### 2.7.6.18 付録 1

#### 2.7.6.18.1 PX-171-008

該当なし.

2.7.6.18.2 PX-171-009

**表 2.7.6.18.2-1　IRC 評価による PFS のサブグループ解析（ITT 集団）（PX-171-009）**

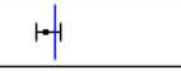
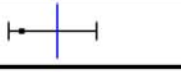
| Subgroup | CRd N | CRd No. of Events (%) | CRd Median (months) (95% CI) | Rd N | Rd No. of Events (%) | Rd Median (months) (95% CI) | Hazard Ratio (CRd/Rd) (95% CI) | Plot of Hazard Ratio |
|---|---|---|---|---|---|---|---|---|
| **Overall** | 396 | 207 (52.3) | 26.3 (23.3, 30.5) | 396 | 224 (56.6) | 17.6 (15.0, 20.6) | 0.690 (0.570, 0.834) |  |
| **Age (years)** | | | | | | | | |
| 18–64 | 211 | 105 (49.8) | 29.7 (24.1, 35.3) | 188 | 111 (59.0) | 16.1 (11.9, 19.4) | 0.601 (0.459, 0.786) |  |
| ≥ 65 | 185 | 102 (55.1) | 24.2 (20.8, 29.6) | 208 | 113 (54.3) | 18.5 (15.6, 24.9) | 0.846 (0.647, 1.106) |  |
| 18–74 | 353 | 185 (52.4) | 26.2 (23.2, 30.5) | 343 | 193 (56.3) | 17.6 (14.9, 21.5) | 0.726 (0.593, 0.888) |  |
| ≥ 75 | 43 | 22 (51.2) | 30.3 (18.0, NE) | 53 | 31 (58.5) | 16.6 (10.3, 22.0) | 0.623 (0.360, 1.079) |  |
| **Sex** | | | | | | | | |
| Male | 215 | 117 (54.4) | 26.8 (20.8, 31.4) | 232 | 135 (58.2) | 16.7 (14.0, 20.7) | 0.742 (0.579, 0.951) |  |
| Female | 181 | 90 (49.7) | 26.2 (23.1, 35.3) | 164 | 89 (54.3) | 17.7 (14.0, 25.0) | 0.684 (0.510, 0.918) |  |
| **Race** | | | | | | | | |
| White | 377 | 198 (52.5) | 26.3 (23.2, 30.5) | 377 | 213 (56.5) | 16.8 (14.8, 21.3) | 0.719 (0.592, 0.873) |  |
| Black | 12 | 7 (58.3) | 23.1 (1.9, NE) | 11 | 6 (54.5) | 18.0 (6.8, NE) | 0.665 (0.220, 2.008) |  |
| Other | 7 | 2 (28.6) | NE (6.5, NE) | 8 | 5 (62.5) | 19.5 (1.9, NE) | 0.332 (0.063, 1.759) |  |

**表 2.7.6.18.2-1　IRC 評価による PFS のサブグループ解析（ITT 集団）（PX-171-009）（続き 1）**

| | CRd | | | Rd | | | | |
|---|---|---|---|---|---|---|---|---|
| Subgroup | N | No. of Events (%) | Median (months) (95% CI) | N | No. of Events (%) | Median (months) (95% CI) | Hazard Ratio (CRd/Rd) (95% CI) | Plot of Hazard Ratio 0.00 1.00 2.00 3.00 |
| **Ethnicity** | | | | | | | | |
| Hispanic or Latino | 20 | 14 (70.0) | 26.3 (9.3, 31.0) | 14 | 5 (35.7) | NE (10.3, NE) | 1.580 (0.562, 4.439) | |
| Not Hispanic or Latino | 376 | 193 (51.3) | 26.4 (23.3, 31.4) | 381 | 219 (57.5) | 16.7 (14.8, 19.5) | 0.684 (0.563, 0.831) | |
| **Geographic Region** | | | | | | | | |
| Europe | 302 | 163 (54.0) | 26.3 (23.1, 30.5) | 288 | 170 (59.0) | 16.6 (14.0, 20.9) | 0.695 (0.560, 0.862) | |
| North America | 84 | 39 (46.4) | 29.3 (19.4, NE) | 87 | 41 (47.1) | 19.8 (16.1, 32.6) | 0.883 (0.569, 1.370) | |
| Rest of World | 10 | 5 (50.0) | 31.4 (0.4, NE) | 21 | 13 (61.9) | 13.9 (6.6, 21.9) | 0.387 (0.133, 1.125) | |
| **Body Surface Area ($m^2$)** | | | | | | | | |
| ≤ 2.2 | 365 | 190 (52.1) | 26.2 (23.2, 30.5) | 342 | 191 (55.8) | 17.8 (15.6, 21.9) | 0.739 (0.604, 0.904) | |
| > 2.2 | 30 | 16 (53.3) | 29.7 (19.6, NE) | 49 | 29 (59.2) | 12.9 (9.3, 22.1) | 0.563 (0.304, 1.044) | |
| **Baseline ECOG PS** | | | | | | | | |
| 0 | 165 | 83 (50.3) | 28.7 (23.3, 34.2) | 175 | 98 (56.0) | 17.6 (14.9, 23.6) | 0.668 (0.498, 0.896) | |
| 1 | 191 | 101 (52.9) | 26.2 (22.1, 31.4) | 186 | 102 (54.8) | 18.0 (14.0, 22.2) | 0.764 (0.580, 1.007) | |
| 2 | 40 | 23 (57.5) | 20.6 (16.6, 30.3) | 35 | 24 (68.6) | 7.5 (2.3, 21.3) | 0.633 (0.356, 1.125) | |

**表 2.7.6.18.2-1　IRC 評価による PFS のサブグループ解析（ITT 集団）（PX-171-009）（続き 2）**

| | CRd | | | Rd | | | | |
|---|---|---|---|---|---|---|---|---|
| Subgroup | N | No. of Events (%) | Median (months) (95% CI) | N | No. of Events (%) | Median (months) (95% CI) | Hazard Ratio (CRd/Rd) (95% CI) | Plot of Hazard Ratio |
| **Baseline Hemoglobin (g/L)** | | | | | | | | |
| < 105 | 133 | 85 (63.9) | 18.5 (15.4, 24.2) | 142 | 92 (64.8) | 13.0 (8.5, 17.6) | 0.726 (0.540, 0.976) | |
| ≥ 105 | 263 | 122 (46.4) | 31.4 (26.1, NE) | 254 | 132 (52.0) | 21.5 (16.6, 27.7) | 0.701 (0.548, 0.897) | |
| **Baseline ANC ($10^9$/L)** | | | | | | | | |
| < 1.5 | 36 | 20 (55.6) | 22.8 (15.2, NE) | 37 | 22 (59.5) | 14.9 (7.2, 21.7) | 0.498 (0.271, 0.916) | |
| ≥ 1.5 | 358 | 185 (51.7) | 28.4 (24.1, 31.4) | 358 | 201 (56.1) | 17.7 (15.0, 21.5) | 0.734 (0.601, 0.897) | |
| **Baseline Platelets ($10^9$/L)** | | | | | | | | |
| <150 | 121 | 80 (66.1) | 18.5 (15.2, 23.2) | 104 | 66 (63.5) | 12.9 (8.3, 17.6) | 0.723 (0.521, 1.003) | |
| ≥150 | 275 | 127 (46.2) | 31.4 (26.0, NE) | 292 | 158 (54.1) | 19.4 (15.8, 25.0) | 0.666 (0.527, 0.842) | |
| **Baseline Corrected Calcium (mg/dL)** | | | | | | | | |
| ≤ 11.5 | 381 | 195 (51.2) | 27.1 (24.1, 31.4) | 381 | 213 (55.9) | 17.6 (15.0, 21.3) | 0.702 (0.578, 0.853) | |
| > 11.5 | 7 | 6 (85.7) | 12.3 (1.0, 31.6) | 11 | 8 (72.7) | 5.7 (2.0, NE) | 1.200 (0.415, 3.471) | |

**表 2.7.6.18.2-1　IRC 評価による PFS のサブグループ解析（ITT 集団）（PX-171-009）（続き 3）**

| | CRd | | | Rd | | | | |
|---|---|---|---|---|---|---|---|---|
| Subgroup | N | No. of Events (%) | Median (months) (95% CI) | N | No. of Events (%) | Median (months) (95% CI) | Hazard Ratio (CRd/Rd) (95% CI) | Plot of Hazard Ratio |
| **Baseline Creatinine Clearance Sponsor Calculated (mL/min)** | | | | | | | | |
| 30 – <50 | 25 | 12 (48.0) | 27.1 (17.8, NE) | 31 | 20 (64.5) | 16.6 (9.6, 28.9) | 0.579 (0.282, 1.189) | |
| 50 – <80 | 171 | 99 (57.9) | 23.2 (18.3, 29.3) | 153 | 88 (57.5) | 16.6 (12.5, 20.9) | 0.811 (0.608, 1.082) | |
| ≥ 80 | 199 | 95 (47.7) | 31.4 (24.4, NE) | 205 | 114 (55.6) | 18.0 (14.6, 23.2) | 0.641 (0.488, 0.843) | |
| **Presence of Neuropathy at Baseline** | | | | | | | | |
| No | 252 | 124 (49.2) | 31.0 (25.9, 34.2) | 259 | 150 (57.9) | 16.8 (14.2, 21.5) | 0.610 (0.480, 0.774) | |
| Yes | 144 | 83 (57.6) | 23.2 (18.0, 25.9) | 137 | 74 (54.0) | 17.6 (13.9, 26.0) | 0.947 (0.692, 1.296) | |
| Grade 1 | 114 | 70 (61.4) | 21.3 (15.8, 25.9) | 106 | 57 (53.8) | 16.7 (12.4, 26.0) | 1.007 (0.709, 1.429) | |
| ≥ Grade 2 | 22 | 12 (54.5) | 24.2 (19.6, NE) | 24 | 14 (58.3) | 14.8 (7.4, NE) | 0.695 (0.321, 1.507) | |
| **Stage at Initial Diagnosis** | | | | | | | | |
| I | 64 | 29 (45.3) | 28.6 (19.6, NE) | 74 | 34 (45.9) | 28.9 (14.5, NE) | 0.797 (0.485, 1.310) | |
| II | 99 | 55 (55.6) | 24.9 (18.0, 31.4) | 94 | 56 (59.6) | 17.6 (11.3, 22.2) | 0.732 (0.504, 1.064) | |
| III | 185 | 99 (53.5) | 28.7 (23.1, 32.3) | 161 | 96 (59.6) | 15.0 (12.4, 18.0) | 0.636 (0.479, 0.844) | |
| Unknown | 48 | 24 (50.0) | 24.4 (17.6, 38.9) | 67 | 38 (56.7) | 18.9 (12.9, 24.3) | 0.753 (0.451, 1.256) | |

**表 2.7.6.18.2-1　IRC 評価による PFS のサブグループ解析（ITT 集団）（PX-171-009）（続き 4）**

| | CRd | | | Rd | | | | |
|---|---|---|---|---|---|---|---|---|
| Subgroup | N | No. of Events (%) | Median (months) (95% CI) | N | No. of Events (%) | Median (months) (95% CI) | Hazard Ratio (CRd/Rd) (95% CI) | Plot of Hazard Ratio |
| **Plasma Cell Involvement** | | | | | | | | |
| < 50% | 295 | 146 (49.5) | 28.7 (24.2, 32.8) | 288 | 158 (54.9) | 19.4 (15.8, 24.2) | 0.703 (0.561, 0.881) | |
| ≥ 50% | 82 | 48 (58.5) | 21.3 (16.0, 31.6) | 86 | 54 (62.8) | 14.8 (10.2, 17.7) | 0.716 (0.484, 1.058) | |
| Not done | 19 | 13 (68.4) | 17.7 (8.5, NE) | 22 | 12 (54.5) | 11.3 (5.7, NE) | 0.824 (0.373, 1.820) | |
| **Risk Group by FISH** | | | | | | | | |
| High | 48 | 31 (64.6)) | 23.1 (12.5, 24.2) | 52 | 32 (61.5) | 13.9 (9.5, 16.7) | 0.703 (0.426, 1.160) | |
| Standard | 147 | 68 (46.3) | 29.6 (24.1, NE) | 170 | 94 (55.3) | 19.5 (14.8, 26.0) | 0.656 (0.480, 0.897) | |
| Unknown | 201 | 108 (53.7) | 28.4 (22.1, 32.3) | 174 | 98 (56.3) | 17.6 (14.0, 22.2) | 0.742 (0.564, 0.976) | |
| **Serum β2 Microglobulin (mg/L) per IVRS** | | | | | | | | |
| < 2.5 | 68 | 25 (36.8) | NE (24.4, NE) | 71 | 32 (45.1) | 32.0 (16.1, NE) | 0.604 (0.357, 1.021) | |
| ≥ 2.5 | 324 | 178 (54.9) | 25.8 (21.4, 29.3) | 319 | 192 (60.2) | 15.9 (13.9, 18.5) | 0.705 (0.575, 0.865) | |

