1	(0.3%)	0		0	
腎機能検査異常	1	(0.3%)	1	(0.3%)	0		0	
血清フェリチン減少	1	(0.3%)	0		1	(0.3%)	0	
レンサ球菌検査陽性	1	(0.3%)	1	(0.3%)	0		0	
トランスアミナーゼ上昇	1	(0.3%)	0		1	(0.3%)	0	
トロポニン増加	1	(0.3%)	0		1	(0.3%)	0	
トロポニンＴ増加	1	(0.3%)	0		0		0	
ウイルス検査陽性	1	(0.3%)	0		1	(0.3%)	0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 29）

System Organ Class	CRd (N=392)		Rd (N=389)	
Preferred Term	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher
血中アルブミン減少	0	0	2 (0.5%)	0
血中重炭酸塩増加	0	0	1 (0.3%)	0
血中フィブリノゲン増加	0	0	1 (0.3%)	0
血中免疫グロブリンＧ減少	0	0	1 (0.3%)	0
血圧低下	0	0	1 (0.3%)	0
尿中血陽性	0	0	2 (0.5%)	0
呼吸音異常	0	0	1 (0.3%)	0
心電図ＳＴ－Ｔ部分異常	0	0	1 (0.3%)	0
心電図異常Ｔ波	0	0	1 (0.3%)	0
心拍数増加	0	0	1 (0.3%)	0
リンパ球数減少	0	0	2 (0.5%)	0
単球数増加	0	0	1 (0.3%)	0
便潜血陽性	0	0	1 (0.3%)	0
総蛋白減少	0	0	1 (0.3%)	0
ビタミンＤ減少	0	0	1 (0.3%)	0
代謝および栄養障害	225 (57.4%)	107 (27.3%)	173 (44.5%)	70 (18.0%)
低カリウム血症	108 (27.6%)	37 (9.4%)	52 (13.4%)	19 (4.9%)
低カルシウム血症	63 (16.1%)	13 (3.3%)	45 (11.6%)	6 (1.5%)
低リン酸血症	52 (13.3%)	33 (8.4%)	29 (7.5%)	18 (4.6%)
高血糖	49 (12.5%)	20 (5.1%)	38 (9.8%)	18 (4.6%)
食欲減退	44 (11.2%)	0	35 (9.0%)	2 (0.5%)
低マグネシウム血症	36 (9.2%)	4 (1.0%)	25 (6.4%)	0
高尿酸血症	18 (4.6%)	2 (0.5%)	10 (2.6%)	0

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 30）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
低ナトリウム血症	15	(3.8%)	6	(1.5%)	9	(2.3%)	6	(1.5%)
低アルブミン血症	9	(2.3%)	1	(0.3%)	11	(2.8%)	1	(0.3%)
高カリウム血症	8	(2.0%)	3	(0.8%)	6	(1.5%)	1	(0.3%)
脱水	6	(1.5%)	0		3	(0.8%)	2	(0.5%)
体液貯留	6	(1.5%)	0		2	(0.5%)	0	
高カルシウム血症	5	(1.3%)	0		13	(3.3%)	7	(1.8%)
低血糖症	5	(1.3%)	1	(0.3%)	2	(0.5%)	0	
水分過負荷	4	(1.0%)	3	(0.8%)	0		0	
高リン酸塩血症	4	(1.0%)	0		0		0	
アシドーシス	3	(0.8%)	2	(0.5%)	0		0	
糖尿病	3	(0.8%)	1	(0.3%)	11	(2.8%)	4	(1.0%)
痛風	3	(0.8%)	0		5	(1.3%)	0	
高コレステロール血症	3	(0.8%)	0		0		0	
鉄欠乏	3	(0.8%)	0		2	(0.5%)	0	
腫瘍崩壊症候群	3	(0.8%)	3	(0.8%)	0		0	
コントロール不良の糖尿病	2	(0.5%)	2	(0.5%)	2	(0.5%)	0	
高脂血症	2	(0.5%)	0		3	(0.8%)	0	
低蛋白血症	2	(0.5%)	0		1	(0.3%)	0	
低尿酸血症	2	(0.5%)	0		0		0	
乳酸アシドーシス	2	(0.5%)	1	(0.3%)	0		0	
代謝性アシドーシス	2	(0.5%)	0		1	(0.3%)	1	(0.3%)
ビタミンＢ１２欠乏	2	(0.5%)	0		1	(0.3%)	0	
ビタミンＤ欠乏	2	(0.5%)	0		1	(0.3%)	0	
糖尿病性ケトアシドーシス	1	(0.3%)	1	(0.3%)	0		0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 31）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
電解質失調	1	(0.3%)	1	(0.3%)	1	(0.3%)	1	(0.3%)
高アルブミン血症	1	(0.3%)	0		0		0	
高クレアチニン血症	1	(0.3%)	0		0		0	
高マグネシウム血症	1	(0.3%)	0		0		0	
高ナトリウム血症	1	(0.3%)	1	(0.3%)	1	(0.3%)	0	
高トリグリセリド血症	1	(0.3%)	1	(0.3%)	0		0	
低クロール血症	1	(0.3%)	0		0		0	
低鉄血症	1	(0.3%)	0		0		0	
鉄過剰	1	(0.3%)	1	(0.3%)	0		0	
多飲症	1	(0.3%)	0		0		0	
テタニー	1	(0.3%)	1	(0.3%)	0		0	
２型糖尿病	1	(0.3%)	0		2	(0.5%)	1	(0.3%)
脂質異常症	0		0		1	(0.3%)	0	
葉酸欠乏	0		0		1	(0.3%)	0	
耐糖能障害	0		0		1	(0.3%)	1	(0.3%)
高蛋白血症	0		0		1	(0.3%)	0	
無機質欠乏	0		0		1	(0.3%)	1	(0.3%)
過体重	0		0		1	(0.3%)	0	
１型糖尿病	0		0		1	(0.3%)	1	(0.3%)
ビタミンＫ欠乏	0		0		1	(0.3%)	0	
筋骨格系および結合組織障害	225	(57.4%)	36	(9.2%)	215	(55.3%)	50	(12.9%)
筋痙縮	104	(26.5%)	4	(1.0%)	82	(21.1%)	3	(0.8%)
背部痛	67	(17.1%)	5	(1.3%)	78	(20.1%)	8	(2.1%)

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 32）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
関節痛	49	(12.5%)	2	(0.5%)	51	(13.1%)	2	(0.5%)
四肢痛	46	(11.7%)	4	(1.0%)	41	(10.5%)	6	(1.5%)
骨痛	39	(9.9%)	2	(0.5%)	36	(9.3%)	5	(1.3%)
筋力低下	27	(6.9%)	5	(1.3%)	22	(5.7%)	6	(1.5%)
筋骨格痛	25	(6.4%)	5	(1.3%)	34	(8.7%)	3	(0.8%)
筋骨格系胸痛	23	(5.9%)	1	(0.3%)	28	(7.2%)	2	(0.5%)
筋肉痛	22	(5.6%)	0		22	(5.7%)	0	
頸部痛	11	(2.8%)	0		18	(4.6%)	1	(0.3%)
関節腫脹	9	(2.3%)	0		3	(0.8%)	0	
顎骨壊死	9	(2.3%)	3	(0.8%)	14	(3.6%)	5	(1.3%)
顎痛	8	(2.0%)	0		8	(2.1%)	0	
筋骨格不快感	7	(1.8%)	0		3	(0.8%)	0	
変形性関節症	7	(1.8%)	0		3	(0.8%)	1	(0.3%)
関節炎	6	(1.5%)	1	(0.3%)	2	(0.5%)	0	
側腹部痛	6	(1.5%)	1	(0.3%)	5	(1.3%)	1	(0.3%)
ミオパチー	6	(1.5%)	3	(0.8%)	2	(0.5%)	0	
筋骨格硬直	4	(1.0%)	0		2	(0.5%)	0	
骨壊死	4	(1.0%)	1	(0.3%)	3	(0.8%)	1	(0.3%)
変形性脊椎症	4	(1.0%)	0		1	(0.3%)	0	
坐骨部痛	3	(0.8%)	0		2	(0.5%)	0	
四肢不快感	3	(0.8%)	0		1	(0.3%)	0	
病的骨折	3	(0.8%)	2	(0.5%)	1	(0.3%)	1	(0.3%)
重感	3	(0.8%)	0		1	(0.3%)	0	
滑液包炎	2	(0.5%)	0		2	(0.5%)	1	(0.3%)

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 33）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
痛風性関節炎	2	(0.5%)	0		1	(0.3%)	0	
椎間板突出	2	(0.5%)	0		0		0	
関節滲出液	2	(0.5%)	0		0		0	
筋拘縮	2	(0.5%)	0		1	(0.3%)	0	
肩回旋筋腱板症候群	2	(0.5%)	1	(0.3%)	1	(0.3%)	0	
腱障害	2	(0.5%)	0		0		0	
指炎	1	(0.3%)	0		0		0	
デュプイトラン拘縮	1	(0.3%)	0		0		0	
外骨腫	1	(0.3%)	0		0		0	
指変形	1	(0.3%)	0		0		0	
骨折による偽関節	1	(0.3%)	1	(0.3%)	0		0	
椎間板圧迫	1	(0.3%)	1	(0.3%)	0		0	
椎間板変性症	1	(0.3%)	0		0		0	
筋萎縮	1	(0.3%)	0		0		0	
筋肉内出血	1	(0.3%)	0		0		0	
筋緊張	1	(0.3%)	0		0		0	
神経障害性関節症	1	(0.3%)	0		0		0	
関節周囲炎	1	(0.3%)	0		0		0	
足底筋膜炎	1	(0.3%)	0		0		0	
軟部組織障害	1	(0.3%)	0		0		0	
軟部組織腫瘤	1	(0.3%)	0		1	(0.3%)	0	
脊柱管狭窄症	1	(0.3%)	0		1	(0.3%)	1	(0.3%)
滑膜炎	1	(0.3%)	0		0		0	
顎関節症候群	1	(0.3%)	0		0		0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 34）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
腱痛	1	(0.3%)	0		0		0	
腱炎	1	(0.3%)	0		1	(0.3%)	0	
腱鞘炎	1	(0.3%)	1	(0.3%)	0		0	
骨嚢腫	0		0		1	(0.3%)	1	(0.3%)
骨病変	0		0		2	(0.5%)	1	(0.3%)
ピロリン酸カルシウム結晶性軟骨石灰化症	0		0		2	(0.5%)	0	
骨折痛	0		0		1	(0.3%)	0	
関節可動域低下	0		0		1	(0.3%)	0	
脊柱後弯症	0		0		1	(0.3%)	0	
腰部脊柱管狭窄症	0		0		1	(0.3%)	1	(0.3%)
運動性低下	0		0		1	(0.3%)	0	
単関節炎	0		0		1	(0.3%)	0	
筋肉疲労	0		0		1	(0.3%)	0	
筋固縮	0		0		1	(0.3%)	1	(0.3%)
骨炎	0		0		2	(0.5%)	1	(0.3%)
骨減少症	0		0		1	(0.3%)	0	
骨粗鬆症	0		0		1	(0.3%)	0	
リウマチ性多発筋痛	0		0		1	(0.3%)	0	
滑液嚢腫	0		0		2	(0.5%)	1	(0.3%)
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）	30	(7.7%)	12	(3.1%)	28	(7.2%)	14	(3.6%)
基底細胞癌	5	(1.3%)	0		4	(1.0%)	1	(0.3%)
形質細胞腫	3	(0.8%)	2	(0.5%)	2	(0.5%)	2	(0.5%)
急性骨髄性白血病	2	(0.5%)	2	(0.5%)	2	(0.5%)	2	(0.5%)

