## 表 2.7.4.7-35　重篤な有害事象の一覧表（PX-171-001）

| Subject ID | PR-171 Dose (mg/m²) | Disease Type | MedDRA System Organ Class/ MedDRA Preferred Term/ Verbatim Adverse Event | Onset Date (Day)/ Stop Date (Day) | Last Cycle/Day Prior to Onset | Duration (Day) | NCI Severity Grade* | Rel | Study Drug Action Taken | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1-03-[redacted] | 2.4 | HD | 感染症および寄生虫症/<br>急性気管支炎/<br>ACUTE BRONCHITIS | 23FEB20[redacted] (11)/<br>27FEB20[redacted] (15) | 1/5 | 5 | 3 | UNLIKELY | 1 | 3, 1 | 1 |
| 1-03-[redacted] | 4 | NHL | 胃腸障害/<br>腹痛/<br>ABDOMINAL PAIN | 05MAY20[redacted] (26)/<br>08MAY20[redacted] (29) | 2/5 | 4 | 3 | UNLIKELY | 5 | 3, 4 | 2 |
| 1-04-[redacted] | 4 | NHL | 感染症および寄生虫症/<br>皮膚感染/<br>INFECTIOUS CUTANEOUS SKIN LESION | 18APR20[redacted] (37)/<br>22APR20[redacted] (41) | 3/5 | 5 | 3 | UNLIKELY | 5 | 1, 3, 4 | 2 |
| 1-03-[redacted] | 11 | NHL | 胃腸障害/<br>胃腸出血/<br>GI BLEED | 22OCT20[redacted] (63)/<br>25OCT20[redacted] (66) | 4/5 | 4 | 3 | UNLIKELY | 5 | 3, 4 | 2 |
| 1-03-[redacted] | 20 | NHL | 血液およびリンパ系障害/<br>好中球減少症/<br>NEUTROPENIA | 10JAN20[redacted] (3)/<br>14JAN20[redacted] (7) | 1/2 | 5 | 3 | POSSIBLE | 3 | 1 | 1 |
| | | NHL | 血液およびリンパ系障害/<br>発熱性好中球減少症/<br>NEUTROPENIC FEVER | 11JAN20[redacted] (4)/<br>11JAN20[redacted] (4) | 1/3 | 1 | 3 | POSSIBLE | 3 | 1, 3 | 1 |

## 表 2.7.4.7-35　重篤な有害事象の一覧表（PX-171-001）（続き 1）

| Subject ID | PR-171 Dose (mg/m²) | Disease Type | MedDRA System Organ Class/ MedDRA Preferred Term/ Verbatim Adverse Event | Onset Date (Day)/ Stop Date (Day) | Last Cycle/Day Prior to Onset | Duration (Day) | NCI Severity Grade* | Rel | Study Drug Action Taken | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1-03-[redacted] | 20 | NHL | 全身障害および投与局所様態/<br>悪寒/<br>CHILLS | 11JAN20[redacted] (4)/<br>11JAN20[redacted] (4) | 1/3 | 1 | 3 | POSSIBLE | 3 | 1, 3 | 1 |
| 1-04-[redacted] | 20 | MM-S | 全身障害および投与局所様態/<br>疾患進行/<br>PROGRESSIVE CNS DISEASE | 30MAR20[redacted] (26)/<br>01APR20[redacted] (28) | 1/5 | 3 | 3 | NONE | 1 | 3, 4 | 2 |
| | | MM-S | 血液およびリンパ系障害/<br>血小板減少症/<br>THROMBOCYTOPENIA | 04APR20[redacted] (31)/<br>16APR20[redacted] (43) | 1/5 | 13 | 4 | NONE | 5 | 3, 4 | 3 |
| | | MM-S | 胃腸障害/<br>吐血/<br>HEMATEMESIS | 04APR20[redacted] (31)/<br>16APR20[redacted] (43) | 1/5 | 13 | 2 | NONE | 5 | 3, 5 | 3 |

DISEASE TYPE: MM-NS/S=MULTIPLE MYELOMA (NON-SECRETORY/SECRETORY), WM=WALDENSTROM'S MACROGLOBULINEMIA, NHL=NON-HODGKIN'S LYMPHOMA, HD=HODGKIN'S DISEASE
NOTE: LISTING OF SERIOUS ADVERSE EVENTS BASED ON THE AE CRF, RATHER THAN THE SAE NARRATIVE DATABASE
* IF NOT NCI GRADED, USE 1=MILD, 2=MODERATE, 3=SEVERE
STUDY DAY FOR TREATMENT-EMERGENT AES = ONSET (OR STOP) DATE - INITIAL STUDY ADMINISTRATION DATE + 1.
STUDY DAY FOR PRE-TREATMENT AES = ONSET (OR STOP) DATE - INITIAL STUDY ADMINISTRATION DATE.
NAV=NOT AVAILABLE, UNK=UNKNOWN
STUDY DRUG ACTION TAKEN: 1=NONE, 2=DOSE REDUCED, 3=TREATMENT INTERRUPTED, 4=TREATMENT DELAYED, 5=DISCONTINUED
OTHER ACTION TAKEN: 1=CONCOMITANT MEDICATION, 2=PROCEDURE REQUIRED, 3=HOSPITALIZATION, 4=PATIENT WITHDRAWN, 5=NONE
OUTCOME: 1=RESOLVED, 2=STABILIZED (NOT RESOLVED), 3=DEATH, 4=UNKNOWN/LOST TO FOLLOW-UP, 5=CONTINUING
MEDDRA VERSION: 8.1

出典［総括報告書5.3.5.2-2（PX-171-001），Listing 16.2.7.1］

**表 2.7.4.7-36　重篤な有害事象の一覧表（PX-171-003 part 1（A0））**

| Subject Number | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Serious | Severity (NCI Grade) | Study Drug Relation-ship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|---|
| 3-05-[redacted] | 筋骨格系および結合組織障害<br>骨痛<br>BONE PAIN (7) | 03FEB20[redacted] (63)<br>to<br>11FEB20[redacted] (71)<br>[9] | Yes | 4 | None | Treatment Permanently Discontinued | Hospitalization, Patient Withdrawn | Stabilized (Not Resolved) |
| | | | | | | | | |
| 3-05-[redacted] | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (1) | 11JAN20[redacted] (39)<br>to<br>23JAN20[redacted] (51)<br>[13] | Yes | 3 | Unlikely | Dose(S) Missed | Concomitant Medication | Resolved |
| | | | | | | | | |
| 3-05-[redacted] | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (42) | 11OCT20[redacted] (304)<br>to<br>17NOV20[redacted] (341)<br>[38] | Yes | 4 | None | None | Hospitalization, Concomitant Medication | Resolved |
| | 感染症および寄生虫症<br>菌血症<br>BACTEREMIA (43) | 11OCT20[redacted] (304)<br>to<br>17NOV20[redacted] (341)<br>[38] | Yes | 4 | None | None | Hospitalization, Concomitant Medication | Resolved |
| | | | | | | | | |
| 3-05-[redacted] | 心臓障害<br>心筋虚血<br>CARDIAC ISCHEMIA (1) | 16JAN20[redacted] (36)<br>to<br>05FEB20[redacted] (56)<br>[21] | Yes | 3 | Unlikely | Treatment Permanently Discontinued | Procedure Required, Hospitalization, Patient Withdrawn | Resolved |
| | | | | | | | | |
| 3-06-[redacted] | 全身障害および投与局所様態<br>非心臓性胸痛<br>CHEST PAIN (NON-CARDIAC) (1) | 24OCT20[redacted] (10)<br>to<br>05NOV20[redacted] (22)<br>[13] | Yes | 3 | None | Dose(S) Missed | Hospitalization | Resolved |
| | 呼吸器、胸郭および縦隔障害<br>呼吸困難<br>DIFFICULTY BREATHING (2) | 24OCT20[redacted] (10)<br>to<br>05NOV20[redacted] (22)<br>[13] | Yes | 3 | None | Dose(S) Missed | Hospitalization | Resolved |
| | 心臓障害<br>うっ血性心不全<br>CONGESTIVE HEART FAILURE (3) | 24NOV20[redacted] (41)<br>to<br>14DEC20[redacted] (61)<br>[21] | Yes | 3 | Unlikely | Dose(S) Missed | Hospitalization | Resolved |

**表 2.7.4.7-36　重篤な有害事象の一覧表（PX-171-003 part 1（A0））（続き 1）**

| Subject Number | System Organ Class PREFERRED TERM Reported Term (AE #) | Date (Study Day) [Duration(days)] | Serious | Severity (NCI Grade) | Study Drug Relation-ship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|---|
| | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (4) | 24NOV20[redacted] (41)<br>to<br>14DEC20[redacted] (61)<br>[21] | Yes | 3 | Unlikely | Dose(S) Missed | Hospitalization | Resolved |
| | 代謝および栄養障害<br>高カルシウム血症<br>HYPERCALCEMIA (22) | 03JAN20[redacted] (81)*<br>to<br>25JAN20[redacted] (103)*<br>[23] | Yes | 4 | None | Treatment Permanently Discontinued | Concomitant Medication | Stabilized (Not Resolved) |
| | 全身障害および投与局所様態<br>疾患進行<br>PROGRESSIVE MULTIPLE MYELOMA (22) | 03JAN20[redacted] (81)*<br>to<br>25JAN20[redacted] (103)*<br>[23] | Yes | 4 | None | Treatment Permanently Discontinued | Patient Withdrawn | Stabilized (Not Resolved) |
| | | | | | | | | |
| 3-06-[redacted] | 呼吸器、胸郭および縦隔障害<br>肺水腫<br>PULMONARY EDEMA (2) | 17OCT20[redacted] (3)<br>to<br>31OCT20[redacted] (17)<br>[15] | Yes | 2 | Unlikely | Dose Delayed, Dose(S) Missed | Hospitalization | Resolved |
| | 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）<br>腫瘍崩壊症候群<br>TUMOR LYSIS SYNDROME (7) | 14NOV20[redacted] (31)<br>to<br>23NOV20[redacted] (40)<br>[10] | Yes | 3 | Probable | Dose(S) Missed | Hospitalization | Resolved |
| | 感染症および寄生虫症<br>クレブシエラ性敗血症<br>GRAM NEGATIVE SEPSIS DUE TO KLEBSIELLA PNEUMONIAE (20) | 01DEC20[redacted] (48)<br>to<br>14DEC20[redacted] (61)<br>[14] | Yes | 3 | None | Dose Delayed | Concomitant Medication | Resolved |
| | 全身障害および投与局所様態<br>疾患進行<br>PROGRESSIVE DISEASE (50) | 29JAN20[redacted] (107)*<br>to<br>06FEB20[redacted] (115)*<br>[9] | Yes | 5 | None | Treatment Permanently Discontinued | Concomitant Medication, Hospitalization | Death |
| | 心臓障害<br>心不全<br>HEART FAILURE (53) | 14NOV20[redacted] (31)<br>to<br>23NOV20[redacted] (40)<br>[10] | Yes | 4 | Probable | Dose(S) Missed | Hospitalization | Stabilized (Not Resolved) |
| | | | | | | | | |
| 3-06-[redacted] | 腎および尿路障害<br>腎結石症<br>RENAL STONE (10) | 10JAN20[redacted] (59)<br>to<br>15JAN20[redacted] (64)<br>[6] | Yes | 3 | Unlikely | None | Concomitant Medication, Hospitalization | Resolved |

**被験者識別コード，年齢以外のマスキングにおいて，**
**マークなし　：「同年」を意味する**
**＊　：「翌年」を意味する**

**表 2.7.4.7-36　重篤な有害事象の一覧表（PX-171-003 part 1（A0））（続き 2）**

| Subject Number | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Serious | Severity (NCI Grade) | Study Drug Relation-ship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|---|
| | 代謝および栄養障害<br>低ナトリウム血症<br>HYPONATREMIA (11) | 10JAN20[redacted] (59)<br>to<br>15JAN20[redacted] (64)<br>[6] | Yes | 4 | Unlikely | None | Concomitant Medication | Resolved |
| | 心臓障害<br>うっ血性心不全<br>CONGESTIVE HEART FAILURE (20) | 17JAN20[redacted] (66)<br>to<br>07FEB20[redacted] (87)<br>[22] | Yes | 2 | Possible | None | Concomitant Medication | Stabilized (Not Resolved) |
| | 感染症および寄生虫症<br>クロストリジウム性大腸炎<br>CLOSTRIDIUM DIFFICILE COLITIS (27) | 09FEB20[redacted] (89)<br>to<br>Continuing | Yes | 4 | None | Treatment Permanently Discontinued | Patient Withdrawn, Hospitalization | Continuing |
| | 全身障害および投与局所様態<br>多臓器不全<br>MULTIPLE SYSTEMS ORGAN FAILURE (49) | 03MAR20[redacted] (112)<br>to<br>09MAR20[redacted] (118)<br>[7] | Yes | 5 | None | None | None | Death |
| | 心臓障害<br>うっ血性心不全<br>CONGESTIVE HEART FAILURE (53) | 10JAN20[redacted] (59)<br>to<br>15JAN20[redacted] (64)<br>[6] | Yes | 4 | Possible | None | Hospitalization | Stabilized (Not Resolved) |
| | | | | | | | | |
| 3-08-[redacted] | 腎および尿路障害<br>腎不全<br>RENAL FAILURE (6) | 13DEC20[redacted] (22)<br>to<br>Continuing | Yes | 4 | Unlikely | None | None | Continuing |
| | 全身障害および投与局所様態<br>疾患進行<br>PROGRESSION OF DISEASE (20) | 06DEC20[redacted] (15)<br>to<br>22DEC20[redacted] (31)<br>[17] | Yes | 5 | Unlikely | Treatment Permanently Discontinued | None | Death |
| | | | | | | | | |
| 3-09-[redacted] | 代謝および栄養障害<br>高カルシウム血症<br>HYPERCALCEMIA (34) | 13OCT20[redacted] (60)<br>to<br>03NOV20[redacted] (81)<br>[22] | Yes | 4 | None | None | Hospitalization | Stabilized (Not Resolved) |
| | | | | | | | | |
| 3-09-[redacted] | 感染症および寄生虫症<br>大葉性肺炎<br>LEFT LOWER LOBE PNEUMONIA (24) | 02DEC20[redacted] (61)<br>to<br>08DEC20[redacted] (67)<br>[7] | Yes | 3 | Unlikely | Dose(S) Missed | Concomitant Medication | Resolved |

**表 2.7.4.7-36　重篤な有害事象の一覧表（PX-171-003 part 1（A0））（続き 3）**

| Subject Number | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Serious | Severity (NCI Grade) | Study Drug Relation-ship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|---|
| | 感染症および寄生虫症<br>菌血症<br>BACTEREMIA (28) | 04JAN20[redacted] (94)*<br>to<br>11JAN20[redacted] (101)*<br>[8] | Yes | 3 | None | Dose(S) Missed | Hospitalization | Resolved |
| | | | | | | | | |
| 3-10-[redacted] | 腎および尿路障害<br>急性腎不全<br>ACUTE RENAL FAILURE (97) | 06FEB20[redacted] (65)<br>to<br>Continuing | Yes | 4 | Possible | Treatment Permanently Discontinued | Procedure Required, Hospitalization, Patient Withdrawn | Continuing |
| | 感染症および寄生虫症<br>肺炎<br>COMMUNITY ACQUIRED PNEUMONIA (98) | 06FEB20[redacted] (65)<br>to<br>16FEB20[redacted] (75)<br>[11] | Yes | 3 | Unlikely | Treatment Permanently Discontinued | Concomitant Medication, Hospitalization, Patient Withdrawn | Resolved |
| | 心臓障害<br>上室性頻脈<br>AVNRT (99) | 07FEB20[redacted] (66)<br>to<br>07FEB20[redacted] (66)<br>[1] | Yes | 3 | Unlikely | None | Concomitant Medication, Hospitalization | Resolved |
| | 呼吸器、胸郭および縦隔障害<br>呼吸不全<br>HYPERCARBIC RESPIRATORY FAILURE (100) | 10FEB20[redacted] (69)<br>to<br>12FEB20[redacted] (71)<br>[3] | Yes | 4 | Unlikely | None | Hospitalization | Resolved |
| | | | | | | | | |
| 3-11-[redacted] | 感染症および寄生虫症<br>敗血症<br>SEPSIS (1) | 10JAN20[redacted] (15)<br>to<br>13JAN20[redacted] (18)<br>[4] | Yes | 3 | None | Treatment Permanently Discontinued | Concomitant Medication, Patient Withdrawn | Resolved |
| | | | | | | | | |
| 3-13-[redacted] | 全身障害および投与局所様態<br>疾患進行<br>PROGRESSIVE DISEASE WITH PLASMACYTOMA (MULTIPLE) INVOLVING GI TRACT (28) | 27DEC20[redacted] (22)<br>to<br>11JAN20[redacted] (37)*<br>[16] | Yes | 5 | None | Treatment Permanently Discontinued | Concomitant Medication, Hospitalization, Patient Withdrawn | Death |
| | | | | | | | | |
| 3-15-[redacted] | 感染症および寄生虫症<br>肺炎<br>INFECTION: PNEUMONIA (37) | 12MAR20[redacted] (122)<br>to<br>18MAR20[redacted] (128)<br>[7] | Yes | 3 | Unlikely | Dose(S) Missed | Hospitalization | Resolved |

被験者識別コード，年齢以外のマスキングにおいて，
マークなし　：「同年」を意味する
＊　：「翌年」を意味する

**表 2.7.4.7-36　重篤な有害事象の一覧表（PX-171-003 part 1（A0））（続き 4）**

| Subject Number | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Serious | Severity (NCI Grade) | Study Drug Relation-ship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |
| 3-15-[redacted] | 腎および尿路障害<br>急性腎不全<br>ACUTE RENAL FAILURE (9) | 17DEC20[redacted] (36)<br>to<br>20DEC20[redacted] (39)<br>[4] | Yes | 3 | Unlikely | Dose(S) Missed | Hospitalization | Resolved |
| | | | | | | | | |
| 3-15-[redacted] | 全身障害および投与局所様態<br>疾患進行<br>PROGRESSION OF DISEASE (18) | 31JAN20[redacted] (74)<br>to<br>Continuing | Yes | 5 | Unlikely | Treatment Permanently Discontinued | Patient Withdrawn | Death |
| | | | | | | | | |
| 3-16-[redacted] | 全身障害および投与局所様態<br>発熱<br>FEVER (1) | 09JAN20[redacted] (29)<br>to<br>10JAN20[redacted] (30)<br>[2] | Yes | 2 | Probable | Dose(S) Missed | Hospitalization, Concomitant Medication | Resolved |
| | 腎および尿路障害<br>急性腎不全<br>ACUTE RENAL FAILURE (2) | 16JAN20[redacted] (36)<br>to<br>25JAN20[redacted] (45)<br>[10] | Yes | 3 | Probable | Treatment Permanently Discontinued | Hospitalization, Patient Withdrawn | Resolved |
| | 全身障害および投与局所様態<br>発熱<br>DRUG FEVER (3) | 16JAN20[redacted] (36)<br>to<br>25JAN20[redacted] (45)<br>[10] | Yes | 4 | Probable | Treatment Permanently Discontinued | Hospitalization, Concomitant Medication, Patient Withdrawn | Resolved |
| | 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）<br>腫瘍崩壊症候群<br>POSSIBLE TUMOR LYSIS SYNDROME (4) | 16JAN20[redacted] (36)<br>to<br>25JAN20[redacted] (45)<br>[10] | Yes | 3 | Possible | Treatment Permanently Discontinued | Hospitalization, Patient Withdrawn | Resolved |
| | | | | | | | | |
| 3-17-[redacted] | 心臓障害<br>心筋症<br>CARDIOMYOPATHY (18) | 18JUN20[redacted] (198)<br>to<br>Continuing | Yes | 3 | Possible | Treatment Permanently Discontinued | Concomitant Medication | Stabilized (Not Resolved) |
| | | | | | | | | |
| 3-18-[redacted] | 腎および尿路障害<br>急性腎不全<br>ACUTE RENAL FAILURE (20) | 21FEB20[redacted] (87)<br>to<br>11MAR20[redacted] (106)<br>[20] | Yes | 3 | None | None | Hospitalization, Procedure Required | Resolved |
| | | | | | | | | |

**表 2.7.4.7-36　重篤な有害事象の一覧表（PX-171-003 part 1（A0））（続き 5）**

| Subject Number | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Serious | Severity (NCI Grade) | Study Drug Relation-ship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|---|
| 3-18-[redacted] | 傷害、中毒および処置合併症<br>処置後出血<br>POST-OPERATIVE BLEEDING (10) | 11JAN20[redacted] (31)<br>to<br>18JAN20[redacted] (38)<br>[8] | Yes | 3 | None | None | Procedure Required | Resolved |
| | 筋骨格系および結合組織障害<br>病的骨折<br>PATHOLOGICAL FRACTURES TO LEFT HUMERUS + CLAVICLE (26) | 16MAY20[redacted] (157)<br>to<br>Continuing | Yes | 2 | None | None | Concomitant Medication, Hospitalization, Procedure Required | Continuing |
| | 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）<br>形質細胞腫<br>PLASMACYTOMA (28) | 14JUN20[redacted] (186)<br>to<br>Continuing | Yes | 3 | None | None | Concomitant Medication, Procedure Required, Hospitalization | Continuing |
| | 筋骨格系および結合組織障害<br>病的骨折<br>PATHOLOGIC RIGHT HUMERUS FRACTURE (30) | 29JUN20[redacted] (201)<br>to<br>10JUL20[redacted] (212)<br>[12] | Yes | 3 | None | None | Concomitant Medication, Procedure Required, Hospitalization | Stabilized (Not Resolved) |
| | | | | | | | | |

出典［総括報告書5.3.5.2-5（PX-171-003 part 1（A0））， Listing 16.2.7.3］

**表 2.7.4.7-37　重篤な有害事象の一覧表（PX-171-004 part 1）**

| Subject Number | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Serious | Severity (NCI Grade) | Study Drug Relation-ship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|---|
| 4-09-[redacted] | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (18) | 02NOV20[redacted] (40)<br>to<br>08NOV20[redacted] (46)<br>[7] | Yes | 3 | Unlikely | Dose(S) Missed | Hospitalization | Resolved |
| | 心臓障害<br>心不全<br>HEART FAILURE (19) | 02NOV20[redacted] (40)<br>to<br>14DEC20[redacted] (82)<br>[43] | Yes | 3 | None | Dose(S) Missed | Hospitalization | Resolved |
| | | | | | | | | |
| 4-10-[redacted] | 筋骨格系および結合組織障害<br>骨病変<br>LESION OF RIGHT FEMORAL HEAD (10) | 06AUG20[redacted] (29)<br>to<br>30AUG20[redacted] (53)<br>[25] | Yes | 3 | None | Treatment Permanently Discontinued | Hospitalization, Procedure Required, Concomitant Medication, Patient Withdrawn | Resolved |
| | | | | | | | | |
| 4-15-[redacted] | 感染症および寄生虫症<br>ＲＳウイルス感染<br>INFECTION WITH KNOWN ANC:RSV. (12) | 13DEC20[redacted] (15)<br>to<br>20DEC20[redacted] (22)<br>[8] | Yes | 3 | None | None | Hospitalization, Concomitant Medication | Resolved |
| | | | | | | | | |
| 4-18-[redacted] | 感染症および寄生虫症<br>クロストリジウム性大腸炎<br>C DIFF COLITIS INFECTION (13) | 08JAN20[redacted] (36)<br>to<br>25JAN20[redacted] (53)<br>[18] | Yes | 4 | None | Dose(S) Missed, Dose Delayed | Concomitant Medication, Procedure Required, Hospitalization | Resolved |
| | 胃腸障害<br>上部消化管出血<br>UPPER GASTROINTESTINAL BLEED (48) | 23MAR20[redacted] (111)<br>to<br>25MAR20[redacted] (113)<br>[3] | Yes | 1 | Unlikely | None | Concomitant Medication, Hospitalization | Resolved |
| | 呼吸器、胸郭および縦隔障害<br>喀血<br>HEMOPTYSIS (63) | 05SEP20[redacted] (277)<br>to<br>08SEP20[redacted] (280)<br>[4] | Yes | 2 | Unlikely | None | Concomitant Medication, Hospitalization | Resolved |
| | | | | | | | | |
| 4-18-[redacted] | 呼吸器、胸郭および縦隔障害<br>呼吸困難<br>SHORTNESS OF BREATH (11) | 19MAR20[redacted] (101)<br>to<br>23MAR20[redacted] (105)<br>[5] | Yes | 3 | Probable | None | Hospitalization | Resolved |