**表 2.7.6.18.2-1　IRC 評価による PFS のサブグループ解析（ITT 集団）（PX-171-009）（続き 5）**

| | CRd | | | Rd | | | | |
|---|---|---|---|---|---|---|---|---|
| Subgroup | N | No. of Events (%) | Median (months) (95% CI) | N | No. of Events (%) | Median (months) (95% CI) | Hazard Ratio (CRd/Rd) (95% CI) | Plot of Hazard Ratio |
| **Number of Prior Regimens** | | | | | | | | |
| 1 | 184 | 91 (49.5) | 29.6 (23.2, 33.5) | 157 | 88 (56.1) | 17.6 (15.0, 22.2) | 0.713 (0.532, 0.957) | |
| 2 | 120 | 65 (54.2) | 26.2 (21.9, 32.3) | 139 | 78 (56.1) | 18.5 (14.0, 25.0) | 0.745 (0.536, 1.036) | |
| 3[a] | 92 | 51 (55.4) | 24.1 (19.6, 32.6) | 100 | 58 (58.0) | 14.8 (10.0, 22.1) | 0.682 (0.468, 0.995) | |
| **Prior Transplant** | | | | | | | | |
| Yes | 217 | 115 (53.0) | 26.3 (23.1, 32.3) | 229 | 127 (55.5) | 17.8 (14.5, 22.2) | 0.678 (0.526, 0.873) | |
| No | 179 | 92 (51.4) | 26.4 (20.5, 31.4) | 167 | 97 (58.1) | 16.6 (13.9, 21.7) | 0.760 (0.571, 1.011) | |
| **Prior Bortezomib per IVRS** | | | | | | | | |
| Yes | 261 | 143 (54.8) | 24.4 (21.9, 29.6) | 260 | 152 (58.5) | 16.6 (12.5, 20.9) | 0.699 (0.556, 0.879) | |
| No | 135 | 64 (47.4) | 30.3 (25.3, NE) | 136 | 72 (52.9) | 18.2 (15.3, 26.0) | 0.726 (0.518, 1.018) | |
| **Prior Lenalidomide per IVRS** | | | | | | | | |
| Yes | 79 | 46 (58.2) | 19.4 (15.0, 31.0) | 78 | 41 (52.6) | 13.9 (9.7, 27.9) | 0.796 (0.522, 1.215) | |
| No | 317 | 161 (50.8) | 28.7 (24.9, 32.3) | 318 | 183 (57.5) | 17.7 (15.8, 21.5) | 0.685 (0.554, 0.847) | |

**表 2.7.6.18.2-1　IRC 評価による PFS のサブグループ解析（ITT 集団）（PX-171-009）（続き 6）**

| | CRd | | | Rd | | | | |
|---|---|---|---|---|---|---|---|---|
| Subgroup | N | No. of Events (%) | Median (months) (95% CI) | N | No. of Events (%) | Median (months) (95% CI) | Hazard Ratio (CRd/Rd) (95% CI) | Plot of Hazard Ratio |
| **Refractory to Prior Bortezomib** | | | | | | | | |
| Yes | 60 | 35 (58.3) | 22.3 (16.7, 29.3) | 58 | 31 (53.4) | 19.4 (8.8, 30.5) | 0.799 (0.492, 1.297) | |
| No | 336 | 172 (51.2) | 28.6 (24.1, 31.6) | 338 | 193 (57.1) | 16.8 (14.9, 20.9) | 0.696 (0.566, 0.855) | |
| **Refractory to Prior IMiD** | | | | | | | | |
| Yes | 85 | 59 (69.4) | 20.8 (14.8, 25.8) | 88 | 60 (68.2) | 11.1 (8.8, 14.8) | 0.636 (0.442, 0.914) | |
| No | 311 | 148 (47.6) | 29.6 (25.3, 34.2) | 308 | 164 (53.2) | 19.5 (16.6, 24.3) | 0.721 (0.577, 0.901) | |
| **Double Refractory to Bortezomib and IMiD** | | | | | | | | |
| Yes | 24 | 17 (70.8) | 14.9 (9.3, 23.8) | 27 | 16 (59.3) | 9.3 (5.8, 22.1) | 0.889 (0.447, 1.768) | |
| No | 372 | 190 (51.1) | 28.7 (24.2, 31.4) | 369 | 208 (56.4) | 17.6 (15.0, 21.3) | 0.699 (0.574, 0.852) | |




Source: Table 14.2.2.5

ANC = absolute neutrophil count; CI = confidence interval; CRd = carfilzomib/Revlimid (lenalidomide)/dexamethasone arm; ECOG PS = Eastern Cooperative Oncology Group Performance Status; FISH = florescence in situ hybridization; IMiD = immunomodulatory drug; ITT= intent-to-treat; IVRS = interactive voice recognition system; NE = not estimable; Rd = Revlimid (lenalidomide)/dexamethasone arm

[a] Including 2 subjects with 4 prior regimens

出典［総括報告書 5.3.5.1-1（PX-171-009）， Table 39］

**表 2.7.6.18.2-2　IRC 評価による OS のサブグループ解析（ITT 集団）（PX-171-009）**

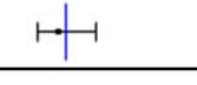
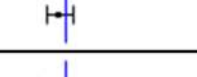
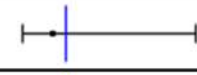
| Subgroup | CRd N | CRd No. of Events (%) | CRd Median (months) (95% CI) | Rd N | Rd No. of Events (%) | Rd Median (months) (95% CI) | Hazard Ratio (CRd/Rd) (95% CI) | Plot of Hazard Ratio (0.00 1.00 2.00 3.00) |
|---|---|---|---|---|---|---|---|---|
| **Overall** | 396 | 143 (36.1) | NE (NE, NE) | 396 | 162 (40.9) | NE (32.1, NE) | 0.787 (0.628, 0.985) |  |
| **Age (years)** | | | | | | | | |
| 18–64 | 211 | 61 (28.9) | NE (NE, NE) | 188 | 75 (39.9) | NE (31.8, NE) | 0.637 (0.454, 0.893) |  |
| ≥ 65 | 185 | 82 (44.3) | 32.9 (31.5, NE) | 208 | 87 (41.8) | NE (30.5, NE) | 0.983 (0.727, 1.329) |  |
| 18–74 | 353 | 124 (35.1) | NE (NE, NE) | 343 | 140 (40.8) | NE (32.1, NE) | 0.779 (0.612, 0.992) |  |
| ≥ 75 | 43 | 19 (44.2) | 32.6 (29.3, NE) | 53 | 22 (41.5) | NE (22.0, NE) | 0.868 (0.469, 1.605) |  |
| **Sex** | | | | | | | | |
| Male | 215 | 86 (40.0) | NE (32.6, NE) | 232 | 100 (43.1) | NE (28.9, NE) | 0.876 (0.656, 1.169) |  |
| Female | 181 | 57 (31.5) | NE (NE, NE) | 164 | 62 (37.8) | NE (32.0, NE) | 0.693 (0.483, 0.993) |  |
| **Race** | | | | | | | | |
| White | 377 | 139 (36.9) | NE (NE, NE) | 377 | 155 (41.1) | NE (32.1, NE) | 0.801 (0.637, 1.007) |  |
| Black | 12 | 3 (25.0) | NE 16.2, NE) | 11 | 4 (36.4) | NE (6.8, NE) | 0.779 (0.173, 3.512) |  |
| Other | 7 | 1 (14.3) | NE (26.1, NE) | 8 | 3 (37.5) | NE (11.0, NE) | 0.306 (0.032, 2.945) |  |

**表 2.7.6.18.2-2　IRC 評価による OS のサブグループ解析（ITT 集団）（PX-171-009）（続き 1）**

| Subgroup | CRd N | CRd No. of Events (%) | CRd Median (months) (95% CI) | Rd N | Rd No. of Events (%) | Rd Median (months) (95% CI) | Hazard Ratio (CRd/Rd) (95% CI) | Plot of Hazard Ratio (0.00, 1.00, 2.00, 3.00) |
|---|---|---|---|---|---|---|---|---|
| **Ethnicity** | | | | | | | | |
| Hispanic or Latino | 20 | 11 (55.0) | 30.1 (22.3, NE) | 14 | 4 (28.6) | NE (28.9, NE) | 2.017 (0.640, 6.357) | |
| Not Hispanic or Latino | 376 | 132 (35.1) | NE (NE, NE) | 381 | 158 (41.5) | NE (32.0, NE) | 0.752 (0.596, 0.947) | |
| **Geographic Region** | | | | | | | | |
| Europe | 302 | 109 (36.1) | NE (NE, NE) | 288 | 123 (42.7) | NE (31.8, NE) | 0.753 (0.581, 0.974) | |
| North America | 84 | 30 (35.7) | NE (31.9, NE) | 87 | 29 (33.3) | NE (NE, NE) | 1.019 (0.612, 1.699) | |
| Rest of World | 10 | 4 (40.0) | NE (0.4, NE) | 21 | 10 (47.6) | 22.4 (11.4, NE) | 0.623 (0.195, 1.994) | |
| **Body Surface Area ($m^2$)** | | | | | | | | |
| ≤ 2.2 | 365 | 134 (36.7) | NE (NE, NE) | 342 | 133 (38.9) | NE (NE, NE) | 0.864 (0.679, 1.098) | |
| > 2.2 | 30 | 8 (26.7) | NE (32.3, NE) | 49 | 24 (49.0) | 30.4 (21.7, NE) | 0.400 (0.179, 0.894) | |
| **Baseline ECOG PS** | | | | | | | | |
| 0 | 165 | 50 (30.3) | NE (NE, NE) | 175 | 65 (37.1) | NE (33.6, NE) | 0.707 (0.489, 1.023) | |
| 1 | 191 | 71 (37.2) | NE (36.0, NE) | 186 | 72 (38.7) | NE (32.0, NE) | 0.892 (0.643, 1.238) | |
| 2 | 40 | 22 (55.0) | 31.5 (21.7, NE) | 35 | 25 (71.4) | 16.6 (9.7, 22.3) | 0.560 (0.315, 0.998) | |

