2.7.6.18.3　　PX-171-011

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
Number of Subjects with at Least One Event	154 (98.1%)	143 (93.5%)
血液およびリンパ系障害	106 (67.5%)	97 (63.4%)
貧血	88 (56.1%)	75 (49.0%)
血小板減少症	59 (37.6%)	46 (30.1%)
好中球減少症	23 (14.6%)	26 (17.0%)
白血球減少症	10 (6.4%)	15 (9.8%)
リンパ球減少症	5 (3.2%)	3 (2.0%)
発熱性好中球減少症	3 (1.9%)	2 (1.3%)
過粘稠度症候群	1 (0.6%)	2 (1.3%)
白血球増加症	1 (0.6%)	2 (1.3%)
微小血管症性溶血性貧血	1 (0.6%)	0
好中球増加症	1 (0.6%)	1 (0.7%)
汎血球減少症	1 (0.6%)	1 (0.7%)
好酸球減少症	0	1 (0.7%)
出血性障害	0	1 (0.7%)

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 1）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
心臓障害	25 (15.9%)	15 (9.8%)
心不全	7 (4.5%)	1 (0.7%)
頻脈	4 (2.5%)	3 (2.0%)
心房細動	3 (1.9%)	2 (1.3%)
心停止	2 (1.3%)	1 (0.7%)
うっ血性心不全	2 (1.3%)	4 (2.6%)
心筋虚血	2 (1.3%)	0
急性左室不全	1 (0.6%)	0
狭心症	1 (0.6%)	0
心房粗動	1 (0.6%)	1 (0.7%)
完全房室ブロック	1 (0.6%)	0
徐脈	1 (0.6%)	0
急性心不全	1 (0.6%)	0
心肺停止	1 (0.6%)	0
心原性ショック	1 (0.6%)	0
心筋症	1 (0.6%)	0
うっ血性心筋症	1 (0.6%)	0
動悸	1 (0.6%)	0

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 2）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
上室性頻脈	1 (0.6%)	0
不整脈	0	1 (0.7%)
僧帽弁閉鎖不全症	0	1 (0.7%)
洞性頻脈	0	1 (0.7%)
耳および迷路障害	5 (3.2%)	7 (4.6%)
聴力低下	2 (1.3%)	2 (1.3%)
耳鳴	2 (1.3%)	2 (1.3%)
耳痛	1 (0.6%)	0
聴覚障害	1 (0.6%)	0
耳出血	0	2 (1.3%)
回転性めまい	0	1 (0.7%)
内分泌障害	0	3 (2.0%)
クッシング様	0	3 (2.0%)
眼障害	8 (5.1%)	9 (5.9%)
結膜出血	2 (1.3%)	0

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 3）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
結膜炎	2 (1.3%)	3 (2.0%)
深径覚の変化	1 (0.6%)	0
眼そう痒症	1 (0.6%)	0
低眼圧	1 (0.6%)	0
眼内血腫	1 (0.6%)	0
涙管腫脹	1 (0.6%)	0
硝子体剥離	1 (0.6%)	0
複視	0	1 (0.7%)
眼痛	0	1 (0.7%)
流涙増加	0	1 (0.7%)
眼窩周囲浮腫	0	1 (0.7%)
潰瘍性角膜炎	0	1 (0.7%)
霧視	0	3 (2.0%)
視力低下	0	1 (0.7%)
胃腸障害	77 (49.0%)	54 (35.3%)
悪心	32 (20.4%)	14 (9.2%)
下痢	24 (15.3%)	18 (11.8%)

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 4）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
嘔吐	15 (9.6%)	5 (3.3%)
便秘	10 (6.4%)	20 (13.1%)
消化不良	10 (6.4%)	4 (2.6%)
腹痛	6 (3.8%)	4 (2.6%)
上腹部痛	5 (3.2%)	3 (2.0%)
腹部膨満	2 (1.3%)	2 (1.3%)
鼓腸	2 (1.3%)	0
胃炎	2 (1.3%)	2 (1.3%)
歯肉出血	2 (1.3%)	0
歯痛	2 (1.3%)	1 (0.7%)
腹部不快感	1 (0.6%)	0
腹部圧痛	1 (0.6%)	0
腹水	1 (0.6%)	0
腸憩室	1 (0.6%)	0
嚥下障害	1 (0.6%)	0
胃出血	1 (0.6%)	0
胃十二指腸炎	1 (0.6%)	0
消化管運動障害	1 (0.6%)	0

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 5）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
胃食道逆流性疾患	1 (0.6%)	0
歯肉痛	1 (0.6%)	0
吐血	1 (0.6%)	0
鼡径ヘルニア	1 (0.6%)	1 (0.7%)
腸閉塞	1 (0.6%)	0
口唇潰瘍	1 (0.6%)	0
メレナ	1 (0.6%)	0
口腔内出血	1 (0.6%)	2 (1.3%)
口腔障害	1 (0.6%)	0
歯周病	1 (0.6%)	2 (1.3%)
直腸出血	1 (0.6%)	2 (1.3%)
上部消化管出血	1 (0.6%)	0
細菌叢異常症	0	1 (0.7%)
便失禁	0	1 (0.7%)
胃腸出血	0	2 (1.3%)
痔出血	0	2 (1.3%)
痔核	0	2 (1.3%)
腸出血	0	1 (0.7%)

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 6）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
急性膵炎	0	1 (0.7%)
一般・全身障害および投与部位の状態	105 (66.9%)	83 (54.2%)
発熱	44 (28.0%)	30 (19.6%)
疲労	29 (18.5%)	28 (18.3%)
無力症	26 (16.6%)	21 (13.7%)
疾患進行	19 (12.1%)	21 (13.7%)
末梢性浮腫	17 (10.8%)	12 (7.8%)
悪寒	8 (5.1%)	1 (0.7%)
疼痛	8 (5.1%)	2 (1.3%)
浮腫	6 (3.8%)	4 (2.6%)
胸痛	5 (3.2%)	9 (5.9%)
インフルエンザ様疾患	5 (3.2%)	1 (0.7%)
全身健康状態低下	3 (1.9%)	3 (2.0%)
胸部不快感	2 (1.3%)	0
多臓器不全	2 (1.3%)	0
非心臓性胸痛	2 (1.3%)	0
カテーテル留置部位浮腫	1 (0.6%)	0

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 7）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
薬物不耐性	1 (0.6%)	0
溢出	1 (0.6%)	0
顔面浮腫	1 (0.6%)	0
低体温	1 (0.6%)	4 (2.6%)
注射部位びらん	1 (0.6%)	0
局所腫脹	1 (0.6%)	0
倦怠感	1 (0.6%)	2 (1.3%)
粘膜の炎症	1 (0.6%)	2 (1.3%)
脊椎痛	1 (0.6%)	2 (1.3%)
カテーテル留置部位そう痒感	0	1 (0.7%)
死亡	0	1 (0.7%)
炎症	0	1 (0.7%)
易刺激性	0	2 (1.3%)
活動状態低下	0	1 (0.7%)
肝胆道系障害	10 (6.4%)	4 (2.6%)
高ビリルビン血症	4 (2.5%)	2 (1.3%)
胆道仙痛	2 (1.3%)	0

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 8）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
胆石症	2 (1.3%)	0
肝腫大	2 (1.3%)	0
胆嚢炎	1 (0.6%)	0
肝機能異常	1 (0.6%)	1 (0.7%)
慢性胆嚢炎	0	1 (0.7%)
免疫系障害	1 (0.6%)	1 (0.7%)
アナフィラキシー反応	1 (0.6%)	0
過敏症	0	1 (0.7%)
感染症および寄生虫症	84 (53.5%)	72 (47.1%)
上気道感染	16 (10.2%)	3 (2.0%)
気管支炎	15 (9.6%)	14 (9.2%)
鼻咽頭炎	14 (8.9%)	10 (6.5%)
肺炎	12 (7.6%)	20 (13.1%)
気道感染	11 (7.0%)	10 (6.5%)
インフルエンザ	8 (5.1%)	4 (2.6%)
尿路感染	8 (5.1%)	5 (3.3%)

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 9）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
気管支肺炎	7 (4.5%)	5 (3.3%)
口腔カンジダ症	4 (2.5%)	1 (0.7%)
感染	3 (1.9%)	5 (3.3%)
敗血症	3 (1.9%)	1 (0.7%)
カンジダ症	2 (1.3%)	0
胃腸炎	2 (1.3%)	3 (2.0%)
消化管感染	2 (1.3%)	0
下気道感染	2 (1.3%)	2 (1.3%)
肺感染	2 (1.3%)	1 (0.7%)
髄膜炎	2 (1.3%)	0
口腔ヘルペス	2 (1.3%)	1 (0.7%)
中耳炎	2 (1.3%)	1 (0.7%)
副鼻腔炎	2 (1.3%)	0
クロストリジウム感染	1 (0.6%)	1 (0.7%)
クロストリジウム・ディフィシレ大腸炎	1 (0.6%)	0
膀胱炎	1 (0.6%)	1 (0.7%)
憩室炎	1 (0.6%)	0
耳感染	1 (0.6%)	0

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 10）

System Organ Class Preferred Term	Regimen C (N=157)		Regimen BSC (N=153)	
毛包炎	1	(0.6%)	1	(0.7%)
ウイルス性胃腸炎	1	(0.6%)	1	(0.7%)
歯肉感染	1	(0.6%)	0	
H1N1 インフルエンザ	1	(0.6%)	0	
単純ヘルペス	1	(0.6%)	0	
ヘルペスウイルス感染	1	(0.6%)	0	
感染性皮膚潰瘍	1	(0.6%)	0	
注入部位感染	1	(0.6%)	0	
関節膿瘍	1	(0.6%)	0	
腎感染	1	(0.6%)	0	
大葉性肺炎	1	(0.6%)	1	(0.7%)
メタニューモウイルス感染	1	(0.6%)	0	
爪感染	1	(0.6%)	0	
口腔感染	1	(0.6%)	0	
爪囲炎	1	(0.6%)	0	
咽頭炎	1	(0.6%)	3	(2.0%)
肺炎球菌性肺炎	1	(0.6%)	0	
レンサ球菌性肺炎	1	(0.6%)	0	

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 11）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
シュードモナス感染	1 (0.6%)	0
慢性腎盂腎炎	1 (0.6%)	0
呼吸器モニリア症	1 (0.6%)	0
ウイルス性気道感染	1 (0.6%)	0
ブドウ球菌感染	1 (0.6%)	0
ブドウ球菌性敗血症	1 (0.6%)	0
歯感染	1 (0.6%)	0
気管気管支炎	1 (0.6%)	0
尿管炎	1 (0.6%)	0
膣感染	1 (0.6%)	0
ウイルス性上気道感染	1 (0.6%)	0
菌血症	0	1 (0.7%)
蜂巣炎	0	2 (1.3%)
慢性副鼻腔炎	0	1 (0.7%)
大腸菌感染	0	1 (0.7%)
眼感染	0	1 (0.7%)
真菌感染	0	1 (0.7%)
皮膚真菌感染	0	1 (0.7%)

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 12）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
歯肉炎	0	1 (0.7%)
帯状疱疹	0	5 (3.3%)
ヘルペス性角膜炎	0	1 (0.7%)
クレブシエラ感染	0	1 (0.7%)
限局性感染	0	1 (0.7%)
好中球減少性敗血症	0	1 (0.7%)
食道カンジダ症	0	1 (0.7%)
真菌性口腔咽頭炎	0	1 (0.7%)
眼窩周囲蜂巣炎	0	1 (0.7%)
鼻炎	0	3 (2.0%)
敗血症症候群	0	1 (0.7%)
敗血症性ショック	0	3 (2.0%)
歯膿瘍	0	2 (1.3%)
気管炎	0	1 (0.7%)
ウイルス感染	0	1 (0.7%)
傷害、中毒および処置合併症	15 (9.6%)	15 (9.8%)
注入に伴う反応	2 (1.3%)	0

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 13）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
化学物質中毒	1 (0.6%)	0
頭蓋脳損傷	1 (0.6%)	0
擦過傷	1 (0.6%)	0
転倒	1 (0.6%)	2 (1.3%)
大腿骨骨折	1 (0.6%)	0
股関節部骨折	1 (0.6%)	0
上腕骨骨折	1 (0.6%)	0
腸骨骨折	1 (0.6%)	0
損傷	1 (0.6%)	0
過量投与	1 (0.6%)	0
肋骨骨折	1 (0.6%)	0
脊椎圧迫骨折	1 (0.6%)	0
熱傷	1 (0.6%)	0
胸椎骨折	1 (0.6%)	0
動物咬傷	0	1 (0.7%)
挫傷	0	2 (1.3%)
大腿骨頚部骨折	0	1 (0.7%)
坐骨骨折	0	1 (0.7%)

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 14）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
手骨折	0	1 (0.7%)
四肢損傷	0	1 (0.7%)
腰椎骨折	0	1 (0.7%)
肉離れ	0	1 (0.7%)
人工関節周囲骨折	0	1 (0.7%)
放射線関連痛	0	1 (0.7%)
放射線嚥下障害	0	1 (0.7%)
胸骨骨折	0	1 (0.7%)
腱断裂	0	1 (0.7%)
輸血反応	0	1 (0.7%)
創傷出血	0	1 (0.7%)
臨床検査	58 (36.9%)	47 (30.7%)
血中クレアチニン増加	13 (8.3%)	10 (6.5%)
好中球数減少	13 (8.3%)	10 (6.5%)
血小板数減少	12 (7.6%)	12 (7.8%)
腎クレアチニン・クリアランス減少	9 (5.7%)	4 (2.6%)
血中乳酸脱水素酵素増加	6 (3.8%)	4 (2.6%)

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 15）

System Organ Class Preferred Term	Regimen C (N=157)		Regimen BSC (N=153)	
C－反応性蛋白増加	4	(2.5%)	2	(1.3%)
アラニンアミノトランスフェラーゼ増加	3	(1.9%)	3	(2.0%)
アスパラギン酸アミノトランスフェラーゼ増加	3	(1.9%)	3	(2.0%)
血中ナトリウム減少	3	(1.9%)	2	(1.3%)
体重減少	3	(1.9%)	2	(1.3%)
血中重炭酸塩減少	2	(1.3%)	0	
血中ビリルビン増加	2	(1.3%)	0	
γ－グルタミルトランスフェラーゼ増加	2	(1.3%)	6	(3.9%)
肝酵素上昇	2	(1.3%)	0	
総蛋白増加	2	(1.3%)	2	(1.3%)
トランスアミナーゼ上昇	2	(1.3%)	0	
αヒドロキシ酪酸脱水素酵素増加	1	(0.6%)	0	
アミラーゼ増加	1	(0.6%)	0	
血中アルブミン減少	1	(0.6%)	0	
血中カルシウム増加	1	(0.6%)	0	
血中カリウム減少	1	(0.6%)	0	
血圧上昇	1	(0.6%)	0	
血中尿素増加	1	(0.6%)	1	(0.7%)

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 16）

System Organ Class Preferred Term	Regimen C (N=157)		Regimen BSC (N=153)	
体温上昇	1	(0.6%)	0	
腎クレアチニン・クリアランス増加	1	(0.6%)	2	(1.3%)
駆出率減少	1	(0.6%)	0	
軽鎖分析値増加	1	(0.6%)	0	
肺機能検査値低下	1	(0.6%)	0	
赤血球数減少	1	(0.6%)	0	
トロポニンＴ増加	1	(0.6%)	0	
尿量減少	1	(0.6%)	0	
白血球数減少	1	(0.6%)	1	(0.7%)
血中アルカリホスファターゼ減少	0		1	(0.7%)
血中アルカリホスファターゼ増加	0		1	(0.7%)
血中鉄増加	0		1	(0.7%)
血中乳酸脱水素酵素減少	0		1	(0.7%)
血中マグネシウム減少	0		3	(2.0%)
血中リン減少	0		1	(0.7%)
血中尿酸減少	0		1	(0.7%)
血中尿酸増加	0		1	(0.7%)
フィブリンＤダイマー増加	0		1	(0.7%)

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 17）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
ヘマトクリット減少	0	1 (0.7%)
ヘモグロビン減少	0	2 (1.3%)
心拍数減少	0	1 (0.7%)
国際標準比増加	0	1 (0.7%)
リンパ球数減少	0	1 (0.7%)
単球数増加	0	1 (0.7%)
血清フェリチン増加	0	1 (0.7%)
体重増加	0	1 (0.7%)
代謝および栄養障害	74 (47.1%)	55 (35.9%)
高尿酸血症	19 (12.1%)	11 (7.2%)
高カルシウム血症	17 (10.8%)	10 (6.5%)
低カリウム血症	14 (8.9%)	13 (8.5%)
低カルシウム血症	11 (7.0%)	10 (6.5%)
低マグネシウム血症	11 (7.0%)	11 (7.2%)
食欲減退	9 (5.7%)	7 (4.6%)
高カリウム血症	8 (5.1%)	2 (1.3%)
高血糖	7 (4.5%)	9 (5.9%)

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 18）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
低リン酸血症	5 (3.2%)	2 (1.3%)
低ナトリウム血症	4 (2.5%)	4 (2.6%)
低アルブミン血症	3 (1.9%)	3 (2.0%)
低血糖症	3 (1.9%)	0
腫瘍崩壊症候群	3 (1.9%)	0
脱水	2 (1.3%)	2 (1.3%)
水分過負荷	2 (1.3%)	0
体液貯留	2 (1.3%)	0
高リン酸塩血症	2 (1.3%)	1 (0.7%)
高蛋白血症	1 (0.6%)	1 (0.7%)
代謝性アシドーシス	1 (0.6%)	1 (0.7%)
アルカローシス	0	1 (0.7%)
糖尿病	0	1 (0.7%)
葉酸欠乏	0	1 (0.7%)
高クレアチニン血症	0	1 (0.7%)
高マグネシウム血症	0	2 (1.3%)
低蛋白血症	0	1 (0.7%)
1 型糖尿病	0	1 (0.7%)

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 19）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
筋骨格系および結合組織障害	67 (42.7%)	57 (37.3%)
骨痛	18 (11.5%)	17 (11.1%)
背部痛	16 (10.2%)	18 (11.8%)
四肢痛	13 (8.3%)	7 (4.6%)
関節痛	11 (7.0%)	7 (4.6%)
筋骨格系胸痛	9 (5.7%)	7 (4.6%)
筋痙縮	7 (4.5%)	7 (4.6%)
筋骨格痛	5 (3.2%)	11 (7.2%)
顎痛	4 (2.5%)	0
筋肉痛	3 (1.9%)	0
頚部痛	2 (1.3%)	0
顎骨壊死	2 (1.3%)	0
病的骨折	2 (1.3%)	2 (1.3%)
関節炎	1 (0.6%)	0
側腹部痛	1 (0.6%)	0
鼡径部痛	1 (0.6%)	0
関節滲出液	1 (0.6%)	0

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 20）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
関節腫脹	1 (0.6%)	1 (0.7%)
筋骨格硬直	1 (0.6%)	0
結節性変形性関節症	1 (0.6%)	0
変形性関節症	1 (0.6%)	0
骨溶解	1 (0.6%)	0
骨粗鬆症	1 (0.6%)	0
肩回旋筋腱板症候群	1 (0.6%)	0
側弯症	1 (0.6%)	0
腱炎	1 (0.6%)	0
滑液包炎	0	1 (0.7%)
尾骨痛	0	2 (1.3%)
筋拘縮	0	2 (1.3%)
ミオパチー	0	1 (0.7%)
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%)	8 (5.2%)
形質細胞腫	2 (1.3%)	2 (1.3%)
癌疼痛	1 (0.6%)	1 (0.7%)
肝の悪性新生物	1 (0.6%)	0