**表 2.7.4.7-37　重篤な有害事象の一覧表（PX-171-004 part 1）（続き 1）**

| Subject Number | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Serious | Severity (NCI Grade) | Study Drug Relation-ship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|---|
| | 内分泌障害<br>甲状腺機能亢進症<br>HYPERTHYROIDISM (30) | 16APR20[redacted] (129)<br>to<br>Continuing | Yes | 3 | None | Treatment Permanently Discontinued | Hospitalization, Patient Withdrawn | Stabilized (Not Resolved) |
| | | | | | | | | |
| 4-18-[redacted] | 心臓障害<br>うっ血性心不全<br>CONGESTIVE HEART FAILURE - CLASS III (1) | 20FEB20[redacted] (23)<br>to<br>26FEB20[redacted] (29)<br>[7] | Yes | 3 | Possible | Treatment Permanently Discontinued | Concomitant Medication, Hospitalization, Patient Withdrawn | Resolved |
| | | | | | | | | |
| 4-18-[redacted] | 全身障害および投与局所様態<br>発熱<br>FEVER (25) | 26JUN20[redacted] (143)<br>to<br>28JUN20[redacted] (145)<br>[3] | Yes | 1 | Unlikely | None | Concomitant Medication | Resolved |
| | 血管障害<br>低血圧<br>HYPOTENSION (26) | 06JUL20[redacted] (153)<br>to<br>09JUL20[redacted] (156)<br>[4] | Yes | 3 | Possible | Dose(S) Missed | None | Resolved |
| | 感染症および寄生虫症<br>喉頭蓋炎<br>STREPTOCOCCUS PNEUMONAIE EPIGLOTTITIS (43) | 12SEP20[redacted] (221)<br>to<br>15SEP20[redacted] (224)<br>[4] | Yes | 3 | Unlikely | Dose Delayed | Hospitalization, Concomitant Medication | Resolved |
| | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (63) | 17DEC20[redacted] (317)<br>to<br>20DEC20[redacted] (320)<br>[4] | Yes | 3 | Unlikely | Dose(S) Missed, Dose Delayed | Concomitant Medication | Resolved |
| | | | | | | | | |
| 4-18-[redacted] | 感染症および寄生虫症<br>上気道感染<br>UPPER RESPIRATORY INFECTION (11) | 14JAN20[redacted] (93)*<br>to<br>17JAN20[redacted] (96)*<br>[4] | Yes | 3 | Unlikely | Dose(S) Missed | Concomitant Medication, Hospitalization | Resolved |
| | 感染症および寄生虫症<br>細菌性敗血症<br>GRAM NEGATIVE SEPSIS ACINETOBACTOR (1) | 17SEP20[redacted] (-27)<br>to<br>20SEP20[redacted] (-24)<br>[4] | Yes | 3 | None | None | Concomitant Medication, Hospitalization | Resolved |
| | | | | | | | | |

**被験者識別コード，年齢以外のマスキングにおいて，**
**マークなし　：「同年」を意味する**
**＊　：「翌年」を意味する**

**表 2.7.4.7-37　重篤な有害事象の一覧表（PX-171-004 part 1）（続き 2）**

| Subject Number | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Serious | Severity (NCI Grade) | Study Drug Relation-ship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|---|
| 4-18-[redacted] | 代謝および栄養障害<br>高カルシウム血症<br>HYPERCALCAEMIA (1) | 02AUG20[redacted] (5)<br>to<br>07AUG20[redacted] (10)<br>[6] | Yes | 2 | Unlikely | None | Concomitant Medication | Stabilized (Not Resolved) |
| | 代謝および栄養障害<br>高カルシウム血症<br>HYPERCALCAEMIA (2) | 14AUG20[redacted] (17)<br>to<br>19AUG20[redacted] (22)<br>[6] | Yes | 2 | Unlikely | None | Concomitant Medication | Stabilized (Not Resolved) |
| | 代謝および栄養障害<br>高カルシウム血症<br>HYPERCALCAEMIA (3) | 27AUG20[redacted] (30)<br>to<br>17SEP20[redacted] (51)<br>[22] | Yes | 4 | Unlikely | Treatment Permanently Discontinued | Concomitant Medication, Patient Withdrawn | Resolved |
| | | | | | | | | |
| 4-19-[redacted] | 全身障害および投与局所様態<br>発熱<br>FEVER (1) | 19FEB20[redacted] (29)<br>to<br>23FEB20[redacted] (33)<br>[5] | Yes | 1 | Probable | Dose(S) Missed | Hospitalization | Resolved |
| | 感染症および寄生虫症<br>気道感染<br>RESPIRATORY INFECTION (2) | 19FEB20[redacted] (29)<br>to<br>27FEB20[redacted] (37)<br>[9] | Yes | 3 | Probable | Dose(S) Missed | Hospitalization, Concomitant Medication | Resolved |
| | 臨床検査<br>血中クレアチニン増加<br>ELEVATED CREATININE (3) | 19FEB20[redacted] (29)<br>to<br>10MAR20[redacted] (49)<br>[21] | Yes | 2 | Probable | Dose Reduced, Dose(S) Missed | Hospitalization | Resolved |
| | | | | | | | | |
| 4-19-[redacted] | 全身障害および投与局所様態<br>疾患進行<br>PROGRESSIVE MULTIPLE MYELOMA (2) | 23OCT20[redacted] (17)<br>to<br>29DEC20[redacted] (84)<br>[68] | Yes | 5 | None | Treatment Permanently Discontinued | Patient Withdrawn, Procedure Required | Death |
| | 代謝および栄養障害<br>高カルシウム血症<br>HYPERCALCEMIA (3) | 11NOV20[redacted] (36)<br>to<br>28NOV20[redacted] (53)<br>[18] | Yes | 4 | None | Treatment Permanently Discontinued | Hospitalization, Patient Withdrawn, Concomitant Medication | Resolved |
| | 呼吸器、胸郭および縦隔障害<br>嚥下性肺炎<br>ASPIRATION PNEUMONIA (5) | 02DEC20[redacted] (57)<br>to<br>Continuing | Yes | 3 | None | Treatment Permanently Discontinued | Concomitant Medication, Hospitalization | Continuing |
| | | | | | | | | |

**表 2.7.4.7-37　重篤な有害事象の一覧表（PX-171-004 part 1）（続き 3）**

| Subject Number | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Serious | Severity (NCI Grade) | Study Drug Relation-ship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|---|
| 4-19-[redacted] | 血液およびリンパ系障害<br>血小板減少症<br>THROMBOCYTOPENIA (30) | 19JUN20[redacted] (242)<br>to<br>23JUN20[redacted] (246)<br>[5] | Yes | 4 | Possible | Treatment Permanently Discontinued | Hospitalization | Stabilized (Not Resolved) |
| | 腎および尿路障害<br>急性腎不全<br>ACUTE RENAL INSUFFICIENCY (31) | 19JUN20[redacted] (242)<br>to<br>Continuing | Yes | 3 | Possible | Treatment Permanently Discontinued | Patient Withdrawn | Stabilized (Not Resolved) |
| | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (32) | 19JUN20[redacted] (242)<br>to<br>06JUL20[redacted] (259)<br>[18] | Yes | 3 | Possible | Dose(S) Missed, Treatment Permanently Discontinued | Hospitalization, Concomitant Medication, Patient Withdrawn | Stabilized (Not Resolved) |

出典［総括報告書5.3.5.2-7（PX-171-004 part 1），Listing 16.2.7.3］

**表 2.7.4.7-38　重篤な有害事象の一覧表（PX-171-004 part 2）**

| Cohort: 20 mg/m2 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Subject Number** | **System Organ Class PREFERRED TERM Reported Term (AE #)** | **Date (Study Day) [Duration(days)]** | **Serious** | **Severity (NCI Grade)** | **Study Drug Relation-ship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| 4-01-[redacted] | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (11) | 05NOV20[redacted] (3)<br>to<br>08NOV20[redacted] (6)<br>[4] | Yes | 3 | Possible | Dose Reduced | Concomitant Medication, Hospitalization, Procedure Required | Stabilized (Not Resolved) |
| | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (16) | 13NOV20[redacted] (11)<br>to<br>22NOV20[redacted] (20)<br>[10] | Yes | 3 | Possible | Treatment Permanently Discontinued | Hospitalization, Procedure Required, Concomitant Medication, Patient Withdrawn | Stabilized (Not Resolved) |
| | | | | | | | | |
| 4-01-[redacted] | 呼吸器、胸郭および縦隔障害<br>肺塞栓症<br>PULMONARY EMBOLUS (9) | 05SEP20[redacted] (236)<br>to<br>10SEP20[redacted] (241)<br>[6] | Yes | 2 | Unlikely | Dose Delayed | Hospitalization, Concomitant Medication, Procedure Required | Resolved |
| | | | | | | | | |
| 4-06-[redacted] | 腎および尿路障害<br>急性腎不全<br>ACUTE RENAL FAILURE (1) | 25JAN20[redacted] (4)<br>to<br>Continuing | Yes | 4 | Probable | None | Concomitant Medication, Hospitalization | Continuing |
| | 血液およびリンパ系障害<br>発熱性好中球減少症<br>FEBRILE NEUTROPENIA (2) | 25JAN20[redacted] (4)<br>to<br>Continuing | Yes | 4 | Possible | None | Concomitant Medication, Hospitalization | Continuing |
| | 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）<br>腫瘍崩壊症候群<br>TUMOUR LYSIS (3) | 25JAN20[redacted] (4)<br>to<br>Continuing | Yes | 4 | Probable | None | Concomitant Medication, Hospitalization | Continuing |
| | 全身障害および投与局所様態<br>多臓器不全<br>MULTI-ORGAN FAILURE (9) | 25JAN20[redacted] (4)<br>to<br>25JAN20[redacted] (4)<br>[1] | Yes | 5 | Probable | Treatment Permanently Discontinued | Hospitalization, Patient Withdrawn | Death |
| | | | | | | | | |
| 4-12-[redacted] | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (1) | 16NOV20[redacted] (4)<br>to<br>20NOV20[redacted] (8)<br>[5] | Yes | 3 | Possible | Dose Delayed | Concomitant Medication, Hospitalization, Procedure Required | Resolved |

**表 2.7.4.7-38　重篤な有害事象の一覧表（PX-171-004 part 2）（続き 1）**

| Cohort: 20 mg/m2 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Subject Number** | **System Organ Class PREFERRED TERM Reported Term (AE #)** | **Date (Study Day) [Duration(days)]** | **Serious** | **Severity (NCI Grade)** | **Study Drug Relation-ship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| | 呼吸器、胸郭および縦隔障害<br>肺水腫<br>PULMONARY EDEMA (2) | 16NOV20[redacted] (4)<br>to<br>20NOV20[redacted] (8)<br>[5] | Yes | 3 | Possible | Dose Delayed | Concomitant Medication, Hospitalization, Procedure Required | Resolved |
| | 精神障害<br>激越<br>MOOD ALTERATION-AGITATION (5) | 16DEC20[redacted] (34)<br>to<br>30DEC20[redacted] (48)<br>[15] | Yes | 2 | Possible | Treatment Permanently Discontinued | Hospitalization | Resolved |
| | 感染症および寄生虫症<br>尿路感染<br>UTI (7) | 16DEC20[redacted] (34)<br>to<br>30DEC20[redacted] (48)<br>[15] | Yes | 2 | Possible | None | Concomitant Medication, Hospitalization | Resolved |
| | | | | | | | | |
| 4-13-[redacted] | 全身障害および投与局所様態<br>疾患進行<br>DISEASE PROGRESSION (5) | 15APR20[redacted] (36)<br>to<br>05JUN20[redacted] (87)<br>[52] | Yes | 5 | None | Treatment Permanently Discontinued | Concomitant Medication, Hospitalization, Patient Withdrawn | Death |
| | | | | | | | | |
| 4-15-[redacted] | 感染症および寄生虫症<br>肺炎<br>INFECTION: PNEUMONIA (15) | 23MAY20[redacted] (202)<br>to<br>26MAY20[redacted] (205)<br>[4] | Yes | 3 | None | None | Hospitalization, Concomitant Medication, Procedure Required | Stabilized (Not Resolved) |
| | | | | | | | | |
| 4-15-[redacted] | 心臓障害<br>うっ血性心不全<br>CONGESTIVE HEART FAILURE (14) | 11DEC20[redacted] (4)<br>to<br>15DEC20[redacted] (8)<br>[5] | Yes | 3 | Unlikely | Dose Delayed | Hospitalization, Concomitant Medication, Procedure Required | Resolved |
| | | | | | | | | |
| 4-18-[redacted] | 感染症および寄生虫症<br>細菌性副鼻腔炎<br>GRAM POSITIVE COCCI SINUSITIS (3) | 14JAN20[redacted] (100)<br>to<br>16JAN20[redacted] (102)<br>[3] | Yes | 3 | Unlikely | Dose(S) Missed | Concomitant Medication | Resolved |
| | 感染症および寄生虫症<br>副鼻腔炎<br>SINUSITIS (4) | 25FEB20[redacted] (142)<br>to<br>28FEB20[redacted] (145)<br>[4] | Yes | 3 | Possible | Dose(S) Missed | Concomitant Medication, Hospitalization | Resolved |

**表 2.7.4.7-38　重篤な有害事象の一覧表（PX-171-004 part 2）（続き 2）**

| Cohort: 20 mg/m2 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Subject Number** | **System Organ Class PREFERRED TERM Reported Term (AE #)** | **Date (Study Day) [Duration(days)]** | **Serious** | **Severity (NCI Grade)** | **Study Drug Relation-ship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| | | | | | | | | |
| 4-18-[redacted] | 胃腸障害<br>腹痛<br>ABDOMINAL PAIN (22) | 12OCT20[redacted] (314)<br>to<br>16OCT20[redacted] (318)<br>[5] | Yes | 2 | Unlikely | Dose(S) Missed, Treatment Permanently Discontinued | Concomitant Medication, Procedure Required, Patient Withdrawn | Resolved |
| | | | | | | | | |
| 4-18-[redacted] | 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）<br>腫瘍崩壊症候群<br>TUMOR LYSIS SYNDROME (1) | 01FEB20[redacted] (4)<br>to<br>13FEB20[redacted] (16)<br>[13] | Yes | 3 | Probable | Treatment Permanently Discontinued | Concomitant Medication, Hospitalization, Patient Withdrawn | Resolved |
| | | | | | | | | |
| 4-18-[redacted] | 全身障害および投与局所様態<br>発熱<br>FEVERS (5) | 30AUG20[redacted] (54)<br>to<br>05SEP20[redacted] (60)<br>[7] | Yes | 2 | None | Dose Delayed | Concomitant Medication, Hospitalization | Resolved |
| | 胃腸障害<br>嘔吐<br>EMESIS (6) | 24SEP20[redacted] (79)<br>to<br>25SEP20[redacted] (80)<br>[2] | Yes | 3 | Probable | Dose(S) Missed | Concomitant Medication, Hospitalization | Resolved |
| | 感染症および寄生虫症<br>シュードモナス感染<br>PSEUDOMONAS AERUGINOSA INFECTION (7) | 04AUG20[redacted] (28)<br>to<br>06AUG20[redacted] (30)<br>[3] | Yes | 3 | Unlikely | Dose Delayed | Concomitant Medication, Hospitalization | Stabilized (Not Resolved) |
| | 感染症および寄生虫症<br>シュードモナス感染<br>PSEUDOMONAS AEURGINOSA INFECTION (8) | 07AUG20[redacted] (31)<br>to<br>18AUG20[redacted] (42)<br>[12] | Yes | 3 | Unlikely | Dose Delayed | Concomitant Medication, Hospitalization | Resolved |
| | 感染症および寄生虫症<br>腸球菌感染<br>ENTEROCOCCUS FAECALIS INFECTION (9) | 29SEP20[redacted] (84)<br>to<br>06OCT20[redacted] (91)<br>[8] | Yes | 3 | Unlikely | Treatment Permanently Discontinued | Concomitant Medication, Hospitalization, Patient Withdrawn | Resolved |
| | 感染症および寄生虫症<br>クロストリジウム性大腸炎<br>CLOSTRIDIUM DIFFICILE COLITIS (10) | 18OCT20[redacted] (103)<br>to<br>24OCT20[redacted] (109)<br>[7] | Yes | 3 | Unlikely | None | Concomitant Medication, Hospitalization | Resolved |
| | | | | | | | | |

**表 2.7.4.7-38　重篤な有害事象の一覧表（PX-171-004 part 2）（続き 3）**

| Cohort: 20 mg/m2 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Subject Number** | **System Organ Class PREFERRED TERM Reported Term (AE #)** | **Date (Study Day) [Duration(days)]** | **Serious** | **Severity (NCI Grade)** | **Study Drug Relation-ship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| 4-18-[redacted] | 代謝および栄養障害<br>高血糖<br>HYPERGLYCEMIC EVENT (7) | 11JUL20[redacted] (4)<br>to<br>14JUL20[redacted] (7)<br>[4] | Yes | 3 | Possible | Dose Reduced | Hospitalization, Concomitant Medication | Resolved |
| | | | | | | | | |
| 4-19-[redacted] | 感染症および寄生虫症<br>ウイルス性上気道感染<br>URI (RSV POSITIVE) (25) | 07FEB20[redacted] (96)<br>to<br>12FEB20[redacted] (101)<br>[6] | Yes | 3 | Unlikely | Dose Delayed | Concomitant Medication | Resolved |
| | | | | | | | | |
| 4-19-[redacted] | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (3) | 29JAN20[redacted] (-18)<br>to<br>10FEB20[redacted] (-6)<br>[13] | Yes | 3 | None | None | Hospitalization | Resolved |
| | 呼吸器、胸郭および縦隔障害<br>肺塞栓症<br>PULMONARY EMBOLISM (27) | 15AUG20[redacted] (181)<br>to<br>16OCT20[redacted] (243)<br>[63] | Yes | 4 | Unlikely | None | Procedure Required, Concomitant Medication | Resolved |
| | 感染症および寄生虫症<br>上気道感染<br>INFECTION, UPPER RESPIRATORY (33) | 25NOV20[redacted] (283)<br>to<br>27NOV20[redacted] (285)<br>[3] | Yes | 3 | Possible | Dose Delayed | Concomitant Medication, Hospitalization | Resolved |
| | | | | | | | | |
| 4-19-[redacted] | 感染症および寄生虫症<br>肺炎<br>INFECTION (PNEUMONIA) (12) | 16JUL20[redacted] (129)<br>to<br>04AUG20[redacted] (148)<br>[20] | Yes | 3 | Possible | Dose Delayed | Hospitalization, Concomitant Medication | Resolved |
| | 腎および尿路障害<br>急性腎不全<br>ACUTE RENAL INSUFFICIENCY (13) | 16JUL20[redacted] (129)<br>to<br>11AUG20[redacted] (155)<br>[27] | Yes | 1 | Unlikely | Dose Delayed | Hospitalization | Resolved |
| | | | | | | | | |
| 4-19-[redacted] | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (2) | 28MAY20[redacted] (3)<br>to<br>09JUL20[redacted] (45)<br>[43] | Yes | 3 | Possible | Treatment Permanently Discontinued | Concomitant Medication, Patient Withdrawn | Resolved |

**表 2.7.4.7-38　重篤な有害事象の一覧表（PX-171-004 part 2）（続き 4）**

| Cohort: 20 mg/m2 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Subject Number** | **System Organ Class PREFERRED TERM Reported Term (AE #)** | **Date (Study Day) [Duration(days)]** | **Serious** | **Severity (NCI Grade)** | **Study Drug Relation-ship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| | 心臓障害<br>うっ血性心不全<br>CONGESTIVE HEART FAILURE (5) | 01JUN20[redacted] (7)<br>to<br>09JUL2009 (45)<br>[39] | Yes | 3 | Probable | Treatment Permanently Discontinued | Concomitant Medication, Patient Withdrawn | Stabilized (Not Resolved) |
| | 心臓障害<br>僧帽弁閉鎖不全症<br>MITRAL REGURGITATION (7) | 01JUN20[redacted] (7)<br>to<br>09JUL20[redacted] (45)<br>[39] | Yes | 3 | Unlikely | Treatment Permanently Discontinued | Concomitant Medication, Patient Withdrawn | Stabilized (Not Resolved) |
| | | | | | | | | |
| 4-19-[redacted] | 全身障害および投与局所様態<br>全身性浮腫<br>GENERALIZED EDEMA (24) | 11AUG20[redacted] (182)<br>to<br>14AUG20[redacted] (185)<br>[4] | Yes | 3 | Possible | Dose(S) Missed, Treatment Permanently Discontinued | Patient Withdrawn | Resolved |
| | 呼吸器、胸郭および縦隔障害<br>呼吸困難<br>SOB (25) | 11AUG20[redacted] (182)<br>to<br>14AUG20[redacted] (185)<br>[4] | Yes | 3 | Possible | Dose(S) Missed, Treatment Permanently Discontinued | Patient Withdrawn | Resolved |
| | 全身障害および投与局所様態<br>顔面浮腫<br>FACIAL EDEMA (30) | 11AUG20[redacted] (182)<br>to<br>Continuing | Yes | 3 | Possible | Treatment Permanently Discontinued | Patient Withdrawn, Concomitant Medication | Continuing |
| | | | | | | | | |
| 4-19-[redacted] | 神経系障害<br>失神<br>SYNCOPE (7) | 09OCT20[redacted] (30)<br>to<br>09OCT20[redacted] (30)<br>[1] | Yes | 4 | Possible | Dose(S) Missed, Treatment Permanently Discontinued | Hospitalization, Procedure Required, Patient Withdrawn, Concomitant Medication | Resolved |
| | 心臓障害<br>心停止<br>CARDIAC ARREST (8) | 09OCT20[redacted] (30)<br>to<br>09OCT20[redacted] (30)<br>[1] | Yes | 4 | Possible | Treatment Permanently Discontinued, Dose(S) Missed | Patient Withdrawn, Procedure Required, Hospitalization, Concomitant Medication | Resolved |
| | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (12) | 09OCT20[redacted] (30)<br>to<br>15OCT20[redacted] (36)<br>[7] | Yes | 3 | Possible | Dose(S) Missed | Hospitalization, Concomitant Medication | Resolved |
| | | | | | | | | |

**表 2.7.4.7-38　重篤な有害事象の一覧表（PX-171-004 part 2）（続き 5）**

| Cohort: 20/27 mg/m2 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Subject Number** | **System Organ Class PREFERRED TERM Reported Term (AE #)** | **Date (Study Day) [Duration(days)]** | **Serious** | **Severity (NCI Grade)** | **Study Drug Relation-ship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| 4-05-[redacted] | 全身障害および投与局所様態<br>非心臓性胸痛<br>CHEST PAIN NON-CARDIAC (6) | 04NOV20[redacted] (178)<br>to<br>05NOV20[redacted] (179)<br>[2] | Yes | 2 | Unlikely | None | Hospitalization, Concomitant Medication | Resolved |
| | | | | | | | | |
| 4-05-[redacted] | 血管障害<br>血腫<br>RIGHT NECK HEMATOMA (1) | 24NOV20[redacted] (9)<br>to<br>26NOV20[redacted] (11)<br>[3] | Yes | 3 | None | Dose(S) Missed | Hospitalization, Concomitant Medication | Resolved |
| | | | | | | | | |
| 4-06-[redacted] | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (5) | 18MAY20[redacted] (-15)<br>to<br>25MAY20[redacted] (-8)<br>[8] | Yes | 3 | None | None | Concomitant Medication | Resolved |
| | 心臓障害<br>心障害<br>QUERY SECONDARY SEIZURE<br>SPECULATE CARDIAC EVENT AS CAUSE (8) | 05JUN20[redacted] (4)<br>to<br>05JUN20[redacted] (4)<br>[1] | Yes | 5 | Possible | Treatment Permanently Discontinued | Patient Withdrawn | Death |
| | | | | | | | | |
| 4-08-[redacted] | 血液およびリンパ系障害<br>好中球減少症<br>NEUTROPENIA (1) | 24JUN20[redacted] (1)<br>to<br>27JUN20[redacted] (4)<br>[4] | Yes | 3 | Possible | None | Concomitant Medication, Hospitalization | Resolved |
| | 代謝および栄養障害<br>低カリウム血症<br>HYPOKALEMIA (2) | 27JUN20[redacted] (4)<br>to<br>02JUL20[redacted] (9)<br>[6] | Yes | 3 | Possible | None | Concomitant Medication, Hospitalization | Resolved |
| | 全身障害および投与局所様態<br>発熱<br>FEVER (3) | 26JUN20[redacted] (3)<br>to<br>27JUN20[redacted] (4)<br>[2] | Yes | 1 | Possible | None | Concomitant Medication, Hospitalization | Resolved |
| | 腎および尿路障害<br>急性腎不全<br>ACUTE RENAL FAILURE (5) | 22JUL20[redacted] (29)<br>to<br>04AUG20[redacted] (42)<br>[14] | Yes | 3 | Probable | Dose Delayed | Concomitant Medication, Hospitalization | Resolved |
| | | | | | | | | |