**表 2.7.6.18.2-2　IRC 評価による OS のサブグループ解析（ITT 集団）（PX-171-009）（続き 2）**

| Subgroup | CRd N | CRd No. of Events (%) | CRd Median (months) (95% CI) | Rd N | Rd No. of Events (%) | Rd Median (months) (95% CI) | Hazard Ratio (CRd/Rd) (95% CI) | Plot of Hazard Ratio (0.00, 1.00, 2.00, 3.00) |
|---|---|---|---|---|---|---|---|---|
| **Baseline Hemoglobin (g/L)** | | | | | | | | |
| < 105 | 133 | 67 (50.4) | 31.6 (25.0, NE) | 142 | 78 (54.9) | 23.8 (18.2, 32.0) | 0.771 (0.556, 1.069) | |
| ≥ 105 | 263 | 76 (28.9) | NE (NE, NE) | 254 | 84 (33.1) | NE (NE, NE) | 0.803 (0.588, 1.095) | |
| **Baseline ANC ($10^9$/L)** | | | | | | | | |
| < 1.5 | 36 | 15 (41.7) | NE (23.2, NE) | 37 | 18 (48.6) | 31.8 (21.7, NE) | 0.689 (0.347, 1.368) | |
| ≥ 1.5 | 358 | 127 (35.5) | NE (NE, NE) | 358 | 144 (40.2) | NE (33.6, NE) | 0.798 (0.628, 1.013) | |
| **Baseline Platelets ($10^9$/L)** | | | | | | | | |
| < 150 | 121 | 58 (47.9) | 32.3 (26.3, NE) | 104 | 68 (65.4) | 20.2 (16.1, 24.5) | 0.559 (0.393, 0.794) | |
| ≥ 150 | 275 | 85 (30.9) | NE (NE, NE) | 292 | 94 (32.2) | NE (NE, NE) | 0.884 (0.659, 1.186) | |
| **Baseline Corrected Calcium (mg/dL)** | | | | | | | | |
| ≤ 11.5 | 381 | 133 (34.9) | NE (NE, NE) | 381 | 152 (39.9) | NE (33.6, NE) | 0.784 (0.621, 0.990) | |
| > 11.5 | 7 | 5 (71.4) | 24.2 (1.3, NE) | 11 | 6 (54.5) | 9.7 (2.2, NE) | 1.249 (0.379, 4.116) | |

**表 2.7.6.18.2-2　IRC 評価による OS のサブグループ解析（ITT 集団）（PX-171-009）（続き 3）**

| Subgroup | CRd N | CRd No. of Events (%) | CRd Median (months) (95% CI) | Rd N | Rd No. of Events (%) | Rd Median (months) (95% CI) | Hazard Ratio (CRd/Rd) (95% CI) | Plot of Hazard Ratio (0.00, 1.00, 2.00, 3.00) |
|---|---|---|---|---|---|---|---|---|
| **Baseline Creatinine Clearance Sponsor Calculated (mL/min)** | | | | | | | | |
| 30 – <50 | 25 | 8 (32.0) | NE (29.3, NE) | 31 | 15 (48.4) | 33.9 (16.9, NE) | 0.586 (0.248, 1.385) | |
| 50 – <80 | 171 | 80 (46.8) | 32.4 (30.1, NE) | 153 | 70 (45.8) | 32.1 (24.1, NE) | 0.925 (0.671, 1.275) | |
| ≥80 | 199 | 54 (27.1) | NE (NE, NE) | 205 | 73 (35.6) | NE (NE, NE | 0.679 (0.477, 0.966) | |
| **Presence of Neuropathy at Baseline** | | | | | | | | |
| No | 252 | 88 (34.9) | NE (NE, NE) | 259 | 110 (42.5) | NE (32.0, NE) | 0.698 (0.527, 0.924) | |
| Yes | 144 | 55 (38.2) | NE (32.9, NE) | 137 | 52 (38.0) | NE (30.9, NE) | 0.988 (0.676, 1.443) | |
| Grade 1 | 114 | 47 (41.2) | NE (29.6, NE) | 106 | 39 (36.8) | NE (30.4, NE) | 1.092 (0.714, 1.669) | |
| ≥ Grade 2 | 22 | 7 (31.8) | NE (27.7, NE) | 24 | 12 (50.0) | 31.8 (16.3, NE) | 0.583 (0.229, 1.482) | |
| **Stage at Initial Diagnosis** | | | | | | | | |
| I | 64 | 16 (25.0) | NE (NE, NE) | 74 | 20 (27.0) | NE (NE, NE) | 0.854 (0.442, 1.650) | |
| II | 99 | 41 (41.4) | NE (31.4, NE) | 94 | 41 (43.6) | NE (25.5, NE) | 0.856 (0.555, 1.319) | |
| III | 185 | 67 (36.2) | NE (NE, NE) | 161 | 73 (45.3) | 32.1 (27.1, NE) | 0.687 (0.493, 0.958) | |
| Unknown | 48 | 19 (39.6) | 36.0 (29.3, NE) | 67 | 28 (41.8) | NE (28.8, NE) | 0.890 (0.497, 1.594) | |

**表 2.7.6.18.2-2　IRC 評価による OS のサブグループ解析（ITT 集団）（PX-171-009）（続き 4）**

| Subgroup | CRd N | CRd No. of Events (%) | CRd Median (months) (95% CI) | Rd N | Rd No. of Events (%) | Rd Median (months) (95% CI) | Hazard Ratio (CRd/Rd) (95% CI) | Plot of Hazard Ratio (0.00, 1.00, 2.00, 3.00) |
|---|---|---|---|---|---|---|---|---|
| **Plasma Cell Involvement** | | | | | | | | |
| < 50% | 295 | 92 (31.2) | NE (NE, NE) | 288 | 116 (40.3) | NE (32.1, NE) | 0.687 (0.523, 0.904) | |
| ≥ 50% | 82 | 43 (52.4) | 31.5 (23.8, NE) | 86 | 40 (46.5) | 30.5 (21.7, NE) | 1.022 (0.664, 1.573) | |
| Not done | 19 | 8 (42.1) | NE (14.4, NE) | 22 | 6 (27.3) | NE (19.4, NE) | 1.448 (0.502, 4.175) | |
| **Risk Group by FISH** | | | | | | | | |
| High | 48 | 21 (43.8) | 36.0 (21.7, NE) | 52 | 22 (42.3) | 33.9 (23.2, NE) | 1.002 (0.551, 1.823) | |
| Standard | 147 | 52 (35.4) | NE (32.9, NE) | 170 | 65 (38.2) | NE (33.6, NE) | 0.830 (0.576, 1.195) | |
| Unknown | 201 | 70 (34.8) | NE (NE, NE) | 174 | 75 (43.1) | NE (30.4, NE) | 0.707 (0.511, 0.980) | |
| **Serum β2 Microglobulin (mg/L) per IVRS** | | | | | | | | |
| < 2.5 | 68 | 9 (13.2) | NE (NE, NE) | 71 | 18 (25.4) | NE (NE, NE) | 0.474 (0.213, 1.056) | |
| ≥ 2.5 | 324 | 133 (41.0) | NE (32.4, NE) | 319 | 143 (44.8) | NE (29.0, NE) | 0.814 (0.643, 1.031) | |

**表 2.7.6.18.2-2　IRC 評価による OS のサブグループ解析（ITT 集団）（PX-171-009）（続き 5）**

| Subgroup | CRd N | CRd No. of Events (%) | CRd Median (months) (95% CI) | Rd N | Rd No. of Events (%) | Rd Median (months) (95% CI) | Hazard Ratio (CRd/Rd) (95% CI) | Plot of Hazard Ratio (0.00, 1.00, 2.00, 3.00) |
|---|---|---|---|---|---|---|---|---|
| **Number of Prior Regimens** | | | | | | | | |
| 1 | 184 | 69 (37.5) | NE (34.5, NE) | 157 | 66 (42.0) | NE (28.9, NE) | 0.815 (0.582, 1.143) | |
| 2 | 120 | 40 (33.3) | NE (NE, NE) | 139 | 53 (38.1) | NE (32.0, NE) | 0.788 (0.523, 1.188) | |
| 3[a] | 92 | 34 (37.0) | NE (32.9, NE) | 100 | 43 (43.0) | NE (28.8, NE) | 0.731 (0.466, 1.147) | |
| **Prior Transplant** | | | | | | | | |
| Yes | 217 | 65 (30.0) | NE (NE, NE) | 229 | 95 (41.5) | NE (30.9, NE) | 0.613 (0.447, 0.841) | |
| No | 179 | 78 (43.6) | 34.5 (31.5, NE) | 167 | 67 (40.1) | NE (31.8, NE) | 1.026 (0.740, 1.422 | |
| **Prior Bortezomib per IVRS** | | | | | | | | |
| Yes | 261 | 94 (36.0) | NE (NE, NE) | 260 | 110 (42.3) | NE (30.9, NE) | 0.761 (0.577, 1.002) | |
| No | 135 | 49 (36.3) | NE (33.2, NE) | 136 | 52 (38.2) | NE (30.2, NE) | 0.857 (0.580, 1.267) | |
| **Prior Lenalidomide per IVRS** | | | | | | | | |
| Yes | 79 | 32 (40.5) | 36.0 (31.0, NE) | 78 | 31 (39.7) | NE (27.5, NE) | 0.903 (0.551, 1.480) | |
| No | 317 | 111 (35.0) | NE (NE, NE) | 318 | 131 (41.2) | NE (32.1, NE) | 0.761 (0.591, 0.980) | |

**表 2.7.6.18.2-2　IRC 評価による OS のサブグループ解析（ITT 集団）（PX-171-009）（続き 6）**

| Subgroup | CRd N | CRd No. of Events (%) | CRd Median (months) (95% CI) | Rd N | Rd No. of Events (%) | Rd Median (months) (95% CI) | Hazard Ratio (CRd/Rd) (95% CI) | Plot of Hazard Ratio (0.00, 1.00, 2.00, 3.00) |
|---|---|---|---|---|---|---|---|---|
| **Refractory to Prior Bortezomib** | | | | | | | | |
| Yes | 60 | 24 (40.0) | NE (29.3, NE) | 58 | 28 (48.3) | 31.8 (21.9, NE) | 0.679 (0.393, 1.172) | |
| No | 336 | 119 (35.4) | NE (NE, NE) | 338 | 134 (39.6) | NE (33.9, NE) | 0.814 (0.636, 1.042) | |
| **Refractory to Prior IMiD** | | | | | | | | |
| Yes | 85 | 39 (45.9) | 33.2 (29.4, NE) | 88 | 44 (50.0) | 30.2 (23.2, NE) | 0.790 (0.513, 1.217) | |
| No | 311 | 104 (33.4) | NE (NE, NE) | 308 | 118 (38.3) | NE (NE, NE) | 0.791 (0.608, 1.030) | |
| **Double Refractory to Bortezomib and IMiD** | | | | | | | | |
| Yes | 24 | 11 (45.8) | 31.9 (21.8, NE) | 27 | 17 (63.0) | 27.7 (12.6, 32.0) | 0.683 (0.320, 1.460) | |
| No | 372 | 132 (35.5) | NE (NE, NE) | 369 | 145 (39.3) | NE (NE, NE) | 0.810 (0.639, 1.025) | |

Source: Table 14.2.3.2

ANC = absolute neutrophil count; CI = confidence interval; CRd = carfilzomib/Revlimid (lenalidomide)/dexamethasone arm; ECOG PS = Eastern Cooperative Oncology Group Performance Status; FISH = florescence in situ hybridization; IMiD = immunomodulatory drug; ITT= intent-to-treat; IVRS = interactive voice recognition system; NE = not estimable; Rd = Revlimid (lenalidomide)/dexamethasone arm