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 35）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
結腸癌	2	(0.5%)	1	(0.3%)	0		0	
脂肪腫	2	(0.5%)	0		0		0	
扁平上皮癌	2	(0.5%)	0		2	(0.5%)	0	
皮膚有棘細胞癌	2	(0.5%)	0		1	(0.3%)	0	
腹部新生物	1	(0.3%)	0		0		0	
膵腺癌	1	(0.3%)	1	(0.3%)	0		0	
骨新生物	1	(0.3%)	0		0		0	
結腸直腸癌	1	(0.3%)	1	(0.3%)	0		0	
肝の悪性新生物	1	(0.3%)	0		1	(0.3%)	1	(0.3%)
形質細胞性白血病	1	(0.3%)	1	(0.3%)	0		0	
胸膜の悪性新生物	1	(0.3%)	1	(0.3%)	0		0	
メラノサイト性母斑	1	(0.3%)	0		2	(0.5%)	0	
骨髄異形成症候群	1	(0.3%)	1	(0.3%)	3	(0.8%)	2	(0.5%)
新生物	1	(0.3%)	0		0		0	
口腔乳頭腫	1	(0.3%)	0		1	(0.3%)	0	
転移性膵癌	1	(0.3%)	1	(0.3%)	0		0	
膵新生物	1	(0.3%)	1	(0.3%)	0		0	
良性副甲状腺腫瘍	1	(0.3%)	0		1	(0.3%)	0	
前立腺腺腫	1	(0.3%)	0		0		0	
皮膚乳頭腫	1	(0.3%)	0		2	(0.5%)	0	
血管筋脂肪腫	0		0		1	(0.3%)	0	
小脳橋角部腫瘍	0		0		1	(0.3%)	0	
消化器新生物	0		0		1	(0.3%)	0	
消化管間質性腫瘍	0		0		1	(0.3%)	1	(0.3%)

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 36）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
肺新生物	0		0		1	(0.3%)	0	
悪性黒色腫	0		0		1	(0.3%)	1	(0.3%)
多発性骨髄腫	0		0		2	(0.5%)	2	(0.5%)
神経鞘腫	0		0		1	(0.3%)	0	
非小細胞肺癌	0		0		1	(0.3%)	1	(0.3%)
下垂体の良性腫瘍	0		0		1	(0.3%)	0	
直腸癌	0		0		1	(0.3%)	1	(0.3%)
脂漏性角化症	0		0		1	(0.3%)	0	
甲状腺新生物	0		0		1	(0.3%)	0	
移行上皮癌	0		0		1	(0.3%)	0	
神経系障害	187	(47.7%)	34	(8.7%)	187	(48.1%)	47	(12.1%)
頭痛	53	(13.5%)	3	(0.8%)	31	(8.0%)	2	(0.5%)
浮動性めまい	48	(12.2%)	2	(0.5%)	44	(11.3%)	2	(0.5%)
末梢性ニューロパチー	29	(7.4%)	6	(1.5%)	27	(6.9%)	6	(1.5%)
振戦	28	(7.1%)	2	(0.5%)	32	(8.2%)	2	(0.5%)
錯感覚	25	(6.4%)	1	(0.3%)	23	(5.9%)	1	(0.3%)
末梢性感覚ニューロパチー	22	(5.6%)	2	(0.5%)	27	(6.9%)	0	
感覚鈍麻	18	(4.6%)	0		13	(3.3%)	0	
味覚異常	13	(3.3%)	0		21	(5.4%)	1	(0.3%)
多発ニューロパチー	13	(3.3%)	2	(0.5%)	8	(2.1%)	4	(1.0%)
記憶障害	12	(3.1%)	0		5	(1.3%)	0	
傾眠	10	(2.6%)	1	(0.3%)	5	(1.3%)	0	
失神	7	(1.8%)	5	(1.3%)	14	(3.6%)	10	(2.6%)

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 37）

System Organ Class / Preferred Term	CRd (N=392) All Grades	CRd (N=392) Grade 3 or Higher	Rd (N=389) All Grades	Rd (N=389) Grade 3 or Higher
認知障害	5 (1.3%)	0	2 (0.5%)	0
片頭痛	5 (1.3%)	0	0	0
注意力障害	4 (1.0%)	0	1 (0.3%)	0
異常感覚	4 (1.0%)	0	4 (1.0%)	0
神経痛	4 (1.0%)	1 (0.3%)	7 (1.8%)	2 (0.5%)
体位性めまい	3 (0.8%)	0	0	0
坐骨神経痛	3 (0.8%)	0	3 (0.8%)	0
反射消失	2 (0.5%)	0	0	0
灼熱感	2 (0.5%)	0	2 (0.5%)	0
馬尾症候群	2 (0.5%)	1 (0.3%)	0	0
脳血管発作	2 (0.5%)	2 (0.5%)	7 (1.8%)	7 (1.8%)
錐体外路障害	2 (0.5%)	0	0	0
知覚過敏	2 (0.5%)	0	3 (0.8%)	0
下肢静止不能症候群	2 (0.5%)	0	0	0
脊髄圧迫	2 (0.5%)	2 (0.5%)	3 (0.8%)	3 (0.8%)
味覚消失	1 (0.3%)	0	3 (0.8%)	0
異痛症	1 (0.3%)	0	0	0
意識変容状態	1 (0.3%)	0	0	0
健忘	1 (0.3%)	0	7 (1.8%)	0
無嗅覚	1 (0.3%)	1 (0.3%)	2 (0.5%)	1 (0.3%)
失声症	1 (0.3%)	0	2 (0.5%)	1 (0.3%)
平衡障害	1 (0.3%)	0	5 (1.3%)	0
脳嚢胞	1 (0.3%)	1 (0.3%)	0	0
昏睡	1 (0.3%)	0	1 (0.3%)	1 (0.3%)

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 38）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
痙攣	1	(0.3%)	0		2	(0.5%)	0	
認知症	1	(0.3%)	0		1	(0.3%)	0	
労作性めまい	1	(0.3%)	0		0		0	
よだれ	1	(0.3%)	0		0		0	
本態性振戦	1	(0.3%)	1	(0.3%)	0		0	
頭蓋内出血	1	(0.3%)	1	(0.3%)	0		0	
水頭症	1	(0.3%)	1	(0.3%)	0		0	
過眠症	1	(0.3%)	0		2	(0.5%)	0	
筋緊張亢進	1	(0.3%)	0		0		0	
味覚減退	1	(0.3%)	0		2	(0.5%)	0	
意識消失	1	(0.3%)	1	(0.3%)	1	(0.3%)	0	
不全対麻痺	1	(0.3%)	1	(0.3%)	0		0	
嗅覚錯誤	1	(0.3%)	0		2	(0.5%)	0	
末梢性運動ニューロパチー	1	(0.3%)	0		2	(0.5%)	0	
ヘルペス後神経痛	1	(0.3%)	0		1	(0.3%)	0	
失神寸前の状態	1	(0.3%)	0		0		0	
精神運動亢進	1	(0.3%)	0		2	(0.5%)	0	
感覚運動障害	1	(0.3%)	0		0		0	
感覚消失	1	(0.3%)	0		0		0	
中毒性ニューロパチー	1	(0.3%)	0		0		0	
三叉神経痛	1	(0.3%)	0		0		0	
第７脳神経麻痺	1	(0.3%)	0		0		0	
筋萎縮性側索硬化症	0		0		1	(0.3%)	1	(0.3%)
運動失調	0		0		1	(0.3%)	0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 39）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
自律神経ニューロパチー	0		0		1	(0.3%)	1	(0.3%)
脳出血	0		0		1	(0.3%)	1	(0.3%)
頸髄神経根痛	0		0		1	(0.3%)	0	
構語障害	0		0		1	(0.3%)	0	
ジスキネジー	0		0		1	(0.3%)	0	
頭部動揺	0		0		1	(0.3%)	0	
低酸素性虚血性脳症	0		0		1	(0.3%)	0	
肋間神経痛	0		0		1	(0.3%)	0	
嗜眠	0		0		1	(0.3%)	0	
精神的機能障害	0		0		1	(0.3%)	0	
筋痙直	0		0		1	(0.3%)	0	
粘液水腫性昏睡	0		0		1	(0.3%)	1	(0.3%)
神経圧迫	0		0		1	(0.3%)	0	
眼振	0		0		1	(0.3%)	0	
末梢神経不全麻痺	0		0		1	(0.3%)	0	
腓骨神経麻痺	0		0		1	(0.3%)	0	
神経根痛	0		0		1	(0.3%)	1	(0.3%)
鎮静	0		0		1	(0.3%)	0	
会話障害	0		0		1	(0.3%)	0	
一過性脳虚血発作	0		0		2	(0.5%)	0	
第６脳神経麻痺	0		0		1	(0.3%)	1	(0.3%)
声帯麻痺	0		0		1	(0.3%)	0	
精神障害	131	(33.4%)	24	(6.1%)	111	(28.5%)	21	(5.4%)

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 40）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
不眠症	75	(19.1%)	11	(2.8%)	63	(16.2%)	11	(2.8%)
不安	31	(7.9%)	1	(0.3%)	15	(3.9%)	2	(0.5%)
うつ病	15	(3.8%)	5	(1.3%)	13	(3.3%)	0	
激越	11	(2.8%)	2	(0.5%)	10	(2.6%)	3	(0.8%)
錯乱状態	10	(2.6%)	2	(0.5%)	11	(2.8%)	3	(0.8%)
気分変化	9	(2.3%)	1	(0.3%)	14	(3.6%)	3	(0.8%)
落ち着きのなさ	8	(2.0%)	3	(0.8%)	4	(1.0%)	1	(0.3%)
睡眠障害	6	(1.5%)	0		6	(1.5%)	1	(0.3%)
抑うつ気分	4	(1.0%)	1	(0.3%)	3	(0.8%)	0	
失見当識	4	(1.0%)	1	(0.3%)	0		0	
神経過敏	3	(0.8%)	0		6	(1.5%)	2	(0.5%)
幻覚	2	(0.5%)	0		1	(0.3%)	0	
人格変化	2	(0.5%)	2	(0.5%)	0		0	
異常行動	1	(0.3%)	0		0		0	
感情障害	1	(0.3%)	0		0		0	
自殺既遂	1	(0.3%)	1	(0.3%)	0		0	
転導性	1	(0.3%)	0		0		0	
多幸気分	1	(0.3%)	0		0		0	
表出性言語障害	1	(0.3%)	0		0		0	
リビドー減退	1	(0.3%)	0		0		0	
リビドー亢進	1	(0.3%)	0		0		0	
躁病	1	(0.3%)	1	(0.3%)	1	(0.3%)	0	
精神状態変化	1	(0.3%)	0		1	(0.3%)	1	(0.3%)
気分動揺	1	(0.3%)	1	(0.3%)	3	(0.8%)	1	(0.3%)

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 41）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
パニック発作	1	(0.3%)	0		0		0	
精神的機能代償不全	1	(0.3%)	1	(0.3%)	0		0	
精神病性障害	1	(0.3%)	1	(0.3%)	0		0	
ストレス	1	(0.3%)	0		1	(0.3%)	0	
適応障害	0		0		1	(0.3%)	0	
攻撃性	0		0		1	(0.3%)	0	
怒り	0		0		1	(0.3%)	0	
不安障害	0		0		1	(0.3%)	0	
睡眠時驚愕	0		0		1	(0.3%)	0	
腎および尿路障害	60	(15.3%)	18	(4.6%)	53	(13.6%)	14	(3.6%)
急性腎不全	15	(3.8%)	8	(2.0%)	11	(2.8%)	5	(1.3%)
腎不全	10	(2.6%)	4	(1.0%)	7	(1.8%)	2	(0.5%)
腎機能障害	10	(2.6%)	2	(0.5%)	9	(2.3%)	4	(1.0%)
排尿困難	9	(2.3%)	0		4	(1.0%)	0	
夜間頻尿	5	(1.3%)	0		1	(0.3%)	0	
頻尿	5	(1.3%)	0		6	(1.5%)	0	
慢性腎不全	5	(1.3%)	3	(0.8%)	4	(1.0%)	0	
尿閉	5	(1.3%)	1	(0.3%)	2	(0.5%)	1	(0.3%)
血尿	4	(1.0%)	0		2	(0.5%)	0	
腎嚢胞	3	(0.8%)	1	(0.3%)	1	(0.3%)	0	
高窒素血症	1	(0.3%)	1	(0.3%)	1	(0.3%)	1	(0.3%)
膀胱不快感	1	(0.3%)	0		0		0	
糖尿	1	(0.3%)	0		0		0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 42）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
排尿回数減少	1	(0.3%)	0		0		0	
尿意切迫	1	(0.3%)	0		2	(0.5%)	0	
ネフローゼ症候群	1	(0.3%)	0		0		0	
乏尿	1	(0.3%)	0		0		0	
腎仙痛	1	(0.3%)	0		0		0	
腎尿細管壊死	1	(0.3%)	0		0		0	
有痛性排尿困難	1	(0.3%)	0		1	(0.3%)	0	
尿路痛	1	(0.3%)	0		0		0	
無尿	0		0		1	(0.3%)	0	
膀胱瘻室	0		0		1	(0.3%)	0	
尿管結石	0		0		1	(0.3%)	0	
着色尿	0		0		1	(0.3%)	0	
尿路出血	0		0		2	(0.5%)	0	
腎症	0		0		1	(0.3%)	1	(0.3%)
中毒性ネフロパシー	0		0		1	(0.3%)	0	
多尿	0		0		3	(0.8%)	0	
腎前性腎不全	0		0		1	(0.3%)	0	
腎腫瘤	0		0		1	(0.3%)	0	
尿失禁	0		0		2	(0.5%)	0	
生殖系および乳房障害	21	(5.4%)	2	(0.5%)	9	(2.3%)	2	(0.5%)
良性前立腺肥大症	4	(1.0%)	1	(0.3%)	1	(0.3%)	0	
勃起不全	4	(1.0%)	0		1	(0.3%)	0	
骨盤痛	4	(1.0%)	0		2	(0.5%)	1	(0.3%)