**表 2.7.4.7-38　重篤な有害事象の一覧表（PX-171-004 part 2）（続き 6）**

Cohort: 20/27 mg/m2

| Subject Number | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Serious | Severity (NCI Grade) | Study Drug Relation-ship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|---|
| 4-08-[redacted] | 胃腸障害<br>急性膵炎<br>ACUTE PANCREATITIS (14) | 25OCT20[redacted] (103)<br>to<br>01NOV20[redacted] (110)<br>[8] | Yes | 3 | None | Treatment Permanently Discontinued | Procedure Required, Hospitalization, Concomitant Medication | Stabilized (Not Resolved) |
| | | | | | | | | |
| 4-08-[redacted] | 代謝および栄養障害<br>高カルシウム血症<br>HYPERCALCEMIA (1) | 16OCT20[redacted] (-5)<br>to<br>20OCT20[redacted] (-1)<br>[5] | Yes | 2 | None | None | Hospitalization, Concomitant Medication | Resolved |
| | 腎および尿路障害<br>急性腎不全<br>ACUTE RENAL FAILURE (2) | 24OCT20[redacted] (4)<br>to<br>30OCT20[redacted] (10)<br>[7] | Yes | 5 | Unlikely | Treatment Permanently Discontinued | Patient Withdrawn | Death |
| | | | | | | | | |
| 4-09-[redacted] | 呼吸器、胸郭および縦隔障害<br>急性呼吸不全<br>ACUTE RESPIRATORY FAILURE (13) | 06DEC20[redacted] (56)<br>to<br>05FEB20[redacted] (117)*<br>[62] | Yes | 4 | None | None | Hospitalization | Resolved |
| | 感染症および寄生虫症<br>細菌性肺炎<br>BACTERIAL PNEUMONIA (14) | 14DEC20[redacted] (64)<br>to<br>05FEB20[redacted] (117)*<br>[54] | Yes | 4 | None | None | Hospitalization | Resolved |
| | 血液およびリンパ系障害<br>発熱性好中球減少症<br>NEUTROPENIC FEVER (15) | 06DEC20[redacted] (56)<br>to<br>20DEC20[redacted] (70)<br>[15] | Yes | 4 | None | None | Hospitalization | Resolved |
| | | | | | | | | |
| 4-09-[redacted] | 感染症および寄生虫症<br>ヘモフィルス菌性肺炎<br>HAEMOPHILUS PARAINFLUENZA PNEUMONIA (2) | 29NOV20[redacted] (35)<br>to<br>03DEC20[redacted] (39)<br>[5] | Yes | 3 | Unlikely | Dose(S) Missed | Hospitalization, Concomitant Medication | Resolved |
| | | | | | | | | |
| 4-09-[redacted] | 神経系障害<br>脊髄圧迫<br>CORD COMPRESSION (8) | 09MAR20[redacted] (36)<br>to<br>23MAR20[redacted] (50)<br>[15] | Yes | 3 | Unlikely | Treatment Permanently Discontinued | Hospitalization, Procedure Required, Patient Withdrawn, Concomitant Medication | Resolved |

**被験者識別コード，年齢以外のマスキングにおいて，**
**マークなし　：「同年」を意味する**
**＊　：「翌年」を意味する**

**表 2.7.4.7-38　重篤な有害事象の一覧表（PX-171-004 part 2）（続き 7）**

| Cohort: 20/27 mg/m2 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Subject Number** | **System Organ Class PREFERRED TERM Reported Term (AE #)** | **Date (Study Day) [Duration(days)]** | **Serious** | **Severity (NCI Grade)** | **Study Drug Relation-ship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| | | | | | | | | |
| 4-10-[redacted] | 呼吸器、胸郭および縦隔障害<br>肺塞栓症<br>PULMONARY EMBOLUS (10) | 29DEC20[redacted] (43)<br>to<br>30DEC20[redacted] (44)<br>[2] | Yes | 4 | Possible | Dose(S) Missed | Concomitant Medication, Procedure Required, Hospitalization | Resolved |
| | | | | | | | | |
| 4-11-[redacted] | 心臓障害<br>うっ血性心不全<br>CONGESTIVE HEART FAILURE (6) | 05JUN20[redacted] (74)<br>to<br>09JUN20[redacted] (78)<br>[5] | Yes | 3 | Possible | None | Hospitalization, Concomitant Medication | Resolved |
| | | | | | | | | |
| 4-11-[redacted] | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (2) | 13NOV20[redacted] (18)<br>to<br>18NOV20[redacted] (23)<br>[6] | Yes | 3 | Possible | None | Concomitant Medication, Procedure Required, Hospitalization | Resolved |
| | 心臓障害<br>心房細動<br>ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RESPONSE (4) | 05DEC20[redacted] (40)<br>to<br>10DEC20[redacted] (45)<br>[6] | Yes | 3 | Possible | Dose(S) Missed | Concomitant Medication, Procedure Required, Hospitalization | Resolved |
| | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (7) | 05DEC20[redacted] (40)<br>to<br>10DEC20[redacted] (45)<br>[6] | Yes | 3 | Possible | None | Concomitant Medication, Procedure Required, Hospitalization | Resolved |
| | | | | | | | | |
| 4-15-[redacted] | 傷害、中毒および処置合併症<br>胸骨骨折<br>STERNUM FRACTURE - NON-PATHOLOGICAL (22) | 11MAR20[redacted] (325)<br>to<br>13MAR20[redacted] (327)<br>[3] | Yes | 2 | None | Dose(S) Missed | Concomitant Medication, Procedure Required | Stabilized (Not Resolved) |
| | | | | | | | | |
| 4-15-[redacted] | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (26) | 31MAR20[redacted] (267)<br>to<br>07APR20[redacted] (274)<br>[8] | Yes | 3 | Unlikely | Dose(S) Missed | Concomitant Medication, Procedure Required, Hospitalization | Resolved |

**表 2.7.4.7-38　重篤な有害事象の一覧表（PX-171-004 part 2）（続き 8）**

| Cohort: 20/27 mg/m2 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Subject Number** | **System Organ Class PREFERRED TERM Reported Term (AE #)** | **Date (Study Day) [Duration(days)]** | **Serious** | **Severity (NCI Grade)** | **Study Drug Relation-ship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| | 感染症および寄生虫症<br>歯膿瘍<br>FEVER SECONDARY TO DENTAL ABSCESS (27) | 26MAY20[redacted] (323)<br>to<br>29MAY20[redacted] (326)<br>[4] | Yes | 3 | None | Dose Delayed | Procedure Required, Hospitalization | Resolved |
| | 感染症および寄生虫症<br>肺炎<br>COMMUNITY ACQUIRED PNEUMONIA (35) | 12MAY20[redacted] (309)<br>to<br>23MAY20[redacted] (320)<br>[12] | Yes | 3 | None | Dose Delayed | Procedure Required, Hospitalization, Concomitant Medication | Resolved |
| | | | | | | | | |
| 4-15-[redacted] | 胃腸障害<br>大腸炎<br>COLITIS (6) | 02SEP20[redacted] (24)<br>to<br>03SEP20[redacted] (25)<br>[2] | Yes | 2 | Unlikely | Treatment Permanently Discontinued | Concomitant Medication, Hospitalization, Procedure Required, Patient Withdrawn | Resolved |
| | | | | | | | | |
| 4-15-[redacted] | 神経系障害<br>一過性脳虚血発作<br>TRANSIENT ISCHEMIC ATTACK (10) | 12NOV20[redacted] (11)<br>to<br>14NOV20[redacted] (13)<br>[3] | Yes | 3 | Unlikely | None | Hospitalization, Concomitant Medication, Procedure Required | Resolved |
| | | | | | | | | |
| 4-15-[redacted] | 筋骨格系および結合組織障害<br>骨病変<br>LEFT PROXIMAL FEMORAL TUMOR (19) | 01JUN20[redacted] (177)<br>to<br>05JUN20[redacted] (181)<br>[5] | Yes | 3 | None | Treatment Permanently Discontinued | Procedure Required, Hospitalization, Patient Withdrawn | Resolved |
| | | | | | | | | |
| 4-15-[redacted] | 精神障害<br>精神状態変化<br>MENTAL STATUS CHANGES (11) | 22MAR20[redacted] (84)<br>to<br>Continuing | Yes | 3 | None | None | Procedure Required, Hospitalization | Continuing |
| | 全身障害および投与局所様態<br>発熱<br>FEVER (12) | 22MAR20[redacted] (84)<br>to<br>Continuing | Yes | 2 | None | None | Procedure Required, Hospitalization | Continuing |
| | 感染症および寄生虫症<br>ブドウ球菌性菌血症<br>STAPH AUREUS BACTEREMIA (13) | 22MAR20[redacted] (84)<br>to<br>Continuing | Yes | 4 | None | None | Concomitant Medication, Procedure Required | Continuing |

**表 2.7.4.7-38　重篤な有害事象の一覧表（PX-171-004 part 2）（続き 9）**

| Cohort: 20/27 mg/m2 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Subject Number** | **System Organ Class PREFERRED TERM Reported Term (AE #)** | **Date (Study Day) [Duration(days)]** | **Serious** | **Severity (NCI Grade)** | **Study Drug Relation-ship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| | 神経系障害<br>脳出血<br>CEREBRAL HEMORHAGE (16) | 22MAR20[redacted] (84)<br>to<br>Continuing | Yes | 4 | None | None | Procedure Required | Continuing |
| | 全身障害および投与局所様態<br>疾患進行<br>PROGRESSIVE DISEASE (17) | 22MAR20[redacted] (84)<br>to<br>31MAR20[redacted] (93)<br>[10] | Yes | 5 | None | None | Hospitalization | Death |
| | | | | | | | | |
| 4-15-[redacted] | 呼吸器、胸郭および縦隔障害<br>呼吸困難<br>DYSPNEA (2) | 16FEB20[redacted] (30)<br>to<br>19MAR20[redacted] (61)<br>[32] | Yes | 3 | Unlikely | Treatment Permanently Discontinued | Concomitant Medication, Procedure Required, Hospitalization | Resolved |
| | | | | | | | | |
| 4-15-[redacted] | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (6) | 28APR20[redacted] (85)<br>to<br>05MAY20[redacted] (92)<br>[8] | Yes | 3 | Unlikely | Dose Delayed | Concomitant Medication, Procedure Required, Hospitalization | Resolved |
| | | | | | | | | |
| 4-15-[redacted] | 呼吸器、胸郭および縦隔障害<br>呼吸困難<br>DYSPNEA (8) | 26FEB20[redacted] (10)<br>to<br>03MAR20[redacted] (15)<br>[6] | Yes | 3 | Possible | Treatment Permanently Discontinued | Hospitalization, Concomitant Medication, Procedure Required | Resolved |
| | 呼吸器、胸郭および縦隔障害<br>肺水腫<br>PULMONARY EDEMA (10) | 26FEB20[redacted] (10)<br>to<br>03MAR20[redacted] (15)<br>[6] | Yes | 3 | Possible | Treatment Permanently Discontinued | Procedure Required, Concomitant Medication, Hospitalization | Resolved |
| | | | | | | | | |
| 4-15-[redacted] | 心臓障害<br>うっ血性心不全<br>CONGESTIVE HEART FAILURE (24) | 31MAR20[redacted] (45)<br>to<br>15APR20[redacted] (60)<br>[16] | Yes | 3 | Probable | None | Procedure Required, Hospitalization, Concomitant Medication | Resolved |
| | 全身障害および投与局所様態<br>疼痛<br>PAIN (25) | 18FEB20[redacted] (4)<br>to<br>20FEB20[redacted] (6)<br>[3] | Yes | 3 | Unlikely | None | Concomitant Medication, Procedure Required, Hospitalization | Resolved |
| | | | | | | | | |

**表 2.7.4.7-38　重篤な有害事象の一覧表（PX-171-004 part 2）（続き 10）**

| Cohort: 20/27 mg/m2 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Subject Number** | **System Organ Class PREFERRED TERM Reported Term (AE #)** | **Date (Study Day) [Duration(days)]** | **Serious** | **Severity (NCI Grade)** | **Study Drug Relation-ship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| 4-18-[redacted] | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (1) | 04DEC20[redacted] (46)<br>to<br>18DEC20[redacted] (60)<br>[15] | Yes | 3 | Unlikely | None | Concomitant Medication, Hospitalization | Resolved |
| | | | | | | | | |
| 4-19-[redacted] | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (2) | 09SEP20[redacted] (58)<br>to<br>14SEP20[redacted] (63)<br>[6] | Yes | 3 | Unlikely | Treatment Permanently Discontinued | Hospitalization, Concomitant Medication | Resolved |
| | 血液およびリンパ系障害<br>貧血<br>ANEMIA (3) | 10SEP20[redacted] (59)<br>to<br>11SEP20[redacted] (60)<br>[2] | Yes | 3 | Unlikely | Treatment Permanently Discontinued | Hospitalization | Resolved |
| | 腎および尿路障害<br>腎不全<br>RENAL INSUFFICIENCY (7) | 09SEP20[redacted] (58)<br>to<br>Continuing | Yes | 2 | Possible | Treatment Permanently Discontinued | Hospitalization, Concomitant Medication | Stabilized (Not Resolved) |
| | | | | | | | | |
| 4-19-[redacted] | 腎および尿路障害<br>急性腎不全<br>ACUTE RENAL INSUFFICIENCY (2) | 14JAN20[redacted] (8)<br>to<br>10MAR20[redacted] (63)<br>[56] | Yes | 3 | Possible | Treatment Permanently Discontinued | Concomitant Medication, Hospitalization, Patient Withdrawn | Stabilized (Not Resolved) |
| | | | | | | | | |
| 4-47-[redacted] | 血液およびリンパ系障害<br>貧血<br>ANEMIA WORSENED (1) | 28APR20[redacted] (-2)<br>to<br>06MAY20[redacted] (7)<br>[9] | Yes | 4 | None | None | Hospitalization | Resolved |
| | 血液およびリンパ系障害<br>血小板減少症<br>THROMBOCYTOPENIA (2) | 28APR20[redacted] (-2)<br>to<br>29APR20[redacted] (-1)<br>[2] | Yes | 3 | None | None | Hospitalization | Resolved |
| | | | | | | | | |
| 4-47-[redacted] | 全身障害および投与局所様態<br>発熱<br>FEVER (19) | 23MAY20[redacted] (3)<br>to<br>26MAY20[redacted] (6)<br>[4] | Yes | 1 | Probable | None | Hospitalization, Concomitant Medication | Resolved |

**表 2.7.4.7-38　重篤な有害事象の一覧表（PX-171-004 part 2）（続き 11）**

Cohort: 20/27 mg/m2

| Subject Number | System Organ Class PREFERRED TERM Reported Term (AE #) | Date (Study Day) [Duration(days)] | Serious | Severity (NCI Grade) | Study Drug Relation-ship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|---|
| | 血液およびリンパ系障害<br>好中球減少症<br>NEUTROPENIA (20) | 23MAY20[redacted] (3)<br>to<br>26MAY20[redacted] (6)<br>[4] | Yes | 1 | Probable | None | Hospitalization, Concomitant Medication | Resolved |
| | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (21) | 23MAY20[redacted] (3)<br>to<br>26MAY20[redacted] (6)<br>[4] | Yes | 2 | None | None | Hospitalization, Concomitant Medication | Resolved |
| | 感染症および寄生虫症<br>肺炎<br>NOSOCOMIAL PNEUMONIA (25) | 15FEB20[redacted] (271)*<br>to<br>25FEB20[redacted] (281)*<br>[11] | Yes | 3 | None | Dose(S) Missed | Concomitant Medication | Resolved |
| | 胃腸障害<br>下痢<br>DIARRHEA (26) | 15FEB20[redacted] (271)*<br>to<br>17FEB20[redacted] (273)*<br>[3] | Yes | 1 | None | None | None | Resolved |
| | 血液およびリンパ系障害<br>貧血<br>ANEMIA (29) | 23MAY20[redacted] (3)<br>to<br>26MAY20[redacted] (6)<br>[4] | Yes | 3 | Probable | None | Hospitalization | Resolved |
| | | | | | | | | |
| 4-47-[redacted] | 血管障害<br>高血圧<br>UNCONTROLLED HYPERTENSION (18) | 21NOV20[redacted] (165)<br>to<br>27NOV20[redacted] (171)<br>[7] | Yes | 4 | None | None | Concomitant Medication | Resolved |
| | 感染症および寄生虫症<br>敗血症<br>SEPTICEMIA (21) | 21NOV20[redacted] (165)<br>to<br>27NOV20[redacted] (171)<br>[7] | Yes | 3 | None | None | Hospitalization, Concomitant Medication | Resolved |
| | | | | | | | | |

出典［総括報告書5.3.5.2-8（PX-171-004 part 2），Listing 16.2.7.3］

**被験者識別コード，年齢以外のマスキングにおいて，**
**マークなし　：「同年」を意味する**
**＊　：「翌年」を意味する**

**表 2.7.4.7-39　重篤な有害事象の一覧表（PX-171-005）**

Group 1

| Subject Number | System Organ Class PREFERRED TERM Reported Term (AE #) | Date (Study Day) [Duration(days)] | Serious | Severity (NCI Grade) | Study Drug Relation-ship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|---|
| 5-18-[redacted] | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (12) | 10/08/[redacted] (186)<br>to<br>10/14/[redacted] (192)<br>[7] | Yes | 3 | Possible | Dose Delayed | Concomitant Medication | Resolved |
| | 全身障害および投与局所様態<br>末梢性浮腫<br>LOWER EXTREMITY EDEMA (18) | 10/15/[redacted] (193)<br>to<br>10/21/[redacted] (199)<br>[7] | Yes | 3 | Unlikely | None | Concomitant Medication, Hospitalization | Resolved |
| | 筋骨格系および結合組織障害<br>病的骨折<br>PATHELOGICAL FRACTURE OF THE LEFT FEMUR (21) | 11/18/[redacted] (227)<br>to<br>11/23/[redacted] (232)<br>[6] | Yes | 3 | Unlikely | None | Concomitant Medication, Procedure Required | Resolved |
| | | | | | | | | |
| 5-33-[redacted] | 感染症および寄生虫症<br>上気道感染<br>UPPER RESPIRATORY INFECTION (6) | 12/23/[redacted] (23)<br>to<br>01/06/[redacted] (37) *<br>[15] | Yes | 3 | None | Dose Delayed | Concomitant Medication, Hospitalization | Resolved |
| | 胃腸障害<br>腹痛<br>ABDOMINAL PAIN (15) | 01/13/[redacted] (44) *<br>to<br>01/30/[redacted] (61) *<br>[18] | Yes | 3 | Possible | Dose(S) Missed | Hospitalization, Concomitant Medication | Resolved |
| | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (16) | 01/13/[redacted] (44) *<br>to<br>01/30/[redacted] (61) *<br>[18] | Yes | 2 | Unlikely | Dose(S) Missed | Hospitalization, Concomitant Medication | Resolved |
| | | | | | | | | |
| 5-33-[redacted] | 呼吸器、胸郭および縦隔障害<br>肺塞栓症<br>PULMONARY EMBOLUS (5) | 11/20/[redacted] (110)<br>to<br>11/26/[redacted] (116)<br>[7] | Yes | 3 | Probable | Dose Delayed | Concomitant Medication, Procedure Required, Hospitalization | Resolved |
| | 血管障害<br>深部静脈血栓症<br>DVT (6) | 11/20/[redacted] (110)<br>to<br>11/26/[redacted] (116)<br>[7] | Yes | 3 | Probable | Dose Delayed | Concomitant Medication, Procedure Required | Resolved |
| | | | | | | | | |

**被験者識別コード，年齢以外のマスキングにおいて，**
**マークなし　：「同年」を意味する**
**＊　：「翌年」を意味する**

**表 2.7.4.7-39　重篤な有害事象の一覧表（PX-171-005）（続き 1）**

| Group 1 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Subject Number | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Serious | Severity (NCI Grade) | Study Drug Relation-ship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
| 5-33-[redacted] | 精神障害<br>うつ病<br>SEVERE DEPRESSION (1) | 10/14/[redacted] (49)<br>to<br>10/19/[redacted] (54)<br>[6] | Yes | 3 | None | Dose(S) Missed | Hospitalization | Resolved |
| | 心臓障害<br>不安定狭心症<br>UNSTABLE ANGINA (2) | 10/09/[redacted] (44)<br>to<br>10/10/[redacted] (45)<br>[2] | Yes | 3 | None | Dose(S) Missed | Hospitalization, Procedure Required | Resolved |
| | 心臓障害<br>狭心症<br>CHEST PAIN RELATED TO STABLE ANGINA (5) | 09/11/[redacted] (16)<br>to<br>09/12/[redacted] (17)<br>[2] | Yes | 2 | None | None | Hospitalization, Procedure Required | Resolved |
| | 全身障害および投与局所様態<br>非心臓性胸痛<br>NON CARDIAC CHEST PAIN (6) | 01/02/[redacted] (129)*<br>to<br>01/03/[redacted] (130)*<br>[2] | Yes | 2 | Unlikely | Dose Delayed | Hospitalization | Resolved |
| | 心臓障害<br>不安定狭心症<br>UNSTABLE ANGINA (7) | 01/26/[redacted] (153)*<br>to<br>01/29/[redacted] (156)*<br>[4] | Yes | 3 | None | None | Concomitant Medication, Hospitalization, Procedure Required | Resolved |
| | 神経系障害<br>頭痛<br>INTRACTABLE HEADACHE (41) | 05/11/[redacted] (258)*<br>to<br>05/13/[redacted] (260)*<br>[3] | Yes | 3 | None | Dose(S) Missed | Concomitant Medication, Hospitalization | Resolved |
| | | | | | | | | |
| 5-33-[redacted] | 感染症および寄生虫症<br>蜂巣炎<br>CELLULITIS OF LEFT FOREARM (7) | 11/02/[redacted] (48)<br>to<br>11/09/[redacted] (55)<br>[8] | Yes | 2 | None | None | Hospitalization, Concomitant Medication | Resolved |
| | 心臓障害<br>うっ血性心不全<br>CONGESTIVE HEART FAILURE (8) | 01/03/[redacted] (110)*<br>to<br>01/05/[redacted] (112)*<br>[3] | Yes | 3 | Possible | Treatment Permanently Discontinued | Concomitant Medication, Patient Withdrawn | Stabilized (Not Resolved) |

**被験者識別コード，年齢以外のマスキングにおいて，**
**マークなし　：「同年」を意味する**
**＊　：「翌年」を意味する**

**表 2.7.4.7-39　重篤な有害事象の一覧表（PX-171-005）（続き 2）**

| Group 1 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Subject Number** | **System Organ Class PREFERRED TERM Reported Term (AE #)** | **Date (Study Day) [Duration(days)]** | **Serious** | **Severity (NCI Grade)** | **Study Drug Relation-ship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| | 感染症および寄生虫症<br>爪囲炎<br>PARONYCHIA OF LEFT MIDDLE FINGER (9) | 11/02/[redacted] (48)<br>to<br>11/09/[redacted] (55)<br>[8] | Yes | 2 | None | None | Concomitant Medication, Hospitalization | Resolved |
| | | | | | | | | |

**表 2.7.4.7-39　重篤な有害事象の一覧表（PX-171-005）（続き 3）**

| Group 2 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Subject Number | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Serious | Severity (NCI Grade) | Study Drug Relation-ship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
| 5-28-[redacted] | 全身障害および投与局所様態<br>発熱<br>FEVER (9) | 02/20/[redacted] (10)<br>to<br>02/23/[redacted] (13)<br>[4] | Yes | 1 | None | None | Hospitalization, Concomitant Medication | Resolved |
| | 感染症および寄生虫症<br>レンサ球菌性菌血症<br>STREP VIRIDANS BACTEREMIA (11) | 03/20/[redacted] (38)<br>to<br>03/26/[redacted] (44)<br>[7] | Yes | 3 | None | Dose(S) Missed | Hospitalization, Concomitant Medication | Resolved |
| | | | | | | | | |
| 5-28-[redacted] | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (7) | 02/18/[redacted] (15)<br>to<br>02/20/[redacted] (17)<br>[3] | Yes | 3 | None | Dose(S) Missed | Hospitalization | Resolved |
| | | | | | | | | |
| 5-28-[redacted] | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (4) | 12/03/[redacted] (214)<br>to<br>12/06/[redacted] (217)<br>[4] | Yes | 3 | Unlikely | Dose(S) Missed | Hospitalization | Resolved |
| | 呼吸器、胸郭および縦隔障害<br>呼吸困難<br>SHORTNESS OF BREATHE (5) | 09/14/[redacted] (134)<br>to<br>09/16/[redacted] (136)<br>[3] | Yes | 3 | Unlikely | Dose Reduced, Dose Delayed | Hospitalization | Resolved |
| | | | | | | | | |
| 5-28-[redacted] | 全身障害および投与局所様態<br>疾患進行<br>DISEASE PROGRESSION (1) | 06/03/[redacted] (36)<br>to<br>06/17/[redacted] (50)<br>[15] | Yes | 3 | None | Treatment Permanently Discontinued | Hospitalization, Patient Withdrawn, Procedure Required | Resolved |
| | | | | | | | | |
| 5-33-[redacted] | 臨床検査<br>血中アルカリホスファターゼ増加<br>INCREASED ALKALINE PHOSPHATASE (6) | 02/03/[redacted] (58)<br>to<br>03/17/[redacted] (100)<br>[43] | Yes | 3 | Possible | None | None | Resolved |
| | | | | | | | | |