[a] Including 2 subjects with 4 prior regimens

出典［総括報告書 5.3.5.1-1（PX-171-009）， Table 40］

**表 2.7.6.18.2-3　IRC 評価による ORR のサブグループ解析（ITT 集団）（PX-171-009）**

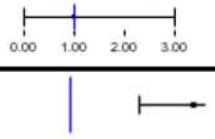
| Subgroup | CRd N | CRd No. of Responders | CRd ORR (%) (95% CI) | Rd N | Rd No. of Responders | Rd ORR (%) (95% CI) | Odds Ratio (CRd/Rd) (95% CI) | Plot of Odds Ratio |
|---|---|---|---|---|---|---|---|---|
| **Overall** | 396 | 345 | 87.1 (83.4,90.3) | 396 | 264 | 66.7 (61.8,71.3) | 3.382 (2.358,4.851) |  |
| **Age (years)** | | | | | | | | |
| 18–64 | 211 | 178 | 84.4 (78.7,89.0) | 188 | 118 | 62.8 (55.4,69.7) | 3.200 (1.990,5.144) | |
| ≥ 65 | 185 | 167 | 90.3 (85.1,94.1) | 208 | 146 | 70.2 (63.5,76.3) | 3.940 (2.229,6.965) | |
| 18–74 | 353 | 308 | 87.3 (83.3,90.5) | 343 | 231 | 67.3 (62.1,72.3) | 3.319 (2.257,4.880) | |
| ≥ 75 | 43 | 37 | 86.0 (72.1,94.7) | 53 | 33 | 62.3 (47.9,75.2) | 3.737 (1.340,10.426) | |
| **Sex** | | | | | | | | |
| Male | 215 | 187 | 87.0 (81.7,91.2) | 232 | 162 | 69.8 (63.5,75.7) | 2.886 (1.775,4.692) | |
| Female | 181 | 158 | 87.3 (81.5,91.8) | 164 | 102 | 62.2 (54.3,69.6) | 4.176 (2.435,7.161) | |
| **Race** | | | | | | | | |
| White | 377 | 331 | 87.8 (84.1,90.9) | 377 | 251 | 66.6 (61.6,71.3) | 3.612 (2.482,5.258) | |
| Black | 12 | 8 | 66.7 (34.9,90.1) | 11 | 7 | 63.6 (30.8,89.1) | 1.143 (0.205,6.366) | |
| Other | 7 | 6 | 85.7 (42.1,99.6) | 8 | 6 | 75.0 (34.9,96.8) | 2.000 (0.141,28.416) | |

**表 2.7.6.18.2-3　IRC 評価による ORR のサブグループ解析（ITT 集団）（PX-171-009）（続き 1）**

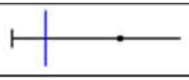
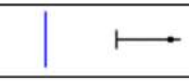
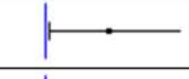
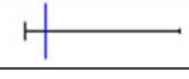
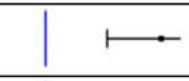
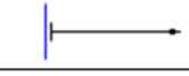
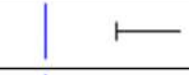
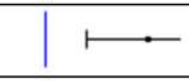
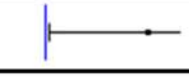
| Subgroup | CRd N | CRd No. of Responders | CRd ORR (%) (95% CI) | Rd N | Rd No. of Responders | Rd ORR (%) (95% CI) | Odds Ratio (CRd/Rd) (95% CI) | Plot of Odds Ratio |
|---|---|---|---|---|---|---|---|---|
| **Ethnicity** | | | | | | | | |
| Hispanic or Latino | 20 | 18 | 90.0 (68.3,98.8) | 14 | 11 | 78.6 (49.2,95.3) | 2.455 (0.353,17.082) |  |
| Not Hispanic or Latino | 376 | 327 | 87.0 (83.1,90.2) | 381 | 252 | 66.1 (61.1,70.9) | 3.416 (2.365,4.934) |  |
| **Geographic Region** | | | | | | | | |
| Europe | 302 | 267 | 88.4 (84.3,91.8) | 288 | 193 | 67.0 (61.3,72.4) | 3.755 (2.444,5.770) |  |
| North America | 84 | 70 | 83.3 (73.6,90.6) | 87 | 60 | 69.0 (58.1,78.5) | 2.250 (1.082,4.677) |  |
| Rest of World | 10 | 8 | 80.0 (44.4,97.5) | 21 | 11 | 52.4 (29.8,74.3) | 3.636 (0.619,21.357) |  |
| **Body Surface Area ($m^2$)** | | | | | | | | |
| ≤ 2.2 | 365 | 319 | 87.4 (83.5,90.6) | 342 | 233 | 68.1 (62.9,73.0) | 3.244 (2.210,4.762) |  |
| > 2.2 | 30 | 25 | 83.3 (65.3,94.4) | 49 | 29 | 59.2 (44.2,73.0) | 3.448 (1.129,10.531) |  |
| **Baseline ECOG PS** | | | | | | | | |
| 0 | 165 | 150 | 90.9 (85.4,94.8) | 175 | 121 | 69.1 (61.7,75.9) | 4.463 (2.400,8.297) |  |
| 1 | 191 | 163 | 85.3 (79.5,90.0) | 186 | 123 | 66.1 (58.8,72.9) | 2.982 (1.803,4.931) |  |
| 2 | 40 | 32 | 80.0 (64.4,90.9) | 35 | 20 | 57.1 (39.4,73.7) | 3.000 (1.078,8.352) |  |

**表 2.7.6.18.2-3　IRC 評価による ORR のサブグループ解析（ITT 集団）（PX-171-009）（続き 2）**

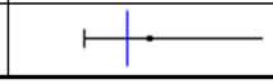
| Subgroup | CRd N | CRd No. of Responders | CRd ORR (%) (95% CI) | Rd N | Rd No. of Responders | Rd ORR (%) (95% CI) | Odds Ratio (CRd/Rd) (95% CI) | Plot of Odds Ratio |
|---|---|---|---|---|---|---|---|---|
| **Baseline Hemoglobin (g/L)** | | | | | | | | |
| < 105 | 133 | 112 | 84.2 (76.9,90.0) | 142 | 79 | 55.6 (47.1,64.0) | 4.253 (2.401,7.533) |  |
| ≥ 105 | 263 | 233 | 88.6 (84.1,92.2) | 254 | 185 | 72.8 (66.9,78.2) | 2.897 (1.810,4.635) |  |
| **Baseline ANC ($10^9$/L)** | | | | | | | | |
| < 1.5 | 36 | 34 | 94.4 (81.3,99.3) | 37 | 19 | 51.4 (34.4,68.1) | 16.105 (3.367,77.028) |  |
| ≥ 1.5 | 358 | 309 | 86.3 (82.3,89.7) | 358 | 244 | 68.2 (63.1,73.0) | 2.946 (2.026,4.285) |  |
| **Baseline Platelets ($10^9$/L)** | | | | | | | | |
| < 150 | 121 | 103 | 85.1 (77.5,90.9) | 104 | 59 | 56.7 (46.7,66.4) | 4.364 (2.317,8.222) |  |
| ≥ 150 | 275 | 242 | 88.0 (83.6,91.6) | 292 | 205 | 70.2 (64.6,75.4) | 3.112 (2.001,4.841) |  |
| **Baseline Corrected Calcium (mg/dL)** | | | | | | | | |
| ≤ 11.5 | 381 | 333 | 87.4 (83.6,90.6) | 381 | 255 | 66.9 (62.0,71.6) | 3.428 (2.367,4.964) |  |
| > 11.5 | 7 | 5 | 71.4 (29.0,96.3) | 11 | 7 | 63.6 (30.8,89.1) | 1.429 (0.184,11.085) |  |

**表 2.7.6.18.2-3　IRC 評価による ORR のサブグループ解析（ITT 集団）（PX-171-009）（続き 3）**

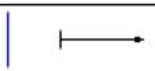
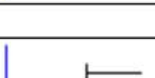
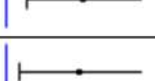
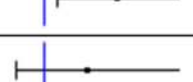
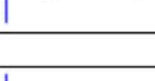
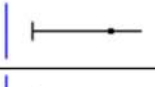
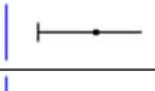
| Subgroup | CRd N | CRd No. of Responders | CRd ORR (%) (95% CI) | Rd N | Rd No. of Responders | Rd ORR (%) (95% CI) | Odds Ratio (CRd/Rd) (95% CI) | Plot of Odds Ratio (0.00 1.00 2.00 3.00) |
|---|---|---|---|---|---|---|---|---|
| **Baseline Creatinine Clearance Sponsor Calculated (mL/min)** | | | | | | | | |
| 30 – <50 | 25 | 19 | 76.0 (54.9,90.6) | 31 | 22 | 71.0 (52.0,85.8) | 1.295 (0.390,4.308) |  |
| 50 – <80 | 171 | 148 | 86.5 (80.5,91.3) | 153 | 99 | 64.7 (56.6,72.3) | 3.510 (2.024,6.086) |  |
| ≥ 80 | 199 | 177 | 88.9 (83.7,92.9) | 205 | 140 | 68.3 (61.4,74.6) | 3.735 (2.195,6.358) |  |
| **Presence of Neuropathy at Baseline** | | | | | | | | |
| No | 252 | 224 | 88.9 (84.3,92.5) | 259 | 171 | 66.0 (59.9,71.8) | 4.117 (2.574,6.584) |  |
| Yes | 144 | 121 | 84.0 (77.0,89.6) | 137 | 93 | 67.9 (59.4,75.6) | 2.489 (1.405,4.411) |  |
| Grade 1 | 114 | 96 | 84.2 (76.2,90.4) | 106 | 73 | 68.9 (59.1,77.5) | 2.411 (1.259,4.618) |  |
| ≥ Grade 2 | 22 | 18 | 81.8 (59.7,94.8) | 24 | 17 | 70.8 (48.9,87.4) | 1.853 (0.459,7.483) |  |
| **Stage at Initial Diagnosis** | | | | | | | | |
| I | 64 | 61 | 95.3 (86.9,99.0) | 74 | 46 | 62.2 (50.1,73.2) | 12.377 (3.544,43.228) |  |
| II | 99 | 84 | 84.8 (76.2,91.3) | 94 | 61 | 64.9 (54.4,74.5) | 3.030 (1.514,6.062) |  |
| III | 185 | 159 | 85.9 (80.1,90.6) | 161 | 111 | 68.9 (61.2,76.0) | 2.755 (1.618,4.691) |  |
| Unknown | 48 | 41 | 85.4 (72.2,93.9) | 67 | 46 | 68.7 (56.2,79.4) | 2.674 (1.031,6.937) |  |

**表 2.7.6.18.2-3　IRC 評価による ORR のサブグループ解析（ITT 集団）（PX-171-009）（続き 4）**

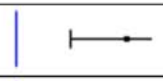
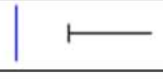
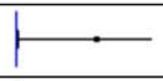
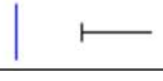
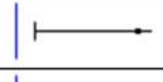
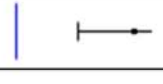
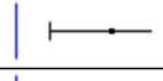
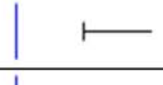
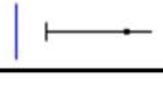
| Subgroup | CRd N | CRd No. of Responders | CRd ORR (%) (95% CI) | Rd N | Rd No. of Responders | Rd ORR (%) (95% CI) | Odds Ratio (CRd/Rd) (95% CI) | Plot of Odds Ratio (0.00 1.00 2.00 3.00) |
|---|---|---|---|---|---|---|---|---|
| **Plasma Cell Involvement** | | | | | | | | |
| < 50% | 295 | 257 | 87.1 (82.8,90.7) | 288 | 197 | 68.4 (62.7,73.7) | 3.124 (2.049,4.762) |  |
| ≥ 50% | 82 | 72 | 87.8 (78.7,94.0) | 86 | 53 | 61.6 (50.5,71.9) | 4.483 (2.032,9.892) |  |
| **Risk Group by FISH** | | | | | | | | |
| High | 48 | 38 | 79.2 (65.0,89.5) | 52 | 31 | 59.6 (45.1,73.0) | 2.574 (1.057,6.268) |  |
| Standard | 147 | 134 | 91.2 (85.4,95.2) | 170 | 125 | 73.5 (66.2,80.0) | 3.711 (1.911,7.205) |  |
| Unknown | 201 | 173 | 86.1 (80.5,90.5) | 174 | 108 | 62.1 (54.4,69.3) | 3.776 (2.283,6.245) |  |
| **Serum β2 Microglobulin (mg/L) per IVRS** | | | | | | | | |
| < 2.5 | 68 | 60 | 88.2 (78.1,94.8) | 71 | 49 | 69.0 (56.9,79.5) | 3.367 (1.379,8.223) |  |
| ≥ 2.5 | 324 | 281 | 86.7 (82.5,90.2) | 319 | 212 | 66.5 (61.0,71.6) | 3.298 (2.219,4.902) |  |
| **Number of Prior Regimens** | | | | | | | | |
| 1 | 184 | 160 | 87.0 (81.2,91.5) | 157 | 110 | 70.1 (62.2,77.1) | 2.848 (1.646,4.929) |  |
| 2 | 120 | 108 | 90.0 (83.2,94.7) | 139 | 92 | 66.2 (57.7,74.0) | 4.598 (2.301,9.187) |  |
| 3[a] | 92 | 77 | 83.7 (74.5,90.6) | 100 | 62 | 62.0 (51.7,71.5) | 3.146 (1.586,6.241) |  |