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 21）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
悪性胸水	1 (0.6%)	0
急性骨髄性白血病	0	1 (0.7%)
基底細胞癌	0	1 (0.7%)
形質細胞性白血病	0	2 (1.3%)
肺の悪性新生物	0	1 (0.7%)
神経系障害	60 (38.2%)	35 (22.9%)
頭痛	17 (10.8%)	6 (3.9%)
浮動性めまい	11 (7.0%)	3 (2.0%)
末梢性ニューロパチー	7 (4.5%)	6 (3.9%)
末梢性感覚ニューロパチー	7 (4.5%)	3 (2.0%)
錯感覚	6 (3.8%)	3 (2.0%)
多発ニューロパチー	6 (3.8%)	3 (2.0%)
坐骨神経痛	3 (1.9%)	0
脊髄圧迫	3 (1.9%)	1 (0.7%)
不全対麻痺	2 (1.3%)	0
神経根痛	2 (1.3%)	0
傾眠	2 (1.3%)	1 (0.7%)

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 22）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
運動失調	1 (0.6%)	0
軸索型ニューロパチー	1 (0.6%)	0
平衡障害	1 (0.6%)	1 (0.7%)
中枢神経系病変	1 (0.6%)	0
脳出血	1 (0.6%)	0
脳血管発作	1 (0.6%)	1 (0.7%)
昏睡	1 (0.6%)	0
痙攣	1 (0.6%)	1 (0.7%)
局在性痙攣	1 (0.6%)	0
体位性めまい	1 (0.6%)	0
異常感覚	1 (0.6%)	0
味覚異常	1 (0.6%)	0
顔面神経障害	1 (0.6%)	0
感覚鈍麻	1 (0.6%)	1 (0.7%)
筋緊張低下	1 (0.6%)	0
意識消失	1 (0.6%)	0
不全単麻痺	1 (0.6%)	0
神経系障害	1 (0.6%)	0

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 23）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
神経痛	1 (0.6%)	0
失神寸前の状態	1 (0.6%)	0
失神	1 (0.6%)	1 (0.7%)
三叉神経痛	1 (0.6%)	0
アルツハイマー型認知症	0	1 (0.7%)
注意力障害	0	1 (0.7%)
てんかん	0	1 (0.7%)
頭蓋内出血	0	1 (0.7%)
運動機能障害	0	1 (0.7%)
運動障害	0	1 (0.7%)
ヘルペス後神経痛	0	1 (0.7%)
一過性脳虚血発作	0	1 (0.7%)
振戦	0	3 (2.0%)
精神障害	13 (8.3%)	26 (17.0%)
不眠症	4 (2.5%)	18 (11.8%)
不安	3 (1.9%)	2 (1.3%)
錯乱状態	3 (1.9%)	2 (1.3%)

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 24）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
うつ病	3 (1.9%)	1 (0.7%)
激越	1 (0.6%)	1 (0.7%)
失見当識	1 (0.6%)	0
攻撃性	0	1 (0.7%)
神経性過食症	0	1 (0.7%)
抑うつ気分	0	1 (0.7%)
不快気分	0	1 (0.7%)
感情的苦悩	0	1 (0.7%)
幻覚	0	2 (1.3%)
神経過敏	0	3 (2.0%)
精神病性障害	0	1 (0.7%)
睡眠障害	0	1 (0.7%)
腎および尿路障害	44 (28.0%)	26 (17.0%)
急性腎不全	15 (9.6%)	6 (3.9%)
腎機能障害	11 (7.0%)	5 (3.3%)
腎不全	10 (6.4%)	3 (2.0%)
血尿	2 (1.3%)	0

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 25）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
乏尿	2 (1.3%)	0
高窒素血症	1 (0.6%)	1 (0.7%)
排尿困難	1 (0.6%)	0
水腎症	1 (0.6%)	0
腎損傷	1 (0.6%)	0
尿失禁	1 (0.6%)	5 (3.3%)
尿閉	1 (0.6%)	0
膀胱拡大	0	1 (0.7%)
失禁	0	1 (0.7%)
白血球尿	0	1 (0.7%)
夜間頻尿	0	2 (1.3%)
頻尿	0	2 (1.3%)
慢性腎不全	0	2 (1.3%)
腎尿細管壊死	0	1 (0.7%)
腹圧性尿失禁	0	1 (0.7%)
生殖系および乳房障害	6 (3.8%)	8 (5.2%)
骨盤痛	3 (1.9%)	5 (3.3%)

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 26）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
不正子宮出血	1 (0.6%)	0
陰嚢痛	1 (0.6%)	0
精巣腫脹	1 (0.6%)	0
前立腺炎	0	1 (0.7%)
膣出血	0	2 (1.3%)
呼吸器、胸郭および縦隔障害	63 (40.1%)	46 (30.1%)
呼吸困難	23 (14.6%)	13 (8.5%)
咳嗽	19 (12.1%)	10 (6.5%)
鼻出血	13 (8.3%)	10 (6.5%)
湿性咳嗽	6 (3.8%)	2 (1.3%)
労作性呼吸困難	3 (1.9%)	6 (3.9%)
口腔咽頭痛	3 (1.9%)	2 (1.3%)
胸水	2 (1.3%)	1 (0.7%)
肺水腫	2 (1.3%)	1 (0.7%)
鼻漏	2 (1.3%)	1 (0.7%)
急性肺水腫	1 (0.6%)	1 (0.7%)
急性呼吸不全	1 (0.6%)	1 (0.7%)

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 27）

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

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 28）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
肺臓炎	0	1 (0.7%)
肺出血	0	1 (0.7%)
ラ音	0	1 (0.7%)
気道うっ血	0	1 (0.7%)
皮膚および皮下組織障害	24 (15.3%)	14 (9.2%)
そう痒症	4 (2.5%)	0
寝汗	3 (1.9%)	1 (0.7%)
発疹	3 (1.9%)	1 (0.7%)
脱毛症	2 (1.3%)	0
多汗症	2 (1.3%)	3 (2.0%)
点状出血	2 (1.3%)	1 (0.7%)
円形脱毛症	1 (0.6%)	0
水疱	1 (0.6%)	0
褥瘡性潰瘍	1 (0.6%)	1 (0.7%)
発汗障害	1 (0.6%)	0
紅斑	1 (0.6%)	1 (0.7%)
逆むけ	1 (0.6%)	0

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 29）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
皮膚病変	1 (0.6%)	2 (1.3%)
皮膚腫瘤	1 (0.6%)	0
皮膚潰瘍	1 (0.6%)	1 (0.7%)
日光性角化症	0	1 (0.7%)
皮膚炎	0	1 (0.7%)
皮膚乾燥	0	1 (0.7%)
斑状出血	0	2 (1.3%)
手掌・足底発赤知覚不全症候群	0	1 (0.7%)
痒疹	0	1 (0.7%)
中毒性皮疹	0	1 (0.7%)
血管障害	34 (21.7%)	18 (11.8%)
高血圧	23 (14.6%)	9 (5.9%)
血腫	5 (3.2%)	4 (2.6%)
ほてり	2 (1.3%)	1 (0.7%)
低血圧	2 (1.3%)	0
高血圧クリーゼ	1 (0.6%)	0
起立性低血圧	1 (0.6%)	0

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 30）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
静脈炎	1 (0.6%)	0
表在性静脈炎	1 (0.6%)	0
静脈血栓症	1 (0.6%)	1 (0.7%)
深部静脈血栓症	0	2 (1.3%)
潮紅	0	1 (0.7%)
蒼白	0	1 (0.7%)
Onyx Grouped Terms		
HLT_呼吸困難	25 (15.9%)	19 (12.4%)
呼吸困難	23 (14.6%)	13 (8.5%)
労作性呼吸困難	3 (1.9%)	6 (3.9%)
HLT_ヘルペスウイルス感染	4 (2.5%)	6 (3.9%)
単純ヘルペス	1 (0.6%)	0
ヘルペス性角膜炎	0	1 (0.7%)
口腔ヘルペス	2 (1.3%)	1 (0.7%)
ONX_帯状疱疹感染	1 (0.6%)	5 (3.3%)
ヘルペスウイルス感染	1 (0.6%)	0

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 31）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
帯状疱疹	0	5 (3.3%)
ONX_好中球減少症	37 (23.6%)	37 (24.2%)
発熱性好中球減少症	3 (1.9%)	2 (1.3%)
好中球減少症	23 (14.6%)	26 (17.0%)
好中球減少性敗血症	0	1 (0.7%)
好中球数減少	13 (8.3%)	10 (6.5%)
ONX_トランスアミナーゼ増加	8 (5.1%)	4 (2.6%)
アラニンアミノトランスフェラーゼ増加	3 (1.9%)	3 (2.0%)
アスパラギン酸アミノトランスフェラーゼ増加	3 (1.9%)	3 (2.0%)
肝酵素上昇	2 (1.3%)	0
トランスアミナーゼ上昇	2 (1.3%)	0
SMQB_貧血	89 (56.7%)	77 (50.3%)
貧血	88 (56.1%)	75 (49.0%)
ヘマトクリット減少	0	1 (0.7%)
ヘモグロビン減少	0	2 (1.3%)

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 32）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
赤血球数減少	1 (0.6%)	0
SMQB_心不全	33 (21.0%)	22 (14.4%)
浮腫	6 (3.8%)	4 (2.6%)
末梢性浮腫	17 (10.8%)	12 (7.8%)
肺うっ血	1 (0.6%)	0
SMQN_心不全	13 (8.3%)	7 (4.6%)
心不全	7 (4.5%)	1 (0.7%)
うっ血性心不全	2 (1.3%)	4 (2.6%)
肺水腫	2 (1.3%)	1 (0.7%)
急性左室不全	1 (0.6%)	0
急性肺水腫	1 (0.6%)	1 (0.7%)
急性心不全	1 (0.6%)	0
心原性ショック	1 (0.6%)	0
駆出率減少	1 (0.6%)	0
SMQB_虚血性心疾患	4 (2.5%)	0
SMQB_心筋梗塞	1 (0.6%)	0

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 33）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
トロポニンＴ増加	1 (0.6%)	0
SMQB_その他の虚血性心疾患	3 (1.9%)	0
心筋虚血	2 (1.3%)	0
狭心症	1 (0.6%)	0
SMQB_末梢性ニューロパチー	28 (17.8%)	17 (11.1%)
異常感覚	1 (0.6%)	0
感覚鈍麻	1 (0.6%)	1 (0.7%)
筋緊張低下	1 (0.6%)	0
運動機能障害	0	1 (0.7%)
錯感覚	6 (3.8%)	3 (2.0%)
SMQN_末梢性ニューロパチー	21 (13.4%)	12 (7.8%)
末梢性ニューロパチー	7 (4.5%)	6 (3.9%)
末梢性感覚ニューロパチー	7 (4.5%)	3 (2.0%)
多発ニューロパチー	6 (3.8%)	3 (2.0%)
軸索型ニューロパチー	1 (0.6%)	0
神経痛	1 (0.6%)	0

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 34）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
SMQB_血小板減少症	69 (43.9%)	56 (36.6%)
血小板数減少	12 (7.6%)	12 (7.8%)
血小板減少症	59 (37.6%)	46 (30.1%)
SMQN_急性腎不全	38 (24.2%)	14 (9.2%)
高窒素血症	1 (0.6%)	1 (0.7%)
乏尿	2 (1.3%)	0
腎不全	10 (6.4%)	3 (2.0%)
急性腎不全	15 (9.6%)	6 (3.9%)
腎機能障害	11 (7.0%)	5 (3.3%)
SMQN_不整脈	5 (3.2%)	4 (2.6%)
SMQN_不整脈用語（徐脈性不整脈および頻脈性不整脈を含む）	5 (3.2%)	4 (2.6%)
心房細動	3 (1.9%)	2 (1.3%)
心房粗動	1 (0.6%)	1 (0.7%)
完全房室ブロック	1 (0.6%)	0
不整脈	0	1 (0.7%)

表 2.7.6.18.3-1　有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 35）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
SMQN_心筋症	3 (1.9%)	0
心筋症	1 (0.6%)	0
うっ血性心筋症	1 (0.6%)	0
駆出率減少	1 (0.6%)	0
SMQN_間質性肺疾患	1 (0.6%)	1 (0.7%)
肺浸潤	1 (0.6%)	0
肺臓炎	0	1 (0.7%)

Regimen BSC=BSC arm; Regimen C= carfilzomib arm.
HLT = High Level Term; Onyx = Onyx defined grouping; SMQB = Standardized MedDRA Query, Broad scope; SMQN = Standardized MedDRA Query, Narrow scope.
Notes: MedDRA version 15.1 used for coding.
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），Table 14.3.2.1］

表 2.7.6.18.3-2　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
Number of Subjects with at Least One Event	96 (61.1%)	76 (49.7%)
血液およびリンパ系障害	56 (35.7%)	31 (20.3%)
血小板減少症	33 (21.0%)	14 (9.2%)
貧血	32 (20.4%)	16 (10.5%)
好中球減少症	11 (7.0%)	14 (9.2%)
リンパ球減少症	5 (3.2%)	1 (0.7%)
白血球減少症	4 (2.5%)	11 (7.2%)
発熱性好中球減少症	3 (1.9%)	0
微小血管症性溶血性貧血	1 (0.6%)	0
好中球増加症	1 (0.6%)	0
心臓障害	7 (4.5%)	5 (3.3%)
心不全	3 (1.9%)	0
狭心症	1 (0.6%)	0

表 2.7.6.18.3-2　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 1）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
完全房室ブロック	1 (0.6%)	0
うっ血性心不全	1 (0.6%)	3 (2.0%)
上室性頻脈	1 (0.6%)	0
頻脈	1 (0.6%)	1 (0.7%)
心房粗動	0	1 (0.7%)
内分泌障害	0	3 (2.0%)
クッシング様	0	3 (2.0%)
眼障害	2 (1.3%)	3 (2.0%)
結膜炎	1 (0.6%)	0
硝子体剥離	1 (0.6%)	0
複視	0	1 (0.7%)
眼窩周囲浮腫	0	1 (0.7%)
潰瘍性角膜炎	0	1 (0.7%)

表 2.7.6.18.3-2　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 2）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
胃腸障害	35 (22.3%)	15 (9.8%)
悪心	19 (12.1%)	5 (3.3%)
嘔吐	9 (5.7%)	1 (0.7%)
下痢	7 (4.5%)	4 (2.6%)
消化不良	4 (2.5%)	0
便秘	3 (1.9%)	2 (1.3%)
腹痛	2 (1.3%)	0
腹部不快感	1 (0.6%)	0
腹部膨満	1 (0.6%)	1 (0.7%)
上腹部痛	1 (0.6%)	1 (0.7%)
胃出血	1 (0.6%)	0
胃炎	1 (0.6%)	2 (1.3%)
胃十二指腸炎	1 (0.6%)	0
吐血	1 (0.6%)	0
メレナ	1 (0.6%)	0
口腔障害	1 (0.6%)	0

表 2.7.6.18.3-2　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 3）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
歯周病	1 (0.6%)	0
細菌叢異常症	0	1 (0.7%)
胃腸出血	0	1 (0.7%)
一般・全身障害および投与部位の状態	37 (23.6%)	18 (11.8%)
発熱	18 (11.5%)	2 (1.3%)
疲労	9 (5.7%)	7 (4.6%)
無力症	8 (5.1%)	3 (2.0%)
悪寒	4 (2.5%)	0
末梢性浮腫	4 (2.5%)	2 (1.3%)
浮腫	3 (1.9%)	4 (2.6%)
胸部不快感	1 (0.6%)	0
溢出	1 (0.6%)	0
顔面浮腫	1 (0.6%)	0
全身健康状態低下	1 (0.6%)	0
インフルエンザ様疾患	1 (0.6%)	0

表 2.7.6.18.3-2　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 4）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
粘膜の炎症	1 (0.6%)	1 (0.7%)
疼痛	1 (0.6%)	0
易刺激性	0	2 (1.3%)
活動状態低下	0	1 (0.7%)
感染症および寄生虫症	19 (12.1%)	22 (14.4%)
肺炎	4 (2.5%)	7 (4.6%)
上気道感染	4 (2.5%)	0
口腔ヘルペス	2 (1.3%)	0
気管支炎	1 (0.6%)	3 (2.0%)
気管支肺炎	1 (0.6%)	2 (1.3%)
膀胱炎	1 (0.6%)	0
感染	1 (0.6%)	0
インフルエンザ	1 (0.6%)	0
注入部位感染	1 (0.6%)	0
下気道感染	1 (0.6%)	0

表 2.7.6.18.3-2　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 5）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
髄膜炎	1 (0.6%)	0
鼻咽頭炎	1 (0.6%)	2 (1.3%)
口腔カンジダ症	1 (0.6%)	0
慢性腎盂腎炎	1 (0.6%)	0
気道感染	1 (0.6%)	1 (0.7%)
ブドウ球菌感染	1 (0.6%)	0
尿路感染	1 (0.6%)	0
蜂巣炎	0	2 (1.3%)
慢性副鼻腔炎	0	1 (0.7%)
歯肉炎	0	1 (0.7%)
帯状疱疹	0	2 (1.3%)
好中球減少性敗血症	0	1 (0.7%)
食道カンジダ症	0	1 (0.7%)
真菌性口腔咽頭炎	0	1 (0.7%)
中耳炎	0	1 (0.7%)
眼窩周囲蜂巣炎	0	1 (0.7%)

表 2.7.6.18.3-2　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 6）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
咽頭炎	0	1 (0.7%)
敗血症性ショック	0	1 (0.7%)
気管炎	0	1 (0.7%)
傷害、中毒および処置合併症	2 (1.3%)	1 (0.7%)
注入に伴う反応	2 (1.3%)	0
手骨折	0	1 (0.7%)
臨床検査	19 (12.1%)	9 (5.9%)
血中クレアチニン増加	5 (3.2%)	0
好中球数減少	4 (2.5%)	4 (2.6%)
血小板数減少	3 (1.9%)	3 (2.0%)
アスパラギン酸アミノトランスフェラーゼ増加	2 (1.3%)	0
γ－グルタミルトランスフェラーゼ増加	2 (1.3%)	1 (0.7%)
トランスアミナーゼ上昇	2 (1.3%)	0
アラニンアミノトランスフェラーゼ増加	1 (0.6%)	0

表 2.7.6.18.3-2　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 7）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
アミラーゼ増加	1 (0.6%)	0
血中アルブミン減少	1 (0.6%)	0
血中乳酸脱水素酵素増加	1 (0.6%)	0
血中ナトリウム減少	1 (0.6%)	0
血中尿素増加	1 (0.6%)	0
トロポニンＴ増加	1 (0.6%)	0
リンパ球数減少	0	1 (0.7%)
代謝および栄養障害	17 (10.8%)	12 (7.8%)
高尿酸血症	5 (3.2%)	1 (0.7%)
低カリウム血症	4 (2.5%)	3 (2.0%)
低カルシウム血症	3 (1.9%)	0
腫瘍崩壊症候群	3 (1.9%)	0
高カルシウム血症	2 (1.3%)	0
高カリウム血症	2 (1.3%)	1 (0.7%)
食欲減退	1 (0.6%)	1 (0.7%)