**表 2.7.4.7-39　重篤な有害事象の一覧表（PX-171-005）（続き 4）**

| Group 2 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Subject Number** | **System Organ Class PREFERRED TERM Reported Term (AE #)** | **Date (Study Day) [Duration(days)]** | **Serious** | **Severity (NCI Grade)** | **Study Drug Relation-ship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| 5-33-[redacted] | 精神障害<br>精神状態変化<br>MENTAL STATUS CHANGE (3) | 03/17/[redacted] (49)<br>to<br>03/20/[redacted] (52)<br>[4] | Yes | 1 | None | None | Hospitalization, Concomitant Medication | Resolved |
| | | | | | | | | |
| 5-33-[redacted] | 腎および尿路障害<br>急性腎不全<br>ACUTE RENAL FAILURE DUE TO PROGRESSIVE MYELOMA (24) | 09/29/[redacted] (232)<br>to<br>10/09/[redacted] (242)<br>[11] | Yes | 3 | None | Treatment Permanently Discontinued | Hospitalization, Procedure Required, Patient Withdrawn | Resolved |
| | 全身障害および投与局所様態<br>疾患進行<br>PROGRESSIVE DISEASE (25) | 09/29/[redacted] (232)<br>to<br>10/26/[redacted] (259)<br>[28] | Yes | 5 | None | None | Hospitalization, Concomitant Medication | Death |
| | | | | | | | | |
| 5-33-[redacted] | 感染症および寄生虫症<br>細菌性気道感染<br>POLYMICROBIAL RESPIRATORY INFECTION (9) | 05/27/[redacted] (45)<br>to<br>Continuing | Yes | 5 | None | Dose(S) Missed | Concomitant Medication, Hospitalization | Continuing |
| | 心臓障害<br>心房粗動<br>ATRIAL FLUTTER (13) | 05/27/[redacted] (45)<br>to<br>05/29/[redacted] (47)<br>[3] | Yes | 2 | None | None | Hospitalization, Concomitant Medication | Resolved |
| | 全身障害および投与局所様態<br>疾患進行<br>PROGRESSIVE MULTIPLE MYELOMA WITH PLASMA CELL LEUKEMIA AND EXTENSIVE EXTRA-MEDULLARY DISEASE (22) | 05/27/[redacted] (45)<br>to<br>06/05/[redacted] (54)<br>[10] | Yes | 5 | None | Treatment Permanently Discontinued | Hospitalization, Patient Withdrawn | Death |
| | | | | | | | | |

**表 2.7.4.7-39　重篤な有害事象の一覧表（PX-171-005）（続き 5）**

| Group 3 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Subject Number** | **System Organ Class PREFERRED TERM Reported Term (AE #)** | **Date (Study Day) [Duration(days)]** | **Serious** | **Severity (NCI Grade)** | **Study Drug Relation-ship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| 5-18-[redacted] | 感染症および寄生虫症<br>敗血症<br>SEPSIS - PSEUDOMONAS AERUGINOSA & FAECALIS (5) | 04/24/[redacted] (18)<br>to<br>05/23/[redacted] (47)<br>[30] | Yes | 5 | Possible | Treatment Permanently Discontinued | Concomitant Medication, Procedure Required, Hospitalization, Patient Withdrawn | Death |
| | | | | | | | | |
| 5-18-[redacted] | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (30) | 09/26/[redacted] (82)<br>to<br>10/03/[redacted] (89)<br>[8] | Yes | 3 | Possible | None | Concomitant Medication, Hospitalization | Resolved |
| | 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）<br>形質細胞腫<br>PARASPINAL PLASMACYTOMA (42) | 10/16/[redacted] (102)<br>to<br>10/27/[redacted] (113)<br>[12] | Yes | 3 | None | Treatment Permanently Discontinued | Hospitalization, Concomitant Medication, Patient Withdrawn | Resolved |
| | | | | | | | | |
| 5-28-[redacted] | 腎および尿路障害<br>腎不全<br>RENAL INSUFFICIENCY (1) | 03/13/[redacted] (-4)<br>to<br>03/19/[redacted] (3)<br>[7] | Yes | 2 | None | None | Hospitalization | Resolved |
| | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (10) | 12/15/[redacted] (274)<br>to<br>12/16/[redacted] (275)<br>[2] | Yes | 2 | None | None | Hospitalization | Resolved |
| | | | | | | | | |
| 5-32-[redacted] | 腎および尿路障害<br>腎不全<br>RENAL FAILURE (5) | 02/19/[redacted] (29)<br>to<br>Continuing | Yes | 3 | Unlikely | Treatment Permanently Discontinued | Hospitalization, Patient Withdrawn, Concomitant Medication | Stabilized (Not Resolved) |
| | | | | | | | | |
| 5-33-[redacted] | 呼吸器、胸郭および縦隔障害<br>肺高血圧症<br>PULMONARY HYPERTENSION (19) | 05/28/[redacted] (45)<br>to<br>08/05/[redacted] (114)<br>[70] | Yes | 3 | None | Treatment Permanently Discontinued | Concomitant Medication, Patient Withdrawn | Resolved |
| | 呼吸器、胸郭および縦隔障害<br>呼吸不全<br>RESPIRATORY FAILURE (8) | 06/12/[redacted] (60)<br>to<br>08/05/[redacted] (114)<br>[55] | Yes | 3 | None | Treatment Permanently Discontinued | Concomitant Medication, Patient Withdrawn | Resolved |

**表 2.7.4.7-39　重篤な有害事象の一覧表（PX-171-005）（続き 6）**

| Group 3 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Subject Number** | **System Organ Class PREFERRED TERM Reported Term (AE #)** | **Date (Study Day) [Duration(days)]** | **Serious** | **Severity (NCI Grade)** | **Study Drug Relation-ship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| | 呼吸器、胸郭および縦隔障害<br>呼吸性アルカローシス<br>PRIMARY CHRONIC RESPIRATORY ALKALOSIS (9) | 06/12/[redacted] (60)<br>to<br>08/05/[redacted] (114)<br>[55] | Yes | 3 | None | Treatment Permanently Discontinued | Concomitant Medication, Patient Withdrawn, Procedure Required | Resolved |
| | 心臓障害<br>右室不全<br>RIGHT HEART FAILURE (11) | 05/28/[redacted] (45)<br>to<br>08/05/[redacted] (114)<br>[70] | Yes | 3 | None | Treatment Permanently Discontinued | Concomitant Medication, Patient Withdrawn | Resolved |
| | 精神障害<br>精神状態変化<br>ALTERED MENTAL STATUS (27) | 05/28/[redacted] (45)<br>to<br>08/05/[redacted] (114)<br>[70] | Yes | 3 | None | Treatment Permanently Discontinued | Patient Withdrawn, Hospitalization, Procedure Required | Resolved |
| | 肝胆道系障害<br>静脈閉塞性肝疾患<br>VENO-OCCLUSIVE DISEASE OF LIVER WITH TENSE ASCITES AND ABDOMINAL COMPARTMENT SYNDROME (28) | 05/28/[redacted] (45)<br>to<br>08/05/[redacted] (114)<br>[70] | Yes | 3 | Probable | Treatment Permanently Discontinued | Patient Withdrawn, Hospitalization, Procedure Required | Resolved |
| | 胃腸障害<br>裂孔ヘルニア<br>HIATAL HERNIA (200) | 05/28/[redacted] (45)<br>to<br>08/05/[redacted] (114)<br>[70] | Yes | 3 | None | None | Hospitalization | Resolved |
| | | | | | | | | |
| 5-33-[redacted] | 感染症および寄生虫症<br>インフルエンザ<br>H1N1 INFLUENZA (24) | 11/03/[redacted] (155)<br>to<br>11/05/[redacted] (157)<br>[3] | Yes | 3 | Unlikely | Dose(S) Missed, Dose Reduced | Concomitant Medication, Hospitalization, Procedure Required | Resolved |
| | 血管障害<br>深部静脈血栓症<br>DVT (25) | 01/04/[redacted] (217)＊<br>to<br>01/11/[redacted] (224)＊<br>[8] | Yes | 3 | Possible | Dose(S) Missed | Concomitant Medication, Hospitalization, Procedure Required | Resolved |
| | 代謝および栄養障害<br>低リン酸血症<br>HYPOPHOSPHOTEMIA (26) | 12/22/[redacted] (204)<br>to<br>12/28/[redacted] (210)<br>[7] | Yes | 4 | Unlikely | None | Concomitant Medication | Resolved |
| | 代謝および栄養障害<br>低リン酸血症<br>HYPOPHOSPHOTEMIA (27) | 01/20/[redacted] (233)＊<br>to<br>01/26/[redacted] (239)＊<br>[7] | Yes | 4 | Possible | None | Concomitant Medication | Resolved |

**被験者識別コード，年齢以外のマスキングにおいて，**
**マークなし　：「同年」を意味する**
**＊　：「翌年」を意味する**

**表 2.7.4.7-39　重篤な有害事象の一覧表（PX-171-005）（続き 7）**

| Group 3 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Subject Number | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Serious | Severity (NCI Grade) | Study Drug Relation-ship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
| | 胃腸障害<br>下痢<br>DIARRHEA (37) | 11/03/[redacted] (155)<br>to<br>11/05/[redacted] (157)<br>[3] | Yes | 3 | Possible | Dose(S) Missed | Hospitalization | Resolved |
| | 代謝および栄養障害<br>脱水<br>DEHYDRATION (38) | 11/03/[redacted] (155)<br>to<br>11/05/[redacted] (157)<br>[3] | Yes | 3 | Unlikely | Dose(S) Missed | Hospitalization, Concomitant Medication | Resolved |
| | 臨床検査<br>血中クレアチニン増加<br>INCREASED CREATININE (39) | 11/03/[redacted] (155)<br>to<br>11/05/[redacted] (157)<br>[3] | Yes | 3 | Unlikely | Dose(S) Missed | Hospitalization, Concomitant Medication | Resolved |
| | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (40) | 11/03/[redacted] (155)<br>to<br>11/05/[redacted] (157)<br>[3] | Yes | 3 | Unlikely | Dose(S) Missed | Hospitalization, Concomitant Medication, Procedure Required | Resolved |
| | 心臓障害<br>心房細動<br>ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RATE (54) | 01/04/[redacted] (217)*<br>to<br>01/11/[redacted] (224)*<br>[8] | Yes | 3 | None | Dose(S) Missed | Hospitalization, Concomitant Medication | Resolved |
| | 感染症および寄生虫症<br>気管支炎<br>BRONCHITIS (55) | 01/04/[redacted] (217)*<br>to<br>01/11/[redacted] (224)*<br>[8] | Yes | 3 | None | Dose(S) Missed | Hospitalization, Concomitant Medication | Resolved |
| | | | | | | | | |
| 5-33-[redacted] | 感染症および寄生虫症<br>インフルエンザ<br>H1N1 INFECTION (29) | 10/31/[redacted] (102)<br>to<br>11/23/[redacted] (125)<br>[24] | Yes | 3 | None | Dose Delayed | Concomitant Medication | Resolved |
| | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (30) | 10/31/[redacted] (102)<br>to<br>11/23/[redacted] (125)<br>[24] | Yes | 3 | None | Dose Delayed | Hospitalization, Concomitant Medication | Resolved |
| | | | | | | | | |
| 5-33-[redacted] | 腎および尿路障害<br>急性腎不全<br>ACUTE RENAL FAILURE (11) | 08/26/[redacted] (29)<br>to<br>Continuing | Yes | 3 | None | Treatment Permanently Discontinued | Concomitant Medication, Patient Withdrawn | Continuing |

**被験者識別コード，年齢以外のマスキングにおいて，**
**マークなし　：「同年」を意味する**
**＊　：「翌年」を意味する**

**表 2.7.4.7-39　重篤な有害事象の一覧表（PX-171-005）（続き 8）**

| Group 3 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Subject Number** | **System Organ Class PREFERRED TERM Reported Term (AE #)** | **Date (Study Day) [Duration(days)]** | **Serious** | **Severity (NCI Grade)** | **Study Drug Relation-ship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| | 精神障害<br>精神状態変化<br>ALTERED MENTAL STATUS (12) | 08/26/[redacted] (29)<br>to<br>Continuing | Yes | 3 | None | Treatment Permanently Discontinued | Procedure Required, Patient Withdrawn | Stabilized (Not Resolved) |
| | | | | | | | | |
| 5-34-[redacted] | 代謝および栄養障害<br>脱水<br>DEHYDRATION (3) | 01/11/[redacted] (26)<br>to<br>01/17/[redacted] (32)<br>[7] | Yes | 3 | Probable | Dose(S) Missed | Concomitant Medication, Hospitalization | Resolved |
| | 精神障害<br>精神状態変化<br>ALTERED MENTAL STATUS (4) | 01/11/[redacted] (26)<br>to<br>01/12/[redacted] (27)<br>[2] | Yes | 1 | Unlikely | None | Hospitalization | Resolved |
| | 腎および尿路障害<br>腎不全<br>WORSENING RENAL FAILURE (14) | 01/11/[redacted] (26)<br>to<br>03/23/[redacted] (97)<br>[72] | Yes | 3 | Unlikely | None | Concomitant Medication, Hospitalization | Stabilized (Not Resolved) |
| | | | | | | | | |
| 5-34-[redacted] | 全身障害および投与局所様態<br>非心臓性胸痛<br>CHEST PAIN NON-CARDIAC (8) | 06/29/[redacted] (139)<br>to<br>06/30/[redacted] (140)<br>[2] | Yes | 3 | Unlikely | Dose(S) Missed | Hospitalization | Resolved |
| | 感染症および寄生虫症<br>注射部位蜂巣炎<br>INFECTION AT INFUSION SITE (CELLULITIS) (9) | 10/16/[redacted] (248)<br>to<br>10/19/[redacted] (251)<br>[4] | Yes | 3 | Unlikely | Dose(S) Missed | Concomitant Medication, Hospitalization | Resolved |
| | 代謝および栄養障害<br>高カルシウム血症<br>HYPERCALCEMIA (20) | 02/05/[redacted] (360)*<br>to<br>02/09/[redacted] (364)*<br>[5] | Yes | 2 | None | None | Concomitant Medication, Hospitalization | Resolved |
| | | | | | | | | |

**被験者識別コード，年齢以外のマスキングにおいて，**
**マークなし　：「同年」を意味する**
**＊　：「翌年」を意味する**

**表 2.7.4.7-39　重篤な有害事象の一覧表（PX-171-005）（続き 9）**

| Group 4 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Subject Number** | **System Organ Class PREFERRED TERM Reported Term (AE #)** | **Date (Study Day) [Duration(days)]** | **Serious** | **Severity (NCI Grade)** | **Study Drug Relation-ship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| 5-18-[redacted] | 全身障害および投与局所様態<br>発熱<br>FEVER (1) | 04/28/[redacted] (14)<br>to<br>05/02/[redacted] (18)<br>[5] | Yes | 2 | Unlikely | Dose Delayed | Hospitalization, Concomitant Medication | Resolved |
| | 腎および尿路障害<br>急性腎不全<br>ACUTE RENAL FAILURE (2) | 05/22/[redacted] (38)<br>to<br>05/30/[redacted] (46)<br>[9] | Yes | 3 | None | None | Procedure Required, Hospitalization | Stabilized (Not Resolved) |
| | | | | | | | | |
| 5-28-[redacted] | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (6) | 04/02/[redacted] (53)<br>to<br>04/10/[redacted] (61)<br>[9] | Yes | 3 | None | Dose Delayed | Hospitalization, Concomitant Medication | Resolved |
| | 神経系障害<br>失神<br>SYNCOPE (7) | 04/02/[redacted] (53)<br>to<br>04/02/[redacted] (53)<br>[1] | Yes | 3 | None | None | Hospitalization | Resolved |
| | 代謝および栄養障害<br>脱水<br>DEHYDRATION (10) | 08/18/[redacted] (191)<br>to<br>08/21/[redacted] (194)<br>[4] | Yes | 3 | None | Dose(S) Missed | Hospitalization | Resolved |
| | | | | | | | | |
| 5-28-[redacted] | 感染症および寄生虫症<br>尿路感染<br>URINARY TRACT INFECTION (2) | 06/03/[redacted] (1)<br>to<br>06/05/[redacted] (3)<br>[3] | Yes | 2 | None | Dose(S) Missed | Hospitalization | Resolved |
| | 感染症および寄生虫症<br>ウイルス性気管支炎<br>VIRAL BRONCHITIS (7) | 09/21/[redacted] (111)<br>to<br>09/24/[redacted] (114)<br>[4] | Yes | 3 | Possible | Dose Delayed | Hospitalization | Resolved |
| | 呼吸器、胸郭および縦隔障害<br>慢性閉塞性肺疾患<br>COPD (9) | 11/27/[redacted] (178)<br>to<br>11/30/[redacted] (181)<br>[4] | Yes | 2 | None | None | Hospitalization | Resolved |
| | 腎および尿路障害<br>腎不全<br>RENAL INSUFFICIENCY (10) | 05/22/[redacted] (-12)<br>to<br>05/23/[redacted] (-11)<br>[2] | Yes | 3 | None | None | Hospitalization | Resolved |

**表 2.7.4.7-39　重篤な有害事象の一覧表（PX-171-005）（続き 10）**

| Group 4 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Subject Number** | **System Organ Class PREFERRED TERM Reported Term (AE #)** | **Date (Study Day) [Duration(days)]** | **Serious** | **Severity (NCI Grade)** | **Study Drug Relation-ship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| | 感染症および寄生虫症<br>気管支炎<br>BRONCHITIS (15) | 01/25/[redacted] (237)*<br>to<br>01/29/[redacted] (241)*<br>[5] | Yes | 3 | Possible | Dose Delayed | Hospitalization, Concomitant Medication | Resolved |
| | 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (30) | 04/21/[redacted] (323)*<br>to<br>Continuing | Yes | 2 | None | Treatment Permanently Discontinued | Hospitalization | Continuing |
| | | | | | | | | |
| 5-28-[redacted] | 心臓障害<br>うっ血性心不全<br>CONGESTIVE HEART FAILURE (6) | 12/10/[redacted] (170)<br>to<br>12/30/[redacted] (190)<br>[21] | Yes | 2 | None | Dose(S) Missed | Hospitalization, Concomitant Medication | Resolved |
| | | | | | | | | |
| 5-28-[redacted] | 心臓障害<br>うっ血性心不全<br>CONGESTIVE HEART FAILURE (1) | 07/22/[redacted] (3)<br>to<br>07/30/[redacted] (11)<br>[9] | Yes | 3 | Probable | Dose(S) Missed | Hospitalization | Resolved |
| | | | | | | | | |
| 5-33-[redacted] | 全身障害および投与局所様態<br>疾患進行<br>PROGRESSIVE DISEASE (5) | 08/24/[redacted] (29)<br>to<br>08/28/[redacted] (33)<br>[5] | Yes | 5 | None | Treatment Permanently Discontinued | Hospitalization, Patient Withdrawn | Death |
| | 腎および尿路障害<br>急性腎不全<br>ACUTE ON CHRONIC RENAL FAILURE DUE TO DEHYDRATION (200) | 08/24/[redacted] (29)<br>to<br>08/28/[redacted] (33)<br>[5] | Yes | 3 | None | None | Hospitalization | Continuing |
| | 心臓障害<br>心房細動<br>ATRIAL FIBRILLATION (201) | 08/24/[redacted] (29)<br>to<br>08/28/[redacted] (33)<br>[5] | Yes | 3 | None | None | Hospitalization | Continuing |
| | 代謝および栄養障害<br>脱水<br>DEHYDRATION (202) | 08/24/[redacted] (29)<br>to<br>08/28/[redacted] (33)<br>[5] | Yes | 3 | None | None | Hospitalization | Continuing |

**被験者識別コード，年齢以外のマスキングにおいて，**
**マークなし　：「同年」を意味する**
**＊　：「翌年」を意味する**

**表 2.7.4.7-39　重篤な有害事象の一覧表（PX-171-005）（続き 11）**

| Group 5 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Subject Number** | **System Organ Class PREFERRED TERM Reported Term (AE #)** | **Date (Study Day) [Duration(days)]** | **Serious** | **Severity (NCI Grade)** | **Study Drug Relation-ship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| 5-18-[redacted] | 免疫系障害<br>アミロイドーシス<br>WORSENING AMYLOIDOSIS OF THE TONGUE (3) | 11/05/[redacted] (17)<br>to<br>11/13/[redacted] (25)<br>[9] | Yes | 3 | None | None | Hospitalization, Procedure Required | Stabilized (Not Resolved) |
| | 全身障害および投与局所様態<br>疾患進行<br>PROGRESSIVE DISEASE (12) | 11/26/[redacted] (38)<br>to<br>11/26/[redacted] (38)<br>[1] | Yes | 5 | None | None | None | Death |
| | | | | | | | | |
| 5-18-[redacted] | 胃腸障害<br>悪心<br>NAUSEA- WORSENED (1) | 03/27/[redacted] (116)<br>to<br>03/28/[redacted] (117)<br>[2] | Yes | 3 | Possible | Treatment Permanently Discontinued | Concomitant Medication, Patient Withdrawn, Hospitalization | Resolved |
| | 胃腸障害<br>嘔吐<br>NAUSEA AND VOMITING (3) | 03/14/[redacted] (103)<br>to<br>03/17/[redacted] (106)<br>[4] | Yes | 3 | Probable | Dose Reduced | Concomitant Medication, Hospitalization | Resolved |
| | 胃腸障害<br>嘔吐<br>NAUSEA AND VOMITING (4) | 03/07/[redacted] (96)<br>to<br>03/11/[redacted] (100)<br>[5] | Yes | 3 | Probable | Dose(S) Missed | Concomitant Medication, Hospitalization | Resolved |
| | | | | | | | | |
| 5-18-[redacted] | 全身障害および投与局所様態<br>疾患進行<br>PROGRESSIVE DISEASE (1) | 01/07/[redacted] (2)<br>to<br>01/19/[redacted] (14)<br>[13] | Yes | 5 | Unlikely | None | Concomitant Medication, Hospitalization | Death |
| | | | | | | | | |
| 5-18-[redacted] | 呼吸器、胸郭および縦隔障害<br>呼吸困難<br>DYSPNEA (9) | 04/05/[redacted] (70)<br>to<br>04/07/[redacted] (72)<br>[3] | Yes | 3 | None | Dose Delayed | Concomitant Medication, Hospitalization | Resolved |
| | 呼吸器、胸郭および縦隔障害<br>呼吸不全<br>HYPERCARBIC RESPIRATORY FAILURE (12) | 04/26/[redacted] (91)<br>to<br>05/20/[redacted] (115)<br>[25] | Yes | 3 | Possible | Dose(S) Missed, Treatment Permanently Discontinued | Concomitant Medication, Hospitalization, Patient Withdrawn | Resolved |

**表 2.7.4.7-39　重篤な有害事象の一覧表（PX-171-005）（続き 12）**

| Group 5 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Subject Number** | **System Organ Class PREFERRED TERM Reported Term (AE #)** | **Date (Study Day) [Duration(days)]** | **Serious** | **Severity (NCI Grade)** | **Study Drug Relation-ship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| | 呼吸器、胸郭および縦隔障害<br>喘息<br>EXACERBATION OF ASTHMA (1) | 02/27/[redacted] (33)<br>to<br>03/05/[redacted] (39)<br>[7] | Yes | 3 | Unlikely | Dose(S) Missed | Concomitant Medication, Hospitalization | Resolved |
| | | | | | | | | |
| 5-28-[redacted] | 胃腸障害<br>小腸閉塞<br>PARTIAL SMALL BOWEL OBSTRUCTION (1) | 10/26/[redacted] (21)<br>to<br>11/30/[redacted] (56)<br>[36] | Yes | 3 | None | Dose Delayed | Hospitalization | Resolved |
| | 感染症および寄生虫症<br>インフルエンザ<br>INFLUENZA A (2) | 11/27/[redacted] (53)<br>to<br>01/21/[redacted] (108)*<br>[56] | Yes | 3 | None | Dose(S) Missed, Dose Delayed | Hospitalization, Concomitant Medication | Resolved |
| | 感染症および寄生虫症<br>胃腸炎<br>GASTROENTERITIS (3) | 02/09/[redacted] (127)*<br>to<br>02/26/[redacted] (144)*<br>[18] | Yes | 2 | Unlikely | Dose Delayed | Hospitalization | Resolved |
| | 胃腸障害<br>下痢<br>DIARRHEA (10) | 05/17/[redacted] (224)*<br>to<br>05/28/[redacted] (235)*<br>[12] | Yes | 3 | None | Dose Delayed | Hospitalization | Resolved |
| | 神経系障害<br>脊髄圧迫<br>PAIN D/T CORD COMPRESSION (11) | 06/15/[redacted] (253)*<br>to<br>07/05/[redacted] (273)*<br>[21] | Yes | 5 | None | Treatment Permanently Discontinued | Hospitalization, Procedure Required, Concomitant Medication, Patient Withdrawn | Death |
| | | | | | | | | |
| 5-33-[redacted] | 血管障害<br>上大静脈閉塞<br>SUPERIOR VENA CAVAL OBSTRUCTION (14) | 09/02/[redacted] (37)<br>to<br>09/04/[redacted] (39)<br>[3] | Yes | 3 | None | None | Hospitalization, Procedure Required | Resolved |
| | 血管障害<br>上大静脈閉塞<br>SUPERIOR VENAL CAVAL OBSTRUCTION (28) | 05/19/[redacted] (296)*<br>to<br>05/21/[redacted] (298)*<br>[3] | Yes | 3 | None | Dose(S) Missed | Procedure Required, Hospitalization | Resolved |