**表 2.7.6.18.2-3　IRC 評価による ORR のサブグループ解析（ITT 集団）（PX-171-009）（続き 5）**

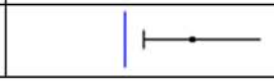
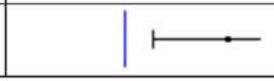
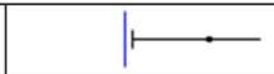
| Subgroup | CRd N | CRd No. of Responders | CRd ORR (%) (95% CI) | Rd N | Rd No. of Responders | Rd ORR (%) (95% CI) | Odds Ratio (CRd/Rd) (95% CI) | Plot of Odds Ratio (0.00 1.00 2.00 3.00) |
|---|---|---|---|---|---|---|---|---|
| **Prior Transplant** | | | | | | | | |
| Yes | 217 | 196 | 90.3 (85.6,93.9) | 229 | 150 | 65.5(59.0,71.6) | 4.916 (2.905,8.319) |  |
| No | 179 | 149 | 83.2 (76.9,88.4) | 167 | 114 | 68.3(60.6,75.2) | 2.309 (1.387,3.845) |  |
| **Prior Bortezomib per IVRS** | | | | | | | | |
| Yes | 261 | 225 | 86.2 (81.4,90.1) | 260 | 165 | 63.5(57.3,69.3) | 3.598 (2.334,5.548) |  |
| No | 135 | 120 | 88.9 (82.3,93.6) | 136 | 99 | 72.8(64.5,80.1) | 2.990 (1.551,5.763) |  |
| **Prior Lenalidomide per IVRS** | | | | | | | | |
| Yes | 79 | 64 | 81.0 (70.6,89.0) | 78 | 39 | 50.0 (38.5,61.5) | 4.267 (2.084,8.733) |  |
| No | 317 | 281 | 88.6 (84.6,91.9) | 318 | 225 | 70.8 (65.4,75.7) | 3.226 (2.114,4.924) |  |
| **Refractory to Prior Bortezomib** | | | | | | | | |
| Yes | 60 | 48 | 80.0 (67.7,89.2) | 58 | 35 | 60.3 (46.6,73.0) | 2.629 (1.155,5.985) |  |
| No | 336 | 297 | 88.4 (84.5,91.6) | 338 | 229 | 67.8 (62.5,72.7) | 3.625 (2.419,5.431) |  |

**表 2.7.6.18.2-3　IRC 評価による ORR のサブグループ解析（ITT 集団）（PX-171-009）（続き 6）**

| Subgroup | CRd N | CRd No. of Responders | CRd ORR (%) (95% CI) | Rd N | Rd No. of Responders | Rd ORR (%) (95% CI) | Odds Ratio (CRd/Rd) (95% CI) | Plot of Odds Ratio |
|---|---|---|---|---|---|---|---|---|
| **Refractory to Prior IMiD** | | | | | | | | |
| Yes | 85 | 70 | 82.4 (72.6,89.8) | 88 | 41 | 46.6 (35.9,57.5) | 5.350 (2.663,10.745) | |
| No | 311 | 275 | 88.4 (84.3,91.8) | 308 | 223 | 72.4 (67.0,77.3) | 2.912 (1.898,4.467) | |
| **Refractory to Bortezomib or IMiD or Both** | | | | | | | | |
| Yes | 121 | 101 | 83.5 (75.6,89.6) | 119 | 63 | 52.9 (43.6,62.2) | 4.489 (2.464,8.177) | |
| No | 275 | 244 | 88.7 (84.4,92.2) | 277 | 201 | 72.6 (66.9,77.7) | 2.976 (1.883,4.703) | |




Source: Table 14.2.4.4

ANC = absolute neutrophil count; CI = confidence interval; CRd = carfilzomib/Revlimid (lenalidomide)/dexamethasone arm; ECOG PS = Eastern Cooperative Oncology Group Performance Status; FISH = florescence in situ hybridization; IMiD = immunomodulatory drug; ITT = intent-to-treat; IVRS = interactive voice recognition system; NE = not estimable; Rd = Revlimid (lenalidomide)/dexamethasone arm