表 2.7.6.18.3-2　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 8）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
高血糖	1 (0.6%)	4 (2.6%)
低リン酸血症	1 (0.6%)	0
低ナトリウム血症	0	1 (0.7%)
低蛋白血症	0	1 (0.7%)
筋骨格系および結合組織障害	4 (2.5%)	5 (3.3%)
骨痛	1 (0.6%)	0
筋痙縮	1 (0.6%)	1 (0.7%)
筋骨格系胸痛	1 (0.6%)	1 (0.7%)
筋肉痛	1 (0.6%)	0
顎痛	1 (0.6%)	0
筋骨格痛	0	1 (0.7%)
ミオパチー	0	1 (0.7%)
四肢痛	0	1 (0.7%)
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 (0.6%)	1 (0.7%)

表 2.7.6.18.3-2　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 9）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
肝の悪性新生物	1 (0.6%)	0
肺の悪性新生物	0	1 (0.7%)
神経系障害	18 (11.5%)	4 (2.6%)
頭痛	6 (3.8%)	1 (0.7%)
浮動性めまい	3 (1.9%)	1 (0.7%)
末梢性感覚ニューロパチー	3 (1.9%)	0
末梢性ニューロパチー	2 (1.3%)	0
多発ニューロパチー	2 (1.3%)	0
軸索型ニューロパチー	1 (0.6%)	0
局在性痙攣	1 (0.6%)	0
味覚異常	1 (0.6%)	0
筋緊張低下	1 (0.6%)	0
神経系障害	1 (0.6%)	0
錯感覚	1 (0.6%)	0
失神	0	1 (0.7%)

表 2.7.6.18.3-2　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 10）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
振戦	0	1 (0.7%)
精神障害	1 (0.6%)	18 (11.8%)
錯乱状態	1 (0.6%)	0
攻撃性	0	1 (0.7%)
不安	0	1 (0.7%)
神経性過食症	0	1 (0.7%)
不快気分	0	1 (0.7%)
感情的苦悩	0	1 (0.7%)
幻覚	0	1 (0.7%)
不眠症	0	14 (9.2%)
神経過敏	0	2 (1.3%)
精神病性障害	0	1 (0.7%)
腎および尿路障害	8 (5.1%)	7 (4.6%)
腎不全	2 (1.3%)	1 (0.7%)

表 2.7.6.18.3-2　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 11）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
腎機能障害	2 (1.3%)	0
血尿	1 (0.6%)	0
乏尿	1 (0.6%)	0
急性腎不全	1 (0.6%)	2 (1.3%)
腎損傷	1 (0.6%)	0
失禁	0	1 (0.7%)
夜間頻尿	0	1 (0.7%)
慢性腎不全	0	1 (0.7%)
腹圧性尿失禁	0	1 (0.7%)
生殖系および乳房障害	1 (0.6%)	0
不正子宮出血	1 (0.6%)	0
呼吸器、胸郭および縦隔障害	17 (10.8%)	7 (4.6%)
呼吸困難	8 (5.1%)	3 (2.0%)
咳嗽	2 (1.3%)	0

表 2.7.6.18.3-2　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 12）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
湿性咳嗽	2 (1.3%)	0
労作性呼吸困難	1 (0.6%)	0
鼻出血	1 (0.6%)	2 (1.3%)
咽頭紅斑	1 (0.6%)	0
胸水	1 (0.6%)	0
肺うっ血	1 (0.6%)	0
肺塞栓症	1 (0.6%)	0
咽喉刺激感	1 (0.6%)	0
しゃっくり	0	1 (0.7%)
肺臓炎	0	1 (0.7%)
皮膚および皮下組織障害	7 (4.5%)	2 (1.3%)
発疹	2 (1.3%)	0
水疱	1 (0.6%)	0
紅斑	1 (0.6%)	1 (0.7%)
点状出血	1 (0.6%)	0

表 2.7.6.18.3-2　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 13）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
そう痒症	1 (0.6%)	0
皮膚潰瘍	1 (0.6%)	0
斑状出血	0	1 (0.7%)
血管障害	9 (5.7%)	4 (2.6%)
高血圧	7 (4.5%)	3 (2.0%)
ほてり	1 (0.6%)	0
低血圧	1 (0.6%)	0
潮紅	0	1 (0.7%)
Onyx Grouped Terms		
HLT_呼吸困難	9 (5.7%)	3 (2.0%)
呼吸困難	8 (5.1%)	3 (2.0%)
労作性呼吸困難	1 (0.6%)	0
HLT_ヘルペスウイルス感染	2 (1.3%)	2 (1.3%)

表 2.7.6.18.3-2　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 14）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
口腔ヘルペス	2 (1.3%)	0
ONX_帯状疱疹感染	0	2 (1.3%)
帯状疱疹	0	2 (1.3%)
ONX_好中球減少症	17 (10.8%)	18 (11.8%)
発熱性好中球減少症	3 (1.9%)	0
好中球減少症	11 (7.0%)	14 (9.2%)
好中球減少性敗血症	0	1 (0.7%)
好中球数減少	4 (2.5%)	4 (2.6%)
ONX_トランスアミナーゼ増加	5 (3.2%)	0
アラニンアミノトランスフェラーゼ増加	1 (0.6%)	0
アスパラギン酸アミノトランスフェラーゼ増加	2 (1.3%)	0
トランスアミナーゼ上昇	2 (1.3%)	0
SMQB_貧血	32 (20.4%)	16 (10.5%)

表 2.7.6.18.3-2　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 15）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
貧血	32 (20.4%)	16 (10.5%)
SMQB_心不全	12 (7.6%)	9 (5.9%)
浮腫	3 (1.9%)	4 (2.6%)
末梢性浮腫	4 (2.5%)	2 (1.3%)
肺うっ血	1 (0.6%)	0
SMQN_心不全	4 (2.5%)	3 (2.0%)
心不全	3 (1.9%)	0
うっ血性心不全	1 (0.6%)	3 (2.0%)
SMQB_虚血性心疾患	2 (1.3%)	0
SMQB_心筋梗塞	1 (0.6%)	0
トロポニンＴ増加	1 (0.6%)	0
SMQB_その他の虚血性心疾患	1 (0.6%)	0
狭心症	1 (0.6%)	0

表 2.7.6.18.3-2　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 16）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
SMQB_末梢性ニューロパチー	9 (5.7%)	0
筋緊張低下	1 (0.6%)	0
錯感覚	1 (0.6%)	0
SMQN_末梢性ニューロパチー	7 (4.5%)	0
末梢性感覚ニューロパチー	3 (1.9%)	0
末梢性ニューロパチー	2 (1.3%)	0
多発ニューロパチー	2 (1.3%)	0
軸索型ニューロパチー	1 (0.6%)	0
SMQB_血小板減少症	36 (22.9%)	17 (11.1%)
血小板数減少	3 (1.9%)	3 (2.0%)
血小板減少症	33 (21.0%)	14 (9.2%)
SMQN_急性腎不全	6 (3.8%)	3 (2.0%)
乏尿	1 (0.6%)	0
腎不全	2 (1.3%)	1 (0.7%)

表 2.7.6.18.3-2　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-011）（続き 17）

System Organ Class Preferred Term	Regimen C (N=157)	Regimen BSC (N=153)
急性腎不全	1 (0.6%)	2 (1.3%)
腎機能障害	2 (1.3%)	0
SMQN_不整脈	1 (0.6%)	1 (0.7%)
SMQN_不整脈用語（徐脈性不整脈および頻脈性不整脈を含む）	1 (0.6%)	1 (0.7%)
完全房室ブロック	1 (0.6%)	0
心房粗動	0	1 (0.7%)
SMQN_間質性肺疾患	0	1 (0.7%)
肺臓炎	0	1 (0.7%)

Regimen BSC=BSC arm; Regimen C= carfilzomib arm.
HLT = High Level Term; Onyx = Onyx defined grouping; SMQB = Standardized MedDRA Query, Broad scope; SMQN = Standardized MedDRA Query, Narrow scope.
Notes: MedDRA version 15.1 used for coding.
Treatment-related AEs are AEs considered related to at least one study drug by investigator, including AEs with missing relationship.
Subjects were counted only once for each System Organ Class and each Preferred Term.
All Grade = Any CTCAE grade, including missing.
出典［総括報告書 5.3.5.1-2（PX-171-011），Table 14.3.3.1］

2.7.6.18.4 ONO-7057-01

表 2.7.6.18.4-1　有害事象及び副作用の発現頻度（第Ⅰ相試験パート及び第Ⅱ相試験パート）（ONO-7057-01）

解析対象集団：SAF

	有害事象								副作用							
	登録時の用量						全体		登録時の用量						全体	
	15 mg/m^2		20 mg/m^2		20/27 mg/m^2				15 mg/m^2		20 mg/m^2		20/27 mg/m^2			
有害事象項目 （MedDRA による SOC・PT 分類）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）
N	4		6		40		50		4		6		40		50	
全体	4	(100.0)	6	(100.0)	40	(100.0)	50	(100.0)	3	(75.0)	5	(83.3)	39	(97.5)	47	(94.0)
血液およびリンパ系障害			1	(16.7)	13	(32.5)	14	(28.0)			1	(16.7)	12	(30.0)	13	(26.0)
貧血					12	(30.0)	12	(24.0)					12	(30.0)	12	(24.0)
鉄欠乏性貧血					1	(2.5)	1	(2.0)								
リンパ球減少症					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
血栓性微小血管症			1	(16.7)			1	(2.0)			1	(16.7)			1	(2.0)
心臓障害			1	(16.7)	4	(10.0)	5	(10.0)			1	(16.7)	4	(10.0)	5	(10.0)
第一度房室ブロック					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
うっ血性心不全					2	(5.0)	2	(4.0)					2	(5.0)	2	(4.0)
心筋症			1	(16.7)			1	(2.0)			1	(16.7)			1	(2.0)
動悸					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
耳および迷路障害	1	(25.0)	1	(16.7)	2	(5.0)	4	(8.0)			1	(16.7)	2	(5.0)	3	(6.0)
回転性めまい	1	(25.0)			2	(5.0)	3	(6.0)					2	(5.0)	2	(4.0)
耳不快感			1	(16.7)			1	(2.0)			1	(16.7)			1	(2.0)
眼障害			1	(16.7)	5	(12.5)	6	(12.0)			1	(16.7)	1	(2.5)	2	(4.0)
白内障					2	(5.0)	2	(4.0)								
結膜出血					1	(2.5)	1	(2.0)								
眼乾燥					1	(2.5)	1	(2.0)								
眼脂			1	(16.7)			1	(2.0)			1	(16.7)			1	(2.0)
眼充血			1	(16.7)	1	(2.5)	2	(4.0)			1	(16.7)	1	(2.5)	2	(4.0)

医師から報告された有害事象名は，MedDRA Version 17.0J を用いて読み替えた．

因果関係の判断基準：因果関係は，「明らかに関連あり」，「多分関連あり」，「関連ないともいえない」，「関連ありそうにない」，「関連なし」の 5 段階で評価され，「明らかに関連あり」，「多分関連あり」，「関連ないともいえない」と判定された場合，若しくは因果関係が不明な場合に，副作用として集計した．

表 2.7.6.18.4-1　有害事象及び副作用の発現頻度（第Ⅰ相試験パート及び第Ⅱ相試験パート）（ONO-7057-01）（続き 1）

解析対象集団：SAF

	有害事象								副作用							
	登録時の用量						全体		登録時の用量						全体	
	15 mg/m^2		20 mg/m^2		20/27 mg/m^2				15 mg/m^2		20 mg/m^2		20/27 mg/m^2			
有害事象項目 （MedDRA による SOC・PT 分類）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）
N	4		6		40		50		4		6		40		50	
羞明					1	(2.5)	1	(2.0)								
胃腸障害	2	(50.0)	3	(50.0)	18	(45.0)	23	(46.0)	1	(25.0)	2	(33.3)	15	(37.5)	18	(36.0)
腹部不快感	1	(25.0)					1	(2.0)								
腹部膨満			1	(16.7)	1	(2.5)	2	(4.0)					1	(2.5)	1	(2.0)
腹痛	1	(25.0)			1	(2.5)	2	(4.0)					1	(2.5)	1	(2.0)
上腹部痛	1	(25.0)			1	(2.5)	2	(4.0)	1	(25.0)			1	(2.5)	2	(4.0)
便秘			2	(33.3)	4	(10.0)	6	(12.0)			2	(33.3)	3	(7.5)	5	(10.0)
下痢	1	(25.0)			5	(12.5)	6	(12.0)					3	(7.5)	3	(6.0)
胃炎					2	(5.0)	2	(4.0)					1	(2.5)	1	(2.0)
腸管虚血			1	(16.7)			1	(2.0)								
悪心	1	(25.0)			8	(20.0)	9	(18.0)					7	(17.5)	7	(14.0)
口内炎			1	(16.7)	1	(2.5)	2	(4.0)					1	(2.5)	1	(2.0)
歯痛					2	(5.0)	2	(4.0)					1	(2.5)	1	(2.0)
上部消化管出血					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
嘔吐	1	(25.0)	1	(16.7)	3	(7.5)	5	(10.0)					2	(5.0)	2	(4.0)
腸壁気腫症			1	(16.7)			1	(2.0)								
門脈ガス血症			1	(16.7)			1	(2.0)								
一般・全身障害および投与部位の状態	3	(75.0)	3	(50.0)	17	(42.5)	23	(46.0)	2	(50.0)	3	(50.0)	15	(37.5)	20	(40.0)
胸痛					3	(7.5)	3	(6.0)					2	(5.0)	2	(4.0)
悪寒					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
疲労					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)

医師から報告された有害事象名は，MedDRA Version 17.0J を用いて読み替えた．

因果関係の判断基準：因果関係は，「明らかに関連あり」，「多分関連あり」，「関連ないともいえない」，「関連ありそうにない」，「関連なし」の 5 段階で評価され，「明らかに関連あり」，「多分関連あり」，「関連ないともいえない」と判定された場合，若しくは因果関係が不明な場合に，副作用として集計した．

表 2.7.6.18.4-1　有害事象及び副作用の発現頻度（第Ⅰ相試験パート及び第Ⅱ相試験パート）（ONO-7057-01）（続き 2）

解析対象集団：SAF

	有害事象								副作用							
	登録時の用量						全体		登録時の用量						全体	
	15 mg/m^2		20 mg/m^2		20/27 mg/m^2				15 mg/m^2		20 mg/m^2		20/27 mg/m^2			
有害事象項目 （MedDRA による SOC・PT 分類）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）
N	4		6		40		50		4		6		40		50	
注射部位反応					2	(5.0)	2	(4.0)					2	(5.0)	2	(4.0)
倦怠感	2	(50.0)	2	(33.3)	7	(17.5)	11	(22.0)	2	(50.0)	2	(33.3)	6	(15.0)	10	(20.0)
末梢性浮腫	1	(25.0)			2	(5.0)	3	(6.0)	1	(25.0)			2	(5.0)	3	(6.0)
疼痛	1	(25.0)	1	(16.7)	2	(5.0)	4	(8.0)			1	(16.7)	1	(2.5)	2	(4.0)
発熱			2	(33.3)	11	(27.5)	13	(26.0)			2	(33.3)	10	(25.0)	12	(24.0)
口渇					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
注入部位血管外漏出					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
肝胆道系障害			1	(16.7)	1	(2.5)	2	(4.0)			1	(16.7)			1	(2.0)
脂肪肝					1	(2.5)	1	(2.0)								
肝障害			1	(16.7)			1	(2.0)			1	(16.7)			1	(2.0)
感染症および寄生虫症	1	(25.0)	3	(50.0)	19	(47.5)	23	(46.0)	1	(25.0)			11	(27.5)	12	(24.0)
気管支肺炎					1	(2.5)	1	(2.0)								
歯肉炎	1	(25.0)			1	(2.5)	2	(4.0)	1	(25.0)					1	(2.0)
ヘルペスウイルス感染			1	(16.7)			1	(2.0)								
インフルエンザ					1	(2.5)	1	(2.0)								
鼻咽頭炎			1	(16.7)	10	(25.0)	11	(22.0)					6	(15.0)	6	(12.0)
咽頭炎	1	(25.0)			5	(12.5)	6	(12.0)					3	(7.5)	3	(6.0)
肺炎			1	(16.7)	1	(2.5)	2	(4.0)					1	(2.5)	1	(2.0)
ウイルス性肺炎					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
上気道感染					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
中咽頭カンジダ症			1	(16.7)			1	(2.0)								

医師から報告された有害事象名は，MedDRA Version 17.0J を用いて読み替えた．

因果関係の判断基準：因果関係は，「明らかに関連あり」，「多分関連あり」，「関連ないともいえない」，「関連ありそうにない」，「関連なし」の 5 段階で評価され，「明らかに関連あり」，「多分関連あり」，「関連ないともいえない」と判定された場合，若しくは因果関係が不明な場合に，副作用として集計した．

表 2.7.6.18.4-1　有害事象及び副作用の発現頻度（第Ⅰ相試験パート及び第Ⅱ相試験パート）（ONO-7057-01）（続き 3）

解析対象集団：SAF

	有害事象								副作用							
	登録時の用量						全体		登録時の用量						全体	
	15 mg/m^2		20 mg/m^2		20/27 mg/m^2				15 mg/m^2		20 mg/m^2		20/27 mg/m^2			
有害事象項目 （MedDRA による SOC・PT 分類）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）
N	4		6		40		50		4		6		40		50	
ブドウ球菌感染			1	(16.7)			1	(2.0)								
感染性腸炎					1	(2.5)	1	(2.0)								
口唇感染					1	(2.5)	1	(2.0)								
傷害、中毒および処置合併症	1	(25.0)	2	(33.3)	4	(10.0)	7	(14.0)			1	(16.7)			1	(2.0)
転倒					1	(2.5)	1	(2.0)								
肋骨骨折			1	(16.7)			1	(2.0)								
挫傷					2	(5.0)	2	(4.0)								
注入に伴う反応	1	(25.0)	1	(16.7)			2	(4.0)			1	(16.7)			1	(2.0)
舌損傷			1	(16.7)			1	(2.0)								
外傷性肺損傷			1	(16.7)			1	(2.0)								
各種物質毒性					1	(2.5)	1	(2.0)								
臨床検査	4	(100.0)	6	(100.0)	40	(100.0)	50	(100.0)	3	(75.0)	4	(66.7)	38	(95.0)	45	(90.0)
活性化部分トロンボプラスチン時間延長			1	(16.7)	1	(2.5)	2	(4.0)			1	(16.7)			1	(2.0)
アラニンアミノトランスフェラーゼ増加			3	(50.0)	8	(20.0)	11	(22.0)			2	(33.3)	7	(17.5)	9	(18.0)
アミラーゼ増加					1	(2.5)	1	(2.0)								
アスパラギン酸アミノトランスフェラーゼ増加			4	(66.7)	9	(22.5)	13	(26.0)			2	(33.3)	8	(20.0)	10	(20.0)
好塩基球数減少			1	(16.7)			1	(2.0)			1	(16.7)			1	(2.0)
血中アルブミン減少	1	(25.0)	1	(16.7)	1	(2.5)	3	(6.0)	1	(25.0)	1	(16.7)	1	(2.5)	3	(6.0)
血中ビリルビン増加	1	(25.0)	3	(50.0)	1	(2.5)	5	(10.0)	1	(25.0)	2	(33.3)			3	(6.0)
血中カルシウム減少			1	(16.7)			1	(2.0)			1	(16.7)			1	(2.0)
血中カルシウム増加			1	(16.7)			1	(2.0)			1	(16.7)			1	(2.0)