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 43）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
前立腺炎	3	(0.8%)	0		0		0	
精巣上体炎	2	(0.5%)	1	(0.3%)	0		0	
外陰腟そう痒症	2	(0.5%)	0		0		0	
乳房痛	1	(0.3%)	0		0		0	
卵巣嚢胞	1	(0.3%)	0		0		0	
陰茎出血	1	(0.3%)	0		0		0	
前立腺異形成	1	(0.3%)	0		0		0	
前立腺痛	1	(0.3%)	0		0		0	
前立腺症	1	(0.3%)	0		1	(0.3%)	0	
女性化乳房	0		0		1	(0.3%)	0	
子宮脱	0		0		1	(0.3%)	1	(0.3%)
外陰腟不快感	0		0		1	(0.3%)	0	
外陰腟乾燥	0		0		1	(0.3%)	0	
呼吸器、胸郭および縦隔障害	217	(55.4%)	43	(11.0%)	162	(41.6%)	31	(8.0%)
咳嗽	113	(28.8%)	1	(0.3%)	67	(17.2%)	0	
呼吸困難	76	(19.4%)	11	(2.8%)	58	(14.9%)	7	(1.8%)
口腔咽頭痛	28	(7.1%)	0		21	(5.4%)	0	
労作性呼吸困難	21	(5.4%)	1	(0.3%)	17	(4.4%)	1	(0.3%)
発声障害	19	(4.8%)	0		11	(2.8%)	0	
鼻出血	19	(4.8%)	1	(0.3%)	16	(4.1%)	1	(0.3%)
湿性咳嗽	18	(4.6%)	1	(0.3%)	12	(3.1%)	0	
肺塞栓症	14	(3.6%)	12	(3.1%)	9	(2.3%)	9	(2.3%)
鼻漏	13	(3.3%)	0		8	(2.1%)	0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 44）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
鼻閉	10	(2.6%)	0		4	(1.0%)	0	
しゃっくり	9	(2.3%)	0		5	(1.3%)	1	(0.3%)
胸水	6	(1.5%)	2	(0.5%)	4	(1.0%)	2	(0.5%)
慢性閉塞性肺疾患	5	(1.3%)	2	(0.5%)	5	(1.3%)	1	(0.3%)
アレルギー性鼻炎	5	(1.3%)	0		3	(0.8%)	0	
肺障害	4	(1.0%)	2	(0.5%)	4	(1.0%)	2	(0.5%)
肺水腫	4	(1.0%)	3	(0.8%)	3	(0.8%)	1	(0.3%)
気道うっ血	4	(1.0%)	0		3	(0.8%)	0	
急性呼吸窮迫症候群	3	(0.8%)	3	(0.8%)	0		0	
低酸素症	3	(0.8%)	2	(0.5%)	2	(0.5%)	1	(0.3%)
呼吸不全	3	(0.8%)	1	(0.3%)	6	(1.5%)	4	(1.0%)
慢性気管支炎	2	(0.5%)	0		1	(0.3%)	0	
気管支痙攣	2	(0.5%)	1	(0.3%)	2	(0.5%)	1	(0.3%)
副鼻腔分泌過多	2	(0.5%)	0		0		0	
誤嚥性肺炎	2	(0.5%)	1	(0.3%)	0		0	
肺臓炎	2	(0.5%)	2	(0.5%)	1	(0.3%)	1	(0.3%)
肺高血圧症	2	(0.5%)	1	(0.3%)	1	(0.3%)	1	(0.3%)
ラ音	2	(0.5%)	0		1	(0.3%)	0	
副鼻腔うっ血	2	(0.5%)	0		4	(1.0%)	1	(0.3%)
急性肺水腫	1	(0.3%)	1	(0.3%)	0		0	
急性呼吸不全	1	(0.3%)	1	(0.3%)	1	(0.3%)	1	(0.3%)
アデノイド肥大	1	(0.3%)	0		0		0	
アレルギー性気管支炎	1	(0.3%)	0		0		0	
胞隔炎	1	(0.3%)	1	(0.3%)	1	(0.3%)	0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 45）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
誤嚥	1	(0.3%)	1	(0.3%)	0		0	
喘息	1	(0.3%)	0		2	(0.5%)	0	
気管支肺症	1	(0.3%)	1	(0.3%)	0		0	
肺気腫	1	(0.3%)	0		0		0	
好酸球性肺炎	1	(0.3%)	1	(0.3%)	0		0	
喀血	1	(0.3%)	0		1	(0.3%)	0	
低換気	1	(0.3%)	0		0		0	
間質性肺疾患	1	(0.3%)	1	(0.3%)	1	(0.3%)	1	(0.3%)
喉頭浮腫	1	(0.3%)	0		0		0	
鼻部不快感	1	(0.3%)	0		0		0	
鼻の炎症	1	(0.3%)	0		0		0	
鼻粘膜障害	1	(0.3%)	0		1	(0.3%)	0	
鼻潰瘍	1	(0.3%)	0		1	(0.3%)	0	
呼吸時疼痛	1	(0.3%)	0		0		0	
咽頭壊死	1	(0.3%)	0		0		0	
胸膜障害	1	(0.3%)	0		0		0	
胸膜線維症	1	(0.3%)	1	(0.3%)	0		0	
胸膜炎	1	(0.3%)	0		0		0	
胸膜痛	1	(0.3%)	0		0		0	
呼吸障害	1	(0.3%)	0		1	(0.3%)	0	
低音性連続性ラ音	1	(0.3%)	0		0		0	
くしゃみ	1	(0.3%)	0		0		0	
いびき	1	(0.3%)	0		0		0	
頻呼吸	1	(0.3%)	0		1	(0.3%)	0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 46）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
咽喉刺激感	1	(0.3%)	0		0		0	
咽喉絞扼感	1	(0.3%)	0		0		0	
上気道うっ血	1	(0.3%)	0		0		0	
喘鳴	1	(0.3%)	0		4	(1.0%)	0	
気管支反応性亢進	0		0		1	(0.3%)	0	
肺浸潤	0		0		1	(0.3%)	0	
口腔咽頭不快感	0		0		1	(0.3%)	0	
起坐呼吸	0		0		1	(0.3%)	0	
咽頭浮腫	0		0		1	(0.3%)	0	
呼気延長	0		0		1	(0.3%)	0	
肺うっ血	0		0		1	(0.3%)	0	
呼吸性アシドーシス	0		0		1	(0.3%)	0	
呼吸窮迫	0		0		1	(0.3%)	0	
気道の炎症	0		0		1	(0.3%)	0	
副鼻腔ポリープ	0		0		2	(0.5%)	0	
変色痰	0		0		1	(0.3%)	0	
上気道咳症候群	0		0		2	(0.5%)	0	
皮膚および皮下組織障害	151	(38.5%)	11	(2.8%)	129	(33.2%)	14	(3.6%)
発疹	52	(13.3%)	5	(1.3%)	60	(15.4%)	6	(1.5%)
紅斑	30	(7.7%)	0		12	(3.1%)	0	
そう痒症	30	(7.7%)	0		16	(4.1%)	1	(0.3%)
多汗症	26	(6.6%)	0		18	(4.6%)	1	(0.3%)
皮膚乾燥	12	(3.1%)	0		15	(3.9%)	0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 47）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
斑状丘疹状皮疹	12	(3.1%)	2	(0.5%)	11	(2.8%)	3	(0.8%)
斑状出血	11	(2.8%)	0		0		0	
日光性角化症	9	(2.3%)	0		0		0	
寝汗	9	(2.3%)	0		10	(2.6%)	0	
皮膚病変	8	(2.0%)	0		2	(0.5%)	0	
脱毛症	5	(1.3%)	0		7	(1.8%)	0	
紅斑性皮疹	5	(1.3%)	0		3	(0.8%)	0	
点状出血	4	(1.0%)	0		2	(0.5%)	0	
全身性皮疹	4	(1.0%)	1	(0.3%)	2	(0.5%)	0	
そう痒性皮疹	4	(1.0%)	1	(0.3%)	3	(0.8%)	0	
皮膚変色	4	(1.0%)	0		2	(0.5%)	0	
皮膚潰瘍	4	(1.0%)	1	(0.3%)	2	(0.5%)	0	
皮膚剥脱	3	(0.8%)	0		1	(0.3%)	0	
皮膚色素過剰	3	(0.8%)	0		3	(0.8%)	0	
顔面腫脹	3	(0.8%)	0		1	(0.3%)	0	
水疱	2	(0.5%)	0		0		0	
冷汗	2	(0.5%)	0		0		0	
皮膚炎	2	(0.5%)	0		1	(0.3%)	0	
アレルギー性皮膚炎	2	(0.5%)	0		2	(0.5%)	0	
紅色症	2	(0.5%)	0		0		0	
汗腺炎	2	(0.5%)	0		1	(0.3%)	0	
男性型多毛症	2	(0.5%)	0		1	(0.3%)	0	
皮膚毒性	2	(0.5%)	0		0		0	
蕁麻疹	2	(0.5%)	1	(0.3%)	2	(0.5%)	0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 48）

System Organ Class	CRd (N=392)		Rd (N=389)	
Preferred Term	All Grades	Grade 3 or Higher	All Grades	Grade 3 or Higher
ざ瘡	1 (0.3%)	0	1 (0.3%)	0
急性熱性好中球性皮膚症	1 (0.3%)	0	0	0
皮膚嚢腫	1 (0.3%)	0	0	0
水疱性皮膚炎	1 (0.3%)	0	0	0
薬疹	1 (0.3%)	0	1 (0.3%)	0
湿疹	1 (0.3%)	0	1 (0.3%)	0
湿潤性湿疹	1 (0.3%)	0	0	0
毛髪成長異常	1 (0.3%)	0	1 (0.3%)	0
過角化	1 (0.3%)	0	4 (1.0%)	0
多毛症	1 (0.3%)	0	1 (0.3%)	0
内出血発生の増加傾向	1 (0.3%)	0	5 (1.3%)	1 (0.3%)
嵌入爪	1 (0.3%)	0	1 (0.3%)	0
内方発育毛	1 (0.3%)	0	0	0
間擦疹	1 (0.3%)	0	0	0
機械性蕁麻疹	1 (0.3%)	0	0	0
爪床障害	1 (0.3%)	0	0	0
爪破損	1 (0.3%)	0	1 (0.3%)	0
手掌・足底発赤知覚不全症候群	1 (0.3%)	0	0	0
アレルギー性そう痒症	1 (0.3%)	0	0	0
全身性そう痒症	1 (0.3%)	0	2 (0.5%)	0
紫斑	1 (0.3%)	0	0	0
丘疹性皮疹	1 (0.3%)	0	1 (0.3%)	0
酒さ	1 (0.3%)	0	0	0
脂漏性皮膚炎	1 (0.3%)	0	1 (0.3%)	0