[a] Including 2 subjects with 4 prior regimens

出典［総括報告書 5.3.5.1-1（PX-171-009）, Table 41］

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| Number of Subjects with at Least One Event | 380 (96.9%) | 378 (97.2%) |
| 血液およびリンパ系障害 | 243 (62.0%) | 232 (59.6%) |
| 貧血 | 167 (42.6%) | 155 (39.8%) |
| 好中球減少症 | 148 (37.8%) | 131 (33.7%) |
| 血小板減少症 | 114 (29.1%) | 88 (22.6%) |
| 白血球減少症 | 31 (7.9%) | 22 (5.7%) |
| 発熱性好中球減少症 | 13 (3.3%) | 5 (1.3%) |
| リンパ球減少症 | 12 (3.1%) | 14 (3.6%) |
| リンパ節症 | 2 (0.5%) | 2 (0.5%) |
| 汎血球減少症 | 2 (0.5%) | 5 (1.3%) |
| 自己免疫性溶血性貧血 | 1 (0.3%) | 0 |
| 大球性貧血 | 1 (0.3%) | 0 |
| 溶血 | 1 (0.3%) | 0 |
| 溶血性貧血 | 1 (0.3%) | 1 (0.3%) |
| 白血球増加症 | 1 (0.3%) | 0 |
| 小球性貧血 | 1 (0.3%) | 0 |
| 単球増加症 | 1 (0.3%) | 0 |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 1）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 好中球増加症 | 1 (0.3%) | 0 |
| 血小板増加症 | 1 (0.3%) | 0 |
| 骨髄機能不全 | 0 | 1 (0.3%) |
| 好酸球増加症 | 0 | 1 (0.3%) |
| 出血性貧血 | 0 | 1 (0.3%) |
| 過粘稠度症候群 | 0 | 1 (0.3%) |
| 鉄欠乏性貧血 | 0 | 2 (0.5%) |
| 血小板障害 | 0 | 1 (0.3%) |
| 心臓障害 | 84 (21.4%) | 72 (18.5%) |
| 動悸 | 14 (3.6%) | 9 (2.3%) |
| 心房細動 | 12 (3.1%) | 18 (4.6%) |
| 心不全 | 11 (2.8%) | 7 (1.8%) |
| 狭心症 | 9 (2.3%) | 8 (2.1%) |
| うっ血性心不全 | 8 (2.0%) | 6 (1.5%) |
| 頻脈 | 8 (2.0%) | 7 (1.8%) |
| 心筋梗塞 | 7 (1.8%) | 2 (0.5%) |
| 洞性徐脈 | 7 (1.8%) | 2 (0.5%) |
| 徐脈 | 5 (1.3%) | 10 (2.6%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 2）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 急性心筋梗塞 | 4 | (1.0%) | 1 | (0.3%) |
| 上室性期外収縮 | 4 | (1.0%) | 2 | (0.5%) |
| 左室機能不全 | 3 | (0.8%) | 0 | |
| 大動脈弁閉鎖不全症 | 2 | (0.5%) | 0 | |
| 不整脈 | 2 | (0.5%) | 1 | (0.3%) |
| 心房粗動 | 2 | (0.5%) | 1 | (0.3%) |
| 心停止 | 2 | (0.5%) | 0 | |
| 冠動脈疾患 | 2 | (0.5%) | 1 | (0.3%) |
| 僧帽弁閉鎖不全症 | 2 | (0.5%) | 0 | |
| 洞性不整脈 | 2 | (0.5%) | 0 | |
| 上室性頻脈 | 2 | (0.5%) | 0 | |
| 大動脈弁石灰化 | 1 | (0.3%) | 0 | |
| 大動脈弁硬化症 | 1 | (0.3%) | 0 | |
| 心房頻脈 | 1 | (0.3%) | 0 | |
| 完全房室ブロック | 1 | (0.3%) | 0 | |
| 第二度房室ブロック | 1 | (0.3%) | 0 | |
| 二束ブロック | 1 | (0.3%) | 0 | |
| 徐脈性不整脈 | 1 | (0.3%) | 0 | |
| 右脚ブロック | 1 | (0.3%) | 1 | (0.3%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 3）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 心アミロイドーシス | 1 (0.3%) | 1 (0.3%) |
| 急性心不全 | 1 (0.3%) | 0 |
| 心肥大 | 1 (0.3%) | 0 |
| 心拡大 | 1 (0.3%) | 0 |
| 心筋症 | 1 (0.3%) | 0 |
| 心肺不全 | 1 (0.3%) | 1 (0.3%) |
| 冠動脈閉塞 | 1 (0.3%) | 0 |
| 拡張機能障害 | 1 (0.3%) | 0 |
| 期外収縮 | 1 (0.3%) | 1 (0.3%) |
| 心臓内血栓 | 1 (0.3%) | 0 |
| 左房拡張 | 1 (0.3%) | 0 |
| 左室肥大 | 1 (0.3%) | 0 |
| 心筋虚血 | 1 (0.3%) | 2 (0.5%) |
| 心嚢液貯留 | 1 (0.3%) | 1 (0.3%) |
| 心嚢内出血 | 1 (0.3%) | 0 |
| 右室不全 | 1 (0.3%) | 0 |
| 洞性頻脈 | 1 (0.3%) | 3 (0.8%) |
| ストレス心筋症 | 1 (0.3%) | 0 |
| 心室性不整脈 | 1 (0.3%) | 0 |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 4）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 心室性期外収縮 | 1 (0.3%) | 3 (0.8%) |
| 心室壁運動低下 | 1 (0.3%) | 0 |
| 心室性頻脈 | 1 (0.3%) | 0 |
| 急性冠動脈症候群 | 0 | 1 (0.3%) |
| 不安定狭心症 | 0 | 1 (0.3%) |
| 大動脈弁疾患 | 0 | 1 (0.3%) |
| 左脚ブロック | 0 | 1 (0.3%) |
| 心障害 | 0 | 1 (0.3%) |
| 心血管不全 | 0 | 1 (0.3%) |
| 伝導障害 | 0 | 1 (0.3%) |
| 冠動脈狭窄 | 0 | 1 (0.3%) |
| 僧帽弁逸脱 | 0 | 1 (0.3%) |
| 発作性不整脈 | 0 | 1 (0.3%) |
| 肺動脈弁閉鎖不全症 | 0 | 1 (0.3%) |
| 洞不全症候群 | 0 | 1 (0.3%) |
| 先天性、家族性および遺伝性障害 | 1 (0.3%) | 1 (0.3%) |
| 先天性凝固亢進 | 1 (0.3%) | 0 |
| 包茎 | 0 | 1 (0.3%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 5）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 耳および迷路障害 | 32 | (8.2%) | 24 | (6.2%) |
| 回転性めまい | 17 | (4.3%) | 13 | (3.3%) |
| 耳鳴 | 4 | (1.0 %) | 1 | (0.3 %) |
| 難聴 | 3 | (0.8 %) | 1 | (0.3 %) |
| 耳痛 | 3 | (0.8 %) | 3 | (0.8 %) |
| 両耳難聴 | 2 | (0.5 %) | 0 | |
| 耳不快感 | 2 | (0.5 %) | 0 | |
| 聴力低下 | 2 | (0.5 %) | 0 | |
| 頭位性回転性めまい | 2 | (0.5 %) | 0 | |
| 感音性難聴 | 1 | (0.3 %) | 0 | |
| 耳管機能障害 | 1 | (0.3 %) | 0 | |
| 耳管炎 | 1 | (0.3 %) | 0 | |
| 鼓膜穿孔 | 1 | (0.3 %) | 1 | (0.3 %) |
| 耳垢栓塞 | 0 | | 1 | (0.3 %) |
| 片耳難聴 | 0 | | 1 | (0.3 %) |
| 耳出血 | 0 | | 1 | (0.3 %) |
| 聴覚障害 | 0 | | 2 | (0.5 %) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 6）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 内分泌障害 | 14 | (3.6%) | 13 | (3.3%) |
| クッシング様 | 4 | (1.0%) | 2 | (0.5%) |
| 副腎機能不全 | 3 | (0.8%) | 2 | (0.5%) |
| 甲状腺機能低下症 | 3 | (0.8%) | 5 | (1.3%) |
| クッシング症候群 | 2 | (0.5%) | 0 | |
| アジソン病 | 1 | (0.3%) | 0 | |
| 甲状腺嚢腫 | 1 | (0.3%) | 1 | (0.3%) |
| 甲状腺障害 | 1 | (0.3%) | 0 | |
| 甲状腺腫 | 0 | | 1 | (0.3%) |
| 甲状腺機能亢進症 | 0 | | 1 | (0.3%) |
| ステロイド離脱症候群 | 0 | | 2 | (0.5%) |
| 眼障害 | 103 | (26.3%) | 70 | (18.0%) |
| 白内障 | 34 | (8.7%) | 26 | (6.7%) |
| 霧視 | 22 | (5.6%) | 15 | (3.9%) |
| 結膜炎 | 15 | (3.8%) | 5 | (1.3%) |
| 眼乾燥 | 11 | (2.8%) | 8 | (2.1%) |
| 視力障害 | 8 | (2.0%) | 4 | (1.0%) |
| 眼刺激 | 4 | (1.0%) | 0 | |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 7）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 眼瞼浮腫 | 4 (1.0%) | 4 (1.0%) |
| 眼充血 | 4 (1.0%) | 3 (0.8%) |
| 緑内障 | 3 (0.8%) | 2 (0.5%) |
| 流涙増加 | 3 (0.8%) | 2 (0.5%) |
| 硝子体浮遊物 | 3 (0.8%) | 0 |
| 失明 | 2 (0.5%) | 0 |
| 複視 | 2 (0.5%) | 2 (0.5%) |
| 眼出血 | 2 (0.5%) | 3 (0.8%) |
| 眼痛 | 2 (0.5%) | 3 (0.8%) |
| 眼部腫脹 | 2 (0.5%) | 2 (0.5%) |
| 眼窩浮腫 | 2 (0.5%) | 0 |
| 視力低下 | 2 (0.5%) | 4 (1.0%) |
| 硝子体剥離 | 2 (0.5%) | 1 (0.3%) |
| 眼の異常感 | 1 (0.3%) | 1 (0.3%) |
| 眼精疲労 | 1 (0.3%) | 0 |
| 眼瞼炎 | 1 (0.3%) | 0 |
| 片側失明 | 1 (0.3%) | 0 |
| 結膜出血 | 1 (0.3%) | 2 (0.5%) |
| 眼の炎症 | 1 (0.3%) | 0 |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 8）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 眼球浮腫 | 1 (0.3%) | 0 |
| 眼そう痒症 | 1 (0.3%) | 1 (0.3%) |
| 角膜炎 | 1 (0.3%) | 0 |
| 夜盲 | 1 (0.3%) | 0 |
| 視神経乳頭浮腫 | 1 (0.3%) | 0 |
| 光視症 | 1 (0.3%) | 0 |
| 瞳孔不同 | 1 (0.3%) | 0 |
| 網膜剥離 | 1 (0.3%) | 1 (0.3%) |
| 暗点 | 1 (0.3%) | 0 |
| 眼瞼痙攣 | 0 | 1 (0.3%) |
| 核性白内障 | 0 | 1 (0.3%) |
| 嚢下白内障 | 0 | 1 (0.3%) |
| 結膜充血 | 0 | 1 (0.3%) |
| 眼瞼下垂 | 0 | 1 (0.3%) |
| 眼の異物感 | 0 | 1 (0.3%) |
| 水晶体混濁 | 0 | 1 (0.3%) |
| 黄斑変性 | 0 | 1 (0.3%) |
| 黄斑円孔 | 0 | 1 (0.3%) |
| 近視 | 0 | 1 (0.3%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 9）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 開放隅角緑内障 | 0 | 2 (0.5%) |
| 眼窩周囲浮腫 | 0 | 2 (0.5%) |
| 網膜血管障害 | 0 | 1 (0.3%) |
| 網膜静脈閉塞 | 0 | 1 (0.3%) |
| 胃腸障害 | 260 (66.3%) | 220 (56.6%) |
| 下痢 | 166 (42.3%) | 131 (33.7%) |
| 便秘 | 79 (20.2%) | 67 (17.2%) |
| 悪心 | 78 (19.9%) | 55 (14.1%) |
| 嘔吐 | 47 (12.0%) | 32 (8.2%) |
| 腹痛 | 34 (8.7%) | 27 (6.9%) |
| 上腹部痛 | 25 (6.4%) | 11 (2.8%) |
| 消化不良 | 23 (5.9%) | 20 (5.1%) |
| 歯痛 | 18 (4.6%) | 11 (2.8%) |
| 痔核 | 15 (3.8%) | 8 (2.1%) |
| 口内炎 | 13 (3.3%) | 5 (1.3%) |
| 腹部不快感 | 12 (3.1%) | 8 (2.1%) |
| 腹部膨満 | 10 (2.6%) | 8 (2.1%) |
| 胃炎 | 9 (2.3%) | 6 (1.5%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 10）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 口内乾燥 | 8 | (2.0%) | 7 | (1.8%) |
| 鼓腸 | 8 | (2.0%) | 5 | (1.3%) |
| 胃食道逆流性疾患 | 7 | (1.8%) | 11 | (2.8%) |
| 嚥下障害 | 6 | (1.5%) | 4 | (1.0%) |
| 口腔内潰瘍形成 | 6 | (1.5%) | 3 | (0.8%) |
| アフタ性口内炎 | 5 | (1.3%) | 0 | |
| 齲歯 | 5 | (1.3%) | 3 | (0.8%) |
| 直腸出血 | 5 | (1.3%) | 1 | (0.3%) |
| 胃腸障害 | 4 | (1.0%) | 1 | (0.3%) |
| 歯肉痛 | 4 | (1.0%) | 2 | (0.5%) |
| 痔出血 | 3 | (0.8%) | 2 | (0.5%) |
| 口腔内不快感 | 3 | (0.8%) | 0 | |
| 臍ヘルニア | 3 | (0.8%) | 0 | |
| 下腹部痛 | 2 | (0.5%) | 3 | (0.8%) |
| 腹部圧痛 | 2 | (0.5%) | 1 | (0.3%) |
| 肛門出血 | 2 | (0.5%) | 0 | |
| 口唇炎 | 2 | (0.5%) | 0 | |
| 血性下痢 | 2 | (0.5%) | 1 | (0.3%) |