医師から報告された有害事象名は，MedDRA Version 17.0J を用いて読み替えた．

因果関係の判断基準：因果関係は，「明らかに関連あり」，「多分関連あり」，「関連ないともいえない」，「関連ありそうにない」，「関連なし」の 5 段階で評価され，「明らかに関連あり」，「多分関連あり」，「関連ないともいえない」と判定された場合，若しくは因果関係が不明な場合に，副作用として集計した．

表 2.7.6.18.4-1　有害事象及び副作用の発現頻度（第Ⅰ相試験パート及び第Ⅱ相試験パート）（ONO-7057-01）（続き 4）

解析対象集団：SAF

	有害事象								副作用							
	登録時の用量						全体		登録時の用量						全体	
	15 mg/m^2		20 mg/m^2		20/27 mg/m^2				15 mg/m^2		20 mg/m^2		20/27 mg/m^2			
有害事象項目 （MedDRA による SOC・PT 分類）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）
N	4		6		40		50		4		6		40		50	
血中コレステロール減少			1	(16.7)			1	(2.0)								
血中コレステロール増加			2	(33.3)	1	(2.5)	3	(6.0)								
血中クレアチニン増加	2	(50.0)	2	(33.3)	15	(37.5)	19	(38.0)	2	(50.0)	2	(33.3)	13	(32.5)	17	(34.0)
血中フィブリノゲン増加					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
血中ブドウ糖増加	1	(25.0)			1	(2.5)	2	(4.0)					1	(2.5)	1	(2.0)
血中免疫グロブリンA増加			1	(16.7)			1	(2.0)								
血中乳酸脱水素酵素増加			4	(66.7)	12	(30.0)	16	(32.0)			2	(33.3)	12	(30.0)	14	(28.0)
血中マグネシウム増加			1	(16.7)			1	(2.0)								
血中カリウム増加			2	(33.3)	1	(2.5)	3	(6.0)			2	(33.3)	1	(2.5)	3	(6.0)
血圧上昇	2	(50.0)	2	(33.3)	3	(7.5)	7	(14.0)	2	(50.0)	1	(16.7)	1	(2.5)	4	(8.0)
血中ナトリウム減少			1	(16.7)			1	(2.0)			1	(16.7)			1	(2.0)
血中ナトリウム増加			1	(16.7)			1	(2.0)			1	(16.7)			1	(2.0)
血中尿素増加			3	(50.0)	8	(20.0)	11	(22.0)			2	(33.3)	8	(20.0)	10	(20.0)
血中尿酸減少			2	(33.3)			2	(4.0)								
血中尿酸増加			2	(33.3)	2	(5.0)	4	(8.0)			1	(16.7)	2	(5.0)	3	(6.0)
Ｃ－反応性蛋白増加			1	(16.7)	5	(12.5)	6	(12.0)					5	(12.5)	5	(10.0)
好酸球数減少			1	(16.7)			1	(2.0)			1	(16.7)			1	(2.0)
好酸球数増加					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
γ－グルタミルトランスフェラーゼ増加			1	(16.7)	1	(2.5)	2	(4.0)					1	(2.5)	1	(2.0)
尿中ブドウ糖陽性			1	(16.7)			1	(2.0)			1	(16.7)			1	(2.0)
ヘマトクリット減少			2	(33.3)	5	(12.5)	7	(14.0)			2	(33.3)	5	(12.5)	7	(14.0)

医師から報告された有害事象名は，MedDRA Version 17.0J を用いて読み替えた．

因果関係の判断基準：因果関係は，「明らかに関連あり」，「多分関連あり」，「関連ないともいえない」，「関連ありそうにない」，「関連なし」の 5 段階で評価され，「明らかに関連あり」，「多分関連あり」，「関連ないともいえない」と判定された場合，若しくは因果関係が不明な場合に，副作用として集計した．

表 2.7.6.18.4-1　有害事象及び副作用の発現頻度（第Ⅰ相試験パート及び第Ⅱ相試験パート）（ONO-7057-01）（続き 5）

解析対象集団：SAF

	有害事象								副作用							
	登録時の用量						全体		登録時の用量						全体	
	15 mg/m^2		20 mg/m^2		20/27 mg/m^2				15 mg/m^2		20 mg/m^2		20/27 mg/m^2			
有害事象項目 （MedDRA による SOC・PT 分類）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）
N	4		6		40		50		4		6		40		50	
尿中血陽性			1	(16.7)	2	(5.0)	3	(6.0)			1	(16.7)	2	(5.0)	3	(6.0)
ヘモグロビン減少	1	(25.0)	2	(33.3)	17	(42.5)	20	(40.0)	1	(25.0)	2	(33.3)	17	(42.5)	20	(40.0)
国際標準比増加			1	(16.7)	1	(2.5)	2	(4.0)			1	(16.7)			1	(2.0)
リンパ球数減少	3	(75.0)	6	(100.0)	33	(82.5)	42	(84.0)	2	(50.0)	3	(50.0)	31	(77.5)	36	(72.0)
リンパ球数増加					1	(2.5)	1	(2.0)								
単球数減少			1	(16.7)	1	(2.5)	2	(4.0)			1	(16.7)	1	(2.5)	2	(4.0)
単球数増加					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
好中球数減少	3	(75.0)	2	(33.3)	23	(57.5)	28	(56.0)	2	(50.0)	1	(16.7)	23	(57.5)	26	(52.0)
好中球数増加			2	(33.3)	7	(17.5)	9	(18.0)								
血小板数減少			4	(66.7)	30	(75.0)	34	(68.0)			2	(33.3)	30	(75.0)	32	(64.0)
総蛋白減少			1	(16.7)			1	(2.0)			1	(16.7)			1	(2.0)
プロトロンビン時間延長			1	(16.7)			1	(2.0)			1	(16.7)			1	(2.0)
赤血球数減少	1	(25.0)	2	(33.3)	4	(10.0)	7	(14.0)	1	(25.0)	2	(33.3)	4	(10.0)	7	(14.0)
網状赤血球数減少			1	(16.7)			1	(2.0)			1	(16.7)			1	(2.0)
網状赤血球数増加					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
体重減少	1	(25.0)			5	(12.5)	6	(12.0)	1	(25.0)			3	(7.5)	4	(8.0)
体重増加					3	(7.5)	3	(6.0)					3	(7.5)	3	(6.0)
白血球数減少	2	(50.0)	2	(33.3)	21	(52.5)	25	(50.0)	1	(25.0)	1	(16.7)	20	(50.0)	22	(44.0)
白血球数増加	1	(25.0)	3	(50.0)	11	(27.5)	15	(30.0)	1	(25.0)	1	(16.7)	4	(10.0)	6	(12.0)
血中リン減少			1	(16.7)			1	(2.0)			1	(16.7)			1	(2.0)
血中リン増加	1	(25.0)	1	(16.7)	2	(5.0)	4	(8.0)	1	(25.0)	1	(16.7)	2	(5.0)	4	(8.0)

医師から報告された有害事象名は，MedDRA Version 17.0J を用いて読み替えた．

因果関係の判断基準：因果関係は，「明らかに関連あり」，「多分関連あり」，「関連ないともいえない」，「関連ありそうにない」，「関連なし」の 5 段階で評価され，「明らかに関連あり」，「多分関連あり」，「関連ないともいえない」と判定された場合，若しくは因果関係が不明な場合に，副作用として集計した．

表 2.7.6.18.4-1　有害事象及び副作用の発現頻度（第Ⅰ相試験パート及び第Ⅱ相試験パート）（ONO-7057-01）（続き 6）

解析対象集団：SAF

	有害事象								副作用							
	登録時の用量						全体		登録時の用量						全体	
	15 mg/m^2		20 mg/m^2		20/27 mg/m^2				15 mg/m^2		20 mg/m^2		20/27 mg/m^2			
有害事象項目 （MedDRA による SOC・PT 分類）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）
N	4		6		40		50		4		6		40		50	
尿中蛋白陽性			1	(16.7)	1	(2.5)	2	(4.0)			1	(16.7)	1	(2.5)	2	(4.0)
グロブリン減少					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
トロポニンＴ増加					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
血中アルカリホスファターゼ増加			1	(16.7)	4	(10.0)	5	(10.0)			1	(16.7)	3	(7.5)	4	(8.0)
細胞マーカー増加					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
血中クレアチンホスホキナーゼ減少			1	(16.7)			1	(2.0)								
尿中ウロビリノーゲン増加					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
代謝および栄養障害	2	(50.0)	5	(83.3)	31	(77.5)	38	(76.0)	1	(25.0)	2	(33.3)	25	(62.5)	28	(56.0)
脱水					1	(2.5)	1	(2.0)								
高カルシウム血症					3	(7.5)	3	(6.0)					2	(5.0)	2	(4.0)
高コレステロール血症					1	(2.5)	1	(2.0)								
高血糖	2	(50.0)	4	(66.7)	9	(22.5)	15	(30.0)					2	(5.0)	2	(4.0)
高カリウム血症			1	(16.7)	6	(15.0)	7	(14.0)					5	(12.5)	5	(10.0)
高マグネシウム血症			1	(16.7)	2	(5.0)	3	(6.0)					1	(2.5)	1	(2.0)
高ナトリウム血症					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
高リン酸塩血症					2	(5.0)	2	(4.0)					1	(2.5)	1	(2.0)
高トリグリセリド血症			1	(16.7)			1	(2.0)								
高尿酸血症					4	(10.0)	4	(8.0)					4	(10.0)	4	(8.0)
低アルブミン血症			1	(16.7)	5	(12.5)	6	(12.0)			1	(16.7)	4	(10.0)	5	(10.0)
低カルシウム血症	1	(25.0)			2	(5.0)	3	(6.0)	1	(25.0)			1	(2.5)	2	(4.0)
低コレステロール血症					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)

医師から報告された有害事象名は，MedDRA Version 17.0J を用いて読み替えた．
因果関係の判断基準：因果関係は，「明らかに関連あり」，「多分関連あり」，「関連ないともいえない」，「関連ありそうにない」，「関連なし」の 5 段階で評価され，
「明らかに関連あり」，「多分関連あり」，「関連ないともいえない」と判定された場合，若しくは因果関係が不明な場合に，副作用として集計した．

表 2.7.6.18.4-1　有害事象及び副作用の発現頻度（第Ⅰ相試験パート及び第Ⅱ相試験パート）（ONO-7057-01）（続き 7）

解析対象集団：SAF

	有害事象								副作用							
	登録時の用量						全体		登録時の用量						全体	
	15 mg/m^2		20 mg/m^2		20/27 mg/m^2				15 mg/m^2		20 mg/m^2		20/27 mg/m^2			
有害事象項目 （MedDRA による SOC・PT 分類）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）
N	4		6		40		50		4		6		40		50	
低血糖症					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
低カリウム血症					2	(5.0)	2	(4.0)					1	(2.5)	1	(2.0)
低ナトリウム血症			1	(16.7)	6	(15.0)	7	(14.0)					4	(10.0)	4	(8.0)
低リン酸血症			1	(16.7)	16	(40.0)	17	(34.0)					16	(40.0)	16	(32.0)
腫瘍崩壊症候群					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
食欲減退	1	(25.0)	1	(16.7)	3	(7.5)	5	(10.0)	1	(25.0)	1	(16.7)	2	(5.0)	4	(8.0)
筋骨格系および結合組織障害	1	(25.0)	1	(16.7)	8	(20.0)	10	(20.0)					3	(7.5)	3	(6.0)
関節痛					2	(5.0)	2	(4.0)								
関節炎	1	(25.0)					1	(2.0)								
背部痛			1	(16.7)	2	(5.0)	3	(6.0)								
筋痙縮					2	(5.0)	2	(4.0)					2	(5.0)	2	(4.0)
筋力低下					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
筋肉痛					1	(2.5)	1	(2.0)								
顎骨壊死					1	(2.5)	1	(2.0)								
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）					2	(5.0)	2	(4.0)					1	(2.5)	1	(2.0)
形質細胞性骨髄腫					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
子宮平滑筋腫					1	(2.5)	1	(2.0)								
神経系障害	2	(50.0)	2	(33.3)	10	(25.0)	14	(28.0)			2	(33.3)	7	(17.5)	9	(18.0)
浮動性めまい			1	(16.7)			1	(2.0)								
頭痛	1	(25.0)			3	(7.5)	4	(8.0)					1	(2.5)	1	(2.0)
末梢性ニューロパチー			1	(16.7)	1	(2.5)	2	(4.0)			1	(16.7)	1	(2.5)	2	(4.0)

医師から報告された有害事象名は，MedDRA Version 17.0J を用いて読み替えた．
因果関係の判断基準：因果関係は，「明らかに関連あり」，「多分関連あり」，「関連ないともいえない」，「関連ありそうにない」，「関連なし」の 5 段階で評価され，
「明らかに関連あり」，「多分関連あり」，「関連ないともいえない」と判定された場合，若しくは因果関係が不明な場合に，副作用として集計した．

表 2.7.6.18.4-1　有害事象及び副作用の発現頻度（第Ⅰ相試験パート及び第Ⅱ相試験パート）（ONO-7057-01）（続き 8）

解析対象集団：SAF

	有害事象								副作用							
	登録時の用量						全体		登録時の用量						全体	
	15 mg/m^2		20 mg/m^2		20/27 mg/m^2				15 mg/m^2		20 mg/m^2		20/27 mg/m^2			
有害事象項目 （MedDRA による SOC・PT 分類）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）
N	4		6		40		50		4		6		40		50	
末梢性感覚ニューロパチー					5	(12.5)	5	(10.0)					5	(12.5)	5	(10.0)
傾眠	1	(25.0)					1	(2.0)								
脊髄圧迫					1	(2.5)	1	(2.0)								
くも膜下出血			1	(16.7)			1	(2.0)			1	(16.7)			1	(2.0)
三叉神経障害					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
感覚運動障害			1	(16.7)			1	(2.0)			1	(16.7)			1	(2.0)
精神障害	1	(25.0)	1	(16.7)	5	(12.5)	7	(14.0)					2	(5.0)	2	(4.0)
譫妄	1	(25.0)					1	(2.0)								
不眠症					4	(10.0)	4	(8.0)					2	(5.0)	2	(4.0)
落ち着きのなさ			1	(16.7)	1	(2.5)	2	(4.0)								
腎および尿路障害	1	(25.0)	1	(16.7)	4	(10.0)	6	(12.0)	1	(25.0)			4	(10.0)	5	(10.0)
頻尿	1	(25.0)					1	(2.0)	1	(25.0)					1	(2.0)
蛋白尿			1	(16.7)	4	(10.0)	5	(10.0)					4	(10.0)	4	(8.0)
生殖系および乳房障害					1	(2.5)	1	(2.0)								
子宮障害					1	(2.5)	1	(2.0)								
呼吸器、胸郭および縦隔障害	1	(25.0)	2	(33.3)	9	(22.5)	12	(24.0)	1	(25.0)	1	(16.7)	5	(12.5)	7	(14.0)
咳嗽					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
呼吸困難					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
しゃっくり					3	(7.5)	3	(6.0)								
胸水					2	(5.0)	2	(4.0)					1	(2.5)	1	(2.0)
上気道の炎症	1	(25.0)	2	(33.3)	2	(5.0)	5	(10.0)	1	(25.0)	1	(16.7)	1	(2.5)	3	(6.0)

医師から報告された有害事象名は，MedDRA Version 17.0J を用いて読み替えた．
因果関係の判断基準：因果関係は，「明らかに関連あり」，「多分関連あり」，「関連ないともいえない」，「関連ありそうにない」，「関連なし」の 5 段階で評価され，
「明らかに関連あり」，「多分関連あり」，「関連ないともいえない」と判定された場合，若しくは因果関係が不明な場合に，副作用として集計した．

表 2.7.6.18.4-1　有害事象及び副作用の発現頻度（第Ⅰ相試験パート及び第Ⅱ相試験パート）（ONO-7057-01）（続き 9）

解析対象集団：SAF

	有害事象								副作用							
	登録時の用量						全体		登録時の用量						全体	
	15 mg/m^2		20 mg/m^2		20/27 mg/m^2				15 mg/m^2		20 mg/m^2		20/27 mg/m^2			
有害事象項目 （MedDRA による SOC・PT 分類）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）	n	（%）
N	4		6		40		50		4		6		40		50	
口腔咽頭痛			1	(16.7)	1	(2.5)	2	(4.0)					1	(2.5)	1	(2.0)
皮膚および皮下組織障害	1	(25.0)	2	(33.3)	9	(22.5)	12	(24.0)					5	(12.5)	5	(10.0)
皮膚炎					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
水疱性皮膚炎					1	(2.5)	1	(2.0)								
皮膚乾燥			1	(16.7)	1	(2.5)	2	(4.0)					1	(2.5)	1	(2.0)
湿疹					2	(5.0)	2	(4.0)					1	(2.5)	1	(2.0)
そう痒症			1	(16.7)	5	(12.5)	6	(12.0)					2	(5.0)	2	(4.0)
蕁麻疹	1	(25.0)					1	(2.0)								
血管障害	1	(25.0)			9	(22.5)	10	(20.0)	1	(25.0)			9	(22.5)	10	(20.0)
高血圧					4	(10.0)	4	(8.0)					4	(10.0)	4	(8.0)
起立性低血圧	1	(25.0)					1	(2.0)	1	(25.0)					1	(2.0)
静脈炎					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
血管痛					2	(5.0)	2	(4.0)					2	(5.0)	2	(4.0)
血管炎					1	(2.5)	1	(2.0)					1	(2.5)	1	(2.0)
ほてり					2	(5.0)	2	(4.0)					2	(5.0)	2	(4.0)

医師から報告された有害事象名は，MedDRA Version 17.0J を用いて読み替えた．

因果関係の判断基準：因果関係は，「明らかに関連あり」，「多分関連あり」，「関連ないともいえない」，「関連ありそうにない」，「関連なし」の 5 段階で評価され，「明らかに関連あり」，「多分関連あり」，「関連ないともいえない」と判定された場合，若しくは因果関係が不明な場合に，副作用として集計した．