**被験者識別コード，年齢以外のマスキングにおいて，**
**マークなし　：「同年」を意味する**
**＊　：「翌年」を意味する**

**表 2.7.4.7-39　重篤な有害事象の一覧表（PX-171-005）（続き 13）**

| Group 5 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Subject Number | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Serious | Severity (NCI Grade) | Study Drug Relation-ship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
| | 感染症および寄生虫症<br>中心静脈カテーテル感染<br>CENTRAL LINE INFECTION AND POSSIBLE STAPH EPIDERMIDIS AND INTERMEDIUS BACTEREMIA (38) | 07/23/[redacted] (361)*<br>to<br>07/30/[redacted] (368)*<br>[8] | Yes | 3 | None | None | Hospitalization, Concomitant Medication | Resolved |
| | 感染症および寄生虫症<br>尿路性敗血症<br>UROSEPSIS (42) | 07/23/[redacted] (361)*<br>to<br>07/29/[redacted] (367)*<br>[7] | Yes | 3 | None | None | Hospitalization, Concomitant Medication | Resolved |
| | 感染症および寄生虫症<br>尿路感染<br>UTI (40) | 07/23/[redacted] (361)*<br>to<br>07/30/[redacted] (368)*<br>[8] | Yes | 3 | None | None | Concomitant Medication, Hospitalization | Resolved |
| | | | | | | | | |
| 5-33-[redacted] | 血液およびリンパ系障害<br>発熱性好中球減少症<br>NEUTROPENIC FEVER (3) | 08/26/[redacted] (30)<br>to<br>08/28/[redacted] (32)<br>[3] | Yes | 3 | None | None | Hospitalization, Concomitant Medication | Resolved |
| | 呼吸器、胸郭および縦隔障害<br>胸水<br>INCREASED PLEURAL EFFUSION (4) | 08/26/[redacted] (30)<br>to<br>08/28/[redacted] (32)<br>[3] | Yes | 3 | None | None | Hospitalization | Resolved |
| | 呼吸器、胸郭および縦隔障害<br>呼吸困難<br>SHORTNESS OF BREATH (26) | 12/09/[redacted] (135)<br>to<br>12/11/[redacted] (137)<br>[3] | Yes | 3 | None | None | Hospitalization | Resolved |
| | 全身障害および投与局所様態<br>疾患進行<br>PROGRESSIVE DISEASE (35) | 12/17/[redacted] (143)<br>to<br>12/30/[redacted] (156)<br>[14] | Yes | 5 | None | Treatment Permanently Discontinued | Hospitalization, Patient Withdrawn | Death |
| | | | | | | | | |
| 5-33-[redacted] | 筋骨格系および結合組織障害<br>病的骨折<br>FRACTURE RT. TIBIA AND RT. FIBULA - PATHOLOGICAL (16) | 09/07/[redacted] (246)<br>to<br>09/13/[redacted] (252)<br>[7] | Yes | 3 | None | Dose Delayed | Concomitant Medication, Hospitalization, Procedure Required | Resolved |

**被験者識別コード，年齢以外のマスキングにおいて，**
**マークなし　：「同年」を意味する**
**＊　：「翌年」を意味する**

**表 2.7.4.7-39　重篤な有害事象の一覧表（PX-171-005）（続き 14）**

| Group 5 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Subject Number | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Serious | Severity (NCI Grade) | Study Drug Relation-ship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
| | 呼吸器、胸郭および縦隔障害<br>嚥下性肺炎<br>ASPIRATION PNEUMONIA (17) | 09/08/[redacted] (247)<br>to<br>09/13/[redacted] (252)<br>[6] | Yes | 3 | None | Dose Delayed | Concomitant Medication, Hospitalization | Resolved |
| | 感染症および寄生虫症<br>細菌性肺炎<br>BACTERIAL PNEUMONIA COMPLICATING INFLUENZA A (29) | 12/29/[redacted] (359)<br>to<br>01/04/[redacted] (365)*<br>[7] | Yes | 5 | None | None | Hospitalization, Concomitant Medication, Procedure Required | Death |
| | 感染症および寄生虫症<br>敗血症性ショック<br>SEPTIC SHOCK (30) | 12/29/[redacted] (359)<br>to<br>Continuing | Yes | 4 | None | None | Hospitalization, Concomitant Medication, Procedure Required | Continuing |
| | 呼吸器、胸郭および縦隔障害<br>呼吸不全<br>HYPOXIC RESPIRATORY FAILURE (31) | 12/29/[redacted] (359)<br>to<br>Continuing | Yes | 4 | None | None | Hospitalization, Concomitant Medication, Procedure Required | Continuing |

出典［総括報告書5.3.5.2-9（PX-171-005），Listing 16.2.7.3］

**被験者識別コード，年齢以外のマスキングにおいて，**
**マークなし　：「同年」を意味する**
**＊　：「翌年」を意味する**

**表 2.7.4.7-40　重篤な有害事象の一覧表（PX-171-007）**

| System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Treatment Emergent AE | Serious | Severity (NCI Grade) | Study Drug Relationship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|---|
| Phase: 1B　Cohort: 20 mg/m2　Subject Number: 7-23-[redacted]　Tumor Type: OTHER (PERITONEUM) | | | | | | | | |
| 全身障害および投与局所様態<br>疼痛<br>INTRACTABLE PAIN (8) | 06MAR20[redacted] (155)<br>to<br>10MAR20[redacted] (159)<br>[5] | Yes | Yes | 3 | NONE | NONE | HOSPITALIZATION | STABILIZED (NOT RESOLVED) |
| Phase: 1B　Cohort: 20/27 mg/m2　Subject Number: 7-23-[redacted]　Tumor Type: OTHER (LEFT NECK (OROPHARYNX)) | | | | | | | | |
| 呼吸器、胸郭および縦隔障害<br>嚥下性肺炎<br>ASPIRATION PNEUMONIA (6) | 28NOV20[redacted] (22)<br>to<br>23DEC20[redacted] (47)<br>[26] | Yes | Yes | 3 | UNLIKELY | TREATMENT PERMANENTLY DISCONTINUED | HOSPITALIZATION, PATIENT WITHDRAWN FROM STUDY | RESOLVED |
| Phase: 1B　Cohort: 20/36 mg/m2　Subject Number: 7-21-[redacted]　Tumor Type: SMALL CELL LUNG CANCER | | | | | | | | |
| 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）<br>髄膜転移<br>LEPTOMENINGEAL METASTASIS (1) | 20DEC20[redacted] (2)<br>to<br>Continuing | Yes | Yes | 3 | NONE | TREATMENT PERMANENTLY DISCONTINUED | HOSPITALIZATION, CONCOMITANT MEDICATION, PROCEDURE REQUIRED | STABILIZED (NOT RESOLVED) |
| Phase: 1B　Cohort: 20/36 mg/m2　Subject Number: 7-21-[redacted]　Tumor Type: SMALL CELL LUNG CANCER | | | | | | | | |
| 呼吸器、胸郭および縦隔障害<br>水気胸<br>HYDROPNEUMOTHORAX (19) | 10MAY20[redacted] (82)<br>to<br>13MAY20[redacted] (85)<br>[4] | Yes | Yes | 2 | NONE | DOSE DELAYED | CONCOMITANT MEDICATION, PROCEDURE REQUIRED, HOSPITALIZATION | RESOLVED |
| 神経系障害<br>不全片麻痺<br>LEFT SIDED HEMIPARESIS (18) | 29JUN20[redacted] (132)<br>to<br>01JUL20[redacted] (134)<br>[3] | Yes | Yes | 3 | NONE | DOSE DELAYED | NONE | RESOLVED |
| Phase: 1B　Cohort: 20/36 mg/m2　Subject Number: 7-23-[redacted]　Tumor Type: SMALL CELL LUNG CANCER | | | | | | | | |
| 全身障害および投与局所様態<br>注入に関連した反応<br>INFUSION REACTION (2) | 11FEB20[redacted] (29)<br>to<br>16FEB20[redacted] (34)<br>[6] | Yes | Yes | 3 | PROBABLE | NONE | HOSPITALIZATION | RESOLVED |
| Phase: 1B　Cohort: 20/36 mg/m2　Subject Number: 7-23-[redacted]　Tumor Type: OTHER (GASTRIC) | | | | | | | | |
| 感染症および寄生虫症<br>敗血症<br>SEPSIS (12) | 23JAN20[redacted] (9)<br>to<br>25JAN20[redacted] (11)<br>[3] | Yes | Yes | 3 | UNLIKELY | DOSE(S) MISSED | HOSPITALIZATION | RESOLVED |

**表 2.7.4.7-40　重篤な有害事象の一覧表（PX-171-007）（続き 1）**

| System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Treatment Emergent AE | Serious | Severity (NCI Grade) | Study Drug Relationship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|---|
| 胃腸障害<br>下痢<br>DIARRHEA (1) | 20FEB20[redacted] (37)<br>to<br>23FEB20[redacted] (40)<br>[4] | Yes | Yes | 4 | PROBABLE | TREATMENT PERMANENTLY DISCONTINUED | HOSPITALIZATION, PATIENT WITHDRAWN FROM STUDY | RESOLVED |
| Phase: 2　Cohort: 20/36 mg/m2 | Subject Number: 7-21-[redacted] | Tumor Type: OTHER (THYROID) | | | | | | |
| 呼吸器、胸郭および縦隔障害<br>慢性閉塞性肺疾患<br>COPD EXACERBATION (13) | 25JUL20[redacted] (47)<br>to<br>28JUL20[redacted] (50)<br>[4] | Yes | Yes | 3 | NONE | NONE | CONCOMITANT MEDICATION, HOSPITALIZATION | RESOLVED |
| Phase: 2　Cohort: 20/36 mg/m2 | Subject Number: 7-21-[redacted] | Tumor Type: OTHER (COLON) | | | | | | |
| 胃腸障害<br>腸管閉塞<br>BOWEL OBSTRUCTION (4) | 07AUG20[redacted] (10)<br>to<br>13AUG20[redacted] (16)<br>[7] | Yes | Yes | 3 | NONE | DOSE(S) MISSED | CONCOMITANT MEDICATION, HOSPITALIZATION, PROCEDURE REQUIRED | RESOLVED |
| 胃腸障害<br>腸管閉塞<br>BOWEL OBSTRUCTION (5) | 20AUG20[redacted] (23)<br>to<br>27AUG20[redacted] (30)<br>[8] | Yes | Yes | 3 | NONE | DOSE(S) MISSED | CONCOMITANT MEDICATION, HOSPITALIZATION, PROCEDURE REQUIRED | RESOLVED |
| Phase: 2　Cohort: 20/36 mg/m2 | Subject Number: 7-21-[redacted] | Tumor Type: OVARIAN | | | | | | |
| 胃腸障害<br>腹水<br>ASCITES-ABDOMINAL (10) | 01DEC20[redacted] (110)<br>to<br>03DEC20[redacted] (112)<br>[3] | Yes | Yes | 3 | UNLIKELY | NONE | CONCOMITANT MEDICATION, PROCEDURE REQUIRED | RESOLVED |
| 胃腸障害<br>イレウス<br>ILEUS (11) | 04DEC20[redacted] (113)<br>to<br>08DEC20[redacted] (117)<br>[5] | Yes | Yes | 3 | NONE | NONE | CONCOMITANT MEDICATION, PROCEDURE REQUIRED | RESOLVED |
| Phase: 2　Cohort: 20/36 mg/m2 | Subject Number: 7-21-[redacted] | Tumor Type: SMALL CELL LUNG CANCER | | | | | | |
| 全身障害および投与局所様態<br>疾患進行<br>PROGRESSION OF SMALL CELL LUNG CANCER (10) | 20JAN20[redacted] (71)<br>to<br>29JAN20[redacted] (80)<br>[10] | Yes | Yes | 5 | NONE | NONE | CONCOMITANT MEDICATION | DEATH |
| Phase: 2　Cohort: 20/36 mg/m2 | Subject Number: 7-21-[redacted] | Tumor Type: NON-SMALL CELL LUNG CANCER | | | | | | |
| 腎および尿路障害<br>急性腎不全<br>ACUTE RENAL FAILURE (18) | 28DEC20[redacted] (25)<br>to<br>01JAN20[redacted] (29)*<br>[5] | Yes | Yes | 3 | PROBABLE | NONE | CONCOMITANT MEDICATION, HOSPITALIZATION | RESOLVED |

**被験者識別コード，年齢以外のマスキングにおいて，**
**マークなし　：「同年」を意味する**
**＊　：「翌年」を意味する**

**表 2.7.4.7-40　重篤な有害事象の一覧表（PX-171-007）（続き 2）**

| System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Treatment Emergent AE | Serious | Severity (NCI Grade) | Study Drug Relationship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|---|
| Phase: 2　Cohort: 20/36 mg/m2 | Subject Number: 7-21-[redacted] | Tumor Type: NON-SMALL CELL LUNG CANCER | | | | | | |
| 感染症および寄生虫症<br>肺炎<br>PNEUMONIA (7) | 16MAY20[redacted] (123)<br>to<br>22MAY20[redacted] (129)<br>[7] | Yes | Yes | 3 | UNLIKELY | NONE | CONCOMITANT MEDICATION, PROCEDURE REQUIRED | RESOLVED |
| Phase: 2　Cohort: 20/36 mg/m2 | Subject Number: 7-21-[redacted] | Tumor Type: NON-SMALL CELL LUNG CANCER | | | | | | |
| 呼吸器、胸郭および縦隔障害<br>呼吸不全<br>RESPIRATORY INSUFFICIENCY (8) | 09MAR20[redacted] (19)<br>to<br>14MAR20[redacted] (24)<br>[6] | Yes | Yes | 3 | NONE | NONE | CONCOMITANT MEDICATION, PROCEDURE REQUIRED | RESOLVED |
| Phase: 2　Cohort: 20/36 mg/m2 | Subject Number: 7-21-[redacted] | Tumor Type: SMALL CELL LUNG CANCER | | | | | | |
| 傷害、中毒および処置合併症<br>転倒<br>MULTIPLE RECURRENT FALLS (4) | 01APR20[redacted] (22)<br>to<br>08APR20[redacted] (29)<br>[8] | Yes | Yes | 3 | NONE | DOSE DELAYED | CONCOMITANT MEDICATION, PROCEDURE REQUIRED | RESOLVED |
| 精神障害<br>精神状態変化<br>ACUTE MENTAL STATUS CHANGES (5) | 23APR20[redacted] (44)<br>to<br>24APR20[redacted] (45)<br>[2] | Yes | Yes | 3 | NONE | DOSE(S) MISSED | PROCEDURE REQUIRED | RESOLVED |
| 全身障害および投与局所様態<br>発熱<br>FEVER (6) | 23APR20[redacted] (44)<br>to<br>24APR20[redacted] (45)<br>[2] | Yes | Yes | 3 | NONE | DOSE(S) MISSED | PROCEDURE REQUIRED | RESOLVED |
| Phase: 2　Cohort: 20/36 mg/m2 | Subject Number: 7-23-[redacted] | Tumor Type: RENAL | | | | | | |
| 呼吸器、胸郭および縦隔障害<br>呼吸困難<br>DYSPNEA (1) | 04DEC20[redacted] (17)<br>to<br>16DEC20[redacted] (29)<br>[13] | Yes | Yes | 3 | UNLIKELY | NONE | HOSPITALIZATION | RESOLVED |
| 血管障害<br>高血圧<br>UNCONTROLLED HYPERTENSION (2) | 04DEC20[redacted] (17)<br>to<br>10DEC20[redacted] (23)<br>[7] | Yes | Yes | 3 | UNLIKELY | NONE | HOSPITALIZATION | STABILIZED (NOT RESOLVED) |
| Phase: 2　Cohort: 20/36 mg/m2 | Subject Number: 7-23-[redacted] | Tumor Type: SMALL CELL LUNG CANCER | | | | | | |
| 全身障害および投与局所様態<br>疾患進行<br>STAGE 4 METASTATIC SMALL CELL LUNG CANCER (1) | 18FEB20[redacted] (8)<br>to<br>20FEB20[redacted] (10)<br>[3] | Yes | Yes | 3 | NONE | NONE | PROCEDURE REQUIRED, HOSPITALIZATION | UNKNOWN/LOST TO FOLLOW-UP |
| Phase: 2　Cohort: 20/36 mg/m2 | Subject Number: 7-24-[redacted] | Tumor Type: OTHER (PANCREAS) | | | | | | |

**表 2.7.4.7-40　重篤な有害事象の一覧表（PX-171-007）（続き 3）**

| System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Treatment Emergent AE | Serious | Severity (NCI Grade) | Study Drug Relationship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|---|
| 全身障害および投与局所様態<br>疾患進行<br>DISEASE PROGRESSION (DEATH) (7) | 14MAY20[redacted] (16)<br>to<br>14MAY20[redacted] (16)<br>[1] | Yes | Yes | 5 | UNLIKELY | NONE | NONE | DEATH |
| Phase: 2　Cohort: 20/36 mg/m2　Subject Number: 7-24-[redacted] | | Tumor Type: OTHER (ESOPHAGEAL) | | | | | | |
| 全身障害および投与局所様態<br>注入に関連した反応<br>INFUSION REACTION (6) | 19JUN20[redacted] (8)<br>to<br>19JUN20[redacted] (8)<br>[1] | Yes | Yes | 2 | PROBABLE | INFUSION INTERRUPTED, TREATMENT PERMANENTLY DISCONTINUED | CONCOMITANT MEDICATION, PATIENT WITHDRAWN FROM STUDY | RESOLVED |
| Phase: 2　Cohort: 20/36 mg/m2　Subject Number: 7-24-[redacted] | | Tumor Type: OVARIAN | | | | | | |
| 皮膚および皮下組織障害<br>発疹<br>RASH (5) | 25AUG20[redacted] (57)<br>to<br>14NOV20[redacted] (138)<br>[82] | Yes | Yes | 3 | POSSIBLE | NONE | CONCOMITANT MEDICATION | RESOLVED |
| Phase: 2　Cohort: 20/36 mg/m2　Subject Number: 7-24-[redacted] | | Tumor Type: OTHER (ESOPHAGUS) | | | | | | |
| 神経系障害<br>脊髄圧迫<br>SPINAL CORD COMPRESSION (2) | 28JUL20[redacted] (12)<br>to<br>02AUG20[redacted] (17)<br>[6] | Yes | Yes | 3 | NONE | TREATMENT PERMANENTLY DISCONTINUED | PROCEDURE REQUIRED, PATIENT WITHDRAWN FROM STUDY | RESOLVED |
| Phase: 2　Cohort: 20/36 mg/m2　Subject Number: 7-24-[redacted] | | Tumor Type: SMALL CELL LUNG CANCER | | | | | | |
| 代謝および栄養障害<br>低ナトリウム血症<br>HYPONATREMIA (4) | 25SEP20[redacted] (29)<br>to<br>12NOV20[redacted] (77)<br>[49] | Yes | Yes | 3 | POSSIBLE | TREATMENT PERMANENTLY DISCONTINUED | CONCOMITANT MEDICATION, PATIENT WITHDRAWN FROM STUDY | RESOLVED |
| Phase: 2　Cohort: 20/36 mg/m2　Subject Number: 7-29-[redacted] | | Tumor Type: OTHER (PANCREATIC) | | | | | | |
| 血管障害<br>深部静脈血栓症<br>DEEP VENOUS THROMBOSIS, BILATERAL LOWER EXTREMITIES (4) | 08JUL20[redacted] (8)<br>to<br>11JUL20[redacted] (11)<br>[4] | Yes | Yes | 3 | POSSIBLE | DOSE(S) MISSED | CONCOMITANT MEDICATION | STABILIZED (NOT RESOLVED) |
| Phase: 2　Cohort: 20/36 mg/m2　Subject Number: 7-29-[redacted] | | Tumor Type: NON-SMALL CELL LUNG CANCER | | | | | | |
| 呼吸器、胸郭および縦隔障害<br>慢性閉塞性肺疾患<br>EXACERBATION OF COPD (14) | 29NOV20[redacted] (81)<br>to<br>10DEC20[redacted] (92)<br>[12] | Yes | Yes | 4 | NONE | NONE | HOSPITALIZATION, CONCOMITANT MEDICATION | RESOLVED |
| Phase: 2　Cohort: 20/36 mg/m2　Subject Number: 7-29-[redacted] | | Tumor Type: OTHER (GALLBLADDER CARCINOMA) | | | | | | |

**表 2.7.4.7-40　重篤な有害事象の一覧表（PX-171-007）（続き 4）**

| System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Treatment Emergent AE | Serious | Severity (NCI Grade) | Study Drug Relationship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|---|
| 全身障害および投与局所様態<br>疼痛<br>INTRACTABLE PAIN (18) | 07DEC20[redacted] (70)<br>to<br>10DEC20[redacted] (73)<br>[4] | Yes | Yes | 4 | NONE | NONE | HOSPITALIZATION, CONCOMITANT MEDICATION | STABILIZED (NOT RESOLVED) |
| Phase: 2　Cohort: 20/36 mg/m2 | Subject Number: 7-29-[redacted] | Tumor Type: SMALL CELL LUNG CANCER | | | | | | |
| 肝胆道系障害<br>肝腎不全<br>HEPATORENAL FAILURE (15) | 31OCT20[redacted] (11)<br>to<br>06NOV20[redacted] (17)<br>[7] | Yes | Yes | 5 | UNLIKELY | TREATMENT PERMANENTLY DISCONTINUED | HOSPITALIZATION, PROCEDURE REQUIRED, PATIENT WITHDRAWN FROM STUDY | DEATH |
| Phase: 2　Cohort: 20/36 mg/m2 | Subject Number: 7-29-[redacted] | Tumor Type: NON-SMALL CELL LUNG CANCER | | | | | | |
| 心臓障害<br>うっ血性心不全<br>CONGESTIVE HEART FAILURE (6) | 04MAR20[redacted] (22)<br>to<br>Continuing | Yes | Yes | 3 | POSSIBLE | TREATMENT PERMANENTLY DISCONTINUED | HOSPITALIZATION, CONCOMITANT MEDICATION, PATIENT WITHDRAWN FROM STUDY | STABILIZED (NOT RESOLVED) |
| Phase: 2　Cohort: 20/36 mg/m2 | Subject Number: 7-30-[redacted] | Tumor Type: OVARIAN | | | | | | |
| 全身障害および投与局所様態<br>疾患進行<br>PROGRESSIVE DISEASE (15) | 08AUG20[redacted] (72)<br>to<br>06SEP20[redacted] (101)<br>[30] | Yes | Yes | 5 | NONE | NONE | PROCEDURE REQUIRED | DEATH |
| 神経系障害<br>脊髄圧迫<br>SPINAL CORD COMPRESSION (18) | 08AUG20[redacted] (72)<br>to<br>Continuing | Yes | Yes | 3 | NONE | NONE | CONCOMITANT MEDICATION, PROCEDURE REQUIRED, HOSPITALIZATION | CONTINUING |
| Phase: 2　Cohort: 20/36 mg/m2 | Subject Number: 7-30-[redacted] | Tumor Type: NON-SMALL CELL LUNG CANCER | | | | | | |
| 代謝および栄養障害<br>低ナトリウム血症<br>HYPONATREMIA (16) | 30JUN20[redacted] (7)<br>to<br>09JUL20[redacted] (16)<br>[10] | Yes | Yes | 3 | NONE | NONE | HOSPITALIZATION | RESOLVED |
| 腎および尿路障害<br>急性腎不全<br>ACUTE RENAL FAILURE (18) | 08JUL20[redacted] (15)<br>to<br>10JUL20[redacted] (17)<br>[3] | Yes | Yes | 3 | POSSIBLE | DOSE(S) MISSED | HOSPITALIZATION | RESOLVED |
| Phase: 2　Cohort: 20/36 mg/m2 | Subject Number: 7-30-[redacted] | Tumor Type: OVARIAN | | | | | | |