| 憩室穿孔 | 2 | (0.5%) | 0 | |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 11）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 心窩部不快感 | 2 (0.5%) | 3 (0.8%) |
| 食中毒 | 2 (0.5%) | 1 (0.3%) |
| 胃腸毒性 | 2 (0.5%) | 1 (0.3%) |
| 歯肉出血 | 2 (0.5%) | 2 (0.5%) |
| 舌痛 | 2 (0.5%) | 1 (0.3%) |
| 血便排泄 | 2 (0.5%) | 2 (0.5%) |
| 胃排出不全 | 2 (0.5%) | 1 (0.3%) |
| 鼠径ヘルニア | 2 (0.5%) | 1 (0.3%) |
| 食道炎 | 2 (0.5%) | 0 |
| 急性膵炎 | 2 (0.5%) | 0 |
| 慢性膵炎 | 2 (0.5%) | 0 |
| 歯の知覚過敏 | 2 (0.5%) | 2 (0.5%) |
| 舌腫脹 | 2 (0.5%) | 0 |
| 閉塞を伴う腹部ヘルニア | 1 (0.3%) | 0 |
| 空気嚥下 | 1 (0.3%) | 1 (0.3%) |
| 裂肛 | 1 (0.3%) | 1 (0.3%) |
| 便習慣変化 | 1 (0.3%) | 0 |
| 大腸炎 | 1 (0.3%) | 0 |
| 結腸ポリープ | 1 (0.3%) | 2 (0.5%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 12）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 憩室 | 1 (0.3%) | 2 (0.5%) |
| 腸憩室 | 1 (0.3%) | 1 (0.3%) |
| 食道憩室 | 1 (0.3%) | 0 |
| 十二指腸狭窄 | 1 (0.3%) | 0 |
| 小腸炎 | 1 (0.3%) | 1 (0.3%) |
| おくび | 1 (0.3%) | 0 |
| 便失禁 | 1 (0.3%) | 2 (0.5%) |
| 変色便 | 1 (0.3%) | 2 (0.5%) |
| 排便回数増加 | 1 (0.3%) | 1 (0.3%) |
| 歯肉の炎症 | 1 (0.3%) | 1 (0.3%) |
| 歯肉腫脹 | 1 (0.3%) | 0 |
| 歯肉潰瘍 | 1 (0.3%) | 0 |
| イレウス | 1 (0.3%) | 0 |
| 排便回数減少 | 1 (0.3%) | 0 |
| 腸閉塞 | 1 (0.3%) | 0 |
| 大腸穿孔 | 1 (0.3%) | 0 |
| 口唇変色 | 1 (0.3%) | 0 |
| 口唇乾燥 | 1 (0.3%) | 0 |
| 口唇腫脹 | 1 (0.3%) | 1 (0.3%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 13）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 下部消化管出血 | 1 (0.3%) | 1 (0.3%) |
| メレナ | 1 (0.3%) | 0 |
| 口腔内出血 | 1 (0.3%) | 1 (0.3%) |
| 好中球減少性大腸炎 | 1 (0.3%) | 0 |
| 嚥下痛 | 1 (0.3%) | 0 |
| 食道痛 | 1 (0.3%) | 0 |
| 口腔障害 | 1 (0.3%) | 1 (0.3%) |
| 口腔粘膜びらん | 1 (0.3%) | 0 |
| 口腔粘膜水疱形成 | 1 (0.3%) | 1 (0.3%) |
| 口の錯感覚 | 1 (0.3%) | 1 (0.3%) |
| 耳下腺管閉塞 | 1 (0.3%) | 0 |
| 肛門周囲痛 | 1 (0.3%) | 0 |
| 歯根嚢胞 | 1 (0.3%) | 0 |
| 直腸ポリープ | 1 (0.3%) | 0 |
| 吐き戻し | 1 (0.3%) | 0 |
| 舌変色 | 1 (0.3%) | 0 |
| 舌障害 | 1 (0.3%) | 0 |
| 変色歯 | 1 (0.3%) | 0 |
| 歯の障害 | 1 (0.3%) | 0 |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 14）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 腹部ヘルニア | 0 | 2 (0.5%) |
| キライディティ症候群 | 0 | 1 (0.3%) |
| 胃出血 | 0 | 1 (0.3%) |
| 胃腸出血 | 0 | 5 (1.3%) |
| 消化器痛 | 0 | 1 (0.3%) |
| 歯肉嚢胞 | 0 | 1 (0.3%) |
| 吐血 | 0 | 2 (0.5%) |
| 口の感覚鈍麻 | 0 | 1 (0.3%) |
| 腸管ポリープ | 0 | 1 (0.3%) |
| 口唇水疱 | 0 | 1 (0.3%) |
| 弛緩歯 | 0 | 1 (0.3%) |
| 口腔瘻 | 0 | 1 (0.3%) |
| 口腔内痛 | 0 | 2 (0.5%) |
| 膵炎 | 0 | 1 (0.3%) |
| 歯周病 | 0 | 3 (0.8%) |
| 直腸炎 | 0 | 1 (0.3%) |
| 小腸閉塞 | 0 | 1 (0.3%) |
| 小腸穿孔 | 0 | 1 (0.3%) |
| 舌苔 | 0 | 1 (0.3%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 15）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 舌潰瘍 | 0 | 2 (0.5%) |
| 歯の脱落 | 0 | 2 (0.5%) |
| 一般・全身障害および投与部位の状態 | 267 (68.1%) | 242 (62.2%) |
| 疲労 | 129 (32.9%) | 119 (30.6%) |
| 発熱 | 112 (28.6%) | 81 (20.8%) |
| 末梢性浮腫 | 85 (21.7%) | 75 (19.3%) |
| 無力症 | 70 (17.9%) | 56 (14.4%) |
| 悪寒 | 25 (6.4%) | 9 (2.3%) |
| 浮腫 | 17 (4.3%) | 19 (4.9%) |
| 疼痛 | 16 (4.1%) | 14 (3.6%) |
| インフルエンザ様疾患 | 15 (3.8%) | 10 (2.6%) |
| 胸痛 | 14 (3.6%) | 16 (4.1%) |
| 倦怠感 | 10 (2.6%) | 5 (1.3%) |
| 非心臓性胸痛 | 10 (2.6%) | 7 (1.8%) |
| 易刺激性 | 9 (2.3%) | 5 (1.3%) |
| 粘膜の炎症 | 9 (2.3%) | 5 (1.3%) |
| 胸部不快感 | 8 (2.0%) | 2 (0.5%) |
| 脊椎痛 | 7 (1.8%) | 5 (1.3%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 16）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 歩行障害 | 6 | (1.5%) | 8 | (2.1%) |
| 注入部位疼痛 | 6 | (1.5%) | 0 | |
| 疾患進行 | 4 | (1.0%) | 8 | (2.1%) |
| 顔面浮腫 | 4 | (1.0%) | 6 | (1.5%) |
| カテーテル留置部位疼痛 | 3 | (0.8%) | 0 | |
| 全身性浮腫 | 3 | (0.8%) | 2 | (0.5%) |
| 死亡 | 2 | (0.5%) | 2 | (0.5%) |
| 医療機器閉塞 | 2 | (0.5%) | 1 | (0.3%) |
| 早期満腹 | 2 | (0.5%) | 0 | |
| 冷感 | 2 | (0.5%) | 1 | (0.3%) |
| 全身健康状態低下 | 2 | (0.5%) | 6 | (1.5%) |
| 多臓器不全 | 2 | (0.5%) | 1 | (0.3%) |
| 医療機器関連の血栓症 | 2 | (0.5%) | 0 | |
| 医薬品副作用 | 1 | (0.3%) | 2 | (0.5%) |
| 腋窩痛 | 1 | (0.3%) | 1 | (0.3%) |
| 突出痛 | 1 | (0.3%) | 0 | |
| カテーテル留置部位紅斑 | 1 | (0.3%) | 0 | |
| カテーテル留置部位出血 | 1 | (0.3%) | 0 | |
| カテーテル留置部位炎症 | 1 | (0.3%) | 0 | |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 17）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 嚢胞 | 1 | (0.3%) | 0 | |
| 異常感 | 1 | (0.3%) | 1 | (0.3%) |
| 熱感 | 1 | (0.3%) | 0 | |
| びくびく感 | 1 | (0.3%) | 1 | (0.3%) |
| ヘルニア | 1 | (0.3%) | 0 | |
| 高熱 | 1 | (0.3%) | 0 | |
| 治癒不良 | 1 | (0.3%) | 1 | (0.3%) |
| 硬結 | 1 | (0.3%) | 1 | (0.3%) |
| 炎症 | 1 | (0.3%) | 1 | (0.3%) |
| 注入部位血管外漏出 | 1 | (0.3%) | 1 | (0.3%) |
| 注入部位硬結 | 1 | (0.3%) | 0 | |
| 注入部位炎症 | 1 | (0.3%) | 0 | |
| 注入部位刺激感 | 1 | (0.3%) | 0 | |
| 注入部位反応 | 1 | (0.3%) | 0 | |
| 注入部位腫脹 | 1 | (0.3%) | 0 | |
| 注入部位小水疱 | 1 | (0.3%) | 0 | |
| 注射部位硬結 | 1 | (0.3%) | 0 | |
| 注射部位反応 | 1 | (0.3%) | 0 | |
| 局所腫脹 | 1 | (0.3%) | 1 | (0.3%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 18）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 限局性浮腫 | 1 (0.3%) | 0 |
| 腫瘤 | 1 (0.3%) | 1 (0.3%) |
| 医療機器合併症 | 1 (0.3%) | 0 |
| 小結節 | 1 (0.3%) | 0 |
| 突然死 | 1 (0.3%) | 1 (0.3%) |
| 全身性炎症反応症候群 | 1 (0.3%) | 0 |
| 圧痛 | 1 (0.3%) | 1 (0.3%) |
| 血管穿刺部位血腫 | 1 (0.3%) | 0 |
| 顔面痛 | 0 | 1 (0.3%) |
| 注射部位分泌物 | 0 | 1 (0.3%) |
| 注射部位静脈炎 | 0 | 1 (0.3%) |
| 粘膜乾燥 | 0 | 1 (0.3%) |
| 活動状態低下 | 0 | 1 (0.3%) |
| 肝胆道系障害 | 37 (9.4%) | 19 (4.9%) |
| 高ビリルビン血症 | 15 (3.8%) | 3 (0.8%) |
| 胆石症 | 4 (1.0%) | 4 (1.0%) |
| 中毒性肝炎 | 4 (1.0%) | 1 (0.3%) |
| 急性胆嚢炎 | 3 (0.8%) | 2 (0.5%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 19）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 肝細胞損傷 | 3 | (0.8%) | 0 | |
| 肝障害 | 3 | (0.8%) | 0 | |
| 胆管炎 | 2 | (0.5%) | 0 | |
| 肝臓うっ血 | 2 | (0.5%) | 0 | |
| 肝毒性 | 2 | (0.5%) | 1 | (0.3%) |
| 胆管結石 | 1 | (0.3%) | 0 | |
| 胆嚢炎 | 1 | (0.3%) | 3 | (0.8%) |
| 慢性胆嚢炎 | 1 | (0.3%) | 0 | |
| 慢性肝炎 | 1 | (0.3%) | 0 | |
| 肝腫大 | 1 | (0.3%) | 1 | (0.3%) |
| 胆道仙痛 | 0 | | 1 | (0.3%) |
| 胆汁うっ滞 | 0 | | 2 | (0.5%) |
| 胆嚢痛 | 0 | | 1 | (0.3%) |
| 肝嚢胞 | 0 | | 1 | (0.3%) |
| 胆汁うっ滞性肝炎 | 0 | | 1 | (0.3%) |
| 水腫性胆嚢炎 | 0 | | 1 | (0.3%) |
| 肝損傷 | 0 | | 1 | (0.3%) |
| 免疫系障害 | 15 | (3.8%) | 12 | (3.1%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 20）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 薬物過敏症 | 5 (1.3%) | 2 (0.5%) |
| 低γグロブリン血症 | 5 (1.3%) | 0 |
| 季節性アレルギー | 2 (0.5%) | 4 (1.0%) |
| アナフィラキシー反応 | 1 (0.3%) | 0 |
| サイトカイン放出症候群 | 1 (0.3%) | 1 (0.3%) |
| 過敏症 | 1 (0.3%) | 3 (0.8%) |
| アレルギー性浮腫 | 0 | 1 (0.3%) |
| 食物アレルギー | 0 | 1 (0.3%) |
| 感染症および寄生虫症 | 310 (79.1%) | 270 (69.4%) |
| 上気道感染 | 112 (28.6%) | 75 (19.3%) |
| 鼻咽頭炎 | 84 (21.4%) | 63 (16.2%) |
| 気管支炎 | 74 (18.9%) | 54 (13.9%) |
| 肺炎 | 68 (17.3%) | 56 (14.4%) |
| 気道感染 | 43 (11.0%) | 39 (10.0%) |
| 尿路感染 | 34 (8.7%) | 21 (5.4%) |
| インフルエンザ | 26 (6.6%) | 12 (3.1%) |
| ウイルス感染 | 24 (6.1%) | 10 (2.6%) |
| 副鼻腔炎 | 22 (5.6%) | 16 (4.1%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 21）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 鼻炎 | 19 | (4.8%) | 8 | (2.1%) |
| 胃腸炎 | 17 | (4.3%) | 12 | (3.1%) |
| 気管支肺炎 | 15 | (3.8%) | 9 | (2.3%) |
| 蜂巣炎 | 14 | (3.6%) | 11 | (2.8%) |
| 咽頭炎 | 13 | (3.3%) | 7 | (1.8%) |
| 膀胱炎 | 8 | (2.0%) | 5 | (1.3%) |
| ウイルス性気道感染 | 8 | (2.0%) | 7 | (1.8%) |
| 感染 | 7 | (1.8%) | 5 | (1.3%) |
| 下気道感染 | 7 | (1.8%) | 8 | (2.1%) |
| クロストリジウム・ディフィシレ大腸炎 | 6 | (1.5%) | 2 | (0.5%) |
| 耳感染 | 6 | (1.5%) | 4 | (1.0%) |
| 丹毒 | 6 | (1.5%) | 3 | (0.8%) |
| 帯状疱疹 | 6 | (1.5%) | 9 | (2.3%) |
| 限局性感染 | 6 | (1.5%) | 3 | (0.8%) |
| 口腔カンジダ症 | 6 | (1.5%) | 6 | (1.5%) |
| 口腔ヘルペス | 6 | (1.5%) | 5 | (1.3%) |