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 49）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
皮膚亀裂	1	(0.3%)	0		2	(0.5%)	0	
皮膚刺激	1	(0.3%)	0		0		0	
日光皮膚炎	1	(0.3%)	0		0		0	
血管性紫斑病	1	(0.3%)	0		0		0	
急性汎発性発疹性膿疱症	0		0		1	(0.3%)	1	(0.3%)
血管浮腫	0		0		2	(0.5%)	2	(0.5%)
ざ瘡様皮膚炎	0		0		1	(0.3%)	0	
接触性皮膚炎	0		0		2	(0.5%)	0	
爪の障害	0		0		2	(0.5%)	0	
ボードレンジ	0		0		1	(0.3%)	0	
乾癬	0		0		1	(0.3%)	0	
皮膚萎縮	0		0		1	(0.3%)	0	
皮膚腫脹	0		0		1	(0.3%)	0	
皮膚のつっぱり感	0		0		1	(0.3%)	0	
うっ滞性皮膚炎	0		0		1	(0.3%)	0	
外科および内科処置	1	(0.3%)	0		2	(0.5%)	0	
胆石摘出	1	(0.3%)	0		0		0	
白内障手術	0		0		1	(0.3%)	0	
抜歯	0		0		1	(0.3%)	0	
血管障害	147	(37.5%)	43	(11.0%)	97	(24.9%)	24	(6.2%)
高血圧	56	(14.3%)	17	(4.3%)	27	(6.9%)	7	(1.8%)
深部静脈血栓症	26	(6.6%)	7	(1.8%)	15	(3.9%)	4	(1.0%)

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 50）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
低血圧	25	(6.4%)	8	(2.0%)	23	(5.9%)	4	(1.0%)
潮紅	13	(3.3%)	0		4	(1.0%)	0	
静脈炎	12	(3.1%)	0		4	(1.0%)	0	
表在性血栓性静脈炎	11	(2.8%)	0		6	(1.5%)	1	(0.3%)
ほてり	10	(2.6%)	3	(0.8%)	1	(0.3%)	0	
血栓性静脈炎	8	(2.0%)	2	(0.5%)	3	(0.8%)	0	
血栓症	6	(1.5%)	1	(0.3%)	5	(1.3%)	3	(0.8%)
四肢静脈血栓症	6	(1.5%)	0		0		0	
血腫	5	(1.3%)	0		12	(3.1%)	3	(0.8%)
起立性低血圧	4	(1.0%)	0		4	(1.0%)	1	(0.3%)
塞栓症	3	(0.8%)	0		1	(0.3%)	1	(0.3%)
血栓後症候群	3	(0.8%)	0		0		0	
大動脈瘤	2	(0.5%)	1	(0.3%)	0		0	
動脈硬化症	2	(0.5%)	0		0		0	
循環虚脱	2	(0.5%)	1	(0.3%)	0		0	
高血圧クリーゼ	2	(0.5%)	2	(0.5%)	1	(0.3%)	1	(0.3%)
末梢冷感	2	(0.5%)	0		0		0	
表在性静脈炎	2	(0.5%)	0		0		0	
静脈瘤	2	(0.5%)	0		0		0	
大動脈硬化症	1	(0.3%)	0		1	(0.3%)	0	
動脈炎	1	(0.3%)	0		0		0	
青趾症候群	1	(0.3%)	0		0		0	
出血	1	(0.3%)	1	(0.3%)	1	(0.3%)	0	
リンパ浮腫	1	(0.3%)	0		1	(0.3%)	0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-15　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-009）（続き 51）

System Organ Class	CRd (N=392)				Rd (N=389)			
Preferred Term	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
末梢動脈狭窄	1	(0.3%)	0		0		0	
収縮期高血圧	1	(0.3%)	1	(0.3%)	0		0	
静脈血栓症	1	(0.3%)	1	(0.3%)	4	(1.0%)	0	
血圧変動	0		0		1	(0.3%)	1	(0.3%)
間欠性跛行	0		0		1	(0.3%)	0	
蒼白	0		0		1	(0.3%)	0	
骨盤静脈血栓症	0		0		1	(0.3%)	0	
末梢動脈瘤	0		0		1	(0.3%)	0	
末梢血管障害	0		0		1	(0.3%)	0	
レイノー現象	0		0		1	(0.3%)	0	
鎖骨下動脈狭窄	0		0		1	(0.3%)	0	
血管炎	0		0		1	(0.3%)	1	(0.3%)
Uncoded	0		0		1	(0.3%)	0	
Feeling of Preposession	0		0		1	(0.3%)	0	

CRd=Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm, Rd=Revlimid (lenalidomide)/dexamethasone arm

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to determine grade

Subjects were counted only once for each System Organ Class and each Preferred Term.

出典［総括報告書5.3.5.1-1（PX-171-009），Listing 16.2.22］

表 2.7.4.7-16　全 Grade 及び Grade 3 以上の有害事象の SOC 及び PT 別発現頻度（PX-171-011）

System Organ Class Preferred Term	Regimen C (N=157)				Regimen BSC (N=153)			
	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
Number of Subjects with at Least One Event	154	(98.1%)	118	(75.2%)	143	(93.5%)	109	(71.2%)
血液およびリンパ系障害	106	(67.5%)	69	(43.9%)	97	(63.4%)	72	(47.1%)
貧血	88	(56.1%)	40	(25.5%)	75	(49.0%)	47	(30.7%)
血小板減少症	59	(37.6%)	38	(24.2%)	46	(30.1%)	34	(22.2%)
好中球減少症	23	(14.6%)	12	(7.6%)	26	(17.0%)	19	(12.4%)
白血球減少症	10	(6.4%)	5	(3.2%)	15	(9.8%)	11	(7.2%)
リンパ球減少症	5	(3.2%)	5	(3.2%)	3	(2.0%)	1	(0.7%)
発熱性好中球減少症	3	(1.9%)	3	(1.9%)	2	(1.3%)	2	(1.3%)
過粘稠度症候群	1	(0.6%)	1	(0.6%)	2	(1.3%)	2	(1.3%)
白血球増加症	1	(0.6%)	1	(0.6%)	2	(1.3%)	2	(1.3%)
微小血管症性溶血性貧血	1	(0.6%)	1	(0.6%)	0		0	
好中球増加症	1	(0.6%)	0		1	(0.7%)	0	
汎血球減少症	1	(0.6%)	0		1	(0.7%)	1	(0.7%)
好酸球減少症	0		0		1	(0.7%)	0	
出血性障害	0		0		1	(0.7%)	0	
心臓障害	25	(15.9%)	13	(8.3%)	15	(9.8%)	5	(3.3%)
心不全	7	(4.5%)	3	(1.9%)	1	(0.7%)	1	(0.7%)
頻脈	4	(2.5%)	0		3	(2.0%)	0	
心房細動	3	(1.9%)	2	(1.3%)	2	(1.3%)	0	
心停止	2	(1.3%)	2	(1.3%)	1	(0.7%)	1	(0.7%)
うっ血性心不全	2	(1.3%)	2	(1.3%)	4	(2.6%)	3	(2.0%)
心筋虚血	2	(1.3%)	1	(0.6%)	0		0	

Regimen BSC=BSC arm, Regimen C=carfilzomib arm.

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to assess severity grade.

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-16　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-011）（続き 1）

System Organ Class Preferred Term	Regimen C (N=157)				Regimen BSC (N=153)			
	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
急性左室不全	1	(0.6%)	1	(0.6%)	0		0	
狭心症	1	(0.6%)	0		0		0	
心房粗動	1	(0.6%)	1	(0.6%)	1	(0.7%)	0	
完全房室ブロック	1	(0.6%)	1	(0.6%)	0		0	
徐脈	1	(0.6%)	0		0		0	
急性心不全	1	(0.6%)	1	(0.6%)	0		0	
心肺停止	1	(0.6%)	1	(0.6%)	0		0	
心原性ショック	1	(0.6%)	1	(0.6%)	0		0	
心筋症	1	(0.6%)	0		0		0	
うっ血性心筋症	1	(0.6%)	1	(0.6%)	0		0	
動悸	1	(0.6%)	0		0		0	
上室性頻脈	1	(0.6%)	1	(0.6%)	0		0	
不整脈	0		0		1	(0.7%)	0	
僧帽弁閉鎖不全症	0		0		1	(0.7%)	0	
洞性頻脈	0		0		1	(0.7%)	0	
耳および迷路障害	5	(3.2%)	0		7	(4.6%)	0	
聴力低下	2	(1.3%)	0		2	(1.3%)	0	
耳鳴	2	(1.3%)	0		2	(1.3%)	0	
耳痛	1	(0.6%)	0		0		0	
聴覚障害	1	(0.6%)	0		0		0	
耳出血	0		0		2	(1.3%)	0	
回転性めまい	0		0		1	(0.7%)	0	

Regimen BSC=BSC arm, Regimen C=carfilzomib arm.

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to assess severity grade.

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-16　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-011）（続き 2）

System Organ Class Preferred Term	Regimen C (N=157)				Regimen BSC (N=153)			
	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
内分泌障害	0		0		3	(2.0%)	0	
クッシング様	0		0		3	(2.0%)	0	
眼障害	8	(5.1%)	1	(0.6%)	9	(5.9%)	1	(0.7%)
結膜出血	2	(1.3%)	0		0		0	
結膜炎	2	(1.3%)	0		3	(2.0%)	0	
深径覚の変化	1	(0.6%)	0		0		0	
眼そう痒症	1	(0.6%)	0		0		0	
低眼圧	1	(0.6%)	1	(0.6%)	0		0	
眼内血腫	1	(0.6%)	0		0		0	
涙管腫脹	1	(0.6%)	0		0		0	
硝子体剥離	1	(0.6%)	0		0		0	
複視	0		0		1	(0.7%)	0	
眼痛	0		0		1	(0.7%)	0	
流涙増加	0		0		1	(0.7%)	0	
眼窩周囲浮腫	0		0		1	(0.7%)	0	
潰瘍性角膜炎	0		0		1	(0.7%)	1	(0.7%)
霧視	0		0		3	(2.0%)	0	
視力低下	0		0		1	(0.7%)	0	
胃腸障害	77	(49.0%)	14	(8.9%)	54	(35.3%)	9	(5.9%)
悪心	32	(20.4%)	2	(1.3%)	14	(9.2%)	2	(1.3%)
下痢	24	(15.3%)	4	(2.5%)	18	(11.8%)	2	(1.3%)
嘔吐	15	(9.6%)	1	(0.6%)	5	(3.3%)	2	(1.3%)

Regimen BSC=BSC arm, Regimen C=carfilzomib arm.

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to assess severity grade.

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-16　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-011）（続き 3）

System Organ Class Preferred Term	Regimen C (N=157)				Regimen BSC (N=153)			
	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
便秘	10	(6.4%)	0		20	(13.1%)	1	(0.7%)
消化不良	10	(6.4%)	1	(0.6%)	4	(2.6%)	1	(0.7%)
腹痛	6	(3.8%)	2	(1.3%)	4	(2.6%)	0	
上腹部痛	5	(3.2%)	0		3	(2.0%)	0	
腹部膨満	2	(1.3%)	0		2	(1.3%)	1	(0.7%)
鼓腸	2	(1.3%)	0		0		0	
胃炎	2	(1.3%)	0		2	(1.3%)	0	
歯肉出血	2	(1.3%)	0		0		0	
歯痛	2	(1.3%)	0		1	(0.7%)	0	
腹部不快感	1	(0.6%)	0		0		0	
腹部圧痛	1	(0.6%)	0		0		0	
腹水	1	(0.6%)	0		0		0	
腸閉塞	1	(0.6%)	1	(0.6%)	0		0	
嚥下障害	1	(0.6%)	0		0		0	
胃出血	1	(0.6%)	1	(0.6%)	0		0	
胃十二指腸炎	1	(0.6%)	0		0		0	
消化管運動障害	1	(0.6%)	0		0		0	
胃食道逆流性疾患	1	(0.6%)	0		0		0	
歯肉痛	1	(0.6%)	0		0		0	
吐血	1	(0.6%)	1	(0.6%)	0		0	
鼠径ヘルニア	1	(0.6%)	0		1	(0.7%)	0	
腸閉塞	1	(0.6%)	1	(0.6%)	0		0	
口唇潰瘍	1	(0.6%)	0		0		0	
メレナ	1	(0.6%)	1	(0.6%)	0		0	

Regimen BSC=BSC arm, Regimen C=carfilzomib arm.

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to assess severity grade.