出典［総括報告書 5.3.5.2-1（ONO7057-01），表 14.3.1.1-4］

2.7.6.18.5 PX-171-001

表 2.7.6.18.5-1　全被験者での MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）

	Maximum NCI Severity					Total Subjects (N= 29)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	4 (13.8%)	11 (37.9%)	11 (37.9%)	3 (10.3%)	0 (0.0%)	29 (100%)
Subjects with No Treatment Emergent Adverse Events						0 (0.0%)
血液およびリンパ系障害	0 (0.0%)	1 (3.4%)	1 (3.4%)	2 (6.9%)	0 (0.0%)	4 (13.8%)
貧血	0 (0.0%)	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
発熱性好中球減少症	0 (0.0%)	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
白血球減少症	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
リンパ球減少症	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
好中球減少症	0 (0.0%)	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
汎血球減少症	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
血小板減少症	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)	0 (0.0%)	2 (6.9%)
心臓障害	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
動悸	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
耳および迷路障害	2 (6.9%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (10.3%)
耳出血	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
耳痛	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
耳漏	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
耳鳴	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
眼障害	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
眼瞼縁痂皮	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
霧視	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
胃腸障害	15 (51.7%)	6 (20.7%)	2 (6.9%)	0 (0.0%)	0 (0.0%)	23 (79.3%)
腹部膨満	1 (3.4%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
腹痛	2 (6.9%)	1 (3.4%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	4 (13.8%)
上腹部痛	1 (3.4%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
腹壁腫瘤	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
便秘	5 (17.2%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (20.7%)
下痢	7 (24.1%)	3 (10.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	10 (34.5%)
口内乾燥	3 (10.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (10.3%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-1　全被験者での MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 1）

	Maximum NCI Severity					Total Subjects (N= 29)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	4 (13.8%)	11 (37.9%)	11 (37.9%)	3 (10.3%)	0 (0.0%)	29 (100%)
Subjects with No Treatment Emergent Adverse Events						0 (0.0%)
胃腸障害 (continued)	15 (51.7%)	6 (20.7%)	2 (6.9%)	0 (0.0%)	0 (0.0%)	23 (79.3%)
消化不良	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
鼓腸	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
胃腸出血	0 (0.0%)	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
消化器痛	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
歯肉痛	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
舌痛	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
吐血	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
口腔内出血	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
悪心	11 (37.9%)	3 (10.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	14 (48.3%)
口腔浮腫	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
口腔内痛	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
口内炎	4 (13.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (13.8%)
嘔吐	2 (6.9%)	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (13.8%)
全身障害および投与局所様態	15 (51.7%)	5 (17.2%)	4 (13.8%)	0 (0.0%)	0 (0.0%)	24 (82.8%)
無力症	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
腋窩痛	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
胸部不快感	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
胸痛	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
悪寒	3 (10.3%)	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	4 (13.8%)
歩行困難	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
疾患進行	0 (0.0%)	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
疲労	10 (34.5%)	3 (10.3%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	14 (48.3%)
注入部位血管外漏出	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
注入部位疼痛	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
注射部位小水疱	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
非心臓性胸痛	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
末梢性浮腫	7 (24.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	7 (24.1%)
疼痛	1 (3.4%)	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	2 (6.9%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-1　全被験者での MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 2）

	Maximum NCI Severity					Total Subjects (N= 29)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	4 (13.8%)	11 (37.9%)	11 (37.9%)	3 (10.3%)	0 (0.0%)	29 (100%)
Subjects with No Treatment Emergent Adverse Events						0 (0.0%)
全身障害および投与局所様態	15 (51.7%)	5 (17.2%)	4 (13.8%)	0 (0.0%)	0 (0.0%)	24 (82.8%)
(continued)						
圧痕浮腫	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
発熱	5 (17.2%)	3 (10.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	8 (27.6%)
肝胆道系障害	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
肝腫大	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
感染症および寄生虫症	5 (17.2%)	3 (10.3%)	2 (6.9%)	0 (0.0%)	0 (0.0%)	10 (34.5%)
急性気管支炎	0 (0.0%)	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
蜂巣炎	1 (3.4%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
鼻咽頭炎	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
皮膚感染	0 (0.0%)	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
上気道感染	4 (13.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (13.8%)
尿路感染	0 (0.0%)	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
傷害、中毒および処置合併症	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
挫傷	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
処置による疼痛	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
臨床検査	5 (17.2%)	7 (24.1%)	3 (10.3%)	0 (0.0%)	0 (0.0%)	15 (51.7%)
アラニン・アミノトランスフェラーゼ増加	0 (0.0%)	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
アスパラギン酸アミノトランスフェラーゼ増加	1 (3.4%)	1 (3.4%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	3 (10.3%)
血中アルブミン減少	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
血中アルカリホスファターゼ増加	0 (0.0%)	1 (3.4%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
血中重炭酸塩減少	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
血中クレアチニン増加	2 (6.9%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (10.3%)
血中ブドウ糖増加	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
血中マグネシウム増加	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
血圧上昇	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-1　全被験者での MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 3）

	Maximum NCI Severity					Total Subjects (N= 29)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	4 (13.8%)	11 (37.9%)	11 (37.9%)	3 (10.3%)	0 (0.0%)	29 (100%)
Subjects with No Treatment Emergent Adverse Events						0 (0.0%)
臨床検査 (continued)	5 (17.2%)	7 (24.1%)	3 (10.3%)	0 (0.0%)	0 (0.0%)	15 (51.7%)
血中尿酸増加	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
心電図 QT 延長	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
心電図異常	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
ヘマトクリット減少	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
ヘモグロビン減少	0 (0.0%)	3 (10.3%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	4 (13.8%)
好中球数減少	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
血小板数減少	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
赤血球数減少	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
トロポニン増加	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
体重減少	1 (3.4%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
体重増加	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
代謝および栄養障害	5 (17.2%)	2 (6.9%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	8 (27.6%)
食欲不振	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
食欲減退	4 (13.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (13.8%)
電解質失調	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
高血糖	0 (0.0%)	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
高カリウム血症	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
低アルブミン血症	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
低カルシウム血症	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
低カリウム血症	3 (10.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (10.3%)
筋骨格系および結合組織障害	11 (37.9%)	4 (13.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	15 (51.7%)
関節痛	3 (10.3%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (13.8%)
背部痛	2 (6.9%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (10.3%)
骨病変	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
胸壁腫瘤	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
胸壁痛	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
側腹部痛	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-1　全被験者での MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 4）

	Maximum NCI Severity					Total Subjects (N= 29)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	4 (13.8%)	11 (37.9%)	11 (37.9%)	3 (10.3%)	0 (0.0%)	29 (100%)
Subjects with No Treatment Emergent Adverse Events						0 (0.0%)
筋骨格系および結合組織障害(continued)	11 (37.9%)	4 (13.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	15 (51.7%)
肢径部痛	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
関節滲出液	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
筋痛	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
頚部痛	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
四肢痛	3 (10.3%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (13.8%)
顎痛	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
肩部痛	2 (6.9%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (10.3%)
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）	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
形質細胞腫	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
神経系障害	14 (48.3%)	5 (17.2%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	20 (69.0%)
味覚消失	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
灼熱感	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
群発頭痛	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
浮動性めまい	2 (6.9%)	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (13.8%)
味覚異常	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
頭痛	7 (24.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	7 (24.1%)
感覚減退	5 (17.2%)	3 (10.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	8 (27.6%)
神経障害性疼痛	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
ニューロパシー	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
末梢性ニューロパシー	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
錯感覚	4 (13.8%)	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (20.7%)
副鼻腔炎に伴う頭痛	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
失神	0 (0.0%)	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	1 (3.4%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-1　全被験者での MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 5）

	Maximum NCI Severity					Total Subjects (N= 29)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	4 (13.8%)	11 (37.9%)	11 (37.9%)	3 (10.3%)	0 (0.0%)	29 (100%)
Subjects with No Treatment Emergent Adverse Events						0 (0.0%)
精神障害	5 (17.2%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (20.7%)
不安	3 (10.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (10.3%)
うつ病	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
不眠症	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
睡眠驚愕	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
腎および尿路障害	3 (10.3%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (13.8%)
排尿困難	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
血尿	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
排尿回数減少	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
頻尿	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
呼吸器、胸郭および縦隔障害	17 (58.6%)	0 (0.0%)	1 (3.4%)	1 (3.4%)	0 (0.0%)	19 (65.5%)
無呼吸	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
無気肺	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
咳嗽	8 (27.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	8 (27.6%)
呼吸困難	6 (20.7%)	0 (0.0%)	1 (3.4%)	1 (3.4%)	0 (0.0%)	8 (27.6%)
労作性呼吸困難	6 (20.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (20.7%)
鼻閉	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
咽頭紅斑	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
咽喉頭疼痛	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
後鼻漏	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
湿性咳嗽	3 (10.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (10.3%)
鼻漏	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
咽喉刺激感	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
喘鳴	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
皮膚および皮下組織障害	10 (34.5%)	4 (13.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	14 (48.3%)
水疱	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
皮膚乾燥	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-1　全被験者での MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 6）

	Maximum NCI Severity					Total Subjects (N= 29)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	4 (13.8%)	11 (37.9%)	11 (37.9%)	3 (10.3%)	0 (0.0%)	29 (100%)
Subjects with No Treatment Emergent Adverse Events						0 (0.0%)
皮膚および皮下組織障害 (continued)	10 (34.5%)	4 (13.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	14 (48.3%)
斑状出血	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
紅斑	3 (10.3%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (13.8%)
爪の障害	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
寝汗	3 (10.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (10.3%)
そう痒症	4 (13.8%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (17.2%)
発疹	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
全身性皮疹	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
そう痒性皮疹	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
皮膚病変	1 (3.4%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
血管障害	4 (13.8%)	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (20.7%)
高血圧	3 (10.3%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (13.8%)
低血圧	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
血栓性静脈炎	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

出典［総括報告書 5.3.5.2-2（PX-171-001），Table 14.3.1.2.1］

表 2.7.6.18.5-2　各用量コホートでの MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）

CARFILZOMIB DOSE - 1.2 mg/m²

	Maximum NCI Severity					Total Subjects (N= 3)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	0 (0.0%)	2 (66.7%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	3 (100%)
Subjects with No Treatment Emergent Adverse Events						0 (0.0%)
胃腸障害	0 (0.0%)	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
腹痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
下痢	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
悪心	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
口内炎	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
嘔吐	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
全身障害および投与局所様態	2 (66.7%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100%)
腋窩痛	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
疲労	3 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100%)
感染症および寄生虫症	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
上気道感染	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
傷害、中毒および処置合併症	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
処置による疼痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
臨床検査	0 (0.0%)	2 (66.7%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	3 (100%)
アラニン・アミノトランスフェラーゼ増加	0 (0.0%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
アスパラギン酸アミノトランスフェラーゼ増加	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
血中アルブミン減少	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
血中アルカリホスファターゼ増加	0 (0.0%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
血中重炭酸塩減少	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
血中クレアチニン増加	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
ヘマトクリット減少	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
ヘモグロビン減少	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
代謝および栄養障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
食欲減退	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
電解質失調	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-2　各用量コホートでの MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 1）

CARFILZOMIB DOSE - 1.2 mg/m²

	Maximum NCI Severity					Total Subjects (N= 3)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	0 (0.0%)	2 (66.7%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	3 (100%)
Subjects with No Treatment Emergent Adverse Events						0 (0.0%)
筋骨格系および結合組織障害	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
背部痛	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
側腹部痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
神経系障害	2 (66.7%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100%)
群発頭痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
浮動性めまい	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
感覚減退	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
神経障害性疼痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
腎および尿路障害	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
排尿困難	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
血尿	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
呼吸器、胸郭および縦隔障害	3 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100%)
咳嗽	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
呼吸困難	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
労作性呼吸困難	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
皮膚および皮下組織障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
皮膚乾燥	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
血管障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
低血圧	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-2　各用量コホートでの MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 2）

CARFILZOMIB DOSE - 2.4 mg/m²

	Maximum NCI Severity					Total Subjects (N= 3)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	0 (0.0%)	1 (33.3%)	2 (66.7%)	0 (0.0%)	0 (0.0%)	3 (100%)
Subjects with No Treatment Emergent Adverse Events						0 (0.0%)
胃腸障害	3 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100%)
便秘	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
下痢	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
歯肉痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
口内炎	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
全身障害および投与局所様態	2 (66.7%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	3 (100%)
胸痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
疲労	1 (33.3%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
非心臓性胸痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
発熱	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
感染症および寄生虫症	0 (0.0%)	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
急性気管支炎	0 (0.0%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
蜂巣炎	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
臨床検査	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
血中ブドウ糖増加	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
心電図 QT 延長	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
心電図異常	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
体重減少	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
代謝および栄養障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
食欲減退	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
筋骨格系および結合組織障害	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
関節痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
背部痛	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
四肢痛	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-2　各用量コホートでの MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 3）

CARFILZOMIB DOSE - 2.4 mg/m²

	Maximum NCI Severity					Total Subjects (N= 3)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	0 (0.0%)	1 (33.3%)	2 (66.7%)	0 (0.0%)	0 (0.0%)	3 (100%)
Subjects with No Treatment Emergent Adverse Events						0 (0.0%)
神経系障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
頭痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
精神障害	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
うつ病	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
不眠症	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
睡眠驚愕	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
腎および尿路障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
頻尿	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
呼吸器、胸郭および縦隔障害	2 (66.7%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	3 (100%)
咳嗽	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
呼吸困難	0 (0.0%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
労作性呼吸困難	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
後鼻漏	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
湿性咳嗽	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
喘鳴	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
皮膚および皮下組織障害	1 (33.3%)	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100%)
そう痒症	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
発疹	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
全身性皮疹	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
血管障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
高血圧	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-2　各用量コホートでの MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 4）

CARFILZOMIB DOSE - 4.0 mg/m²

	Maximum NCI Severity					Total Subjects (N= 3)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	0 (0.0%)	0 (0.0%)	3 (100%)	0 (0.0%)	0 (0.0%)	3 (100%)
Subjects with No Treatment Emergent Adverse Events						0 (0.0%)
眼障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
眼瞼縁痂皮	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
霧視	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
胃腸障害	2 (66.7%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	3 (100%)
腹部膨満	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
腹痛	0 (0.0%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
上腹部痛	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
便秘	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
下痢	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
悪心	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
全身障害および投与局所様態	2 (66.7%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100%)
疲労	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
末梢性浮腫	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
発熱	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
感染症および寄生虫症	0 (0.0%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
皮膚感染	0 (0.0%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
臨床検査	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
血中アルカリホスファターゼ増加	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
代謝および栄養障害	0 (0.0%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
食欲減退	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
高血糖	0 (0.0%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
筋骨格系および結合組織障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
頚部痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
肩部痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-2　各用量コホートでの MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 5）

CARFILZOMIB DOSE - 4.0 mg/m²

	Maximum NCI Severity					Total Subjects (N= 3)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	0 (0.0%)	0 (0.0%)	3 (100%)	0 (0.0%)	0 (0.0%)	3 (100%)
Subjects with No Treatment Emergent Adverse Events						0 (0.0%)
神経系障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
味覚消失	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
錯感覚	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
呼吸器、胸郭および縦隔障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
呼吸困難	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
皮膚および皮下組織障害	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
水疱	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
紅斑	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
そう痒症	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
皮膚病変	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-2　各用量コホートでの MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 6）

CARFILZOMIB DOSE - 6.0 mg/m²

	Maximum NCI Severity					Total Subjects (N= 3)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	2 (66.7%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100%)
Subjects with No Treatment Emergent Adverse Events						0 (0.0%)
胃腸障害	3 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100%)
上腹部痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
便秘	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
下痢	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
口内乾燥	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
口腔内出血	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
悪心	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
全身障害および投与局所様態	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
疲労	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
肝胆道系障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
肝腫大	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
臨床検査	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
ヘモグロビン減少	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
代謝および栄養障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
低カリウム血症	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
筋骨格系および結合組織障害	2 (66.7%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100%)
骨病変	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
胸壁痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
四肢痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
顎痛	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
肩部痛	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
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）	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
形質細胞腫	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-2　各用量コホートでの MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 7）

CARFILZOMIB DOSE - 6.0 mg/m²

	Maximum NCI Severity					Total Subjects (N= 3)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	2 (66.7%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100%)
Subjects with No Treatment Emergent Adverse Events						0 (0.0%)
神経系障害	3 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100%)
味覚異常	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
頭痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
感覚減退	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
ニューロパシー	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
錯感覚	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
精神障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
不安	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
呼吸器、胸郭および縦隔障害	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
咳嗽	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
呼吸困難	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
咽喉刺激感	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
皮膚および皮下組織障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
紅斑	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-2　各用量コホートでの MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 8）

CARFILZOMIB DOSE - 8.4 mg/m²

	Maximum NCI Severity					Total Subjects (N= 3)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	0 (0.0%)	2 (66.7%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	3 (100%)
Subjects with No Treatment Emergent Adverse Events						0 (0.0%)
心臓障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
動悸	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
耳および迷路障害	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
耳鳴	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
胃腸障害	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
便秘	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
口内乾燥	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
悪心	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
口腔内痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
全身障害および投与局所様態	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
疲労	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
末梢性浮腫	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
臨床検査	0 (0.0%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
血中クレアチニン増加	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
血中マグネシウム増加	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
ヘモグロビン減少	0 (0.0%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
好中球数減少	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
赤血球数減少	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
代謝および栄養障害	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
高カリウム血症	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
筋骨格系および結合組織障害	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
関節痛	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-2　各用量コホートでの MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 9）

CARFILZOMIB DOSE - 8.4 mg/m²

	Maximum NCI Severity					Total Subjects (N= 3)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	0 (0.0%)	2 (66.7%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	3 (100%)
Subjects with No Treatment Emergent Adverse Events						0 (0.0%)
神経系障害	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
浮動性めまい	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
頭痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
末梢性ニューロパシー	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
精神障害	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
不安	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
不眠症	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
呼吸器、胸郭および縦隔障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
咳嗽	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
労作性呼吸困難	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
咽喉頭疼痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
皮膚および皮下組織障害	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
寝汗	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
そう痒性皮疹	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
皮膚病変	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
血管障害	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
高血圧	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-2　各用量コホートでの MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）

（続き 10）

CARFILZOMIB DOSE - 11.0 mg/m²

	Maximum NCI Severity					Total Subjects (N= 3)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	1 (33.3%)	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	3 (100%)
Subjects with No Treatment Emergent Adverse Events						0 (0.0%)
胃腸障害	1 (33.3%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
腹痛	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
便秘	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
下痢	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
胃腸出血	0 (0.0%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
消化器痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
舌痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
悪心	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
口内炎	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
全身障害および投与局所様態	3 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100%)
疲労	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
注射部位小水疱	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
末梢性浮腫	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
感染症および寄生虫症	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
鼻咽頭炎	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
臨床検査	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
血中マグネシウム増加	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
代謝および栄養障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
食欲減退	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
神経系障害	0 (0.0%)	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
頭痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
感覚減退	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
錯感覚	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
副鼻腔炎に伴う頭痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-2　各用量コホートでの MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 11）

CARFILZOMIB DOSE - 11.0 mg/m²

	Maximum NCI Severity					Total Subjects (N= 3)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	1 (33.3%)	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	3 (100%)
Subjects with No Treatment Emergent Adverse Events						0 (0.0%)
呼吸器、胸郭および縦隔障害	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
無気肺	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
咳嗽	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
労作性呼吸困難	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
鼻閉	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
後鼻漏	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
皮膚および皮下組織障害	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
寝汗	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
そう痒症	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-2　各用量コホートでの MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 12）