**表 2.7.4.7-40　重篤な有害事象の一覧表（PX-171-007）（続き 5）**

| System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Treatment Emergent AE | Serious | Severity (NCI Grade) | Study Drug Relationship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|---|
| 神経系障害<br>神経炎<br>SACRAL NEURITIS (16) | 28JUL20[redacted] (35)<br>to<br>01AUG20[redacted] (39)<br>[5] | Yes | Yes | 3 | NONE | TREATMENT PERMANENTLY DISCONTINUED | HOSPITALIZATION, PATIENT WITHDRAWN FROM STUDY | RESOLVED |
| Phase: 2　Cohort: 20/36 mg/m2　Subject Number: 7-30-[redacted]　Tumor Type: NON-SMALL CELL LUNG CANCER | | | | | | | | |
| 感染症および寄生虫症<br>肺炎<br>COMMUNITY ACQUIRED PNEUMONIA (12) | 12FEB20[redacted] (17)<br>to<br>15FEB20[redacted] (20)<br>[4] | Yes | Yes | 4 | POSSIBLE | TREATMENT PERMANENTLY DISCONTINUED | HOSPITALIZATION, PROCEDURE REQUIRED, CONCOMITANT MEDICATION | RESOLVED |
| 感染症および寄生虫症<br>敗血症性ショック<br>SEPTIC SHOCK (13) | 12FEB20[redacted] (17)<br>to<br>15FEB20[redacted] (20)<br>[4] | Yes | Yes | 4 | POSSIBLE | TREATMENT PERMANENTLY DISCONTINUED | HOSPITALIZATION, PROCEDURE REQUIRED, CONCOMITANT MEDICATION | RESOLVED |
| Phase: 2　Cohort: 20/36 mg/m2　Subject Number: 7-30-[redacted]　Tumor Type: NON-SMALL CELL LUNG CANCER | | | | | | | | |
| 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）<br>悪性胸水<br>MALIGNANT PLEURAL EFFUSIONS (32) | 16MAR20[redacted] (41)<br>to<br>23MAR20[redacted] (48)<br>[8] | Yes | Yes | 3 | UNLIKELY | TREATMENT PERMANENTLY DISCONTINUED | HOSPITALIZATION, PATIENT WITHDRAWN FROM STUDY, CONCOMITANT MEDICATION | RESOLVED |
| 代謝および栄養障害<br>水分過負荷<br>FLUID OVERLOAD (35) | 16MAR20[redacted] (41)<br>to<br>23MAR20[redacted] (48)<br>[8] | Yes | Yes | 3 | UNLIKELY | NONE | HOSPITALIZATION | RESOLVED |
| 全身障害および投与局所様態<br>疾患進行<br>PROGRESSION OF DISEASE RESULTING IN DEATH (34) | 03APR20[redacted] (59)<br>to<br>03APR20[redacted] (59)<br>[1] | Yes | Yes | 5 | NONE | NONE | NONE | DEATH |
| Phase: 2　Cohort: 20/36 mg/m2　Subject Number: 7-30-[redacted]　Tumor Type: RENAL | | | | | | | | |
| 呼吸器、胸郭および縦隔障害<br>肺塞栓症<br>SOB - DYSPNEA SECONDARY TO PE (50) | 18AUG20[redacted] (160)<br>to<br>26AUG20[redacted] (168)<br>[9] | Yes | Yes | 3 | UNLIKELY | DOSE(S) MISSED | HOSPITALIZATION, PROCEDURE REQUIRED | RESOLVED |
| 血管障害<br>深部静脈血栓症<br>DEEP VEIN THROMBOSIS (51) | 18AUG20[redacted] (160)<br>to<br>26AUG20[redacted] (168)<br>[9] | Yes | Yes | 3 | UNLIKELY | DOSE(S) MISSED | HOSPITALIZATION, PROCEDURE REQUIRED | STABILIZED (NOT RESOLVED) |

**表 2.7.4.7-40　重篤な有害事象の一覧表（PX-171-007）（続き 6）**

| System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Treatment Emergent AE | Serious | Severity (NCI Grade) | Study Drug Relationship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|---|
| 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）<br>転移性新生物<br>METASTATIC DISEASE TO THORACIC SPINE (63) | 24AUG20[redacted] (166)<br>to<br>03SEP20[redacted] (176)<br>[11] | Yes | Yes | 3 | UNLIKELY | NONE | PROCEDURE REQUIRED, HOSPITALIZATION | RESOLVED |
| Phase: 2　Cohort: 20/36 mg/m2　Subject Number: 7-30-[redacted]　Tumor Type: RENAL | | | | | | | | |
| 代謝および栄養障害<br>脱水<br>DEHYDRATION (26) | 20APR20[redacted] (35)<br>to<br>24APR20[redacted] (39)<br>[5] | Yes | Yes | 3 | UNLIKELY | NONE | HOSPITALIZATION | RESOLVED |
| 全身障害および投与局所様態<br>疼痛<br>INTRACTABLE PAIN (34) | 20APR20[redacted] (35)<br>to<br>24APR20[redacted] (39)<br>[5] | Yes | Yes | 4 | UNLIKELY | NONE | HOSPITALIZATION | RESOLVED |

出典［総括報告書5.3.5.2-11（PX-171-007），Listing 16.2.1.29］

**表 2.7.4.7-41　重篤な有害事象の一覧表（PX-171-008）**

| Subject Number | Carfilzomib Treatment | System Organ Class Preferred Term Reported Term (AE #) | Date (Study Day) [Duration(days)] | Severity (NCI Grade) | Relationship to Carfilzomib/ Midazolam | Action Taken Regarding Carfilzomib/ Midazolam | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |
| 8-21-[redacted] | 27 mg/m2 | 感染症および寄生虫症<br>尿路感染<br>Urinary tract infection (2) | 12FEB20[redacted] (9)<br>to<br>18FEB20[redacted] (15)<br>[7] | Grade 2 | None / None | Dose Delayed / Dose Delayed | Concomitant Medication, Hospitalization | Resolved |
| 8-21-[redacted] | 27 mg/m2 | 血管障害<br>高血圧<br>Hypertension (11) | 23FEB20[redacted] (20)<br>to<br>27FEB20[redacted] (24)<br>[5] | Grade 3 | None / None | Discontinued / Discontinued | Concomitant Medication, Hospitalization, Patient Withdrawn From Study | Stabilized (not resolved) |
| | | | | | | | | |
| 8-21-[redacted] | 27 mg/m2 | 感染症および寄生虫症<br>肺炎<br>Pneumonia (2) | 19FEB20[redacted] (12)<br>to<br>24FEB20[redacted] (17)<br>[6] | Grade 3 | None / None | Discontinued / Discontinued | Concomitant Medication, Hospitalization, Patient Withdrawn From Study | Resolved |
| | | | | | | | | |
| 8-21-[redacted] | 0 mg/m2 | 感染症および寄生虫症<br>肺炎<br>Pneumonia (5) | 05FEB20[redacted] (-)<br>to<br>10FEB20[redacted] (-)<br>[6] | Grade 3 | None / None | None / Discontinued | Concomitant Medication, Hospitalization, Patient Withdrawn From Study | Death |
| | | | | | | | | |
| 8-21-[redacted] | 27 mg/m2 | 腎および尿路障害<br>血尿<br>Hematuria (6) | 04MAR20[redacted] (11)<br>to<br>09MAR20[redacted] (16)<br>[6] | Grade 1 | None / None | Discontinued / Discontinued | Concomitant Medication, Hospitalization | Resolved |
| 8-21-[redacted] | 27 mg/m2 | 感染症および寄生虫症<br>肺炎<br>Pneumonia (16) | 04MAR20[redacted] (11)<br>to<br>09MAR20[redacted] (16)<br>[6] | Grade 3 | None / None | Discontinued / Discontinued | Concomitant Medication, Hospitalization, Patient Withdrawn From Study | Resolved |
| | | | | | | | | |
| 8-21-[redacted] | 27 mg/m2 | 全身障害および投与局所様態<br>疼痛<br>Generalized pain (5) | 01APR20[redacted] (1)<br>to<br>06APR20[redacted] (6)<br>[6] | Grade 3 | None / None | Discontinued / Discontinued | Concomitant Medication, Hospitalization, Patient Withdrawn From Study | Resolved |
| 8-21-[redacted] | 27 mg/m2 | 血管障害<br>低血圧<br>Hypotension (4) | 01APR20[redacted] (1)<br>to<br>06APR20[redacted] (6)<br>[6] | Grade 3 | Possible / Possible | Discontinued / Discontinued | Concomitant Medication, Hospitalization, Patient Withdrawn From Study | Resolved |

**表 2.7.4.7-41　重篤な有害事象の一覧表（PX-171-008）（続き）**

| Subject Number | Carfilzomib Treatment | System Organ Class<br>Preferred Term<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Severity (NCI Grade) | Relationship to Carfilzomib/ Midazolam | Action Taken Regarding Carfilzomib/ Midazolam | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |
| 8-21-[redacted] | 27 mg/m2 | 腎および尿路障害<br>急性腎不全<br>Acute renal failure (2) | 07MAY20[redacted] (2)<br>to<br>10MAY20[redacted] (5)<br>[4] | Grade 3 | Possible / None | Discontinued / None | Concomitant Medication, Hospitalization, Patient Withdrawn From Study | Resolved |

出典［総括報告書5.3.3.4-1（PX-171-008），Listing 16.2.7.2］

**表 2.7.4.7-42　重篤な有害事象の一覧表（PX-171-010）**

| System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Serious | Severity<br>(NCI Grade) | Study Drug<br>Relationship | Action Taken<br>Regarding<br>Study Drug | Other<br>Action Taken | Outcome |
|---|---|---|---|---|---|---|---|
| Subject Number: 03-01-[redacted] | | | | | | | |
| 感染症および寄生虫症<br>感染<br>Infection (1) | 15JUL[redacted] (39)<br>to<br>19JUL[redacted] (43)<br>[5] | Yes | SEVERE | POSSIBLE | DOSE(S)<br>MISSED | CONCOMITANT<br>MEDICATION,<br>PROCEDURE<br>REQUIRED,<br>HOSPITALIZATION | RESOLVED |
| 神経系障害<br>頭痛<br>Severe Headache (3) | 27OCT[redacted] (143) | Yes | SEVERE | UNLIKELY | DOSE DELAYED | HOSPITALIZATION | CONTINUING |
| Subject Number: 03-15-[redacted] | | | | | | | |
| 神経系障害<br>脳血管発作<br>Cva (1) | 06NOV[redacted] (202) | Yes | LIFE<br>THREATENI<br>NG OR<br>DISABLING | POSSIBLE | | HOSPITALIZATION | |
| Subject Number: 03-15-[redacted] | | | | | | | |
| 筋骨格系および結合組織障害<br>病的骨折<br>Pathologic Fracture Left Humerus (2) | 24SEP[redacted] (128)<br>to<br>25SEP[redacted] (129)<br>[2] | Yes | SEVERE | NONE | NONE | PROCEDURE<br>REQUIRED,<br>HOSPITALIZATION | RESOLVED |
| 感染症および寄生虫症<br>大葉性肺炎<br>Right Lower Lobe Pneumonia (3) | 15OCT[redacted] (149)<br>to<br>19OCT[redacted] (153)<br>[5] | Yes | SEVERE | NONE | NONE | PROCEDURE<br>REQUIRED,<br>HOSPITALIZATION | RESOLVED |
| Subject Number: 03-15-[redacted] | | | | | | | |
| 胃腸障害<br>下痢<br>Diarrhea (1) | 18OCT[redacted] (99)<br>to<br>20OCT[redacted] (101)<br>[3] | Yes | SEVERE | UNLIKELY | DOSE(S)<br>MISSED | HOSPITALIZATION | RESOLVED |
| Subject Number: 03-15-[redacted] | | | | | | | |
| 呼吸器、胸郭および縦隔障害<br>呼吸困難<br>Shortness Of Breath (2) | 16JUL[redacted] (213)<br>to<br>18JUL[redacted] (215)<br>[3] | Yes | SEVERE | PROBABLE | NONE | HOSPITALIZATION | RESOLVED |
| 呼吸器、胸郭および縦隔障害<br>呼吸困難<br>Dyspnea (6) | 20AUG[redacted] (248)<br>to<br>24AUG[redacted] (252)<br>[5] | Yes | SEVERE | POSSIBLE | NONE | PROCEDURE<br>REQUIRED,<br>HOSPITALIZATION | RESOLVED |
| Subject Number: 03-18-[redacted] | | | | | | | |

**表 2.7.4.7-42　重篤な有害事象の一覧表（PX-171-010）（続き 1）**

| System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Serious | Severity<br>(NCI Grade) | Study Drug<br>Relationship | Action Taken<br>Regarding<br>Study Drug | Other<br>Action Taken | Outcome |
|---|---|---|---|---|---|---|---|
| 感染症および寄生虫症<br>インフルエンザ<br>Influenza　A (1) | 09MAR[redacted] (149)<br>to<br>15MAR[redacted] (155)<br>[7] | Yes | SEVERE | UNLIKELY | DOSE(S)<br>MISSED | HOSPITALIZATION,<br>CONCOMITANT<br>MEDICATION | RESOLVED |
| 全身障害および投与局所様態<br>疼痛<br>Pain (2) | 09OCT[redacted] (363)<br>to<br>15OCT[redacted] (369)<br>[7] | Yes | SEVERE | NONE | DOSE(S)<br>MISSED | HOSPITALIZATION,<br>CONCOMITANT<br>MEDICATION | RESOLVED |
| 全身障害および投与局所様態<br>発熱<br>Fevers (3) | 01NOV[redacted] (386)<br>to<br>04NOV[redacted] (389)<br>[4] | Yes | SEVERE | POSSIBLE | NONE | CONCOMITANT<br>MEDICATION,<br>HOSPITALIZATION | RESOLVED |
| Subject Number: 04-15-[redacted] | | | | | | | |
| 神経系障害<br>失神<br>Syncope (1) | 17OCT[redacted] (159)<br>to<br>18OCT[redacted] (160)<br>[2] | Yes | SEVERE | UNLIKELY | NONE | PROCEDURE<br>REQUIRED,<br>HOSPITALIZATION | RESOLVED |
| Subject Number: 04-18-[redacted] | | | | | | | |
| 感染症および寄生虫症<br>肺炎<br>Community Acquired Pneumonia (1) | 31OCT[redacted] (102)<br>to<br>03NOV[redacted] (105)<br>[4] | Yes | SEVERE | UNLIKELY | NONE | HOSPITALIZATION,<br>CONCOMITANT<br>MEDICATION | RESOLVED |
| 感染症および寄生虫症<br>気管支炎<br>Bronchitis (2) | 26APR[redacted] (279)*<br>to<br>29APR[redacted] (282)*<br>[4] | Yes | SEVERE | POSSIBLE | DOSE DELAYED | HOSPITALIZATION,<br>CONCOMITANT<br>MEDICATION | RESOLVED |
| 全身障害および投与局所様態<br>無力症<br>Weakness (3) | 01JUN[redacted] (315)*<br>to<br>04JUN[redacted] (318)*<br>[4] | Yes | SEVERE | POSSIBLE | DOSE DELAYED | CONCOMITANT<br>MEDICATION,<br>HOSPITALIZATION | RESOLVED |
| 全身障害および投与局所様態<br>無力症<br>Weakness (5) | 01JUN[redacted] (315) *<br>to<br>04JUN[redacted] (318)*<br>[4] | Yes | SEVERE | UNLIKELY | DOSE DELAYED | HOSPITALIZATION,<br>CONCOMITANT<br>MEDICATION | RESOLVED |
| Subject Number: 04-47-[redacted] | | | | | | | |
| 神経系障害<br>脳血管発作<br>Cerebral Vascular Accident (1) | 24JUL[redacted] (45)<br>to<br>27JUL[redacted] (48)<br>[4] | Yes | LIFE<br>THREATENI<br>NG OR<br>DISABLING | NONE | DOSE(S)<br>MISSED | HOSPITALIZATION | STABILIZED (NOT<br>RESOLVED) |

**被験者識別コード，年齢以外のマスキングにおいて，**
**マークなし　：「同年」を意味する**
**＊　：「翌年」を意味する**

**表 2.7.4.7-42　重篤な有害事象の一覧表（PX-171-010）（続き 2）**

| System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (Study Day)<br>[Duration(days)] | Serious | Severity<br>(NCI Grade) | Study Drug<br>Relationship | Action Taken<br>Regarding<br>Study Drug | Other<br>Action Taken | Outcome |
|---|---|---|---|---|---|---|---|
| Subject Number: 07-21-[redacted] | | | | | | | |
| 筋骨格系および結合組織障害<br>関節痛<br>Right Hip Pain (1) | 13JUL[redacted] (62)<br>to<br>05AUG[redacted] (85)<br>[24] | Yes | SEVERE | NONE | TREATMENT<br>PERMANENTLY<br>DISCONTINUED | CONCOMITANT<br>MEDICATION,<br>PROCEDURE<br>REQUIRED,<br>HOSPITALIZATION | RESOLVED |
| Subject Number: 07-21-[redacted] | | | | | | | |
| 感染症および寄生虫症<br>肺炎<br>Pneumonia (22) | 17JUL[redacted] (465)<br>to<br>26JUL[redacted] (474)<br>[10] | Yes | SEVERE | NONE | DOSE<br>INTERRUPTED | CONCOMITANT<br>MEDICATION,<br>HOSPITALIZATION | RESOLVED |
| 腎および尿路障害<br>急性腎不全<br>Acute Renal Failure (24) | 21JUL[redacted] (469)<br>to<br>26JUL[redacted] (474)<br>[6] | Yes | SEVERE | NONE | DOSE<br>INTERRUPTED | CONCOMITANT<br>MEDICATION | RESOLVED |
| Subject Number: 08-21-[redacted] | | | | | | | |
| 心臓障害<br>心筋症<br>Non-Ischemic Cardiomyopathy (3) | 19FEB[redacted] (38)<br>to<br>22FEB[redacted] (41)<br>[4] | Yes | SEVERE | POSSIBLE | TREATMENT<br>PERMANENTLY<br>DISCONTINUED | CONCOMITANT<br>MEDICATION,<br>HOSPITALIZATION | RESOLVED |
| Subject Number: 08-21-[redacted] | | | | | | | |
| 感染症および寄生虫症<br>感染<br>Infection - Unknown Origin (4) | 08JUL[redacted] (137)<br>to<br>09JUL[redacted] (138)<br>[2] | Yes | SEVERE | NONE | NONE | CONCOMITANT<br>MEDICATION,<br>HOSPITALIZATION | RESOLVED |
| 感染症および寄生虫症<br>敗血症<br>Sepsis (5) | 16JUL[redacted] (145)<br>to<br>19JUL[redacted] (148)<br>[4] | Yes | SEVERE | NONE | NONE | CONCOMITANT<br>MEDICATION,<br>HOSPITALIZATION | RESOLVED |

出典［総括報告書5.3.5.4-1（PX-171-010），Listing 4.2］

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

| REGIMEN BSC | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Subject ID** | **System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #)** | **Date (#Days from First Dose)<br>[Duration(days)]** | **Severity (NCI Grade)** | **Study Drug Relationship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| 10-376-1[redacted] | 一般・全身障害および投与部位の状態<br>胸痛<br>Thoracic Pain (12) | 20[redacted]-09-27 (-4)<br>to<br>20[redacted]-09-29 (-2)<br>[3] | 1 | Not Related | Dose Not Changed | Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 10-378-1[redacted] | 感染症および寄生虫症<br>帯状疱疹<br>Herpes Zoster Left Shoulder, Ventral And Dorsal (1) | 20[redacted]-08-20 (20)<br>to<br>20[redacted]-08-30 (30)<br>[11] | 3 | Related | Drug Interrupted | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 10-378-1[redacted] | 感染症および寄生虫症<br>肺炎<br>Pneumonia (3) | 20[redacted]-02-27 (154)<br>to<br>20[redacted]-03-07 (162)<br>[9] | 5 | Related | Drug Interrupted | Concomitant Medication, Hospitalization | Fatal |
| | | | | | | | |
| 10-392-1[redacted] | 筋骨格系および結合組織障害<br>背部痛<br>Back Pain (1) | 20[redacted]-08-29 (10)<br>to<br>20[redacted]-09-27 (39)<br>[30] | 3 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved With Sequelae |
| | 胃腸障害<br>悪心<br>Nausea (4) | 20[redacted]-10-12 (54)<br>to<br>20[redacted]-10-24 (66)<br>[13] | 3 | Related | Drug Interrupted | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | 胃腸障害<br>嘔吐<br>Vometing (5) | 20[redacted]-10-12 (54)<br>to<br>20[redacted]-10-24 (66)<br>[13] | 3 | Related | Drug Interrupted | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 10-392-1[redacted] | 筋骨格系および結合組織障害<br>背部痛<br>Back Pain (5) | 20[redacted]-09-16 (-9)<br>to<br>20[redacted]-10-08 (13)<br>[23] | 3 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved With Sequelae |
| | | | | | | | |
| 12-860-1[redacted] | 感染症および寄生虫症<br>尿路感染<br>Urinary Tract Infection (3) | 20[redacted]-06-02 (32)<br>to<br>20[redacted]-06-03 (33)<br>[2] | 2 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |

**表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 1）**

| REGIMEN BSC | | | | | | | |
|---|---|---|---|---|---|---|---|
| Subject ID | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (#Days from First Dose) [Duration(days)] | Severity (NCI Grade) | Study Drug Relationship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
| | 感染症および寄生虫症<br>尿路感染<br>Urinary Tract Infection (10) | 20[redacted]-06-04 (34)<br>to<br>20[redacted]-06-11 (41)<br>[8] | 2 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | 免疫系障害<br>過敏症<br>Allergic Reaction To Mouthwash (24) | 20[redacted]-08-25 (116)<br>to<br>20[redacted]-08-26 (117)<br>[2] | 3 | Not Related | Drug Interrupted | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 12-860-1[redacted] | 一般・全身障害および投与部位の状態<br>疾患進行<br>Disease Progression (4) | 20[redacted]-05-17 (9)<br>to<br>Continuing | 3 | Not Related | Dose Not Changed | Concomitant Medication, Procedure Required | Not Recovered/ Not Resolved |
| | | | | | | | |
| 12-860-1[redacted] | 感染症および寄生虫症<br>肺炎<br>Pneumonia (10) | 20[redacted]-08-27 (48)<br>to<br>20[redacted]-08-29 (50)<br>[3] | 5 | Not Related | Dose Not Changed | Hospitalization | Fatal |
| | | | | | | | |
| 12-860-1[redacted] | 感染症および寄生虫症<br>眼窩周囲蜂巣炎<br>Periorbital Cellulitis (Right Eye) (30) | 20[redacted]-12-11 (505)<br>to<br>20[redacted]-12-16 (510)<br>[6] | 3 | Related | Drug Interrupted | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 12-860-1[redacted] | 筋骨格系および結合組織障害<br>骨痛<br>Bone Pain (4) | 20[redacted]-11-15 (51)<br>to<br>20[redacted]-11-20 (56)<br>[6] | 2 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | 血液およびリンパ系障害<br>貧血<br>Anemia (5) | 20[redacted]-01-09 (106)<br>＊ to<br>Continuing | 4 | Not Related | Dose Not Changed | Concomitant Medication, Procedure Required, Hospitalization | Not Recovered/ Not Resolved |
| | 一般・全身障害および投与部位の状態<br>疾患進行<br>Disease Progression (8) | 20[redacted]-02-03 (131)<br>＊ to<br>20[redacted]-02-03 (131)<br>＊ [1] | 5 | Not Related | Dose Not Changed | None | Fatal |

**被験者識別コード，年齢以外のマスキングにおいて，**
**マークなし　：「同年」を意味する**
**＊　：「翌年」を意味する**

**表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 2）**

| REGIMEN BSC | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Subject ID** | **System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #)** | **Date (#Days from First Dose)<br>[Duration(days)]** | **Severity (NCI Grade)** | **Study Drug Relationship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| 12-863-1[redacted] | 血液およびリンパ系障害<br>貧血<br>Anaemia (2) | 20[redacted]-10-01 (15)<br>to<br>20[redacted]-10-02 (16)<br>[2] | 2 | Not Related | Dose Not Changed | Procedure Required, Hospitalization | Recovered/ Resolved |
| | 感染症および寄生虫症<br>感染<br>Infection ?source (1) | 20[redacted]-10-07 (21)<br>to<br>Continuing | 3 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Not Recovered/ Not Resolved |
| | 傷害、中毒および処置合併症<br>腰椎骨折<br>L2 Compression Fracture (3) | 20[redacted]-10-07 (21)<br>to<br>Continuing | 3 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Not Recovered/ Not Resolved |
| | 腎および尿路障害<br>急性腎不全<br>Acute Renal Failure (4) | 20[redacted]-10-07 (21)<br>to<br>Continuing | 4 | Not Related | Dose Not Changed | Concomitant Medication, Procedure Required, Hospitalization | Not Recovered/ Not Resolved |
| | | | | | | | |
| 12-865-1[redacted] | 血液およびリンパ系障害<br>貧血<br>Anaemia (5) | 20[redacted]-09-10 (26)<br>to<br>20[redacted]-09-12 (28)<br>[3] | 4 | Related | Drug Interrupted | Procedure Required, Hospitalization | Recovered/ Resolved |
| | 感染症および寄生虫症<br>好中球減少性敗血症<br>Neutropaenic Sepsis (4) | 20[redacted]-09-10 (26)<br>to<br>20[redacted]-09-12 (28)<br>[3] | 4 | Related | Drug Interrupted | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | 感染症および寄生虫症<br>好中球減少性敗血症<br>Neutropenic Sepsis (6) | 20[redacted]-10-18 (64)<br>to<br>20[redacted]-10-19 (65)<br>[2] | 5 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Fatal |
| | | | | | | | |
| 12-865-1[redacted] | 代謝および栄養障害<br>脱水<br>Dehydration (4) | 20[redacted]-08-05 (-4)<br>to<br>20[redacted]-08-14 (5)<br>[10] | 2 | Not Related | Dose Not Changed | Hospitalization | Recovered/ Resolved |
| | 代謝および栄養障害<br>高血糖<br>Hyperglycemia (3) | 20[redacted]-08-05 (-4)<br>to<br>20[redacted]-08-14 (5)<br>[10] | 2 | Not Related | Dose Not Changed | Concomitant Medication, Procedure Required, Hospitalization | Recovered/ Resolved |