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-16　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-011）（続き 4）

System Organ Class Preferred Term	Regimen C (N=157) All Grades		Regimen C (N=157) Grade 3 or Higher		Regimen BSC (N=153) All Grades		Regimen BSC (N=153) Grade 3 or Higher	
口腔内出血	1	(0.6%)	0		2	(1.3%)	0	
口腔障害	1	(0.6%)	0		0		0	
歯周病	1	(0.6%)	0		2	(1.3%)	1	(0.7%)
直腸出血	1	(0.6%)	0		2	(1.3%)	0	
上部消化管出血	1	(0.6%)	1	(0.6%)	0		0	
細菌叢異常症	0		0		1	(0.7%)	0	
便失禁	0		0		1	(0.7%)	0	
胃腸出血	0		0		2	(1.3%)	1	(0.7%)
痔出血	0		0		2	(1.3%)	0	
痔核	0		0		2	(1.3%)	0	
腸出血	0		0		1	(0.7%)	0	
急性膵炎	0		0		1	(0.7%)	0	
一般・全身障害および投与部位の状態	105	(66.9%)	27	(17.2%)	83	(54.2%)	26	(17.0%)
発熱	44	(28.0%)	5	(3.2%)	30	(19.6%)	0	
疲労	29	(18.5%)	2	(1.3%)	28	(18.3%)	2	(1.3%)
無力症	26	(16.6%)	4	(2.5%)	21	(13.7%)	5	(3.3%)
疾患進行	19	(12.1%)	18	(11.5%)	21	(13.7%)	18	(11.8%)
末梢性浮腫	17	(10.8%)	0		12	(7.8%)	0	
悪寒	8	(5.1%)	0		1	(0.7%)	0	
疼痛	8	(5.1%)	1	(0.6%)	2	(1.3%)	1	(0.7%)
浮腫	6	(3.8%)	1	(0.6%)	4	(2.6%)	0	
胸痛	5	(3.2%)	0		9	(5.9%)	1	(0.7%)
インフルエンザ様疾患	5	(3.2%)	0		1	(0.7%)	0	

Regimen BSC=BSC arm, Regimen C=carfilzomib arm.

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to assess severity grade.

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-16　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-011）（続き 5）

System Organ Class / Preferred Term	Regimen C (N=157) All Grades		Regimen C (N=157) Grade 3 or Higher		Regimen BSC (N=153) All Grades		Regimen BSC (N=153) Grade 3 or Higher	
全身健康状態低下	3	(1.9%)	2	(1.3%)	3	(2.0%)	2	(1.3%)
胸部不快感	2	(1.3%)	0		0		0	
多臓器不全	2	(1.3%)	2	(1.3%)	0		0	
非心臓性胸痛	2	(1.3%)	0		0		0	
カテーテル留置部位浮腫	1	(0.6%)	0		0		0	
薬物不耐性	1	(0.6%)	0		0		0	
溢出	1	(0.6%)	0		0		0	
顔面浮腫	1	(0.6%)	0		0		0	
低体温	1	(0.6%)	0		4	(2.6%)	0	
注射部位ぴらん	1	(0.6%)	0		0		0	
局所腫脹	1	(0.6%)	0		0		0	
倦怠感	1	(0.6%)	0		2	(1.3%)	0	
粘膜の炎症	1	(0.6%)	0		2	(1.3%)	1	(0.7%)
背椎痛	1	(0.6%)	0		2	(1.3%)	0	
カテーテル留置部位そう痒感	0		0		1	(0.7%)	0	
死亡	0		0		1	(0.7%)	1	(0.7%)
炎症	0		0		1	(0.7%)	0	
易刺激性	0		0		2	(1.3%)	0	
活動状態低下	0		0		1	(0.7%)	1	(0.7%)
肝胆道系障害	10	(6.4%)	5	(3.2%)	4	(2.6%)	1	(0.7%)
高ビリルビン血症	4	(2.5%)	1	(0.6%)	2	(1.3%)	0	
胆道仙痛	2	(1.3%)	1	(0.6%)	0		0	
胆石症	2	(1.3%)	1	(0.6%)	0		0	

Regimen BSC=BSC arm, Regimen C=carfilzomib arm.

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to assess severity grade.

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-16　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-011）（続き 6）

System Organ Class Preferred Term	Regimen C (N=157) All Grades		Regimen C (N=157) Grade 3 or Higher		Regimen BSC (N=153) All Grades		Regimen BSC (N=153) Grade 3 or Higher	
肝腫大	2	(1.3%)	1	(0.6%)	0		0	
胆嚢炎	1	(0.6%)	0		0		0	
肝機能異常	1	(0.6%)	1	(0.6%)	1	(0.7%)	1	(0.7%)
慢性胆嚢炎	0		0		1	(0.7%)	0	
免疫系障害	1	(0.6%)	1	(0.6%)	1	(0.7%)	1	(0.7%)
アナフィラキシー反応	1	(0.6%)	1	(0.6%)	0		0	
過敏症	0		0		1	(0.7%)	1	(0.7%)
感染症および寄生虫症	84	(53.5%)	33	(21.0%)	72	(47.1%)	35	(22.9%)
上気道感染	16	(10.2%)	2	(1.3%)	3	(2.0%)	0	
気管支炎	15	(9.6%)	3	(1.9%)	14	(9.2%)	2	(1.3%)
鼻咽頭炎	14	(8.9%)	0		10	(6.5%)	0	
肺炎	12	(7.6%)	10	(6.4%)	20	(13.1%)	19	(12.4%)
気道感染	11	(7.0%)	1	(0.6%)	10	(6.5%)	3	(2.0%)
インフルエンザ	8	(5.1%)	0		4	(2.6%)	0	
尿路感染	8	(5.1%)	4	(2.5%)	5	(3.3%)	0	
気管支肺炎	7	(4.5%)	5	(3.2%)	5	(3.3%)	5	(3.3%)
口腔カンジダ症	4	(2.5%)	0		1	(0.7%)	0	
感染	3	(1.9%)	1	(0.6%)	5	(3.3%)	2	(1.3%)
敗血症	3	(1.9%)	3	(1.9%)	1	(0.7%)	1	(0.7%)
カンジダ症	2	(1.3%)	0		0		0	
胃腸炎	2	(1.3%)	0		3	(2.0%)	0	
消化管感染	2	(1.3%)	1	(0.6%)	0		0	

Regimen BSC=BSC arm, Regimen C=carfilzomib arm.

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to assess severity grade.

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-16　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-011）（続き 7）

System Organ Class / Preferred Term	Regimen C (N=157) All Grades		Regimen C (N=157) Grade 3 or Higher		Regimen BSC (N=153) All Grades		Regimen BSC (N=153) Grade 3 or Higher	
下気道感染	2	(1.3%)	1	(0.6%)	2	(1.3%)	0	
肺感染	2	(1.3%)	1	(0.6%)	1	(0.7%)	0	
髄膜炎	2	(1.3%)	2	(1.3%)	0		0	
口腔ヘルペス	2	(1.3%)	0		1	(0.7%)	0	
中耳炎	2	(1.3%)	0		1	(0.7%)	0	
副鼻腔炎	2	(1.3%)	0		0		0	
クロストリジウム感染	1	(0.6%)	0		1	(0.7%)	0	
クロストリジウム・ディフィシレ大腸炎	1	(0.6%)	1	(0.6%)	0		0	
膀胱炎	1	(0.6%)	0		1	(0.7%)	0	
膿瘍炎	1	(0.6%)	0		0		0	
耳感染	1	(0.6%)	0		0		0	
毛包炎	1	(0.6%)	0		1	(0.7%)	0	
ウイルス性胃腸炎	1	(0.6%)	1	(0.6%)	1	(0.7%)	0	
歯肉感染	1	(0.6%)	0		0		0	
Ｈ１Ｎ１インフルエンザ	1	(0.6%)	0		0		0	
単純ヘルペス	1	(0.6%)	0		0		0	
ヘルペスウイルス感染	1	(0.6%)	0		0		0	
感染性皮膚潰瘍	1	(0.6%)	0		0		0	
注入部位感染	1	(0.6%)	0		0		0	
関節膿瘍	1	(0.6%)	0		0		0	
腎感染	1	(0.6%)	1	(0.6%)	0		0	
大葉性肺炎	1	(0.6%)	1	(0.6%)	1	(0.7%)	1	(0.7%)
メタニューモウイルス感染	1	(0.6%)	1	(0.6%)	0		0	
爪感染	1	(0.6%)	0		0		0	

Regimen BSC=BSC arm, Regimen C=carfilzomib arm.

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to assess severity grade.

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-16　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-011）（続き 8）

System Organ Class Preferred Term	Regimen C (N=157) All Grades	Regimen C (N=157) Grade 3 or Higher	Regimen BSC (N=153) All Grades	Regimen BSC (N=153) Grade 3 or Higher
口腔感染	1 (0.6%)	0	0	0
爪囲炎	1 (0.6%)	0	0	0
咽頭炎	1 (0.6%)	0	3 (2.0%)	1 (0.7%)
肺炎球菌性肺炎	1 (0.6%)	0	0	0
レンサ球菌性肺炎	1 (0.6%)	1 (0.6%)	0	0
シュードモナス感染	1 (0.6%)	0	0	0
慢性腎盂腎炎	1 (0.6%)	1 (0.6%)	0	0
呼吸器モニリア症	1 (0.6%)	0	0	0
ウイルス性気道感染	1 (0.6%)	0	0	0
ブドウ球菌感染	1 (0.6%)	0	0	0
ブドウ球菌性敗血症	1 (0.6%)	1 (0.6%)	0	0
歯感染	1 (0.6%)	0	0	0
気管気管支炎	1 (0.6%)	1 (0.6%)	0	0
尿管炎	1 (0.6%)	0	0	0
膣感染	1 (0.6%)	0	0	0
ウイルス性上気道感染	1 (0.6%)	0	0	0
菌血症	0	0	1 (0.7%)	1 (0.7%)
蜂巣炎	0	0	2 (1.3%)	0
慢性副鼻腔炎	0	0	1 (0.7%)	1 (0.7%)
大腸菌感染	0	0	1 (0.7%)	1 (0.7%)
眼感染	0	0	1 (0.7%)	0
真菌感染	0	0	1 (0.7%)	0
皮膚真菌感染	0	0	1 (0.7%)	0
歯肉炎	0	0	1 (0.7%)	0

Regimen BSC=BSC arm, Regimen C=carfilzomib arm.

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to assess severity grade.

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-16　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-011）（続き 9）

System Organ Class Preferred Term	Regimen C (N=157) All Grades		Regimen C (N=157) Grade 3 or Higher		Regimen BSC (N=153) All Grades		Regimen BSC (N=153) Grade 3 or Higher	
帯状疱疹	0		0		5	(3.3%)	2	(1.3%)
ヘルペス性角膜炎	0		0		1	(0.7%)	0	
クレブシエラ感染	0		0		1	(0.7%)	0	
限局性感染	0		0		1	(0.7%)	0	
好中球減少性敗血症	0		0		1	(0.7%)	1	(0.7%)
食道カンジダ症	0		0		1	(0.7%)	0	
真菌性口腔咽頭炎	0		0		1	(0.7%)	1	(0.7%)
眼窩周囲蜂巣炎	0		0		1	(0.7%)	1	(0.7%)
鼻炎	0		0		3	(2.0%)	0	
敗血症症候群	0		0		1	(0.7%)	0	
敗血症性ショック	0		0		3	(2.0%)	3	(2.0%)
歯膿瘍	0		0		2	(1.3%)	0	
気管炎	0		0		1	(0.7%)	0	
ウイルス感染	0		0		1	(0.7%)	0	
傷害、中毒および処置合併症	15	(9.6%)	2	(1.3%)	15	(9.8%)	2	(1.3%)
注入に伴う反応	2	(1.3%)	0		0		0	
化学物質中毒	1	(0.6%)	0		0		0	
頭蓋脳損傷	1	(0.6%)	0		0		0	
擦過傷	1	(0.6%)	0		0		0	
転倒	1	(0.6%)	0		2	(1.3%)	0	
大腿骨骨折	1	(0.6%)	0		0		0	
股関節部骨折	1	(0.6%)	0		0		0	
上腕骨骨折	1	(0.6%)	0		0		0	

Regimen BSC=BSC arm, Regimen C=carfilzomib arm.

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to assess severity grade.