CARFILZOMIB DOSE - 15.0 mg/m²

	Maximum NCI Severity					Total Subjects (N= 6)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	1 (16.7%)	2 (33.3%)	2 (33.3%)	1 (16.7%)	0 (0.0%)	6 (100%)
Subjects with No Treatment Emergent Adverse Events						0 (0.0%)
血液およびリンパ系障害	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	1 (16.7%)
貧血	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
血小板減少症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	1 (16.7%)
心臓障害	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
動悸	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
胃腸障害	4 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (66.7%)
腹部膨満	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
腹壁腫瘤	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
下痢	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
口内乾燥	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
鼓腸	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
悪心	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
口内炎	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
嘔吐	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (33.3%)
全身障害および投与局所様態	3 (50.0%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	5 (83.3%)
胸部不快感	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
悪寒	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (33.3%)
疲労	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
末梢性浮腫	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (33.3%)
疼痛	1 (16.7%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	2 (33.3%)
圧痕浮腫	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
発熱	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
感染症および寄生虫症	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (33.3%)
上気道感染	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (33.3%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-2　各用量コホートでの MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 13）

CARFILZOMIB DOSE - 15.0 mg/m²

	Maximum NCI Severity					Total Subjects (N= 6)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	1 (16.7%)	2 (33.3%)	2 (33.3%)	1 (16.7%)	0 (0.0%)	6 (100%)
Subjects with No Treatment Emergent Adverse Events						0 (0.0%)
臨床検査	1 (16.7%)	2 (33.3%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	4 (66.7%)
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%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
血圧上昇	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
ヘモグロビン減少	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
血小板数減少	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
体重減少	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
体重増加	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
代謝および栄養障害	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (33.3%)
食欲不振	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
低アルブミン血症	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
低カルシウム血症	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
低カリウム血症	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (33.3%)
筋骨格系および結合組織障害	4 (66.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (83.3%)
関節痛	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
胸壁腫瘤	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
関節滲出液	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
筋痛	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
四肢痛	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (33.3%)
肩部痛	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
神経系障害	4 (66.7%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	5 (83.3%)
頭痛	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (33.3%)
感覚減退	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
錯感覚	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
失神	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
腎および尿路障害	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
排尿回数減少	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-2　各用量コホートでの MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 14）

CARFILZOMIB DOSE - 15.0 mg/m²

	Maximum NCI Severity					Total Subjects (N= 6)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	1 (16.7%)	2 (33.3%)	2 (33.3%)	1 (16.7%)	0 (0.0%)	6 (100%)
Subjects with No Treatment Emergent Adverse Events						0 (0.0%)
呼吸器、胸郭および縦隔障害	3 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (50.0%)
無呼吸	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
咳嗽	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
呼吸困難	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
皮膚および皮下組織障害	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
爪の障害	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
血管障害	0 (0.0%)	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (33.3%)
高血圧	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
血栓性静脈炎	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-2　各用量コホートでの MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 15）

CARFILZOMIB DOSE - 20.0 mg/m²

	Maximum NCI Severity					Total Subjects (N= 5)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	0 (0.0%)	2 (40.0%)	1 (20.0%)	2 (40.0%)	0 (0.0%)	5 (100%)
Subjects with No Treatment Emergent Adverse Events						0 (0.0%)
血液およびリンパ系障害	0 (0.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	0 (0.0%)	3 (60.0%)
発熱性好中球減少症	0 (0.0%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
白血球減少症	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
リンパ球減少症	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
好中球減少症	0 (0.0%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
汎血球減少症	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
血小板減少症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	1 (20.0%)
耳および迷路障害	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (40.0%)
耳出血	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
耳痛	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
耳漏	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
胃腸障害	0 (0.0%)	4 (80.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (80.0%)
腹痛	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
下痢	0 (0.0%)	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (40.0%)
消化不良	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
吐血	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
悪心	2 (40.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (60.0%)
口腔浮腫	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
嘔吐	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
全身障害および投与局所様態	1 (20.0%)	2 (40.0%)	2 (40.0%)	0 (0.0%)	0 (0.0%)	5 (100%)
無力症	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
悪寒	1 (20.0%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	2 (40.0%)
歩行困難	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
疾患進行	0 (0.0%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
疲労	0 (0.0%)	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (40.0%)
注入部位血管外漏出	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
注入部位疼痛	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (40.0%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-2　各用量コホートでの MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 16）

CARFILZOMIB DOSE - 20.0 mg/m²

	Maximum NCI Severity					Total Subjects (N= 5)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	0 (0.0%)	2 (40.0%)	1 (20.0%)	2 (40.0%)	0 (0.0%)	5 (100%)
Subjects with No Treatment Emergent Adverse Events						0 (0.0%)
全身障害および投与局所様態 (continued)	1 (20.0%)	2 (40.0%)	2 (40.0%)	0 (0.0%)	0 (0.0%)	5 (100%)
末梢性浮腫	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
発熱	2 (40.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (60.0%)
感染症および寄生虫症	1 (20.0%)	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (60.0%)
蜂巣炎	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
上気道感染	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
尿路感染	0 (0.0%)	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (40.0%)
傷害、中毒および処置合併症	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
挫傷	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
臨床検査	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (40.0%)
アスパラギン酸アミノトランスフェラーゼ増加	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
血中クレアチニン増加	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
血中尿酸増加	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
血小板数減少	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
トロポニン増加	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
筋骨格系および結合組織障害	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
関節痛	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
胤径部痛	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
神経系障害	2 (40.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (60.0%)
灼熱感	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
浮動性めまい	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (40.0%)
頭痛	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
感覚減退	2 (40.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (60.0%)
錯感覚	1 (20.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (40.0%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-2　各用量コホートでの MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）

（続き 17）

CARFILZOMIB DOSE - 20.0 mg/m²

	Maximum NCI Severity					Total Subjects (N= 5)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	0 (0.0%)	2 (40.0%)	1 (20.0%)	2 (40.0%)	0 (0.0%)	5 (100%)
Subjects with No Treatment Emergent Adverse Events						0 (0.0%)
神経系障害 (continued)	2 (40.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (60.0%)
副鼻腔炎に伴う頭痛	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
精神障害	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
不安	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
呼吸器、胸郭および縦隔障害	3 (60.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	4 (80.0%)
咳嗽	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (40.0%)
呼吸困難	2 (40.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	3 (60.0%)
労作性呼吸困難	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
鼻閉	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
咽頭紅斑	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
湿性咳嗽	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (40.0%)
鼻漏	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
皮膚および皮下組織障害	2 (40.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (60.0%)
斑状出血	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
紅斑	1 (20.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (40.0%)
寝汗	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

出典［総括報告書 5.3.5.2-2（PX-171-001），Tables 14.3.1.2.2～14.3.1.2.9］

表 2.7.6.18.5-3　全被験者でのすべての治験薬との因果関係が否定できない有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）

	Maximum NCI Severity					Total Subjects (N= 29)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events Possibly or Probably Related to PR-171	9 (31.0%)	12 (41.4%)	6 (20.7%)	2 (6.9%)	0 (0.0%)	29 (100%)
血液およびリンパ系障害	0 (0.0%)	0 (0.0%)	2 (6.9%)	1 (3.4%)	0 (0.0%)	3 (10.3%)
貧血	0 (0.0%)	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
発熱性好中球減少症	0 (0.0%)	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
白血球減少症	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
好中球減少症	0 (0.0%)	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
汎血球減少症	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
血小板減少症	0 (0.0%)	0 (0.0%)	1 (3.4%)	1 (3.4%)	0 (0.0%)	2 (6.9%)
心臓障害	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
動悸	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
眼障害	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
眼瞼縁痂皮	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
霧視	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
胃腸障害	13 (44.8%)	5 (17.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	18 (62.1%)
便秘	5 (17.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (17.2%)
下痢	6 (20.7%)	3 (10.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	9 (31.0%)
口内乾燥	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
消化器痛	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
歯肉痛	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
悪心	9 (31.0%)	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	11 (37.9%)
口腔浮腫	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
口内炎	4 (13.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (13.8%)
嘔吐	2 (6.9%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (10.3%)
全身障害および投与局所様態	15 (51.7%)	4 (13.8%)	2 (6.9%)	0 (0.0%)	0 (0.0%)	21 (72.4%)
無力症	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
悪寒	1 (3.4%)	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
歩行困難	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-3　全被験者でのすべての治験薬との因果関係が否定できない有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 1）

	Maximum NCI Severity					Total Subjects (N= 29)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events Possibly or Probably Related to PR-171	9 (31.0%)	12 (41.4%)	6 (20.7%)	2 (6.9%)	0 (0.0%)	29 (100%)
全身障害および投与局所様態	15 (51.7%)	4 (13.8%)	2 (6.9%)	0 (0.0%)	0 (0.0%)	21 (72.4%)
(continued)						
疲労	7 (24.1%)	3 (10.3%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	11 (37.9%)
注入部位血管外漏出	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
注入部位疼痛	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
注射部位小水疱	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
末梢性浮腫	6 (20.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (20.7%)
疼痛	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
発熱	5 (17.2%)	3 (10.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	8 (27.6%)
肝胆道系障害	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
肝腫大	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
感染症および寄生虫症	1 (3.4%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
蜂巣炎	1 (3.4%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
傷害、中毒および処置合併症	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
挫傷	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
臨床検査	4 (13.8%)	5 (17.2%)	2 (6.9%)	0 (0.0%)	0 (0.0%)	11 (37.9%)
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%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
血中アルブミン減少	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
血中アルカリホスファターゼ増加	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
血中重炭酸塩減少	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
血中クレアチニン増加	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
血中ブドウ糖増加	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
血中マグネシウム増加	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
心電図 QT 延長	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
心電図異常	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
ヘマトクリット減少	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-3　全被験者でのすべての治験薬との因果関係が否定できない有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 2）

	Maximum NCI Severity					Total Subjects (N= 29)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events Possibly or Probably Related to PR-171	9 (31.0%)	12 (41.4%)	6 (20.7%)	2 (6.9%)	0 (0.0%)	29 (100%)
臨床検査 (continued)	4 (13.8%)	5 (17.2%)	2 (6.9%)	0 (0.0%)	0 (0.0%)	11 (37.9%)
ヘモグロビン減少	0 (0.0%)	3 (10.3%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	4 (13.8%)
好中球数減少	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
血小板数減少	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
赤血球数減少	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
トロポニン増加	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
体重減少	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
代謝および栄養障害	5 (17.2%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (20.7%)
食欲不振	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
食欲減退	3 (10.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (10.3%)
電解質失調	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
高カリウム血症	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
低カルシウム血症	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
低カリウム血症	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
筋骨格系および結合組織障害	4 (13.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (13.8%)
筋痛	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
頚部痛	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
四肢痛	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
肩部痛	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
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 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
形質細胞腫	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
神経系障害	13 (44.8%)	3 (10.3%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	17 (58.6%)
味覚消失	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
浮動性めまい	3 (10.3%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (13.8%)
頭痛	4 (13.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (13.8%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-3　全被験者でのすべての治験薬との因果関係が否定できない有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 3）

	Maximum NCI Severity					Total Subjects (N= 29)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events Possibly or Probably Related to PR-171	9 (31.0%)	12 (41.4%)	6 (20.7%)	2 (6.9%)	0 (0.0%)	29 (100%)
神経系障害 (continued)	13 (44.8%)	3 (10.3%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	17 (58.6%)
感覚減退	4 (13.8%)	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (20.7%)
神経障害性疼痛	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
ニューロパシー	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
錯感覚	4 (13.8%)	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (20.7%)
失神	0 (0.0%)	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
精神障害	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
不眠症	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
睡眠驚愕	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
腎および尿路障害	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
頻尿	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
呼吸器、胸郭および縦隔障害	8 (27.6%)	0 (0.0%)	0 (0.0%)	1 (3.4%)	0 (0.0%)	9 (31.0%)
咳嗽	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
呼吸困難	4 (13.8%)	0 (0.0%)	0 (0.0%)	1 (3.4%)	0 (0.0%)	5 (17.2%)
労作性呼吸困難	3 (10.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (10.3%)
皮膚および皮下組織障害	8 (27.6%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	9 (31.0%)
水疱	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
皮膚乾燥	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
紅斑	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
爪の障害	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
そう痒症	4 (13.8%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (17.2%)
全身性皮疹	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
皮膚病変	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)
血管障害	1 (3.4%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
高血圧	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-3　全被験者でのすべての治験薬との因果関係が否定できない有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 4）

	Maximum NCI Severity					Total Subjects (N= 29)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events Possibly or Probably Related to PR-171	9 (31.0%)	12 (41.4%)	6 (20.7%)	2 (6.9%)	0 (0.0%)	29 (100%)
血管障害 (continued)	1 (3.4%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)
血栓性静脈炎	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.4%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

出典［総括報告書 5.3.5.2-2（PX-171-001），Table 14.3.1.3.1］

表 2.7.6.18.5-4　各用量コホートでのすべての治験薬との因果関係が否定できない有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）

CARFILZOMIB DOSE - 1.2 mg/m²

	Maximum NCI Severity					Total Subjects (N= 3)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events Possibly or Probably Related to PR-171	0 (0.0%)	3 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100%)
胃腸障害	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
下痢	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
悪心	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
口内炎	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
嘔吐	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
全身障害および投与局所様態	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
疲労	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
臨床検査	0 (0.0%)	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
血中アルブミン減少	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
血中重炭酸塩減少	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
血中クレアチニン増加	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
ヘマトクリット減少	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
ヘモグロビン減少	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
代謝および栄養障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
食欲減退	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
電解質失調	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
神経系障害	2 (66.7%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100%)
浮動性めまい	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
感覚減退	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
神経障害性疼痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
呼吸器、胸郭および縦隔障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
呼吸困難	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
皮膚および皮下組織障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
皮膚乾燥	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-4　各用量コホートでのすべての治験薬との因果関係が否定できない有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 1）

CARFILZOMIB DOSE - 2.4 mg/m²

	Maximum NCI Severity					Total Subjects (N= 3)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events Possibly or Probably Related to PR-171	0 (0.0%)	2 (66.7%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	3 (100%)
胃腸障害	3 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100%)
便秘	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
歯肉痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
口内炎	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
全身障害および投与局所様態	2 (66.7%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	3 (100%)
疲労	1 (33.3%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
発熱	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
感染症および寄生虫症	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
蜂巣炎	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
臨床検査	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
血中ブドウ糖増加	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
心電図 QT 延長	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
心電図異常	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
代謝および栄養障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
食欲減退	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
神経系障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
頭痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
精神障害	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
不眠症	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
睡眠驚愕	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
腎および尿路障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
頻尿	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-4　各用量コホートでのすべての治験薬との因果関係が否定できない有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 2）

CARFILZOMIB DOSE - 2.4 mg/m²

	Maximum NCI Severity					Total Subjects (N= 3)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events Possibly or Probably Related to PR-171	0 (0.0%)	2 (66.7%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	3 (100%)
呼吸器、胸郭および縦隔障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
労作性呼吸困難	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
皮膚および皮下組織障害	2 (66.7%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100%)
そう痒症	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
全身性皮疹	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-4　各用量コホートでのすべての治験薬との因果関係が否定できない有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 3）

CARFILZOMIB DOSE - 4.0 mg/m²

	Maximum NCI Severity					Total Subjects (N= 3)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events Possibly or Probably Related to PR-171	2 (66.7%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100%)
眼障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
眼瞼縁痂皮	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
霧視	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
胃腸障害	2 (66.7%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100%)
便秘	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
下痢	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
悪心	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
全身障害および投与局所様態	2 (66.7%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100%)
疲労	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
末梢性浮腫	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
発熱	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
臨床検査	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
血中アルカリホスファターゼ増加	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
筋骨格系および結合組織障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
頚部痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
肩部痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
神経系障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
味覚消失	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
錯感覚	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
呼吸器、胸郭および縦隔障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
呼吸困難	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
皮膚および皮下組織障害	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
水疱	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-4　各用量コホートでのすべての治験薬との因果関係が否定できない有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 4）

CARFILZOMIB DOSE - 4.0 mg/m²

	Maximum NCI Severity					Total Subjects (N= 3)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events Possibly or Probably Related to PR-171	2 (66.7%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100%)
皮膚および皮下組織障害 (continued)	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
紅斑	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
そう痒症	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
皮膚病変	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-4　各用量コホートでのすべての治験薬との因果関係が否定できない有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 5）

CARFILZOMIB DOSE - 6.0 mg/m²

	Maximum NCI Severity					Total Subjects (N= 3)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events Possibly or Probably Related to PR-171	2 (66.7%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100%)
胃腸障害	3 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100%)
便秘	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
下痢	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
悪心	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
全身障害および投与局所様態	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
疲労	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
肝胆道系障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
肝腫大	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
臨床検査	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
ヘモグロビン減少	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
筋骨格系および結合組織障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
四肢痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
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）	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
形質細胞腫	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
神経系障害	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
感覚減退	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
ニューロパシー	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
錯感覚	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
呼吸器、胸郭および縦隔障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
咳嗽	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-4　各用量コホートでのすべての治験薬との因果関係が否定できない有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 6）

CARFILZOMIB DOSE - 8.4 mg/m²

	Maximum NCI Severity					Total Subjects (N= 3)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events Possibly or Probably Related to PR-171	1 (33.3%)	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	3 (100%)
心臓障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
動悸	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
胃腸障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
便秘	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
口内乾燥	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
悪心	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
全身障害および投与局所様態	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
疲労	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
末梢性浮腫	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
臨床検査	0 (0.0%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
血中マグネシウム増加	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
ヘモグロビン減少	0 (0.0%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
好中球数減少	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
赤血球数減少	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
代謝および栄養障害	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
高カリウム血症	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
神経系障害	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
浮動性めまい	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
頭痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
呼吸器、胸郭および縦隔障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
労作性呼吸困難	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
血管障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
高血圧	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-4　各用量コホートでのすべての治験薬との因果関係が否定できない有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）

（続き 7）

CARFILZOMIB DOSE - 11.0 mg/m²

	Maximum NCI Severity					Total Subjects (N= 3)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events Possibly or Probably Related to PR-171	2 (66.7%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100%)
胃腸障害	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
便秘	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
下痢	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
消化器痛	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
悪心	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
口内炎	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
全身障害および投与局所様態	3 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100%)
疲労	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
注射部位小水疱	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
末梢性浮腫	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
臨床検査	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
血中マグネシウム増加	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
代謝および栄養障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
食欲減退	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
神経系障害	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
錯感覚	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
皮膚および皮下組織障害	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
そう痒症	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-4　各用量コホートでのすべての治験薬との因果関係が否定できない有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 8）

CARFILZOMIB DOSE - 15.0 mg/m²

	Maximum NCI Severity					Total Subjects (N= 6)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events Possibly or Probably Related to PR-171	1 (16.7%)	2 (33.3%)	3 (50.0%)	0 (0.0%)	0 (0.0%)	6 (100%)
血液およびリンパ系障害	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
貧血	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
血小板減少症	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
心臓障害	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
動悸	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
胃腸障害	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
下痢	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
悪心	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
口内炎	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
嘔吐	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
全身障害および投与局所様態	3 (50.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (66.7%)
悪寒	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
疲労	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
末梢性浮腫	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (33.3%)
疼痛	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
発熱	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
臨床検査	0 (0.0%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	2 (33.3%)
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%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
ヘモグロビン減少	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
血小板数減少	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
体重減少	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
代謝および栄養障害	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (33.3%)
食欲不振	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
低カルシウム血症	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
低カリウム血症	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (33.3%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-4　各用量コホートでのすべての治験薬との因果関係が否定できない有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 9）