**表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 3）**

| REGIMEN BSC | | | | | | | |
|---|---|---|---|---|---|---|---|
| Subject ID | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (#Days from First Dose)<br>[Duration(days)] | Severity<br>(NCI Grade) | Study Drug Relationship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
| | 血液およびリンパ系障害<br>血小板減少症<br>Thrombocytopaenia (5) | 20[redacted]-09-07 (29)<br>to<br>20[redacted]-09-08 (30)<br>[2] | 4 | Not Related | Dose Not Changed | Procedure Required, Hospitalization | Recovering/ Resolving |
| | 神経系障害<br>痙攣<br>Seizures (2) | 20[redacted]-09-07 (29)<br>to<br>20[redacted]-09-07 (29)<br>[1] | 3 | Not Related | Dose Not Changed | Hospitalization | Recovered/ Resolved |
| | 神経系障害<br>頭蓋内出血<br>Small Intracranial Bleed (1) | 20[redacted]-09-07 (29)<br>to<br>20[redacted]-09-11 (33)<br>[5] | 3 | Not Related | Dose Not Changed | Procedure Required, Hospitalization | Recovered/ Resolved |
| | 感染症および寄生虫症<br>肺炎<br>Pneumonia (9) | 20[redacted]-09-24 (46)<br>to<br>20[redacted]-09-29 (51)<br>[6] | 5 | Not Related | Drug Withdrawn | Hospitalization | Fatal |
| | 神経系障害<br>痙攣<br>Seizures (8) | 20[redacted]-09-24 (46)<br>to<br>20[redacted]-09-24 (46)<br>[1] | 3 | Not Related | Dose Not Changed | Procedure Required, Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 12-865-1[redacted] | 一般・全身障害および投与部位の状態<br>発熱<br>Fever (3) | 20[redacted]-11-17 (80)<br>to<br>20[redacted]-11-19 (82)<br>[3] | 2 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 12-865-1[redacted] | 血液およびリンパ系障害<br>貧血<br>Anaemia (3) | 20[redacted]-09-23 (10)<br>to<br>20[redacted]-09-28 (15)<br>[6] | 3 | Related | Dose Not Changed | Concomitant Medication, Procedure Required, Hospitalization | Recovered/ Resolved |
| | 感染症および寄生虫症<br>大葉性肺炎<br>Right Lower Lobe Pneumonia (2) | 20[redacted]-09-23 (10)<br>to<br>20[redacted]-09-28 (15)<br>[6] | 3 | Not Related | Dose Not Changed | Concomitant Medication, Procedure Required, Hospitalization | Recovered/ Resolved |
| | 腎および尿路障害<br>急性腎不全<br>Acute Kidney Injury (1) | 20[redacted]-09-23 (10)<br>to<br>20[redacted]-09-28 (15)<br>[6] | 2 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |

**表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 4）**

| REGIMEN BSC | | | | | | | |
|---|---|---|---|---|---|---|---|
| Subject ID | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (#Days from First Dose) [Duration(days)] | Severity (NCI Grade) | Study Drug Relationship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
| | 呼吸器、胸郭および縦隔障害<br>呼吸困難<br>Dyspnoea (5) | 20[redacted]-10-11 (28)<br>to<br>20[redacted]-10-19 (36)<br>[9] | 2 | Not Related | Drug Withdrawn | Procedure Required, Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 16-329-1[redacted] | 筋骨格系および結合組織障害<br>骨痛<br>Dorsal Bone Pain (1) | 20[redacted]-11-16 (45)<br>to<br>20[redacted]-11-30 (59)<br>[15] | 2 | Not Related | Dose Not Changed | Hospitalization | Recovered/ Resolved |
| | 感染症および寄生虫症<br>敗血症症候群<br>Septic Syndrom (3) | 20[redacted]-01-11 (101)<br>＊<br>to<br>20[redacted]-01-25 (115)<br>＊<br>[15] | 2 | Not Related | Drug Interrupted | Hospitalization | Recovered/ Resolved |
| | 一般・全身障害および投与部位の状態<br>疾患進行<br>Disease Progression (11) | 20[redacted]-04-19 (199)<br>＊<br>to<br>20[redacted]-05-06 (216)<br>＊<br>[18] | 5 | Not Related | Dose Not Changed | Hospitalization | Fatal |
| | | | | | | | |
| 16-342-1[redacted] | 筋骨格系および結合組織障害<br>関節痛<br>Right Hip Pain Worsening (2) | 20[redacted]-09-21 (2)<br>to<br>20[redacted]-10-29 (40)<br>[39] | 3 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | 代謝および栄養障害<br>高カルシウム血症<br>Hypercalcemia (8) | 20[redacted]-10-18 (29)<br>to<br>20[redacted]-11-01 (43)<br>[15] | 4 | Not Related | Dose Not Changed | None | Recovering/ Resolving |
| | 一般・全身障害および投与部位の状態<br>疾患進行<br>Disease Progression (1) | 20[redacted]-10-30 (41)<br>to<br>20[redacted]-11-26 (68)<br>[28] | 5 | Not Related | Drug Interrupted | Hospitalization | Fatal |
| | 代謝および栄養障害<br>高尿酸血症<br>Hyperuricemia (6) | 20[redacted]-11-02 (44)<br>to<br>Continuing | 4 | Not Related | Dose Not Changed | None | Not Recovered/ Not Resolved |
| | 血液およびリンパ系障害<br>血小板減少症<br>Thrombopenia (49) | 20[redacted]-11-20 (62)<br>to<br>20[redacted]-11-21 (63)<br>[2] | 4 | Not Related | Dose Not Changed | Procedure Required | Recovering/ Resolving |

**被験者識別コード，年齢以外のマスキングにおいて，**
**マークなし　：「同年」を意味する**
**＊　：「翌年」を意味する**

**表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 5）**

| REGIMEN BSC | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Subject ID** | **System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #)** | **Date (#Days from First Dose)<br>[Duration(days)]** | **Severity (NCI Grade)** | **Study Drug Relationship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| | | | | | | | |
| 16-342-1[redacted] | 血液およびリンパ系障害<br>血小板減少症<br>Thrombopenia (13) | 20[redacted]-10-31 (38)<br>to<br>20[redacted]-10-31 (38)<br>[1] | 4 | Not Related | Dose Not Changed | Procedure Required | Recovered/ Resolved |
| | 一般・全身障害および投与部位の状態<br>疾患進行<br>Progressive Disease (1) | 20[redacted]-10-31 (38)<br>to<br>20[redacted]-11-08 (46)<br>[9] | 5 | Not Related | Dose Not Changed | Hospitalization | Fatal |
| | 血液およびリンパ系障害<br>血小板減少症<br>Thrombopenia (15) | 20[redacted]-11-04 (42)<br>to<br>20[redacted]-11-05 (43)<br>[2] | 4 | Not Related | Dose Not Changed | Procedure Required | Recovered/ Resolved |
| | | | | | | | |
| 18-451-1[redacted] | 血液およびリンパ系障害<br>貧血<br>Anemia (3) | 20[redacted]-05-07 (-6)<br>to<br>20[redacted]-05-07 (-6)<br>[1] | 3 | Not Related | Dose Not Changed | Procedure Required, Hospitalization | Recovered/ Resolved |
| | 代謝および栄養障害<br>高カルシウム血症<br>Hypercalcemia (5) | 20[redacted]-05-12 (-1)<br>to<br>20[redacted]-05-15 (2)<br>[4] | 4 | Not Related | Dose Not Changed | Concomitant Medication | Recovered/ Resolved |
| | 血液およびリンパ系障害<br>血小板減少症<br>Thrombocytopenia (9) | 20[redacted]-05-28 (15)<br>to<br>Continuing | 3 | Not Related | Dose Not Changed | Procedure Required | Not Recovered/ Not Resolved |
| | 感染症および寄生虫症<br>肺炎<br>Pneumonia (1) | 20[redacted]-05-28 (15)<br>to<br>20[redacted]-06-20 (38)<br>[24] | 5 | Not Related | Drug Withdrawn | Concomitant Medication, Hospitalization | Fatal |
| | | | | | | | |
| 18-455-1[redacted] | 血液およびリンパ系障害<br>血小板減少症<br>Thrombocytopenia (7) | 20[redacted]-07-21 (107)<br>to<br>20[redacted]-07-27 (113)<br>[7] | 3 | Not Related | Dose Not Changed | Hospitalization | Recovered/ Resolved |
| | | | | | | | |

**表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 6）**

| REGIMEN BSC | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Subject ID** | **System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #)** | **Date (#Days from First Dose) [Duration(days)]** | **Severity (NCI Grade)** | **Study Drug Relationship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| 18-458-1[redacted] | 血液およびリンパ系障害<br>貧血<br>Anemia (2) | 20[redacted]-05-16 (57)<br>to<br>20[redacted]-05-16 (57)<br>[1] | 3 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 18-460-1[redacted] | 筋骨格系および結合組織障害<br>病的骨折<br>Right Femur Pathological Fracture (2) | 20[redacted]-10-15 (23)<br>to<br>20[redacted]-11-09 (48)<br>[26] | 3 | Not Related | Dose Not Changed | Procedure Required, Hospitalization | Recovered/ Resolved With Sequelae |
| | | | | | | | |
| 22-526-1[redacted] | 血液およびリンパ系障害<br>好中球減少症<br>Neutropenia (3) | 20[redacted]-04-11 (34)<br>to<br>20[redacted]-05-13 (66)<br>[33] | 3 | Related | Dose Not Changed | Procedure Required, Hospitalization | Recovered/ Resolved |
| | 感染症および寄生虫症<br>肺炎<br>Pneumonia (4) | 20[redacted]-04-11 (34)<br>to<br>20[redacted]-05-13 (66)<br>[33] | 3 | Related | Dose Not Changed | Hospitalization | Recovered/ Resolved |
| | 腎および尿路障害<br>急性腎不全<br>Acute Renal Failure (Creatinine Value=7) (5) | 20[redacted]-04-11 (34)<br>to<br>20[redacted]-05-13 (66)<br>[33] | 4 | Related | Dose Not Changed | Hospitalization | Recovered/ Resolved |
| | 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）<br>形質細胞性白血病<br>Plasmacellular Leukemia (4%) (9) | 20[redacted]-05-17 (70)<br>to<br>Continuing | 3 | Not Related | Dose Not Changed | None | Not Recovered/ Not Resolved |
| | 一般・全身障害および投与部位の状態<br>疾患進行<br>Disease Progression (6) | 20[redacted]-05-26 (79)<br>to<br>20[redacted]-05-28 (81)<br>[3] | 5 | Not Related | Dose Not Changed | None | Fatal |
| | | | | | | | |
| 22-526-1[redacted] | 代謝および栄養障害<br>高カルシウム血症<br>Hypercalcemia (4) | 20[redacted]-04-15 (47)<br>to<br>Continuing | 3 | Not Related | Dose Not Changed | Hospitalization | Unknown |
| | | | | | | | |

**表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 7）**

| REGIMEN BSC | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Subject ID** | **System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #)** | **Date (#Days from First Dose) [Duration(days)]** | **Severity (NCI Grade)** | **Study Drug Relationship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| 22-532-1[redacted] | 眼障害<br>潰瘍性角膜炎<br>Corneal Ulcer Of Right Eye (1) | 20[redacted]-03-06 (48)<br>to<br>Continuing | 3 | Related | Drug Interrupted | Concomitant Medication, Procedure Required, Hospitalization | Not Recovered/ Not Resolved |
| | | | | | | | |
| 22-532-1[redacted] | 神経系障害<br>脳血管発作<br>Cerebrovascular Stroke (1) | 20[redacted]-03-27 (-15)<br>to<br>20[redacted]-04-06 (-5)<br>[11] | 4 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved With Sequelae |
| | 神経系障害<br>脳血管発作<br>Confirmed Stroke (5) | 20[redacted]-06-14 (64)<br>to<br>20[redacted]-07-20 (100)<br>[37] | 3 | Not Related | Drug Withdrawn | Concomitant Medication, Procedure Required, Hospitalization | Recovering/ Resolving |
| | | | | | | | |
| 22-532-1[redacted] | 感染症および寄生虫症<br>気管支肺炎<br>Bilateral Bronchopneumonia (13) | 20[redacted]-10-29 (484)<br>to<br>20[redacted]-10-30 (485)<br>[2] | 3 | Related | Drug Interrupted | Concomitant Medication, Hospitalization | Recovered/ Resolved With Sequelae |
| | 一般・全身障害および投与部位の状態<br>死亡<br>Death (17) | 20[redacted]-06-29 (727)<br>＊ to<br>20[redacted]-06-29 (727)<br>＊ [1] | 5 | Not Related | Drug Withdrawn | None | Fatal |
| | | | | | | | |
| 24-719-1[redacted] | 血液およびリンパ系障害<br>過粘稠度症候群<br>Hyperviscosity Syndrome. (5) | 20[redacted]-12-09 (29)<br>to<br>20[redacted]-12-24 (44)<br>[16] | 3 | Not Related | Drug Withdrawn | Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 24-719-1[redacted] | 感染症および寄生虫症<br>敗血症性ショック<br>Septic Shock (10) | 20[redacted]-12-19 (155)<br>to<br>20[redacted]-12-28 (164)<br>[10] | 4 | Not Related | Dose Not Changed | Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 24-721-1[redacted] | 呼吸器、胸郭および縦隔障害<br>急性肺水腫<br>Pulmonary Accute Edema (1) | 20[redacted]-01-02 (4)<br>to<br>20[redacted]-01-05 (7)<br>[4] | 5 | Not Related | Drug Withdrawn | Concomitant Medication, Procedure Required, Hospitalization | Fatal |

**被験者識別コード，年齢以外のマスキングにおいて，**
**マークなし　：「同年」を意味する**
**＊　：「翌年」を意味する**

**表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 8）**

| Subject ID | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (#Days from First Dose)<br>[Duration(days)] | Severity (NCI Grade) | Study Drug Relationship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|
| REGIMEN BSC | | | | | | | |
| 24-721-1[redacted] | 一般・全身障害および投与部位の状態<br>疾患進行<br>Progression Disease (1) | 20[redacted]-05-15 (14)<br>to<br>20[redacted]-05-15 (14)<br>[1] | 5 | Not Related | Dose Not Changed | None | Fatal |
| 24-722-1[redacted] | 感染症および寄生虫症<br>肺炎<br>Pneumonia (3) | 20[redacted]-01-17 (63)<br>to<br>20[redacted]-01-25 (71)<br>[9] | 3 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | 感染症および寄生虫症<br>肺炎<br>Pneumonia (4) | 20[redacted]-02-16 (93)<br>to<br>20[redacted]-02-29 (106)<br>[14] | 3 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovering/ Resolving |
| | 感染症および寄生虫症<br>肺炎<br>Pneumonia (21) | 20[redacted]-04-05 (507)<br>＊ to<br>20[redacted]-04-15 (517)<br>＊ [11] | 2 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | 感染症および寄生虫症<br>気道感染<br>Respiratory Infection (51) | 20[redacted]-03-04 (840)<br>＊＊ to<br>20[redacted]-03-11 (847)<br>＊＊ [8] | 3 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | 感染症および寄生虫症<br>気道感染<br>Respiratory Infection (52) | 20[redacted]-03-28 (864)<br>＊＊ to<br>20[redacted]-04-08 (875)<br>＊＊ [12] | 3 | Not Related | Dose Not Changed | Concomitant Medication | Recovered/ Resolved |
| | 感染症および寄生虫症<br>気道感染<br>Respiratory Infection (53) | 20[redacted]-05-03 (900)<br>＊＊ to<br>20[redacted]-05-08 (905)<br>＊＊ [6] | 3 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | 感染症および寄生虫症<br>菌血症<br>Bacteriemia Due To Gram Negative Bacteria (57) | 20[redacted]-07-07 (965)<br>＊＊ to<br>Continuing | 3 | Not Related | Dose Not Changed | Concomitant Medication, Procedure Required, Hospitalization | Recovering/ Resolving |

**被験者識別コード，年齢以外のマスキングにおいて，**
**マークなし　：「同年」を意味する**
**＊　：「翌年」を意味する**
**＊＊　：「翌々年」を意味する**

**表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 9）**

| REGIMEN BSC | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Subject ID** | **System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #)** | **Date (#Days from First Dose) [Duration(days)]** | **Severity (NCI Grade)** | **Study Drug Relationship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| 24-722-1[redacted] | 感染症および寄生虫症<br>気道感染<br>Respiratory Infection (3) | 20[redacted]-08-04 (81)<br>to<br>20[redacted]-08-08 (85)<br>[5] | 2 | Not Related | Dose Not Changed | Hospitalization | Recovered/ Resolved |
| | 感染症および寄生虫症<br>気道感染<br>Respiratory Infection (4) | 20[redacted]-09-04 (112)<br>to<br>20[redacted]-09-17 (125)<br>[14] | 2 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | 感染症および寄生虫症<br>肺炎<br>Pneumonia (5) | 20[redacted]-10-19 (157)<br>to<br>20[redacted]-11-12 (181)<br>[25] | 4 | Not Related | Dose Not Changed | Procedure Required, Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 24-724-1[redacted] | 感染症および寄生虫症<br>肺炎<br>Bilateral Pneumonia (12) | 20[redacted]-04-24 (35)<br>to<br>20[redacted]-04-29 (40)<br>[6] | 3 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | 一般・全身障害および投与部位の状態<br>疾患進行<br>Disease Progression (13) | 20[redacted]-05-06 (47)<br>to<br>20[redacted]-05-06 (47)<br>[1] | 5 | Not Related | Dose Not Changed | None | Fatal |
| | | | | | | | |
| 24-724-1[redacted] | 感染症および寄生虫症<br>肺炎<br>Pneumonia (11) | 20[redacted]-12-12 (605)<br>to<br>20[redacted]-12-18 (611)<br>[7] | 3 | Not Related | Drug Interrupted | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 24-724-1[redacted] | 血液およびリンパ系障害<br>好中球減少症<br>Neutropenia (3) | 20[redacted]-07-22 (37)<br>to<br>20[redacted]-07-25 (40)<br>[4] | 4 | Not Related | Drug Interrupted | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | 一般・全身障害および投与部位の状態<br>発熱<br>Fever (2) | 20[redacted]-07-22 (37)<br>to<br>20[redacted]-07-23 (38)<br>[2] | 1 | Not Related | Drug Interrupted | Concomitant Medication | Recovered/ Resolved |
| | | | | | | | |

**表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 10）**

| REGIMEN BSC | | | | | | | |
|---|---|---|---|---|---|---|---|
| Subject ID | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (#Days from First Dose)<br>[Duration(days)] | Severity (NCI Grade) | Study Drug Relationship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
| 24-724-1[redacted] | 血管障害<br>深部静脈血栓症<br>Right Femoral Vein Thrombosis (2) | 20[redacted]-04-19 (113)<br>to<br>20[redacted]-04-27 (121)<br>[9] | 3 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| 24-724-1[redacted] | 呼吸器、胸郭および縦隔障害<br>肺出血<br>Massive Pulmonary Hemorrhage (2) | 20[redacted]-06-19 (79)<br>to<br>20[redacted]-06-19 (79)<br>[1] | 5 | Not Related | Dose Not Changed | Hospitalization | Fatal |
| 24-726-1[redacted] | 一般・全身障害および投与部位の状態<br>疾患進行<br>Disease Progression (4) | 20[redacted]-08-11 (81)<br>to<br>20[redacted]-08-11 (81)<br>[1] | 5 | Not Related | Dose Not Changed | None | Fatal |
| 24-729-1[redacted] | 感染症および寄生虫症<br>肺炎<br>Pneumonia (16) | 20[redacted]-07-08 (574)<br>to<br>20[redacted]-07-16 (582)<br>[9] | 3 | Not Related | Drug Interrupted | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| 28-227-1[redacted] | 一般・全身障害および投与部位の状態<br>疾患進行<br>Decreased General Condition Due To Underlying Disease' To 'disease Progression (1) | 20[redacted]-10-15 (49)<br>to<br>20[redacted]-10-17 (51)<br>[3] | 5 | Not Related | Dose Not Changed | Hospitalization | Fatal |
| 28-228-1[redacted] | 血液およびリンパ系障害<br>貧血<br>Anemia (1) | 20[redacted]-07-24 (14)<br>to<br>20[redacted]-07-25 (15)<br>[2] | 4 | Not Related | Dose Not Changed | Procedure Required, Hospitalization | Recovering/ Resolving |
| 28-231-1[redacted] | 一般・全身障害および投与部位の状態<br>倦怠感<br>General Malaise (1) | 20[redacted]-07-10 (20)<br>to<br>20[redacted]-07-13 (23)<br>[4] | 2 | Not Related | Dose Not Changed | Hospitalization | Recovered/ Resolved |

**表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 11）**

| REGIMEN BSC | | | | | | | |
|---|---|---|---|---|---|---|---|
| Subject ID | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (#Days from First Dose)<br>[Duration(days)] | Severity (NCI Grade) | Study Drug Relationship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
| | 生殖系および乳房障害<br>腟出血<br>Vaginal Hemorrage Unrelated To Menses (11) | 20[redacted]-07-19 (29)<br>to<br>20[redacted]-07-20 (30)<br>[2] | 3 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | 一般・全身障害および投与部位の状態<br>疾患進行<br>Progressive Myeloma (12) | 20[redacted]-08-06 (47)<br>to<br>20[redacted]-08-13 (54)<br>[8] | 5 | Not Related | Dose Not Changed | Hospitalization | Fatal |
| | | | | | | | |
| 38-276-1[redacted] | 感染症および寄生虫症<br>気管支肺炎<br>Bronchopneumonia (8) | 20[redacted]-05-19 (349)<br>to<br>20[redacted]-05-20 (350)<br>[2] | 3 | Not Related | Drug Interrupted | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | 感染症および寄生虫症<br>敗血症性ショック<br>Septic Shock (7) | 20[redacted]-05-19 (349)<br>to<br>20[redacted]-05-20 (350)<br>[2] | 5 | Not Related | Drug Withdrawn | Concomitant Medication, Hospitalization | Fatal |
| | | | | | | | |
| 38-276-1[redacted] | 一般・全身障害および投与部位の状態<br>疾患進行<br>Disease Progression (1) | 20[redacted]-01-30 (42)<br>to<br>Continuing | 3 | Not Related | Dose Not Changed | Hospitalization | Not Recovered/ Not Resolved |
| | 感染症および寄生虫症<br>気管支肺炎<br>Bronchopneumonia (10) | 20[redacted]-02-02 (45)<br>to<br>20[redacted]-02-06 (49)<br>[5] | 5 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Fatal |
| | | | | | | | |
| 38-277-1[redacted] | 神経系障害<br>てんかん<br>Epiparoxysm (2) | 20[redacted]-05-02 (56)<br>to<br>20[redacted]-05-02 (56)<br>[1] | 3 | Not Related | Dose Not Changed | Hospitalization | Recovered/ Resolved |
| | 一般・全身障害および投与部位の状態<br>疾患進行<br>Disease Progression (13) | 20[redacted]-05-04 (58)<br>to<br>20[redacted]-05-18 (72)<br>[15] | 3 | Not Related | Dose Not Changed | Hospitalization | Recovering/ Resolving |
| | | | | | | | |