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-16　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-011）（続き 10）

System Organ Class Preferred Term	Regimen C (N=157) All Grades		Regimen C (N=157) Grade 3 or Higher		Regimen BSC (N=153) All Grades		Regimen BSC (N=153) Grade 3 or Higher	
腸骨骨折	1	(0.6%)	0		0		0	
損傷	1	(0.6%)	0		0		0	
過量投与	1	(0.6%)	0		0		0	
肋骨骨折	1	(0.6%)	0		0		0	
脊椎圧迫骨折	1	(0.6%)	0		0		0	
熱傷	1	(0.6%)	1	(0.6%)	0		0	
胸椎骨折	1	(0.6%)	1	(0.6%)	0		0	
動物咬傷	0		0		1	(0.7%)	0	
挫傷	0		0		2	(1.3%)	0	
大腿骨頸部骨折	0		0		1	(0.7%)	1	(0.7%)
坐骨骨折	0		0		1	(0.7%)	0	
手骨折	0		0		1	(0.7%)	0	
四肢損傷	0		0		1	(0.7%)	0	
腰椎骨折	0		0		1	(0.7%)	1	(0.7%)
肉離れ	0		0		1	(0.7%)	0	
人工関節周囲骨折	0		0		1	(0.7%)	0	
放射線関連痛	0		0		1	(0.7%)	0	
放射線嚥下障害	0		0		1	(0.7%)	0	
胸骨骨折	0		0		1	(0.7%)	0	
腱断裂	0		0		1	(0.7%)	0	
輸血反応	0		0		1	(0.7%)	0	
創傷出血	0		0		1	(0.7%)	0	
臨床検査	58	(36.9%)	26	(16.6%)	47	(30.7%)	17	(11.1%)

Regimen BSC=BSC arm, Regimen C=carfilzomib arm.

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to assess severity grade.

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-16　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-011）（続き 11）

System Organ Class / Preferred Term	Regimen C (N=157) All Grades		Regimen C (N=157) Grade 3 or Higher		Regimen BSC (N=153) All Grades		Regimen BSC (N=153) Grade 3 or Higher	
血中クレアチニン増加	13	(8.3%)	3	(1.9%)	10	(6.5%)	1	(0.7%)
好中球数減少	13	(8.3%)	5	(3.2%)	10	(6.5%)	4	(2.6%)
血小板数減少	12	(7.6%)	5	(3.2%)	12	(7.8%)	7	(4.6%)
腎クレアチニン・クリアランス減少	9	(5.7%)	1	(0.6%)	4	(2.6%)	3	(2.0%)
血中乳酸脱水素酵素増加	6	(3.8%)	2	(1.3%)	4	(2.6%)	0	
Ｃ－反応性蛋白増加	4	(2.5%)	4	(2.5%)	2	(1.3%)	0	
アラニンアミノトランスフェラーゼ増加	3	(1.9%)	2	(1.3%)	3	(2.0%)	0	
アスパラギン酸アミノトランスフェラーゼ増加	3	(1.9%)	2	(1.3%)	3	(2.0%)	0	
血中ナトリウム減少	3	(1.9%)	2	(1.3%)	2	(1.3%)	2	(1.3%)
体重減少	3	(1.9%)	0		2	(1.3%)	0	
血中重炭酸塩減少	2	(1.3%)	0		0		0	
血中ビリルビン増加	2	(1.3%)	1	(0.6%)	0		0	
γ－グルタミルトランスフェラーゼ増加	2	(1.3%)	1	(0.6%)	6	(3.9%)	0	
肝酵素上昇	2	(1.3%)	1	(0.6%)	0		0	
総蛋白増加	2	(1.3%)	1	(0.6%)	2	(1.3%)	0	
トランスアミナーゼ上昇	2	(1.3%)	2	(1.3%)	0		0	
αヒドロキシ酪酸脱水素酵素増加	1	(0.6%)	1	(0.6%)	0		0	
アミラーゼ増加	1	(0.6%)	0		0		0	
血中アルブミン減少	1	(0.6%)	1	(0.6%)	0		0	
血中カルシウム増加	1	(0.6%)	0		0		0	
血中カリウム減少	1	(0.6%)	0		0		0	
血圧上昇	1	(0.6%)	0		0		0	
血中尿素増加	1	(0.6%)	0		1	(0.7%)	0	
体温上昇	1	(0.6%)	0		0		0	

Regimen BSC=BSC arm, Regimen C=carfilzomib arm.

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to assess severity grade.

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-16　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-011）（続き 12）

System Organ Class / Preferred Term	Regimen C (N=157) All Grades		Regimen C (N=157) Grade 3 or Higher		Regimen BSC (N=153) All Grades		Regimen BSC (N=153) Grade 3 or Higher	
腎クレアチニン・クリアランス増加	1	(0.6%)	0		2	(1.3%)	0	
駆出率減少	1	(0.6%)	1	(0.6%)	0		0	
軽鎖分析値増加	1	(0.6%)	0		0		0	
肺機能検査値低下	1	(0.6%)	0		0		0	
赤血球数減少	1	(0.6%)	0		0		0	
トロポニンＴ増加	1	(0.6%)	0		0		0	
尿量減少	1	(0.6%)	0		0		0	
白血球数減少	1	(0.6%)	1	(0.6%)	1	(0.7%)	1	(0.7%)
血中アルカリホスファターゼ減少	0		0		1	(0.7%)	0	
血中アルカリホスファターゼ増加	0		0		1	(0.7%)	0	
血中鉄増加	0		0		1	(0.7%)	0	
血中乳酸脱水素酵素減少	0		0		1	(0.7%)	0	
血中マグネシウム減少	0		0		3	(2.0%)	0	
血中リン減少	0		0		1	(0.7%)	1	(0.7%)
血中尿酸減少	0		0		1	(0.7%)	0	
血中尿酸増加	0		0		1	(0.7%)	0	
フィブリンＤダイマー増加	0		0		1	(0.7%)	1	(0.7%)
ヘマトクリット減少	0		0		1	(0.7%)	0	
ヘモグロビン減少	0		0		2	(1.3%)	1	(0.7%)
心拍数減少	0		0		1	(0.7%)	0	
国際標準比増加	0		0		1	(0.7%)	0	
リンパ球数減少	0		0		1	(0.7%)	0	
単球数増加	0		0		1	(0.7%)	0	
血清フェリチン増加	0		0		1	(0.7%)	0	

Regimen BSC=BSC arm, Regimen C=carfilzomib arm.

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to assess severity grade.

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-16　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-011）（続き 13）

System Organ Class / Preferred Term	Regimen C (N=157) All Grades		Regimen C (N=157) Grade 3 or Higher		Regimen BSC (N=153) All Grades		Regimen BSC (N=153) Grade 3 or Higher	
体重増加	0		0		1	(0.7%)	0	
代謝および栄養障害	74	(47.1%)	28	(17.8%)	55	(35.9%)	19	(12.4%)
高尿酸血症	19	(12.1%)	4	(2.5%)	11	(7.2%)	3	(2.0%)
高カルシウム血症	17	(10.8%)	6	(3.8%)	10	(6.5%)	7	(4.6%)
低カリウム血症	14	(8.9%)	3	(1.9%)	13	(8.5%)	1	(0.7%)
低カルシウム血症	11	(7.0%)	3	(1.9%)	10	(6.5%)	2	(1.3%)
低マグネシウム血症	11	(7.0%)	0		11	(7.2%)	0	
食欲減退	9	(5.7%)	1	(0.6%)	7	(4.6%)	1	(0.7%)
高カリウム血症	8	(5.1%)	3	(1.9%)	2	(1.3%)	1	(0.7%)
高血糖	7	(4.5%)	4	(2.5%)	9	(5.9%)	2	(1.3%)
低リン酸血症	5	(3.2%)	1	(0.6%)	2	(1.3%)	0	
低ナトリウム血症	4	(2.5%)	2	(1.3%)	4	(2.6%)	2	(1.3%)
低アルブミン血症	3	(1.9%)	0		3	(2.0%)	1	(0.7%)
低血糖症	3	(1.9%)	1	(0.6%)	0		0	
腫瘍崩壊症候群	3	(1.9%)	3	(1.9%)	0		0	
脱水	2	(1.3%)	1	(0.6%)	2	(1.3%)	0	
水分過負荷	2	(1.3%)	0		0		0	
体液貯留	2	(1.3%)	0		0		0	
高リン酸塩血症	2	(1.3%)	0		1	(0.7%)	0	
高蛋白血症	1	(0.6%)	0		1	(0.7%)	0	
代謝性アシドーシス	1	(0.6%)	0		1	(0.7%)	0	
アルカローシス	0		0		1	(0.7%)	0	
糖尿病	0		0		1	(0.7%)	0	

Regimen BSC=BSC arm, Regimen C=carfilzomib arm.

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to assess severity grade.

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-16　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-011）（続き 14）

System Organ Class Preferred Term	Regimen C (N=157) All Grades		Regimen C (N=157) Grade 3 or Higher		Regimen BSC (N=153) All Grades		Regimen BSC (N=153) Grade 3 or Higher	
葉酸欠乏	0		0		1	(0.7%)	0	
高クレアチニン血症	0		0		1	(0.7%)	0	
高マグネシウム血症	0		0		2	(1.3%)	1	(0.7%)
低蛋白血症	0		0		1	(0.7%)	0	
１型糖尿病	0		0		1	(0.7%)	1	(0.7%)
筋骨格系および結合組織障害	67	(42.7%)	10	(6.4%)	57	(37.3%)	12	(7.8%)
骨痛	18	(11.5%)	3	(1.9%)	17	(11.1%)	5	(3.3%)
背部痛	16	(10.2%)	5	(3.2%)	18	(11.8%)	2	(1.3%)
四肢痛	13	(8.3%)	0		7	(4.6%)	0	
関節痛	11	(7.0%)	0		7	(4.6%)	1	(0.7%)
筋骨格系胸痛	9	(5.7%)	0		7	(4.6%)	0	
筋痙縮	7	(4.5%)	0		7	(4.6%)	0	
筋骨格痛	5	(3.2%)	0		11	(7.2%)	2	(1.3%)
顎痛	4	(2.5%)	0		0		0	
筋肉痛	3	(1.9%)	0		0		0	
頚部痛	2	(1.3%)	0		0		0	
顎骨壊死	2	(1.3%)	0		0		0	
病的骨折	2	(1.3%)	2	(1.3%)	2	(1.3%)	2	(1.3%)
関節炎	1	(0.6%)	0		0		0	
側腹部痛	1	(0.6%)	0		0		0	
肩径部痛	1	(0.6%)	0		0		0	
関節滲出液	1	(0.6%)	0		0		0	
関節腫脹	1	(0.6%)	0		1	(0.7%)	0	

Regimen BSC=BSC arm, Regimen C=carfilzomib arm.

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to assess severity grade.

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-16　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-011）（続き 15）

System Organ Class Preferred Term	Regimen C (N=157) All Grades		Regimen C (N=157) Grade 3 or Higher		Regimen BSC (N=153) All Grades		Regimen BSC (N=153) Grade 3 or Higher	
筋骨格硬直	1	(0.6%)	0		0		0	
結節性変形性関節症	1	(0.6%)	0		0		0	
変形性関節症	1	(0.6%)	0		0		0	
骨溶解	1	(0.6%)	1	(0.6%)	0		0	
骨粗鬆症	1	(0.6%)	0		0		0	
肩回旋筋腱板症候群	1	(0.6%)	0		0		0	
側弯症	1	(0.6%)	0		0		0	
腱炎	1	(0.6%)	0		0		0	
滑液包炎	0		0		1	(0.7%)	0	
尾骨痛	0		0		2	(1.3%)	0	
筋拘縮	0		0		2	(1.3%)	0	
ミオパチー	0		0		1	(0.7%)	0	
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）	5	(3.2%)	3	(1.9%)	8	(5.2%)	6	(3.9%)
形質細胞腫	2	(1.3%)	1	(0.6%)	2	(1.3%)	2	(1.3%)
癌疼痛	1	(0.6%)	0		1	(0.7%)	0	
肝の悪性新生物	1	(0.6%)	1	(0.6%)	0		0	
悪性胸水	1	(0.6%)	1	(0.6%)	0		0	
急性骨髄性白血病	0		0		1	(0.7%)	1	(0.7%)
基底細胞癌	0		0		1	(0.7%)	0	
形質細胞性白血病	0		0		2	(1.3%)	2	(1.3%)
肺の悪性新生物	0		0		1	(0.7%)	1	(0.7%)
神経系障害	60	(38.2%)	9	(5.7%)	35	(22.9%)	6	(3.9%)

Regimen BSC=BSC arm, Regimen C=carfilzomib arm.

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to assess severity grade.