CARFILZOMIB DOSE - 15.0 mg/m²

	Maximum NCI Severity					Total Subjects (N= 6)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events Possibly or Probably Related to PR-171	1 (16.7%)	2 (33.3%)	3 (50.0%)	0 (0.0%)	0 (0.0%)	6 (100%)
筋骨格系および結合組織障害	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (33.3%)
筋痛	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
肩部痛	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
神経系障害	3 (50.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	4 (66.7%)
頭痛	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (33.3%)
錯感覚	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
失神	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
呼吸器、胸郭および縦隔障害	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
呼吸困難	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
皮膚および皮下組織障害	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
爪の障害	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
血管障害	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
血栓性静脈炎	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-4　各用量コホートでのすべての治験薬との因果関係が否定できない有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）（続き 10）

CARFILZOMIB DOSE - 20.0 mg/m²

	Maximum NCI Severity					Total Subjects (N= 5)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events Possibly or Probably Related to PR-171	1 (20.0%)	1 (20.0%)	1 (20.0%)	2 (40.0%)	0 (0.0%)	5 (100%)
血液およびリンパ系障害	0 (0.0%)	0 (0.0%)	1 (20.0%)	1 (20.0%)	0 (0.0%)	2 (40.0%)
発熱性好中球減少症	0 (0.0%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
白血球減少症	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
好中球減少症	0 (0.0%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
汎血球減少症	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
血小板減少症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	1 (20.0%)
胃腸障害	0 (0.0%)	3 (60.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (60.0%)
下痢	0 (0.0%)	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (40.0%)
悪心	1 (20.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (40.0%)
口腔浮腫	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
嘔吐	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
全身障害および投与局所様態	2 (40.0%)	2 (40.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	5 (100%)
無力症	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
悪寒	0 (0.0%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
歩行困難	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
疲労	0 (0.0%)	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (40.0%)
注入部位血管外漏出	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
注入部位疼痛	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (40.0%)
発熱	2 (40.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (60.0%)
感染症および寄生虫症	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
蜂巣炎	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
傷害、中毒および処置合併症	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
挫傷	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
臨床検査	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (40.0%)
血小板数減少	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.5-4　各用量コホートでのすべての治験薬との因果関係が否定できない有害事象（Grade 別）（安全性解析対象集団）（PX-171-001）

（続き 11）

CARFILZOMIB DOSE - 20.0 mg/m²

	Maximum NCI Severity					Total Subjects (N= 5)
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events Possibly or Probably Related to PR-171	1 (20.0%)	1 (20.0%)	1 (20.0%)	2 (40.0%)	0 (0.0%)	5 (100%)
臨床検査 (continued)	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (40.0%)
トロポニン増加	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
神経系障害	2 (40.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (60.0%)
浮動性めまい	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (40.0%)
感覚減退	2 (40.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (60.0%)
錯感覚	1 (20.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (40.0%)
呼吸器、胸郭および縦隔障害	2 (40.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	3 (60.0%)
呼吸困難	1 (20.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	2 (40.0%)
労作性呼吸困難	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
皮膚および皮下組織障害	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
紅斑	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

出典［総括報告書 5.3.5.2-2（PX-171-001）, Tables 14.3.1.3.2～14.3.1.3.9］

2.7.6.18.6 PX-171-002 part 1

表 2.7.6.18.6-1　MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-002 part 1）

	Maximum NCI Severity					Total Subjects N= 37
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	3 (8.1%)	8 (21.6%)	20 (54.1%)	6 (16.2%)	0 (0.0%)	37 (100%)
Subjects with No Treatment Emergent Adverse Events	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
血液およびリンパ系障害	1 (2.7%)	6 (16.2%)	9 (24.3%)	5 (13.5%)	0 (0.0%)	21 (56.8%)
貧血	1 (2.7%)	6 (16.2%)	8 (21.6%)	2 (5.4%)	0 (0.0%)	17 (45.9%)
発熱性好中球減少症	0 (0.0%)	1 (2.7%)	2 (5.4%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
過粘稠度症候群	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
白血球減少症	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
リンパ節痛	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
好中球減少症	0 (0.0%)	2 (5.4%)	2 (5.4%)	0 (0.0%)	0 (0.0%)	4 (10.8%)
汎血球減少症	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
血小板減少症	2 (5.4%)	0 (0.0%)	6 (16.2%)	4 (10.8%)	0 (0.0%)	12 (32.4%)
心臓障害	2 (5.4%)	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (10.8%)
徐脈	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
心粗動	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
心拡大	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
洞性頻脈	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
頻脈	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
耳および迷路障害	3 (8.1%)	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	5 (13.5%)
ろう	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
耳痛	1 (2.7%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
耳鳴	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
回転性めまい	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
眼障害	7 (18.9%)	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	9 (24.3%)
白内障	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
眼乾燥	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
眼球突出症	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
眼痛	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
眼瞼刺激	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
眼瞼浮腫	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.6-1　MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-002 part 1）（続き 1）

	Maximum NCI Severity					Total Subjects N= 37
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	3 (8.1%)	8 (21.6%)	20 (54.1%)	6 (16.2%)	0 (0.0%)	37 (100%)
Subjects with No Treatment Emergent Adverse Events	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
眼障害 (continued)	7 (18.9%)	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	9 (24.3%)
眼充血	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
霧視	3 (8.1%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (10.8%)
胃腸障害	18 (48.6%)	7 (18.9%)	6 (16.2%)	0 (0.0%)	0 (0.0%)	31 (83.8%)
腹部膨満	0 (0.0%)	1 (2.7%)	2 (5.4%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
腹痛	3 (8.1%)	0 (0.0%)	2 (5.4%)	0 (0.0%)	0 (0.0%)	5 (13.5%)
上腹部痛	1 (2.7%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
口唇炎	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
便秘	9 (24.3%)	7 (18.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	16 (43.2%)
下痢	8 (21.6%)	1 (2.7%)	3 (8.1%)	0 (0.0%)	0 (0.0%)	12 (32.4%)
口内乾燥	3 (8.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
消化不良	2 (5.4%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
嚥下障害	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
心窩部不快感	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
変色便	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
歯肉出血	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
歯肉痛	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
歯肉炎	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
舌痛	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
鼠径ヘルニア	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
悪心	17 (45.9%)	4 (10.8%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	22 (59.5%)
口腔浮腫	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
膵炎	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
小腸閉塞	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
口内炎	3 (8.1%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (10.8%)
嘔吐	10 (27%)	3 (8.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	13 (35.1%)
全身障害および投与局所様態	10 (27%)	15 (40.5%)	6 (16.2%)	0 (0.0%)	0 (0.0%)	31 (83.8%)
医薬品副作用	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.6-1　MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-002 part 1）（続き 2）

	Maximum NCI Severity					Total Subjects N= 37
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	3 (8.1%)	8 (21.6%)	20 (54.1%)	6 (16.2%)	0 (0.0%)	37 (100%)
Subjects with No Treatment Emergent Adverse Events	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
全身障害および投与局所様態	10 (27%)	15 (40.5%)	6 (16.2%)	0 (0.0%)	0 (0.0%)	31 (83.8%)
(continued)						
無力症	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
カテーテル留置部位血腫	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
胸部不快感	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
悪寒	7 (18.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	7 (18.9%)
顔面浮腫	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
疲労	7 (18.9%)	8 (21.6%)	4 (10.8%)	0 (0.0%)	0 (0.0%)	19 (51.4%)
注入に関連した反応	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
注入部位疼痛	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
注射部位出血	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
倦怠感	0 (0.0%)	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
粘膜の炎症	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
非心臓性胸痛	1 (2.7%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
浮腫	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
末梢性浮腫	6 (16.2%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	7 (18.9%)
疼痛	1 (2.7%)	2 (5.4%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	4 (10.8%)
圧痕浮腫	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
発熱	9 (24.3%)	6 (16.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	15 (40.5%)
免疫系障害	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
薬物過敏症	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
感染症および寄生虫症	7 (18.9%)	8 (21.6%)	3 (8.1%)	2 (5.4%)	0 (0.0%)	20 (54.1%)
細気管支炎	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
気管支炎	0 (0.0%)	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
カンジダ症	3 (8.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
耳感染	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
毛包炎	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
せつ	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.6-1　MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-002 part 1）（続き 3）

	Maximum NCI Severity					Total Subjects N= 37
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	3 (8.1%)	8 (21.6%)	20 (54.1%)	6 (16.2%)	0 (0.0%)	37 (100%)
Subjects with No Treatment Emergent Adverse Events	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
感染症および寄生虫症 (continued)	7 (18.9%)	8 (21.6%)	3 (8.1%)	2 (5.4%)	0 (0.0%)	20 (54.1%)
単純ヘルペス	2 (5.4%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
帯状疱疹	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
口腔カンジダ症	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
肺炎	0 (0.0%)	1 (2.7%)	4 (10.8%)	0 (0.0%)	0 (0.0%)	5 (13.5%)
原発性異型肺炎	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
敗血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	1 (2.7%)
敗血症性ショック	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	1 (2.7%)
副鼻腔炎	2 (5.4%)	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	4 (10.8%)
ブドウ球菌感染	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
上気道感染	5 (13.5%)	5 (13.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	10 (27%)
尿路感染	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
傷害、中毒および処置合併症	1 (2.7%)	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
挫傷	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
転倒	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
肋骨骨折	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
臨床検査	6 (16.2%)	8 (21.6%)	9 (24.3%)	1 (2.7%)	0 (0.0%)	24 (64.9%)
アラニン・アミノトランスフェラーゼ増加	2 (5.4%)	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	4 (10.8%)
アスパラギン酸アミノトランスフェラーゼ増加	1 (2.7%)	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
心房性ナトリウム利尿ペプチド上昇	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
血中アミラーゼ増加	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
血中ビリルビン増加	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
血中クレアチニン増加	5 (13.5%)	3 (8.1%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	9 (24.3%)
血中マグネシウム減少	4 (10.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (10.8%)
血中リン減少	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
血中リン増加	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
血中カリウム減少	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
血圧上昇	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.6-1　MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-002 part 1）（続き 4）

	Maximum NCI Severity					Total Subjects N= 37
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	3 (8.1%)	8 (21.6%)	20 (54.1%)	6 (16.2%)	0 (0.0%)	37 (100%)
Subjects with No Treatment Emergent Adverse Events	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
臨床検査 (continued)	6 (16.2%)	8 (21.6%)	9 (24.3%)	1 (2.7%)	0 (0.0%)	24 (64.9%)
血中ナトリウム減少	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
血中尿素増加	3 (8.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
心電図 QT 補正間隔延長	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
γ－グルタミルトランスフェラーゼ増加	0 (0.0%)	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
糸球体濾過率減少	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
ヘマトクリット減少	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
ヘモグロビン減少	0 (0.0%)	1 (2.7%)	3 (8.1%)	0 (0.0%)	0 (0.0%)	4 (10.8%)
リパーゼ増加	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
リンパ球数増加	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
好中球数減少	0 (0.0%)	2 (5.4%)	1 (2.7%)	1 (2.7%)	0 (0.0%)	4 (10.8%)
酸素飽和度低下	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
血小板数減少	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
赤血球数減少	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
トランスアミナーゼ上昇	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
トロポニン I 増加	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
尿量減少	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
体重減少	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
体重増加	3 (8.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
白血球数減少	0 (0.0%)	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
代謝および栄養障害	6 (16.2%)	9 (24.3%)	7 (18.9%)	1 (2.7%)	0 (0.0%)	23 (62.2%)
食欲不振	7 (18.9%)	5 (13.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	12 (32.4%)
食欲減退	3 (8.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
脱水	3 (8.1%)	1 (2.7%)	3 (8.1%)	0 (0.0%)	0 (0.0%)	7 (18.9%)
水分過負荷	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
体液貯留	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
高カルシウム血症	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
高コレステロール血症	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
高血糖	3 (8.1%)	4 (10.8%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	8 (21.6%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.6-1　MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-002 part 1）（続き 5）

	Maximum NCI Severity					Total Subjects N= 37
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	3 (8.1%)	8 (21.6%)	20 (54.1%)	6 (16.2%)	0 (0.0%)	37 (100%)
Subjects with No Treatment Emergent Adverse Events	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
代謝および栄養障害 (continued)	6 (16.2%)	9 (24.3%)	7 (18.9%)	1 (2.7%)	0 (0.0%)	23 (62.2%)
高リン酸塩血症	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
高尿酸血症	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
低アルブミン血症	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
低カルシウム血症	2 (5.4%)	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	3 (8.1%)
低カリウム血症	1 (2.7%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
低マグネシウム血症	4 (10.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (10.8%)
低ナトリウム血症	2 (5.4%)	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	4 (10.8%)
低リン酸血症	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
筋骨格系および結合組織障害	11 (29.7%)	6 (16.2%)	4 (10.8%)	0 (0.0%)	0 (0.0%)	21 (56.8%)
関節痛	4 (10.8%)	2 (5.4%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	7 (18.9%)
背部痛	2 (5.4%)	1 (2.7%)	3 (8.1%)	0 (0.0%)	0 (0.0%)	6 (16.2%)
骨痛	3 (8.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
胸壁痛	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
側腹部痛	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
鼡径部痛	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
筋痙縮	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
筋骨格不快感	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
筋痛	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
四肢痛	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
顎痛	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
肩部痛	6 (16.2%)	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	8 (21.6%)
腱炎	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
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 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
脂肪腫	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
皮膚癌	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.6-1　MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-002 part 1）（続き 6）

	Maximum NCI Severity					Total Subjects N= 37
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	3 (8.1%)	8 (21.6%)	20 (54.1%)	6 (16.2%)	0 (0.0%)	37 (100%)
Subjects with No Treatment Emergent Adverse Events	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
神経系障害	10 (27%)	6 (16.2%)	3 (8.1%)	0 (0.0%)	0 (0.0%)	19 (51.4%)
浮動性めまい	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
頭痛	8 (21.6%)	3 (8.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	11 (29.7%)
感覚減退	0 (0.0%)	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
嗜眠	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
記憶障害	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
ニューロパシー	2 (5.4%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
末梢性ニューロパシー	2 (5.4%)	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (10.8%)
副鼻腔炎に伴う頭痛	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
傾眠	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
会話障害	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
脊髄圧迫	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
失神	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
言語刺激無反応	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
精神障害	8 (21.6%)	4 (10.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	12 (32.4%)
不安	5 (13.5%)	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	7 (18.9%)
うつ病	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
不眠症	6 (16.2%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	7 (18.9%)
精神状態変化	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
妄想症	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
腎および尿路障害	3 (8.1%)	4 (10.8%)	3 (8.1%)	0 (0.0%)	0 (0.0%)	10 (27%)
膀胱障害	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
膀胱痙縮	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
排尿困難	4 (10.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (10.8%)
腎不全	0 (0.0%)	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
急性腎不全	0 (0.0%)	2 (5.4%)	2 (5.4%)	0 (0.0%)	0 (0.0%)	4 (10.8%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.6-1　MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-002 part 1）（続き 7）

	Maximum NCI Severity					Total Subjects
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	N= 37
Subjects with Any Treatment Emergent Adverse Events	3 (8.1%)	8 (21.6%)	20 (54.1%)	6 (16.2%)	0 (0.0%)	37 (100%)
Subjects with No Treatment Emergent Adverse Events	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
呼吸器、胸郭および縦隔障害	13 (35.1%)	8 (21.6%)	4 (10.8%)	1 (2.7%)	0 (0.0%)	26 (70.3%)
気管支痙攣	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
咳嗽	11 (29.7%)	3 (8.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	14 (37.8%)
肺ラ音	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
咽喉乾燥	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
発声障害	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
呼吸困難	8 (21.6%)	3 (8.1%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	12 (32.4%)
呼吸困難増悪	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
労作性呼吸困難	4 (10.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (10.8%)
鼻出血	3 (8.1%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	4 (10.8%)
しゃっくり	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
低酸素症	0 (0.0%)	1 (2.7%)	1 (2.7%)	1 (2.7%)	0 (0.0%)	3 (8.1%)
鼻閉	5 (13.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (13.5%)
咽喉頭疼痛	4 (10.8%)	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (16.2%)
胸水	1 (2.7%)	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
後鼻漏	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
湿性咳嗽	3 (8.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
肺うっ血	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
肺高血圧症	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
肺水腫	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
気道うっ血	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
鼻漏	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
低音性連続性ラ音	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
副鼻腔うっ血	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
喘鳴	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
皮膚および皮下組織障害	10 (27%)	5 (13.5%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	16 (43.2%)
脱毛症	3 (8.1%)	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (13.5%)
冷汗	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
皮膚乾燥	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.6-1　MedDRA SOC 別及び PT 別のすべての有害事象（Grade 別）（安全性解析対象集団）（PX-171-002 part 1）（続き 8）

	Maximum NCI Severity					Total Subjects N= 37
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events	3 (8.1%)	8 (21.6%)	20 (54.1%)	6 (16.2%)	0 (0.0%)	37 (100%)
Subjects with No Treatment Emergent Adverse Events	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
皮膚および皮下組織障害 (continued)	10 (27%)	5 (13.5%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	16 (43.2%)
斑状出血	2 (5.4%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
多汗症	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
貧毛症	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
挫傷発生の増加傾向	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
寝汗	3 (8.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
皮膚疼痛	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
そう痒症	3 (8.1%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	4 (10.8%)
発疹	2 (5.4%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
全身性皮疹	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
そう痒性皮疹	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
皮膚変色	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
血管障害	2 (5.4%)	6 (16.2%)	3 (8.1%)	0 (0.0%)	0 (0.0%)	11 (29.7%)
動脈瘤	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
深部静脈血栓症	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
血腫	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
高血圧	2 (5.4%)	3 (8.1%)	2 (5.4%)	0 (0.0%)	0 (0.0%)	7 (18.9%)
低血圧	0 (0.0%)	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
起立性低血圧	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

出典［総括報告書 5.3.5.2-3（PX-171-002 part 1），Table 14.3.1.2.1］

表 2.7.6.18.6-2　すべての治験薬との因果関係が否定できない有害事象（Grade 別）（安全性解析対象集団）（PX-171-002 part 1）

	Maximum NCI Severity					
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	Total Subjects N= 37
Subjects with Any Treatment Emergent Adverse Events Possibly or Probably Related to Carfilzomib	7 (18.9%)	12 (32.4%)	10 (27%)	3 (8.1%)	0 (0.0%)	32 (86.5%)
血液およびリンパ系障害	2 (5.4%)	0 (0.0%)	5 (13.5%)	2 (5.4%)	0 (0.0%)	9 (24.3%)
貧血	1 (2.7%)	0 (0.0%)	2 (5.4%)	2 (5.4%)	0 (0.0%)	5 (13.5%)
発熱性好中球減少症	0 (0.0%)	0 (0.0%)	2 (5.4%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
白血球減少症	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
リンパ節痛	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
好中球減少症	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
汎血球減少症	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
血小板減少症	0 (0.0%)	0 (0.0%)	3 (8.1%)	1 (2.7%)	0 (0.0%)	4 (10.8%)
眼障害	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
眼乾燥	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
胃腸障害	17 (45.9%)	3 (8.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	20 (54.1%)
腹痛	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
口唇炎	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
便秘	2 (5.4%)	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (10.8%)
下痢	7 (18.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	7 (18.9%)
変色便	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
歯肉痛	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
歯肉炎	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
舌痛	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
悪心	13 (35.1%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	14 (37.8%)
膵炎	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
口内炎	3 (8.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
嘔吐	8 (21.6%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	9 (24.3%)
全身障害および投与局所様態	10 (27%)	9 (24.3%)	3 (8.1%)	0 (0.0%)	0 (0.0%)	22 (59.5%)
悪寒	6 (16.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (16.2%)
疲労	4 (10.8%)	5 (13.5%)	2 (5.4%)	0 (0.0%)	0 (0.0%)	11 (29.7%)
注入に関連した反応	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.6-2　すべての治験薬との因果関係が否定できない有害事象（Grade 別）（安全性解析対象集団）（PX-171-002 part 1）（続き 1）