**表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 12）**

| REGIMEN BSC | | | | | | | |
|---|---|---|---|---|---|---|---|
| Subject ID | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (#Days from First Dose)<br>[Duration(days)] | Severity (NCI Grade) | Study Drug Relationship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
| 38-277-1[redacted] | 一般・全身障害および投与部位の状態<br>疾患進行<br>Disease Progression (6) | 20[redacted]-06-20 (59)<br>to<br>20[redacted]-06-26 (65)<br>[7] | 5 | Not Related | Dose Not Changed | Hospitalization | Fatal |
| | | | | | | | |
| 38-277-1[redacted] | 一般・全身障害および投与部位の状態<br>無力症<br>Weakness (1) | 20[redacted]-06-27 (10)<br>to<br>20[redacted]-07-02 (15)<br>[6] | 3 | Not Related | Dose Not Changed | Hospitalization | Recovered/ Resolved |
| | 一般・全身障害および投与部位の状態<br>疾患進行<br>Disease Progression (4) | 20[redacted]-07-11 (24)<br>to<br>20[redacted]-07-11 (24)<br>[1] | 5 | Not Related | Dose Not Changed | None | Fatal |
| | | | | | | | |
| 38-278-1[redacted] | 一般・全身障害および投与部位の状態<br>疾患進行<br>Progression Disease (3) | 20[redacted]-12-17 (26)<br>to<br>20[redacted]-12-25 (34)<br>[9] | 5 | Not Related | Dose Not Changed | Procedure Required | Fatal |
| | | | | | | | |
| 38-278-1[redacted] | 胃腸障害<br>下痢<br>Diarrhoea (6) | 20[redacted]-11-30 (102)<br>to<br>20[redacted]-12-07 (109)<br>[8] | 2 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 38-278-1[redacted] | 傷害、中毒および処置合併症<br>胸骨骨折<br>Sternum Fracture (8) | 20[redacted]-12-07 (86)<br>to<br>20[redacted]-12-13 (92)<br>[7] | 2 | Not Related | Dose Not Changed | Hospitalization | Recovered/ Resolved |
| | 感染症および寄生虫症<br>気管支肺炎<br>Bronchopneumonia (9) | 20[redacted]-01-17 (127)<br>＊ to<br>20[redacted]-01-24 (134)<br>＊ [8] | 3 | Not Related | Drug Interrupted | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 38-279-1[redacted] | 筋骨格系および結合組織障害<br>筋骨格痛<br>Vertebrogenic Pain Syndrome Worsening (24) | 20[redacted]-10-08 (190)<br>to<br>20[redacted]-10-16 (198)<br>[9] | 3 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |

**被験者識別コード，年齢以外のマスキングにおいて，**
**マークなし　：「同年」を意味する**
**＊　：「翌年」を意味する**

**表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 13）**

| REGIMEN BSC | | | | | | | |
|---|---|---|---|---|---|---|---|
| Subject ID | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (#Days from First Dose)<br>[Duration(days)] | Severity<br>(NCI Grade) | Study Drug Relationship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
| | | | | | | | |
| 38-279-1[redacted] | 感染症および寄生虫症<br>気道感染<br>Respiratory Infection (1) | 20[redacted]-10-15 (29)<br>to<br>20[redacted]-10-26 (40)<br>[12] | 3 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | 一般・全身障害および投与部位の状態<br>疾患進行<br>Disease Progression (7) | 20[redacted]-12-30 (105)<br>to<br>20[redacted]-01-03 (109)<br>＊ [5] | 5 | Not Related | Dose Not Changed | None | Fatal |
| | | | | | | | |
| 39-477-1[redacted] | 傷害、中毒および処置合併症<br>大腿骨頚部骨折<br>Left Subcapital Fracture Of Neck Of Femur (9) | 20[redacted]-02-17 (299)<br>to<br>20[redacted]-03-09 (319)<br>[21] | 3 | Not Related | Drug Withdrawn, Drug Interrupted | Concomitant Medication, Procedure Required, Hospitalization | Recovered/ Resolved With Sequelae |
| | 腎および尿路障害<br>急性腎不全<br>Acute Renal Failure (15) | 20[redacted]-03-09 (319)<br>to<br>20[redacted]-03-24 (334)<br>[16] | 3 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 39-477-1[redacted] | 感染症および寄生虫症<br>肺炎<br>Pneumonia (19) | 20[redacted]-03-13 (689)<br>to<br>20[redacted]-03-17 (693)<br>[5] | 3 | Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 39-477-1[redacted] | 腎および尿路障害<br>急性腎不全<br>Acute Renal Failure (1) | 20[redacted]-07-30 (15)<br>to<br>20[redacted]-07-31 (16)<br>[2] | 3 | Not Related | Drug Interrupted | Concomitant Medication, Hospitalization | Recovering/ Resolving |
| | 神経系障害<br>脊髄圧迫<br>Cord Compression (5) | 20[redacted]-08-13 (29)<br>to<br>Continuing | 3 | Not Related | Dose Not Changed | Hospitalization | Not Recovered/ Not Resolved |
| | 腎および尿路障害<br>急性腎不全<br>Acute Renal Failure (2) | 20[redacted]-08-13 (29)<br>to<br>20[redacted]-08-17 (33)<br>[5] | 3 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovering/ Resolving |

**被験者識別コード，年齢以外のマスキングにおいて，**
**マークなし　：「同年」を意味する**
**＊　：「翌年」を意味する**

**表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 14）**

| REGIMEN BSC | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Subject ID** | **System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #)** | **Date (#Days from First Dose) [Duration(days)]** | **Severity (NCI Grade)** | **Study Drug Relationship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| | 一般・全身障害および投与部位の状態<br>疾患進行<br>Disease Progression (3) | 20[redacted]-09-23 (70)<br>to<br>20[redacted]-09-23 (70)<br>[1] | 5 | Not Related | Dose Not Changed | Hospitalization | Fatal |
| | | | | | | | |
| 39-477-1[redacted] | 感染症および寄生虫症<br>敗血症性ショック<br>Septic Shock (2) | 20[redacted]-10-14 (55)<br>to<br>20[redacted]-10-14 (55)<br>[1] | 5 | Related | Drug Withdrawn | Concomitant Medication, Hospitalization | Fatal |
| | | | | | | | |
| 39-482-1[redacted] | 感染症および寄生虫症<br>肺炎<br>Pneumonia (3) | 20[redacted]-01-26 (122)<br>to<br>20[redacted]-01-27 (123)<br>[2] | 2 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 39-487-1[redacted] | 一般・全身障害および投与部位の状態<br>疾患進行<br>Disease Progression (2) | 20[redacted]-07-19 (39)<br>to<br>20[redacted]-07-30 (50)<br>[12] | 1 | Not Related | Dose Not Changed | Hospitalization | Recovered/ Resolved |
| | 血液およびリンパ系障害<br>発熱性好中球減少症<br>Neutropenic Fever Post Chemotherapy (3) | 20[redacted]-07-31 (51)<br>to<br>20[redacted]-08-09 (60)<br>[10] | 3 | Not Related | Dose Not Changed | Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 44-202-1[redacted] | 代謝および栄養障害<br>高カルシウム血症<br>Hypercalcemia (17) | 20[redacted]-02-09 (-4)<br>to<br>20[redacted]-02-16 (3)<br>[8] | 3 | Not Related | Dose Not Changed | Hospitalization | Recovered/ Resolved |
| | 一般・全身障害および投与部位の状態<br>胸痛<br>Sternum Pain (1) | 20[redacted]-03-08 (23)<br>to<br>20[redacted]-03-24 (39)<br>[17] | 3 | Not Related | Dose Not Changed | Concomitant Medication, Procedure Required, Hospitalization | Recovering/ Resolving |
| | 胃腸障害<br>悪心<br>Nausea (15) | 20[redacted]-04-08 (54)<br>to<br>20[redacted]-04-09 (55)<br>[2] | 2 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovering/ Resolving |

**表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 15）**

| REGIMEN BSC | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Subject ID** | **System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #)** | **Date (#Days from First Dose) [Duration(days)]** | **Severity (NCI Grade)** | **Study Drug Relationship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| | 胃腸障害<br>嘔吐<br>Vomiting (16) | 20[redacted]-04-08 (54)<br>to<br>20[redacted]-04-09 (55)<br>[2] | 2 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovering/ Resolving |
| | | | | | | | |
| 44-203-1[redacted] | 血液およびリンパ系障害<br>貧血<br>Anemia (1) | 20[redacted]-07-26 (12)<br>to<br>20[redacted]-07-29 (15)<br>[4] | 3 | Not Related | Dose Not Changed | Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 44-203-1[redacted] | 筋骨格系および結合組織障害<br>背部痛<br>Back Pain (1) | 20[redacted]-09-23 (38)<br>to<br>20[redacted]-09-27 (42)<br>[5] | 2 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 44-206-1[redacted] | 感染症および寄生虫症<br>肺炎<br>Pneumonia (10) | 20[redacted]-05-04 (103)<br>to<br>20[redacted]-05-11 (110)<br>[8] | 4 | Not Related | Drug Interrupted | Hospitalization | Recovered/ Resolved |
| | 感染症および寄生虫症<br>肺炎<br>Pneumonia (25) | 20[redacted]-01-30 (374)<br>＊ to<br>20[redacted]-02-06 (381)<br>＊ [8] | 4 | Not Related | Drug Interrupted | Hospitalization | Recovered/ Resolved |
| | 感染症および寄生虫症<br>肺炎<br>Pneumonia (26) | 20[redacted]-03-01 (404)<br>＊ to<br>20[redacted]-03-07 (410)<br>＊ [7] | 3 | Related | Drug Interrupted | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | 一般・全身障害および投与部位の状態<br>全身健康状態低下<br>Deterioration Of General Condition - Caused By Primary Disease (31) | 20[redacted]-06-08 (503)<br>＊ to<br>20[redacted]-07-02 (527)<br>＊ [25] | 5 | Not Related | Drug Withdrawn | Hospitalization | Fatal |
| | 精神障害<br>錯乱状態<br>Confusion (29) | 20[redacted]-06-08 (503)<br>＊ to<br>Continuing | 3 | Not Related | Drug Withdrawn | Hospitalization | Not Recovered/ Not Resolved |

**被験者識別コード，年齢以外のマスキングにおいて，**
**マークなし　：「同年」を意味する**
**＊　：「翌年」を意味する**

**表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 16）**

| REGIMEN BSC | | | | | | | |
|---|---|---|---|---|---|---|---|
| Subject ID | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (#Days from First Dose) [Duration(days)] | Severity (NCI Grade) | Study Drug Relationship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
| | 傷害、中毒および処置合併症<br>人工関節周囲骨折<br>Periprosthetic Hip Fracture (30) | 20[redacted]-06-15 (510)<br>＊ to<br>20[redacted]-06-18 (513)<br>＊ [4] | 2 | Not Related | Dose Not Changed | Procedure Required, Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 46-301-1[redacted] | 呼吸器、胸郭および縦隔障害<br>呼吸不全<br>Respiratory Insufficiency (4) | 20[redacted]-02-16 (58)<br>to<br>20[redacted]-02-16 (58)<br>[1] | 5 | Not Related | Dose Not Changed | None | Fatal |
| | | | | | | | |
| 46-303-1[redacted] | 心臓障害<br>うっ血性心不全<br>Congestive Heart Failure, Grade 3 (11) | 20[redacted]-01-04 (182)<br>to<br>20[redacted]-01-11 (189)<br>[8] | 3 | Related | Drug Interrupted | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | 心臓障害<br>うっ血性心不全<br>Congestive Heart Failure, Grade 3 (14) | 20[redacted]-07-12 (372)<br>to<br>20[redacted]-07-19 (379)<br>[8] | 3 | Related | Drug Interrupted, Drug Interrupted | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | 心臓障害<br>うっ血性心不全<br>Congestive Heart Failure Gr Iv (21) | 20[redacted]-10-18 (470)<br>to<br>20[redacted]-11-12 (495)<br>[26] | 4 | Not Related | Dose Not Changed | Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 46-303-1[redacted] | 一般・全身障害および投与部位の状態<br>疾患進行<br>Myeloma Progression (9) | 20[redacted]-01-28 (241)<br>to<br>20[redacted]-02-23 (267)<br>[27] | 5 | Not Related | Dose Not Changed | Hospitalization | Fatal |
| | 代謝および栄養障害<br>高血糖<br>Hyperglycaemia, Grade 3 (7) | 20[redacted]-01-28 (241)<br>to<br>Continuing | 3 | Related | Dose Not Changed | Hospitalization | Unknown |
| | | | | | | | |
| 46-303-1[redacted] | 血液およびリンパ系障害<br>貧血<br>Anemia (3) | 20[redacted]-11-03 (7)<br>to<br>Continuing | 4 | Related | Dose Not Changed | Concomitant Medication, Procedure Required, Hospitalization | Not Recovered/ Not Resolved |

**被験者識別コード，年齢以外のマスキングにおいて，**
**マークなし　：「同年」を意味する**
**＊　：「翌年」を意味する**

**表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 17）**

| REGIMEN BSC | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Subject ID** | **System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #)** | **Date (#Days from First Dose)<br>[Duration(days)]** | **Severity (NCI Grade)** | **Study Drug Relationship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| | 心臓障害<br>うっ血性心不全<br>Congestive Heart (4) | 20[redacted]-11-03 (7)<br>to<br>Continuing | 3 | Related | Dose Not Changed | Concomitant Medication, Hospitalization | Not Recovered/ Not Resolved |
| | 胃腸障害<br>胃腸出血<br>Gastrointestinal Hemorrhage (5) | 20[redacted]-11-07 (11)<br>to<br>20[redacted]-12-13 (47)<br>[37] | 4 | Related | Drug Withdrawn | Concomitant Medication, Procedure Required, Hospitalization | Recovered/ Resolved |
| | 胃腸障害<br>胃腸出血<br>Gastrointestinal Hemorrhage (10) | 20[redacted]-12-14 (48)<br>to<br>20[redacted]-12-14 (48)<br>[1] | 5 | Related | Dose Not Changed | None | Fatal |
| | | | | | | | |
| 46-303-1[redacted] | 一般・全身障害および投与部位の状態<br>疾患進行<br>Progressive Disease (1) | 20[redacted]-06-26 (63)<br>to<br>20[redacted]-07-16 (83)<br>[21] | 2 | Not Related | Dose Not Changed | Concomitant Medication, Procedure Required, Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 46-303-1[redacted] | 感染症および寄生虫症<br>肺炎<br>Pneumonia (1) | 20[redacted]-08-27 (91)<br>to<br>20[redacted]-08-27 (91)<br>[1] | 5 | Not Related | Drug Withdrawn | None | Fatal |
| | | | | | | | |
| 46-303-1[redacted] | 心臓障害<br>うっ血性心不全<br>Congestive Heart Failure (2) | 20[redacted]-08-10 (18)<br>to<br>20[redacted]-08-14 (22)<br>[5] | 3 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | 感染症および寄生虫症<br>敗血症<br>Septicaemia (7) | 20[redacted]-08-28 (36)<br>to<br>20[redacted]-08-29 (37)<br>[2] | 5 | Not Related | Dose Not Changed | Concomitant Medication, Procedure Required, Hospitalization | Fatal |
| | | | | | | | |
| 46-303-1[redacted] | 感染症および寄生虫症<br>気管支炎<br>Acute Bronchitis (14) | 20[redacted]-01-27 (133)<br>to<br>20[redacted]-01-30 (136)<br>[4] | 3 | Related | Drug Interrupted | Concomitant Medication, Hospitalization | Recovered/ Resolved |

**表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 18）**

REGIMEN BSC

| Subject ID | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (#Days from First Dose) [Duration(days)] | Severity (NCI Grade) | Study Drug Relationship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|
| | 感染症および寄生虫症<br>気管支肺炎<br>Bronchopneumonia (15) | 20[redacted]-06-22 (279)<br>to<br>20[redacted]-07-03 (290)<br>[12] | 3 | Related | Dose Not Changed | Concomitant Medication, Procedure Required, Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 46-304-1[redacted] | 心臓障害<br>心不全<br>Heart Failure (2) | 20[redacted]-07-10 (88)<br>to<br>20[redacted]-07-12 (90)<br>[3] | 5 | Not Related | Drug Withdrawn | Concomitant Medication, Hospitalization | Fatal |
| | | | | | | | |
| 46-304-1[redacted] | 感染症および寄生虫症<br>肺炎<br>Pneumonia (3) | 20[redacted]-02-10 (289)<br>to<br>20[redacted]-02-17 (296)<br>[8] | 3 | Not Related | Drug Interrupted | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 46-307-1[redacted] | 感染症および寄生虫症<br>肺炎<br>Pneumonia (14) | 20[redacted]-01-03 (68)<br>to<br>20[redacted]-01-31 (96)<br>[29] | 5 | Not Related | Dose Not Changed | Hospitalization | Fatal |
| | | | | | | | |
| 46-308-1[redacted] | 感染症および寄生虫症<br>肺炎<br>Pneumonia (4) | 20[redacted]-12-22 (71)<br>to<br>20[redacted]-12-29 (78)<br>[8] | 3 | Not Related | Dose Not Changed | Hospitalization | Recovered/ Resolved |
| | 血液およびリンパ系障害<br>好中球減少症<br>Grade 4 Neutropenia (6) | 20[redacted]-01-10 (90)<br>＊ to<br>20[redacted]-01-19 (99)<br>＊ [10] | 4 | Related | Drug Withdrawn | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | | | | | | | |
| 49-426-1[redacted] | 感染症および寄生虫症<br>気道感染<br>Respiratory Track Infection (1) | 20[redacted]-06-21 (29)<br>to<br>20[redacted]-06-28 (36)<br>[8] | 3 | Not Related | Drug Interrupted | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | | | | | | | |

**被験者識別コード，年齢以外のマスキングにおいて，**
**マークなし　：「同年」を意味する**
**＊　：「翌年」を意味する**

**表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 19）**

| REGIMEN BSC | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Subject ID** | **System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #)** | **Date (#Days from First Dose)<br>[Duration(days)]** | **Severity (NCI Grade)** | **Study Drug Relationship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| 49-428-1[redacted] | 一般・全身障害および投与部位の状態<br>無力症<br>Weakness (2) | 20[redacted]-09-21 (78)<br>to<br>Continuing | 3 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Not Recovered/ Not Resolved |
| | 一般・全身障害および投与部位の状態<br>疼痛<br>Pain (4) | 20[redacted]-09-30 (87)<br>to<br>20[redacted]-10-01 (88)<br>[2] | 3 | Not Related | Dose Not Changed | Concomitant Medication | Recovered/ Resolved |
| | 心臓障害<br>心停止<br>Cardiac Arrest (3) | 20[redacted]-10-01 (88)<br>to<br>20[redacted]-10-01 (88)<br>[1] | 5 | Not Related | Drug Withdrawn | Hospitalization | Fatal |
| | | | | | | | |
| 56-930-1[redacted] | 感染症および寄生虫症<br>肺炎<br>Pneumonia (6) | 20[redacted]-10-31 (64)<br>to<br>20[redacted]-11-03 (67)<br>[4] | 5 | Related | Drug Withdrawn | Concomitant Medication, Hospitalization | Fatal |
| | 腎および尿路障害<br>急性腎不全<br>Acute Renal Failure (7) | 20[redacted]-10-31 (64)<br>to<br>20[redacted]-11-03 (67)<br>[4] | 3 | Related | Dose Not Changed | Concomitant Medication, Hospitalization | Not Recovered/ Not Resolved |
| | | | | | | | |
| 89-629-1[redacted] | 血液およびリンパ系障害<br>白血球増加症<br>Leukocytosis (6) | 20[redacted]-02-01 (134)<br>to<br>20[redacted]-02-06 (139)<br>[6] | 3 | Not Related | Dose Not Changed | Procedure Required, Hospitalization | Recovering/ Resolving |
| | 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）<br>急性骨髄性白血病<br>Acute Myeloid Leucemia (8) | 20[redacted]-02-07 (140)<br>to<br>20[redacted]-02-16 (149)<br>[10] | 5 | Not Related | Dose Not Changed | None | Fatal |
| | | | | | | | |

**表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 20）**

REGIMEN C

| Subject ID | System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #) | Date (#Days from First Dose)<br>[Duration(days)] | Severity (NCI Grade) | Study Drug Relationship | Action Taken Regarding Study Drug | Other Action Taken | Outcome |
|---|---|---|---|---|---|---|---|
| 10-391-1[redacted] | 心臓障害<br>完全房室ブロック<br>Av-Block Third Degree (4) | 20[redacted]-08-31 (10)<br>to<br>20[redacted]-09-18 (28)<br>[19] | 4 | Related | Dose Not Changed | Concomitant Medication, Procedure Required, Hospitalization | Recovering/ Resolving |
| 10-394-1[redacted] | 呼吸器、胸郭および縦隔障害<br>呼吸困難<br>Dyspnea (2) | 20[redacted]-09-28 (10)<br>to<br>20[redacted]-10-01 (13)<br>[4] | 2 | Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| 12-860-1[redacted] | 筋骨格系および結合組織障害<br>関節滲出液<br>Joint Effusion (Left Knee) (14) | 20[redacted]-08-02 (72)<br>to<br>20[redacted]-08-08 (78)<br>[7] | 2 | Not Related | Dose Not Changed | Procedure Required, Hospitalization | Recovered/ Resolved |
| 12-860-1[redacted] | 血液およびリンパ系障害<br>発熱性好中球減少症<br>Febrile Neutropenia (3) | 20[redacted]-06-29 (30)<br>to<br>20[redacted]-07-01 (32)<br>[3] | 3 | Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| 12-860-1[redacted] | 感染症および寄生虫症<br>敗血症<br>Sepsis Of Unknown Cause (17) | 20[redacted]-05-10 (269)<br>to<br>20[redacted]-05-11 (270)<br>[2] | 4 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | 感染症および寄生虫症<br>尿路感染<br>Urinary Tract Infection (25) | 20[redacted]-09-03 (385)<br>to<br>20[redacted]-09-08 (390)<br>[6] | 3 | Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| 12-860-1[redacted] | 腎および尿路障害<br>急性腎不全<br>Acute Kidney Injury (12) | 20[redacted]-10-31 (70)<br>to<br>20[redacted]-11-05 (75)<br>[6] | 3 | Not Related | Drug Interrupted | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | 感染症および寄生虫症<br>下気道感染<br>Chest Infection (13) | 20[redacted]-12-20 (120)<br>to<br>20[redacted]-01-03 (134)<br>＊ [15] | 3 | Not Related | Drug Interrupted | Concomitant Medication, Hospitalization | Recovered/ Resolved |

**被験者識別コード，年齢以外のマスキングにおいて，**
**マークなし　：「同年」を意味する**
**＊　：「翌年」を意味する**

**表 2.7.4.7-43　重篤な有害事象の一覧表（PX-171-011）（続き 21）**

| REGIMEN C | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Subject ID** | **System Organ Class<br>PREFERRED TERM<br>Reported Term (AE #)** | **Date (#Days from First Dose)<br>[Duration(days)]** | **Severity (NCI Grade)** | **Study Drug Relationship** | **Action Taken Regarding Study Drug** | **Other Action Taken** | **Outcome** |
| 12-865-1[redacted] | 感染症および寄生虫症<br>大葉性肺炎<br>Right Sided Mid Lobe Pneumonia (20) | 20[redacted]-10-13 (375)<br>to<br>20[redacted]-10-19 (381)<br>[7] | 3 | Not Related | Drug Interrupted | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| 12-866-1[redacted] | 感染症および寄生虫症<br>メタニューモウイルス感染<br>Lung Infection (Metapneumovirus) (18) | 20[redacted]-02-18 (196)<br>to<br>20[redacted]-02-27 (205)<br>[10] | 3 | Not Related | Drug Interrupted | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| 16-329-1[redacted] | 腎および尿路障害<br>急性腎不全<br>Acute Renal Insufficiency (1) | 20[redacted]-09-21 (30)<br>to<br>Continuing | 4 | Not Related | Dose Not Changed | Hospitalization | Not Recovered/ Not Resolved |
| | 一般・全身障害および投与部位の状態<br>疾患進行<br>Disease Progression (2) | 20[redacted]-10-11 (50)<br>to<br>20[redacted]-10-11 (50)<br>[1] | 5 | Not Related | Dose Not Changed | None | Fatal |
| 16-332-1[redacted] | 腎および尿路障害<br>急性腎不全<br>Acute Renal Failure (1) | 20[redacted]-10-11 (15)<br>to<br>20[redacted]-10-13 (17)<br>[3] | 3 | Not Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| 18-454-1[redacted] | 血液およびリンパ系障害<br>発熱性好中球減少症<br>Neutropenic Fever (2) | 20[redacted]-01-05 (3)<br>to<br>20[redacted]-01-12 (10)<br>[8] | 3 | Related | Dose Not Changed | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | 感染症および寄生虫症<br>肺炎<br>Bilateral Pneumonia (4) | 20[redacted]-01-19 (17)<br>to<br>20[redacted]-02-02 (31)<br>[15] | 3 | Related | Drug Interrupted | Concomitant Medication, Hospitalization | Recovered/ Resolved |
| | 腎および尿路障害<br>腎不全<br>Renal Failure (6) | 20[redacted]-02-11 (40)<br>to<br>20[redacted]-04-12 (101)<br>[62] | 3 | Not Related | Drug Interrupted | Concomitant Medication, Hospitalization | Recovering/ Resolving |