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-16　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-011）（続き 16）

System Organ Class / Preferred Term	Regimen C (N=157) All Grades		Regimen C (N=157) Grade 3 or Higher		Regimen BSC (N=153) All Grades		Regimen BSC (N=153) Grade 3 or Higher	
頭痛	17	(10.8%)	1	(0.6%)	6	(3.9%)	0	
浮動性めまい	11	(7.0%)	1	(0.6%)	3	(2.0%)	0	
末梢性ニューロパチー	7	(4.5%)	1	(0.6%)	6	(3.9%)	0	
末梢性感覚ニューロパチー	7	(4.5%)	1	(0.6%)	3	(2.0%)	0	
錯感覚	6	(3.8%)	0		3	(2.0%)	0	
多発ニューロパチー	6	(3.8%)	0		3	(2.0%)	0	
坐骨神経痛	3	(1.9%)	0		0		0	
脊髄圧迫	3	(1.9%)	2	(1.3%)	1	(0.7%)	1	(0.7%)
不全対麻痺	2	(1.3%)	1	(0.6%)	0		0	
神経根痛	2	(1.3%)	0		0		0	
傾眠	2	(1.3%)	0		1	(0.7%)	0	
運動失調	1	(0.6%)	0		0		0	
軸索型ニューロパチー	1	(0.6%)	0		0		0	
平衡障害	1	(0.6%)	0		1	(0.7%)	0	
中枢神経系病変	1	(0.6%)	0		0		0	
脳出血	1	(0.6%)	1	(0.6%)	0		0	
脳血管発作	1	(0.6%)	1	(0.6%)	1	(0.7%)	1	(0.7%)
昏睡	1	(0.6%)	1	(0.6%)	0		0	
痙攣	1	(0.6%)	0		1	(0.7%)	1	(0.7%)
局在性痙攣	1	(0.6%)	0		0		0	
体位性めまい	1	(0.6%)	0		0		0	
異常感覚	1	(0.6%)	0		0		0	
味覚異常	1	(0.6%)	0		0		0	
顔面神経障害	1	(0.6%)	0		0		0	

Regimen BSC=BSC arm, Regimen C=carfilzomib arm.

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to assess severity grade.

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-16　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-011）（続き 17）

System Organ Class Preferred Term	Regimen C (N=157) All Grades		Regimen C (N=157) Grade 3 or Higher		Regimen BSC (N=153) All Grades		Regimen BSC (N=153) Grade 3 or Higher	
感覚鈍麻	1	(0.6%)	0		1	(0.7%)	0	
筋緊張低下	1	(0.6%)	0		0		0	
意識消失	1	(0.6%)	0		0		0	
不全単麻痺	1	(0.6%)	0		0		0	
神経系障害	1	(0.6%)	1	(0.6%)	0		0	
神経痛	1	(0.6%)	0		0		0	
失神寸前の状態	1	(0.6%)	0		0		0	
失神	1	(0.6%)	1	(0.6%)	1	(0.7%)	1	(0.7%)
三叉神経痛	1	(0.6%)	0		0		0	
アルツハイマー型認知症	0		0		1	(0.7%)	1	(0.7%)
注意力障害	0		0		1	(0.7%)	0	
てんかん	0		0		1	(0.7%)	1	(0.7%)
頭蓋内出血	0		0		1	(0.7%)	1	(0.7%)
運動機能障害	0		0		1	(0.7%)	0	
運動障害	0		0		1	(0.7%)	0	
ヘルペス後神経痛	0		0		1	(0.7%)	0	
一過性脳虚血発作	0		0		1	(0.7%)	0	
振戦	0		0		3	(2.0%)	0	
精神障害	13	(8.3%)	2	(1.3%)	26	(17.0%)	4	(2.6%)
不眠症	4	(2.5%)	0		18	(11.8%)	2	(1.3%)
不安	3	(1.9%)	1	(0.6%)	2	(1.3%)	0	
錯乱状態	3	(1.9%)	1	(0.6%)	2	(1.3%)	1	(0.7%)
うつ病	3	(1.9%)	0		1	(0.7%)	0	

Regimen BSC=BSC arm, Regimen C=carfilzomib arm.

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to assess severity grade.

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-16　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-011）（続き 18）

System Organ Class Preferred Term	Regimen C (N=157) All Grades		Regimen C (N=157) Grade 3 or Higher		Regimen BSC (N=153) All Grades		Regimen BSC (N=153) Grade 3 or Higher	
激越	1	(0.6%)	0		1	(0.7%)	0	
失見当識	1	(0.6%)	1	(0.6%)	0		0	
攻撃性	0		0		1	(0.7%)	0	
神経性過食症	0		0		1	(0.7%)	0	
抑うつ気分	0		0		1	(0.7%)	0	
不快気分	0		0		1	(0.7%)	0	
感情的苦悩	0		0		1	(0.7%)	1	(0.7%)
幻覚	0		0		2	(1.3%)	0	
神経過敏	0		0		3	(2.0%)	0	
精神病性障害	0		0		1	(0.7%)	0	
睡眠障害	0		0		1	(0.7%)	0	
腎および尿路障害	44	(28.0%)	27	(17.2%)	26	(17.0%)	8	(5.2%)
急性腎不全	15	(9.6%)	12	(7.6%)	6	(3.9%)	5	(3.3%)
腎機能障害	11	(7.0%)	6	(3.8%)	5	(3.3%)	1	(0.7%)
腎不全	10	(6.4%)	8	(5.1%)	3	(2.0%)	2	(1.3%)
血尿	2	(1.3%)	0		0		0	
乏尿	2	(1.3%)	1	(0.6%)	0		0	
高窒素血症	1	(0.6%)	0		1	(0.7%)	1	(0.7%)
排尿困難	1	(0.6%)	0		0		0	
水腎症	1	(0.6%)	0		0		0	
腎損傷	1	(0.6%)	0		0		0	
尿失禁	1	(0.6%)	0		5	(3.3%)	0	
尿閉	1	(0.6%)	0		0		0	

Regimen BSC=BSC arm, Regimen C=carfilzomib arm.

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to assess severity grade.

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-16　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-011）（続き 19）

System Organ Class / Preferred Term	Regimen C (N=157) All Grades		Regimen C (N=157) Grade 3 or Higher		Regimen BSC (N=153) All Grades		Regimen BSC (N=153) Grade 3 or Higher	
激越	1	(0.6%)	0		1	(0.7%)	0	
失見当識	1	(0.6%)	1	(0.6%)	0		0	
攻撃性	0		0		1	(0.7%)	0	
神経性過食症	0		0		1	(0.7%)	0	
抑うつ気分	0		0		1	(0.7%)	0	
不快気分	0		0		1	(0.7%)	0	
感情的苦悩	0		0		1	(0.7%)	1	(0.7%)
幻覚	0		0		2	(1.3%)	0	
神経過敏	0		0		3	(2.0%)	0	
精神病性障害	0		0		1	(0.7%)	0	
睡眠障害	0		0		1	(0.7%)	0	
腎および尿路障害	44	(28.0%)	27	(17.2%)	26	(17.0%)	8	(5.2%)
急性腎不全	15	(9.6%)	12	(7.6%)	6	(3.9%)	5	(3.3%)
腎機能障害	11	(7.0%)	6	(3.8%)	5	(3.3%)	1	(0.7%)
腎不全	10	(6.4%)	8	(5.1%)	3	(2.0%)	2	(1.3%)
血尿	2	(1.3%)	0		0		0	
乏尿	2	(1.3%)	1	(0.6%)	0		0	
高窒素血症	1	(0.6%)	0		1	(0.7%)	1	(0.7%)
排尿困難	1	(0.6%)	0		0		0	
水腎症	1	(0.6%)	0		0		0	
腎損傷	1	(0.6%)	0		0		0	
尿失禁	1	(0.6%)	0		5	(3.3%)	0	
尿閉	1	(0.6%)	0		0		0	

Regimen BSC=BSC arm, Regimen C=carfilzomib arm.

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to assess severity grade.

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-16　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-011）（続き 20）

System Organ Class Preferred Term	Regimen C (N=157) All Grades		Regimen C (N=157) Grade 3 or Higher		Regimen BSC (N=153) All Grades		Regimen BSC (N=153) Grade 3 or Higher	
膀胱拡大	0		0		1	(0.7%)	0	
失禁	0		0		1	(0.7%)	0	
白血球尿	0		0		1	(0.7%)	0	
夜間頻尿	0		0		2	(1.3%)	0	
頻尿	0		0		2	(1.3%)	0	
慢性腎不全	0		0		2	(1.3%)	0	
腎尿細管壊死	0		0		1	(0.7%)	0	
腹圧性尿失禁	0		0		1	(0.7%)	0	
生殖系および乳房障害	6	(3.8%)	0		8	(5.2%)	1	(0.7%)
骨盤痛	3	(1.9%)	0		5	(3.3%)	0	
不正子宮出血	1	(0.6%)	0		0		0	
陰嚢痛	1	(0.6%)	0		0		0	
精巣腫脹	1	(0.6%)	0		0		0	
前立腺炎	0		0		1	(0.7%)	0	
膣出血	0		0		2	(1.3%)	1	(0.7%)
呼吸器、胸郭および縦隔障害	63	(40.1%)	17	(10.8%)	46	(30.1%)	8	(5.2%)
呼吸困難	23	(14.6%)	2	(1.3%)	13	(8.5%)	0	
咳嗽	19	(12.1%)	1	(0.6%)	10	(6.5%)	1	(0.7%)
鼻出血	13	(8.3%)	5	(3.2%)	10	(6.5%)	2	(1.3%)
湿性咳嗽	6	(3.8%)	0		2	(1.3%)	0	
労作性呼吸困難	3	(1.9%)	1	(0.6%)	6	(3.9%)	0	
口腔咽頭痛	3	(1.9%)	0		2	(1.3%)	0	

Regimen BSC=BSC arm, Regimen C=carfilzomib arm.

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to assess severity grade.

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-16　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-011）（続き 21）

System Organ Class / Preferred Term	Regimen C (N=157) All Grades		Regimen C (N=157) Grade 3 or Higher		Regimen BSC (N=153) All Grades		Regimen BSC (N=153) Grade 3 or Higher	
胸水	2	(1.3%)	0		1	(0.7%)	0	
肺水腫	2	(1.3%)	2	(1.3%)	1	(0.7%)	0	
鼻漏	2	(1.3%)	0		1	(0.7%)	0	
急性肺水腫	1	(0.6%)	1	(0.6%)	1	(0.7%)	1	(0.7%)
急性呼吸不全	1	(0.6%)	1	(0.6%)	1	(0.7%)	0	
慢性閉塞性肺疾患	1	(0.6%)	1	(0.6%)	1	(0.7%)	1	(0.7%)
発声障害	1	(0.6%)	0		0		0	
しゃっくり	1	(0.6%)	0		1	(0.7%)	0	
肺浸潤	1	(0.6%)	1	(0.6%)	0		0	
鼻中隔障害	1	(0.6%)	0		0		0	
咽頭紅斑	1	(0.6%)	0		0		0	
咽頭の炎症	1	(0.6%)	0		0		0	
胸膜痛	1	(0.6%)	0		1	(0.7%)	0	
呼気延長	1	(0.6%)	1	(0.6%)	0		0	
肺うっ血	1	(0.6%)	1	(0.6%)	0		0	
肺塞栓症	1	(0.6%)	1	(0.6%)	0		0	
呼吸不全	1	(0.6%)	1	(0.6%)	2	(1.3%)	1	(0.7%)
変色痰	1	(0.6%)	0		0		0	
咽喉刺激感	1	(0.6%)	0		0		0	
喘鳴	1	(0.6%)	0		0		0	
喘息	0		0		1	(0.7%)	0	
慢性気管支炎	0		0		1	(0.7%)	1	(0.7%)
気管支痙攣	0		0		1	(0.7%)	0	
肺臓炎	0		0		1	(0.7%)	0	

Regimen BSC=BSC arm, Regimen C=carfilzomib arm.

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to assess severity grade.