	Maximum NCI Severity					Total Subjects N= 37
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events Possibly or Probably Related to Carfilzomib	7 (18.9%)	12 (32.4%)	10 (27%)	3 (8.1%)	0 (0.0%)	32 (86.5%)
全身障害および投与局所様態 (continued)	10 (27%)	9 (24.3%)	3 (8.1%)	0 (0.0%)	0 (0.0%)	22 (59.5%)
注入部位疼痛	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
倦怠感	0 (0.0%)	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
粘膜の炎症	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
非心臓性胸痛	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
浮腫	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
末梢性浮腫	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
発熱	6 (16.2%)	3 (8.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	9 (24.3%)
感染症および寄生虫症	1 (2.7%)	3 (8.1%)	1 (2.7%)	2 (5.4%)	0 (0.0%)	7 (18.9%)
細気管支炎	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
耳感染	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
単純ヘルペス	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
帯状疱疹	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
肺炎	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
敗血症	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	1 (2.7%)
敗血症性ショック	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	1 (2.7%)
副鼻腔炎	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
上気道感染	2 (5.4%)	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (10.8%)
尿路感染	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
臨床検査	5 (13.5%)	6 (16.2%)	4 (10.8%)	1 (2.7%)	0 (0.0%)	16 (43.2%)
アラニン・アミノトランスフェラーゼ増加	1 (2.7%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
アスパラギン酸アミノトランスフェラーゼ増加	0 (0.0%)	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
血中アミラーゼ増加	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
血中クレアチニン増加	3 (8.1%)	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (13.5%)
血中マグネシウム減少	3 (8.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
血中尿素増加	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
心電図 QT 補正間隔延長	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.6-2　すべての治験薬との因果関係が否定できない有害事象（Grade 別）（安全性解析対象集団）（PX-171-002 part 1）（続き 2）

	Maximum NCI Severity					Total Subjects
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	N= 37
Subjects with Any Treatment Emergent Adverse Events Possibly or Probably Related to Carfilzomib	7 (18.9%)	12 (32.4%)	10 (27%)	3 (8.1%)	0 (0.0%)	32 (86.5%)
臨床検査 (continued)	5 (13.5%)	6 (16.2%)	4 (10.8%)	1 (2.7%)	0 (0.0%)	16 (43.2%)
γ－グルタミルトランスフェラーゼ増加	0 (0.0%)	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
糸球体濾過率減少	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
リパーゼ増加	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
リンパ球数増加	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
好中球数減少	0 (0.0%)	2 (5.4%)	1 (2.7%)	1 (2.7%)	0 (0.0%)	4 (10.8%)
トロポニンＩ増加	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
体重減少	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
白血球数減少	0 (0.0%)	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
代謝および栄養障害	3 (8.1%)	3 (8.1%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	7 (18.9%)
食欲不振	2 (5.4%)	3 (8.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (13.5%)
食欲減退	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
脱水	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
低カルシウム血症	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
低カリウム血症	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
低マグネシウム血症	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
筋骨格系および結合組織障害	1 (2.7%)	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
関節痛	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
骨痛	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
筋痙縮	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
四肢痛	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
顎痛	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
神経系障害	6 (16.2%)	5 (13.5%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	12 (32.4%)
浮動性めまい	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
頭痛	2 (5.4%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
嗜眠	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
ニューロパシー	2 (5.4%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (8.1%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.6-2　すべての治験薬との因果関係が否定できない有害事象（Grade 別）（安全性解析対象集団）（PX-171-002 part 1）（続き 3）

	Maximum NCI Severity					Total Subjects N= 37
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events Possibly or Probably Related to Carfilzomib	7 (18.9%)	12 (32.4%)	10 (27%)	3 (8.1%)	0 (0.0%)	32 (86.5%)
神経系障害 (continued)	6 (16.2%)	5 (13.5%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	12 (32.4%)
末梢性ニューロパシー	2 (5.4%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
傾眠	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
会話障害	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
精神障害	3 (8.1%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (10.8%)
不眠症	3 (8.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
精神状態変化	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
腎および尿路障害	0 (0.0%)	2 (5.4%)	2 (5.4%)	0 (0.0%)	0 (0.0%)	4 (10.8%)
腎不全	0 (0.0%)	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
急性腎不全	0 (0.0%)	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
呼吸器、胸郭および縦隔障害	8 (21.6%)	2 (5.4%)	2 (5.4%)	1 (2.7%)	0 (0.0%)	13 (35.1%)
咳嗽	5 (13.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (13.5%)
呼吸困難	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
労作性呼吸困難	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
鼻出血	1 (2.7%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
低酸素症	0 (0.0%)	0 (0.0%)	1 (2.7%)	1 (2.7%)	0 (0.0%)	2 (5.4%)
鼻閉	2 (5.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
咽喉頭疼痛	3 (8.1%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (10.8%)
胸水	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
低音性連続性ラ音	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
皮膚および皮下組織障害	5 (13.5%)	3 (8.1%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	9 (24.3%)
脱毛症	2 (5.4%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
斑状出血	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
多汗症	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
貧毛症	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
そう痒症	2 (5.4%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	3 (8.1%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

表 2.7.6.18.6-2　すべての治験薬との因果関係が否定できない有害事象（Grade 別）（安全性解析対象集団）（PX-171-002 part 1）（続き 4）

	Maximum NCI Severity					Total Subjects N= 37
	Grade I	Grade II	Grade III	Grade IV	N/A[1]	
Subjects with Any Treatment Emergent Adverse Events Possibly or Probably Related to Carfilzomib	7 (18.9%)	12 (32.4%)	10 (27%)	3 (8.1%)	0 (0.0%)	32 (86.5%)
皮膚および皮下組織障害 (continued)	5 (13.5%)	3 (8.1%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	9 (24.3%)
発疹	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.4%)
全身性皮疹	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
そう痒性皮疹	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
皮膚変色	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
血管障害	1 (2.7%)	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	3 (8.1%)
高血圧	1 (2.7%)	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	3 (8.1%)

[1]Category N/A means NCI severity grade was not provided
Note: A subject experiencing more than one AE within a given MedDRA System Organ Class or Preferred Term is counted once within that MedDRA System Organ Class or Preferred Term, and at the highest observed severity grade.

出典［総括報告書 5.3.5.2-3（PX-171-002 part 1），Table 14.3.1.3.1］

2.7.6.18.7 PX-171-002 part 2

表 2.7.6.18.7-1　すべての有害事象の MedDRA SOC 別，PT 別発現頻度（Grade 別）（安全性解析対象集団）（PX-171-002 part 2）

	Number (%) of Subjects (N=11)					
		Maximum Severity				
System Organ Class Preferred Term[1]	Total	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Number of Subjects with at Least One TEAE[1]	11 (100.0)	0 (0.0)	2 (18.2)	6 (54.5)	1 (9.1)	2 (18.2)
血液およびリンパ系障害	9 (81.8)	1 (9.1)	3 (27.3)	4 (36.4)	1 (9.1)	0 (0.0)
貧血	8 (72.7)	0 (0.0)	3 (27.3)	5 (45.5)	0 (0.0)	0 (0.0)
血小板減少症	7 (63.6)	3 (27.3)	0 (0.0)	3 (27.3)	1 (9.1)	0 (0.0)
好中球減少症	3 (27.3)	2 (18.2)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
白血球減少症	2 (18.2)	2 (18.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
リンパ球減少症	1 (9.1)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
心臓障害	2 (18.2)	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
頻脈	2 (18.2)	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
眼障害	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
結膜充血	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
眼乾燥	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
胃腸障害	7 (63.6)	5 (45.5)	1 (9.1)	0 (0.0)	1 (9.1)	0 (0.0)
下痢	5 (45.5)	5 (45.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
悪心	3 (27.3)	3 (27.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
便秘	2 (18.2)	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
消化不良	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
食道痛	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
上部消化管出血	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)
嘔吐	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

[1] A subject with multiple severity ratings for a given AE was counted only once under the maximum severity.

表 2.7.6.18.7-1　すべての有害事象の MedDRA SOC 別，PT 別発現頻度（Grade 別）（安全性解析対象集団）（PX-171-002 part 2）（続き 1）

	Number (%) of Subjects (N=11)					
		Maximum Severity				
System Organ Class Preferred Term[1]	Total	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
全身障害および投与局所様態	7 (63.6)	0 (0.0)	5 (45.5)	1 (9.1)	0 (0.0)	1 (9.1)
疲労	5 (45.5)	1 (9.1)	4 (36.4)	0 (0.0)	0 (0.0)	0 (0.0)
末梢性浮腫	3 (27.3)	2 (18.2)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
発熱	3 (27.3)	1 (9.1)	2 (18.2)	0 (0.0)	0 (0.0)	0 (0.0)
悪寒	2 (18.2)	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
カテーテル留置部位疼痛	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
全身性浮腫	1 (9.1)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
注入部位紅斑	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
注入部位疼痛	1 (9.1)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
多臓器不全	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (9.1)
非心臓性胸痛	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
疼痛	1 (9.1)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
感染症および寄生虫症	7 (63.6)	1 (9.1)	5 (45.5)	1 (9.1)	0 (0.0)	0 (0.0)
上気道感染	2 (18.2)	0 (0.0)	2 (18.2)	0 (0.0)	0 (0.0)	0 (0.0)
尿路感染	2 (18.2)	0 (0.0)	2 (18.2)	0 (0.0)	0 (0.0)	0 (0.0)
気管支炎	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
包虫症	1 (9.1)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
真菌感染	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
感染	1 (9.1)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
肺感染	1 (9.1)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
鼻咽頭炎	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
傷害、中毒および処置合併症	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
転倒	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

[1] A subject with multiple severity ratings for a given AE was counted only once under the maximum severity.

表 2.7.6.18.7-1　すべての有害事象の MedDRA SOC 別，PT 別発現頻度（Grade 別）（安全性解析対象集団）（PX-171-002 part 2）（続き 2）

	Number (%) of Subjects (N=11)					
		Maximum Severity				
System Organ Class Preferred Term[1]	Total	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
臨床検査	5 (45.5)	3 (27.3)	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)
血中クレアチニン増加	3 (27.3)	2 (18.2)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
アラニン・アミノトランスフェラーゼ増加	1 (9.1)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
アスパラギン酸アミノトランスフェラーゼ増加	1 (9.1)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
血中アルカリホスファターゼ増加	1 (9.1)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
血中乳酸脱水素酵素増加	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
体温上昇	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
代謝および栄養障害	8 (72.7)	3 (27.3)	1 (9.1)	3 (27.3)	1 (9.1)	0 (0.0)
高カリウム血症	3 (27.3)	2 (18.2)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
低アルブミン血症	3 (27.3)	0 (0.0)	0 (0.0)	3 (27.3)	0 (0.0)	0 (0.0)
食欲減退	2 (18.2)	2 (18.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
高血糖	2 (18.2)	0 (0.0)	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)
高マグネシウム血症	2 (18.2)	2 (18.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
低カルシウム血症	2 (18.2)	0 (0.0)	0 (0.0)	1 (9.1)	1 (9.1)	0 (0.0)
低マグネシウム血症	2 (18.2)	1 (9.1)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
低ナトリウム血症	2 (18.2)	2 (18.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
低リン酸血症	2 (18.2)	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
食欲不振	1 (9.1)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
高ナトリウム血症	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
低血糖症	1 (9.1)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
低カリウム血症	1 (9.1)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)

[1] A subject with multiple severity ratings for a given AE was counted only once under the maximum severity.

表 2.7.6.18.7-1　すべての有害事象の MedDRA SOC 別，PT 別発現頻度（Grade 別）（安全性解析対象集団）（PX-171-002 part 2）（続き 3）

	Number (%) of Subjects (N=11)					
		Maximum Severity				
System Organ Class Preferred Term[1]	Total	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
筋骨格系および結合組織障害	2 (18.2)	0 (0.0)	0 (0.0)	2 (18.2)	0 (0.0)	0 (0.0)
関節痛	1 (9.1)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
骨痛	1 (9.1)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
胸壁痛	1 (9.1)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
骨溶解	1 (9.1)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
四肢痛	1 (9.1)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
病的骨折	1 (9.1)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)	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 (9.1)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
腫瘍熱	1 (9.1)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
神経系障害	3 (27.3)	1 (9.1)	2 (18.2)	0 (0.0)	0 (0.0)	0 (0.0)
頭痛	2 (18.2)	2 (18.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
固定姿勢保持困難	1 (9.1)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
脳症	1 (9.1)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
錯感覚	1 (9.1)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
精神障害	5 (45.5)	5 (45.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
不眠症	4 (36.4)	4 (36.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
錯乱状態	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

[1] A subject with multiple severity ratings for a given AE was counted only once under the maximum severity.

表 2.7.6.18.7-1　すべての有害事象の MedDRA SOC 別，PT 別発現頻度（Grade 別）（安全性解析対象集団）（PX-171-002 part 2）（続き 4）

	Number (%) of Subjects (N=11)					
		Maximum Severity				
System Organ Class Preferred Term[1]	Total	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
呼吸器、胸郭および縦隔障害	8 (72.7)	4 (36.4)	2 (18.2)	2 (18.2)	0 (0.0)	0 (0.0)
咳嗽	4 (36.4)	4 (36.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
呼吸困難	2 (18.2)	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
咽喉頭疼痛	2 (18.2)	2 (18.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
胸水	2 (18.2)	0 (0.0)	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)
発声障害	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
鼻出血	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
低酸素症	1 (9.1)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
鼻閉	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
後鼻漏	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
湿性咳嗽	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
鼻漏	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
上気道うっ血	1 (9.1)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
喘鳴	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
皮膚および皮下組織障害	3 (27.3)	2 (18.2)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
褥瘡性潰瘍	1 (9.1)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
貧毛症	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
挫傷発生の増加傾向	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
外科および内科処置	1 (9.1)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
副鼻腔ドレナージ	1 (9.1)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
血管障害	3 (27.3)	1 (9.1)	0 (0.0)	1 (9.1)	0 (0.0)	1 (9.1)
低血圧	2 (18.2)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (9.1)
深部静脈血栓症	1 (9.1)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)

[1] A subject with multiple severity ratings for a given AE was counted only once under the maximum severity.
出典［総括報告書 5.3.5.2-4（PX-171-002 part 2），Table 14.3.1.2.1］

表 2.7.6.18.7-2　治験薬との因果関係が否定できない有害事象の MedDRA SOC 別，PT 別発現頻度（Grade 別）（安全性解析対象集団）（PX-171-002 part 2）

	Number (%) of Subjects (N=11)				
		Maximum Severity			
System Organ Class Preferred Term[1]	Total	Grade 1	Grade 2	Grade 3	Grade 4
Number of Subjects with at Least One Related TEAE[l]	10 (90.9)	0 (0.0)	6 (54.5)	3 (27.3)	1 (9.1)
血液およびリンパ系障害	8 (72.7)	1 (9.1)	3 (27.3)	3 (27.3)	1 (9.1)
貧血	7 (63.6)	0 (0.0)	3 (27.3)	4 (36.4)	0 (0.0)
血小板減少症	6 (54.5)	3 (27.3)	0 (0.0)	2 (18.2)	1 (9.1)
好中球減少症	3 (27.3)	2 (18.2)	0 (0.0)	1 (9.1)	0 (0.0)
白血球減少症	2 (18.2)	2 (18.2)	0 (0.0)	0 (0.0)	0 (0.0)
心臓障害	1 (9.1)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
頻脈	1 (9.1)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
胃腸障害	5 (45.5)	4 (36.4)	1 (9.1)	0 (0.0)	0 (0.0)
悪心	3 (27.3)	3 (27.3)	0 (0.0)	0 (0.0)	0 (0.0)
下痢	2 (18.2)	2 (18.2)	0 (0.0)	0 (0.0)	0 (0.0)
便秘	1 (9.1)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
消化不良	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
食道痛	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
嘔吐	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
全身障害および投与局所様態	5 (45.5)	0 (0.0)	5 (45.5)	0 (0.0)	0 (0.0)
疲労	5 (45.5)	1 (9.1)	4 (36.4)	0 (0.0)	0 (0.0)
悪寒	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
注入部位紅斑	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
注入部位疼痛	1 (9.1)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
非心臓性胸痛	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)

[1] A subject with multiple severity ratings for a given AE was counted only once under the maximum severity.

表 2.7.6.18.7-2　治験薬との因果関係が否定できない有害事象の MedDRA SOC 別，PT 別発現頻度（Grade 別）（安全性解析対象集団）（PX-171-002 part 2）（続き 1）

	Number (%) of Subjects (N=11)				
		Maximum Severity			
System Organ Class Preferred Term[1]	Total	Grade 1	Grade 2	Grade 3	Grade 4
臨床検査	4 (36.4)	2 (18.2)	1 (9.1)	1 (9.1)	0 (0.0)
血中クレアチニン増加	3 (27.3)	2 (18.2)	1 (9.1)	0 (0.0)	0 (0.0)
アラニン・アミノトランスフェラーゼ増加	1 (9.1)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)
アスパラギン酸アミノトランスフェラーゼ増加	1 (9.1)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)
血中アルカリホスファターゼ増加	1 (9.1)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)
代謝および栄養障害	3 (27.3)	2 (18.2)	1 (9.1)	0 (0.0)	0 (0.0)
高カリウム血症	2 (18.2)	2 (18.2)	0 (0.0)	0 (0.0)	0 (0.0)
食欲不振	1 (9.1)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
食欲減退	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
低ナトリウム血症	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
低リン酸血症	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
神経系障害	3 (27.3)	2 (18.2)	1 (9.1)	0 (0.0)	0 (0.0)
頭痛	2 (18.2)	2 (18.2)	0 (0.0)	0 (0.0)	0 (0.0)
脳症	1 (9.1)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
精神障害	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
不眠症	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
呼吸器、胸郭および縦隔障害	2 (18.2)	1 (9.1)	0 (0.0)	1 (9.1)	0 (0.0)
呼吸困難	1 (9.1)	0 (0.0)	1 (9.1)	0 (0.0)	0 (0.0)
低酸素症	1 (9.1)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)
鼻閉	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)

[1] A subject with multiple severity ratings for a given AE was counted only once under the maximum severity.

表 2.7.6.18.7-2　治験薬との因果関係が否定できない有害事象の MedDRA SOC 別，PT 別発現頻度（Grade 別）（安全性解析対象集団）（PX-171-002 part 2）（続き 2）

	Number (%) of Subjects (N=11)				
		Maximum Severity			
System Organ Class Preferred Term[1]	Total	Grade 1	Grade 2	Grade 3	Grade 4
皮膚および皮下組織障害	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)
貧毛症	1 (9.1)	1 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)

[1] A subject with multiple severity ratings for a given AE was counted only once under the maximum severity.
出典［総括報告書 5.3.5.2-4（PX-171-002 part 2），Table 14.3.1.3.1］