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-16　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-011）（続き 22）

System Organ Class Preferred Term	Regimen C (N=157) All Grades		Regimen C (N=157) Grade 3 or Higher		Regimen BSC (N=153) All Grades		Regimen BSC (N=153) Grade 3 or Higher	
肺出血	0		0		1	(0.7%)	1	(0.7%)
ラ音	0		0		1	(0.7%)	0	
気道うっ血	0		0		1	(0.7%)	0	
皮膚および皮下組織障害	24	(15.3%)	0		14	(9.2%)	0	
そう痒症	4	(2.5%)	0		0		0	
寝汗	3	(1.9%)	0		1	(0.7%)	0	
発疹	3	(1.9%)	0		1	(0.7%)	0	
脱毛症	2	(1.3%)	0		0		0	
多汗症	2	(1.3%)	0		3	(2.0%)	0	
点状出血	2	(1.3%)	0		1	(0.7%)	0	
円形脱毛症	1	(0.6%)	0		0		0	
水疱	1	(0.6%)	0		0		0	
褥瘡性潰瘍	1	(0.6%)	0		1	(0.7%)	0	
発汗障害	1	(0.6%)	0		0		0	
紅斑	1	(0.6%)	0		1	(0.7%)	0	
逆むけ	1	(0.6%)	0		0		0	
皮膚病変	1	(0.6%)	0		2	(1.3%)	0	
皮膚腫瘤	1	(0.6%)	0		0		0	
皮膚潰瘍	1	(0.6%)	0		1	(0.7%)	0	
日光性角化症	0		0		1	(0.7%)	0	
皮膚炎	0		0		1	(0.7%)	0	
皮膚乾燥	0		0		1	(0.7%)	0	
斑状出血	0		0		2	(1.3%)	0	

Regimen BSC=BSC arm, Regimen C=carfilzomib arm.

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to assess severity grade.

Subjects were counted only once for each System Organ Class and each Preferred Term.

表 2.7.4.7-16　全 Grade 及び Grade 3 以上の有害事象の SOC 別，PT 別発現頻度（PX-171-011）（続き 23）

System Organ Class Preferred Term	Regimen C (N=157)				Regimen BSC (N=153)			
	All Grades		Grade 3 or Higher		All Grades		Grade 3 or Higher	
手掌・足底発赤知覚不全症候群	0		0		1	(0.7%)	0	
痒疹	0		0		1	(0.7%)	0	
中毒性皮疹	0		0		1	(0.7%)	0	
血管障害	34	(21.7%)	9	(5.7%)	18	(11.8%)	1	(0.7%)
高血圧	23	(14.6%)	5	(3.2%)	9	(5.9%)	0	
血腫	5	(3.2%)	0		4	(2.6%)	0	
ほてり	2	(1.3%)	0		1	(0.7%)	0	
低血圧	2	(1.3%)	2	(1.3%)	0		0	
高血圧クリーゼ	1	(0.6%)	1	(0.6%)	0		0	
起立性低血圧	1	(0.6%)	0		0		0	
静脈炎	1	(0.6%)	0		0		0	
表在性静脈炎	1	(0.6%)	0		0		0	
静脈血栓症	1	(0.6%)	1	(0.6%)	1	(0.7%)	0	
深部静脈血栓症	0		0		2	(1.3%)	1	(0.7%)
潮紅	0		0		1	(0.7%)	0	
蒼白	0		0		1	(0.7%)	0	

Regimen BSC=BSC arm, Regimen C=carfilzomib arm.

Notes: MedDRA version 15.1 was used for coding NCI-CTCAE version 4.0 was used to assess severity grade.

Subjects were counted only once for each System Organ Class and each Preferred Term.

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

表 2.7.4.7-17　死亡例の一覧表（PX-171-002 part 1）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
PX-171-002 Part 1	Carfilzomib	PX171002-14-02-[redacted]	6[redacted]/ Male	26JAN20[redacted]	409	2	2	Adverse Event (Renal Failure: Cardiac, Pulmonary)	Possible		敗血症(38), 死亡(39), 下痢(69), 発熱性好中球減少症(69), 多臓器不全, 肺炎(69), 急性腎不全(69), 敗血症(69)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.

Notes: MedDRA version 15.1 used for coding.

This listing Includes deaths that occurred less than or equal to 30 days of last dose.

Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.

Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.

In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-17　死亡例の一覧表（PX-171-002 part 1）（続き）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
		PX171002-14-02-[redacted]	7[redacted]/ Male	03OCT20[redacted]	7	5	5	Progressive Disease (Not Applicable)	Unlikely		腹部膨満(1)，腹水(23)，再発暗殻細胞リンパ腫(23)，小腸閉塞(23)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

出典［総括報告書5.3.5.2-3（PX-171-002 part 1），Listing 16.2.7.1］

表 2.7.4.7-18　死亡例の一覧表（PX-171-002 part 2）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Supportive Safety Population											
PX-171-002 Part 2	Carfilzomib	PX171002-14-31-[redacted]	7[redacted]/ Female	14DEC20[redacted]	41	25	25	Progressive Disease (Primary Malignancy)	None		多臓器不全(14)
		PX171002-14-31-[redacted]	5[redacted]/ Female	29JAN20[redacted]	32	15	15	Progressive Disease (Primary Malignancy)	None		低血圧(29)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

出典［総括報告書5.3.5.2-4（PX-171-002 part 2），Listing 16.2.7.4］

表 2.7.4.7-19　死亡例の一覧表（PX-171-003 part 2（A1））

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control 20/27 mg/m^2											
PX-171-003 A1	Carfilzomib	PX171003-1 4-09-[redacted]	6[redacted]/ Male	03JAN20[redacted]	67	22	22	Adverse Event (Progressive Disease)	Possible	CFZ: Possible	呼吸困難(15)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-19　死亡例の一覧表（PX-171-003 part 2（A1））（続き 1）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control 20/27 mg/m^2											
PX-171-003-A1	Carfilzomib	PX171003-14-09-[redacted]	8[redacted]/ Male	09NOV20[redacted]	5	3	3	Adverse Event	Possible	CFZ: Possible	心停止(3)
		PX171003-14-10-[redacted]	6[redacted]/ Male	09OCT20[redacted]	32	16	16	Progressive Disease (Unknown)	Unlikely	CFZ: Unlikely	多発性骨髄腫 (13)
		PX171003-14-11-[redacted]	6[redacted]/ Male	04FEB20[redacted]	92	1	1	Adverse Event (Unknown)	Possible	CFZ: Possible	心停止(7)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-19　死亡例の一覧表（PX-171-003 part 2（A1））（続き 2）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control 20/27 mg/m^2											
PX-171-003 A1	Carfilzomib	PX171003-14-15-[redacted]	6[redacted]/ Female	10MAY20[redacted]	12	3	3	Adverse Event (Other: Cardiac Aresst.)	None	CFZ: None	敗血症(8)
		PX171003-14-15-[redacted]	5[redacted]/ Male	13AUG20[redacted]	9	0	0	Adverse Event (Other: Hypercholesteremia, Iddm, Htn, Copd.)	Unlikely	CFZ: Possible	心停止(6)
		PX171003-14-15-[redacted]	5[redacted]/ Male	01DEC20[redacted]	29	14	14	Progressive Disease		CFZ: None	

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-19　死亡例の一覧表（PX-171-003 part 2（A1））（続き 3）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control 20/27 mg/m^2											
PX-171-003-A1	Carfilzomib	PX171003-14-16-[redacted]	6[redacted]/ Male	23JUN20[redacted]	100	14	14	Progressive Disease (Adverse Event)	None	CFZ: None	敗血症(4), 多発性骨髄腫 (8)
		PX171003-14-16-[redacted]	7[redacted]/ Female	18JUL20[redacted]	10	8	8	Progressive Disease (Unknown)	None	CFZ: Possible	多発性骨髄腫 (7)
		PX171003-14-16-[redacted]	6[redacted]/ Male	12AUG20[redacted]	35	19	19	Progressive Disease	None	CFZ: None	多発性骨髄腫 (6)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-19　死亡例の一覧表（PX-171-003 part 2（A1））（続き 4）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control 20/27 mg/m^2											
PX-171-003 A1	Carfilzomib	PX171003-14-16-[redacted]	7[redacted]/ Male	03SEP20[redacted]	32	3	3	Progressive Disease	None	CFZ: Possible	多発性骨髄腫(8)
		PX171003-14-16-[redacted]	5[redacted]/ Male	26NOV20[redacted]	67	29	29	Adverse Event	None	CFZ: None	多発性骨髄腫(3)
		PX171003-14-16-[redacted]	6[redacted]/ Female	04NOV20[redacted]	37	6	6	Unknown (Unknown)	Probable	CFZ: Probable	死亡(9)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-19　死亡例の一覧表（PX-171-003 part 2（A1））（続き 5）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control 20/27 mg/m^2											
PX-171-003 A1	Carfilzomib	PX171003-14-16-[redacted]	7[redacted]/ Male	22MAR20[redacted]	166	4	4	Adverse Event	None	CFZ: None	頭蓋内出血(13)
		PX171003-14-20-[redacted]	6[redacted]/ Male	26OCT20[redacted]	28	11	11	Progressive Disease (Progressive Disease)	None	CFZ: None	疾患進行(6)
		PX171003-14-34-[redacted]	5[redacted]/ Male	07NOV20[redacted]	10	8	8	Adverse Event (Progressive Disease)	Unlikely	CFZ: Unlikely	肺炎(1)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.

Notes: MedDRA version 15.1 used for coding.

This listing Includes deaths that occurred less than or equal to 30 days of last dose.

Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.

Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.

In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-19　死亡例の一覧表（PX-171-003 part 2（A1））（続き 6）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control 20/27 mg/m^2											
PX-171-003-A1	Carfilzomib	PX171003-14-34-[redacted]	6[redacted]/ Female	12DEC20[redacted]	25	9	9	Adverse Event (Progressive Disease)	Unlikely	CFZ: Unlikely	肝不全(4)
		PX171003-14-34-[redacted]	6[redacted]/ Male	13APR20[redacted]	28	12	12	Progressive Disease (Unknown)	Unlikely	CFZ: Unlikely	疾患進行(7)
		PX171003-26-06-[redacted]	7[redacted]/ Male	16MAR20[redacted]	127	13	13	Adverse Event (Progressive Disease)	Probable	CFZ: Probable	急性肝不全(15)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-19　死亡例の一覧表（PX-171-003 part 2（A1））（続き 7）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control 20/27 mg/m^2											
PX-171-003 A1	Carfilzomib	PX171003-2 6-06-[redacted]	6[redacted]/ Male	29APR20[redacted]	93	29	29	Progressive Disease (Progressive Disease)	None	CFZ: None	疾患進行(16)
		PX171003-2 6-08-[redacted]	5[redacted]/ Male	23MAR20[redacted]	35	18	18	Adverse Event (Adverse Event)	Unlikely	CFZ: Possible	急性冠動脈症候群(3), 疾患進行(15)
		PX171003-2 6-37-[redacted]	7[redacted]/ Male	18JUL20[redacted]	40	24	24	Progressive Disease	None	CFZ: None	疾患進行(13)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

表 2.7.4.7-19　死亡例の一覧表（PX-171-003 part 2（A1））（続き 8）

Study	Treatment Group	Subject ID	Age/ Sex	Death Date	Number of Days from First Dose of Any Study Drug	Number of Days from Last Dose of Any Study Drug	Number of Days from Last Dose of Carfilzomib	Cause of Death Primary (Secondary)	Relationship to Study Treatment by Investigator	Relationship to Study Treatment by Sponsor	Fatal AE Preferred Term (AE Number)
Safety Population: Carfilzomib monotherapy and Control 20/27 mg/m^2											
PX-171-003 A1	Carfilzomib	PX171003-2 6-37-[redacted]	7[redacted]/ Female	16OCT20[redacted]	53	10	10	Progressive Disease	Unlikely	CFZ: Unlikely	疾患進行 (19)
		PX171003-2 6-37-[redacted]	6[redacted]/ Female	14DEC20[redacted]	118	18	18	Progressive Disease	None	CFZ: None	疾患進行(25)

AE=Adverse Event; CFZ=carfilzomib; DEX=Dexamethasone ; LEN=lenalidomide; mg/m2=milligram per meter squared.
Notes: MedDRA version 15.1 used for coding.
This listing Includes deaths that occurred less than or equal to 30 days of last dose.
Number of Days from First Dose of Any Study Drug= Death date-first dosing date of any study drug +1.
Number of Days from Last Dose of Any Study Drug /Carfilzomib= Death date- last dosing date of any study drug /Carfilzomib.
In studies PX-171-009, PX-171-011 and 2011-002, Relationship to Study Treatment by Investigator is based on relationship to study drugs of grade 5 TEAEs if primary cause of death is AE. In other studies, it is from death case report form.

出典［総括報告書5.3.5.2-6（PX-171-003 part 2（A1）），Listing 16.2.7.5］