| 歯膿瘍 | 6 | (1.5%) | 3 | (0.8%) |
| 肺感染 | 5 | (1.3%) | 3 | (0.8%) |
| 敗血症 | 5 | (1.3%) | 5 | (1.3%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 22）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 急性副鼻腔炎 | 4 (1.0%) | 6 (1.5%) |
| カンジダ症 | 4 (1.0%) | 2 (0.5%) |
| クロストリジウム感染 | 4 (1.0%) | 0 |
| 医療機器関連感染 | 4 (1.0%) | 1 (0.3%) |
| 眼感染 | 4 (1.0%) | 3 (0.8%) |
| せつ | 4 (1.0%) | 5 (1.3%) |
| 口腔真菌感染 | 4 (1.0%) | 4 (1.0%) |
| 気管気管支炎 | 4 (1.0%) | 0 |
| ウイルス性上気道感染 | 4 (1.0%) | 4 (1.0%) |
| 菌血症 | 3 (0.8%) | 0 |
| ウイルス性胃腸炎 | 3 (0.8%) | 2 (0.5%) |
| ウイルス性消化管感染 | 3 (0.8%) | 0 |
| 歯肉炎 | 3 (0.8%) | 1 (0.3%) |
| 骨髄炎 | 3 (0.8%) | 2 (0.5%) |
| 中耳炎 | 3 (0.8%) | 2 (0.5%) |
| 急性中耳炎 | 3 (0.8%) | 1 (0.3%) |
| 敗血症性ショック | 3 (0.8%) | 3 (0.8%) |
| 歯感染 | 3 (0.8%) | 2 (0.5%) |
| 腹部膿瘍 | 2 (0.5%) | 0 |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 23）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 細菌感染 | 2 (0.5%) | 0 |
| 細気管支炎 | 2 (0.5%) | 1 (0.3%) |
| サイトメガロウイルス感染 | 2 (0.5%) | 0 |
| 憩室炎 | 2 (0.5%) | 3 (0.8%) |
| 心内膜炎 | 2 (0.5%) | 0 |
| 毛包炎 | 2 (0.5%) | 7 (1.8%) |
| 単純ヘルペス | 2 (0.5%) | 3 (0.8%) |
| 喉頭炎 | 2 (0.5%) | 3 (0.8%) |
| 大葉性肺炎 | 2 (0.5%) | 1 (0.3%) |
| 口腔感染 | 2 (0.5%) | 0 |
| パラインフルエンザウイルス感染 | 2 (0.5%) | 0 |
| 歯周炎 | 2 (0.5%) | 2 (0.5%) |
| 皮膚感染 | 2 (0.5%) | 2 (0.5%) |
| ブドウ球菌性菌血症 | 2 (0.5%) | 0 |
| 気管炎 | 2 (0.5%) | 1 (0.3%) |
| 細菌性上気道感染 | 2 (0.5%) | 1 (0.3%) |
| 創傷感染 | 2 (0.5%) | 1 (0.3%) |
| アデノウイルス感染 | 1 (0.3%) | 0 |
| 細菌性関節炎 | 1 (0.3%) | 0 |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 24）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 感染性関節炎 | 1 | (0.3%) | 0 | |
| 節足動物寄生 | 1 | (0.3%) | 0 | |
| 細菌性腎盂腎炎 | 1 | (0.3%) | 0 | |
| カンピロバクター感染 | 1 | (0.3%) | 0 | |
| カテーテル留置部位蜂巣炎 | 1 | (0.3%) | 0 | |
| 化膿性胆管炎 | 1 | (0.3%) | 0 | |
| 慢性 C 型肝炎 | 1 | (0.3%) | 0 | |
| 慢性副鼻腔炎 | 1 | (0.3%) | 2 | (0.5%) |
| 感染性結膜炎 | 1 | (0.3%) | 0 | |
| ウイルス性結膜炎 | 1 | (0.3%) | 0 | |
| エンテロバクター性敗血症 | 1 | (0.3%) | 0 | |
| 細菌性腸炎 | 1 | (0.3%) | 0 | |
| 大腸菌性菌血症 | 1 | (0.3%) | 0 | |
| 大腸菌性敗血症 | 1 | (0.3%) | 0 | |
| 大腸菌性尿路感染 | 1 | (0.3%) | 2 | (0.5%) |
| 皮膚真菌感染 | 1 | (0.3%) | 5 | (1.3%) |
| 消化管感染 | 1 | (0.3%) | 2 | (0.5%) |
| 歯肉感染 | 1 | (0.3%) | 0 | |
| 鼡径部膿瘍 | 1 | (0.3%) | 0 | |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 25）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| H1N1 インフルエンザ | 1 | (0.3%) | 0 | |
| 切開部位感染 | 1 | (0.3%) | 0 | |
| 咬傷感染 | 1 | (0.3%) | 0 | |
| 感染性嚢腫 | 1 | (0.3%) | 0 | |
| 感染性皮膚嚢腫 | 1 | (0.3%) | 0 | |
| 迷路炎 | 1 | (0.3%) | 1 | (0.3%) |
| 細菌性喉頭炎 | 1 | (0.3%) | 0 | |
| 潜伏結核 | 1 | (0.3%) | 0 | |
| 肝膿瘍 | 1 | (0.3%) | 0 | |
| ウイルス性下気道感染 | 1 | (0.3%) | 1 | (0.3%) |
| 好中球減少性敗血症 | 1 | (0.3%) | 0 | |
| 食道カンジダ症 | 1 | (0.3%) | 0 | |
| 爪真菌症 | 1 | (0.3%) | 2 | (0.5%) |
| 精巣炎 | 1 | (0.3%) | 0 | |
| 細菌性中耳炎 | 1 | (0.3%) | 0 | |
| 直腸周囲膿瘍 | 1 | (0.3%) | 0 | |
| 腹膜炎 | 1 | (0.3%) | 0 | |
| 細菌性咽頭炎 | 1 | (0.3%) | 0 | |
| レンサ球菌性咽頭炎 | 1 | (0.3%) | 0 | |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 26）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| ニューモシスティスジロヴェシ肺炎 | 1 | (0.3%) | 1 | (0.3%) |
| インフルエンザ性肺炎 | 1 | (0.3%) | 0 | |
| RS ウイルス肺炎 | 1 | (0.3%) | 1 | (0.3%) |
| 術後膿瘍 | 1 | (0.3%) | 1 | (0.3%) |
| 術後創感染 | 1 | (0.3%) | 0 | |
| 進行性多巣性白質脳症 | 1 | (0.3%) | 0 | |
| 腎盂腎炎 | 1 | (0.3%) | 0 | |
| 慢性腎盂腎炎 | 1 | (0.3%) | 0 | |
| 膿疱性皮疹 | 1 | (0.3%) | 0 | |
| 呼吸器モニリア症 | 1 | (0.3%) | 0 | |
| RS ウイルス細気管支炎 | 1 | (0.3%) | 0 | |
| RS ウイルス感染 | 1 | (0.3%) | 1 | (0.3%) |
| サルモネラ性敗血症 | 1 | (0.3%) | 0 | |
| サルモネラ症 | 1 | (0.3%) | 0 | |
| 敗血症症候群 | 1 | (0.3%) | 0 | |
| 軟部組織感染 | 1 | (0.3%) | 0 | |
| 膿性痰 | 1 | (0.3%) | 0 | |
| ブドウ球菌感染 | 1 | (0.3%) | 0 | |
| レンサ球菌性菌血症 | 1 | (0.3%) | 1 | (0.3%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 27）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 皮下組織膿瘍 | 1 | (0.3%) | 0 | |
| 精巣膿瘍 | 1 | (0.3%) | 0 | |
| 白癬感染 | 1 | (0.3%) | 0 | |
| 足部白癬 | 1 | (0.3%) | 2 | (0.5%) |
| 細菌性扁桃炎 | 1 | (0.3%) | 0 | |
| 細菌性尿路感染 | 1 | (0.3%) | 0 | |
| 尿路性敗血症 | 1 | (0.3%) | 2 | (0.5%) |
| 腟感染 | 1 | (0.3%) | 0 | |
| ウイルス性咽頭炎 | 1 | (0.3%) | 0 | |
| 外陰部腟カンジダ症 | 1 | (0.3%) | 0 | |
| 四肢膿瘍 | 0 | | 2 | (0.5%) |
| 肛門カンジダ症 | 0 | | 1 | (0.3%) |
| 体部白癬 | 0 | | 1 | (0.3%) |
| ボレリア感染 | 0 | | 1 | (0.3%) |
| ウイルス性気管支炎 | 0 | | 1 | (0.3%) |
| 気管支肺アスペルギルス症 | 0 | | 1 | (0.3%) |
| カンピロバクター胃腸炎 | 0 | | 1 | (0.3%) |
| カテーテル留置部位感染 | 0 | | 1 | (0.3%) |
| 赤痢 | 0 | | 1 | (0.3%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 28）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 細菌性眼感染 | 0 | 1 (0.3%) |
| 真菌感染 | 0 | 2 (0.5%) |
| 性器カンジダ症 | 0 | 1 (0.3%) |
| 陰部ヘルペス | 0 | 1 (0.3%) |
| 泌尿生殖器感染 | 0 | 1 (0.3%) |
| 肝感染 | 0 | 1 (0.3%) |
| ヘルペスウイルス感染 | 0 | 2 (0.5%) |
| 播種性帯状疱疹 | 0 | 1 (0.3%) |
| 口唇感染 | 0 | 2 (0.5%) |
| リステリア性敗血症 | 0 | 1 (0.3%) |
| 粘膜感染 | 0 | 1 (0.3%) |
| ムンプス | 0 | 1 (0.3%) |
| 爪感染 | 0 | 1 (0.3%) |
| 中咽頭カンジダ症 | 0 | 1 (0.3%) |
| 爪囲炎 | 0 | 1 (0.3%) |
| 百日咳 | 0 | 1 (0.3%) |
| 咽頭扁桃炎 | 0 | 1 (0.3%) |
| 細菌性肺炎 | 0 | 3 (0.8%) |
| ウイルス性肺炎 | 0 | 1 (0.3%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 29）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 肺敗血症 | 0 | 1 (0.3%) |
| 歯髄炎 | 0 | 1 (0.3%) |
| 急性腎盂腎炎 | 0 | 1 (0.3%) |
| 陰嚢感染 | 0 | 1 (0.3%) |
| 扁桃炎 | 0 | 2 (0.5%) |
| 結核 | 0 | 1 (0.3%) |
| 腸球菌性尿路感染 | 0 | 1 (0.3%) |
| 外陰腟真菌感染 | 0 | 1 (0.3%) |
| 傷害、中毒および処置合併症 | 77 (19.6%) | 65 (16.7%) |
| 挫傷 | 12 (3.1%) | 16 (4.1%) |
| 転倒 | 11 (2.8%) | 13 (3.3%) |
| 歯牙破折 | 6 (1.5%) | 7 (1.8%) |
| 大腿骨骨折 | 5 (1.3%) | 2 (0.5%) |
| 処置による疼痛 | 4 (1.0%) | 6 (1.5%) |
| 創傷 | 4 (1.0%) | 1 (0.3%) |
| 注入に伴う反応 | 3 (0.8%) | 1 (0.3%) |
| 靱帯捻挫 | 3 (0.8%) | 0 |
| 四肢損傷 | 3 (0.8%) | 0 |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 30）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 節足動物咬傷 | 2 | (0.5%) | 3 | (0.8%) |
| 顔面骨骨折 | 2 | (0.5%) | 0 | |
| 腓骨骨折 | 2 | (0.5%) | 0 | |
| 足骨折 | 2 | (0.5%) | 0 | |
| 眼窩周囲出血 | 2 | (0.5%) | 0 | |
| 肋骨骨折 | 2 | (0.5%) | 1 | (0.3%) |
| 交通事故 | 2 | (0.5%) | 0 | |
| 脊椎圧迫骨折 | 2 | (0.5%) | 4 | (1.0%) |
| 外傷性骨折 | 2 | (0.5%) | 0 | |
| 創合併症 | 2 | (0.5%) | 0 | |
| 免疫後有害事象 | 1 | (0.3%) | 0 | |
| 背部損傷 | 1 | (0.3%) | 0 | |
| 粉砕骨折 | 1 | (0.3%) | 0 | |
| 脳振盪 | 1 | (0.3%) | 0 | |
| 角膜擦過傷 | 1 | (0.3%) | 0 | |
| 焼痂 | 1 | (0.3%) | 0 | |
| 擦過傷 | 1 | (0.3%) | 2 | (0.5%) |
| 眼外傷 | 1 | (0.3%) | 0 | |
| 胆嚢損傷 | 1 | (0.3%) | 0 | |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 31）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 消化管ストーマ合併症 | 1 | (0.3%) | 0 | |
| 頭部損傷 | 1 | (0.3%) | 0 | |
| 股関節部骨折 | 1 | (0.3%) | 3 | (0.8%) |
| 上腕骨骨折 | 1 | (0.3%) | 1 | (0.3%) |
| 切開部位合併症 | 1 | (0.3%) | 0 | |
| 切開部位痛 | 1 | (0.3%) | 0 | |
| 損傷 | 1 | (0.3%) | 0 | |
| 裂傷 | 1 | (0.3%) | 3 | (0.8%) |
| 口唇損傷 | 1 | (0.3%) | 0 | |
| 下肢骨折 | 1 | (0.3%) | 0 | |
| 肉離れ | 1 | (0.3%) | 1 | (0.3%) |
| 過量投与 | 1 | (0.3%) | 0 | |
| 膝蓋骨骨折 | 1 | (0.3%) | 0 | |
| 外傷後疼痛 | 1 | (0.3%) | 0 | |
| 術後創合併症 | 1 | (0.3%) | 0 | |
| 放射線関連痛 | 1 | (0.3%) | 0 | |
| 橈骨骨折 | 1 | (0.3%) | 0 | |
| 骨格損傷 | 1 | (0.3%) | 0 | |
| 刺創 | 1 | (0.3%) | 0 | |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 32）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 皮下血腫 | 1 (0.3%) | 0 |
| 硬膜下血腫 | 1 (0.3%) | 1 (0.3%) |
| 血管確保合併症 | 1 (0.3%) | 0 |
| 創し開 | 1 (0.3%) | 0 |
| 鎖骨骨折 | 0 | 2 (0.5%) |
| 大腿骨頚部骨折 | 0 | 1 (0.3%) |
| 顎の骨折 | 0 | 1 (0.3%) |
| 関節脱臼 | 0 | 1 (0.3%) |
| 腰椎骨折 | 0 | 2 (0.5%) |
| 半月板障害 | 0 | 1 (0.3%) |
| 多発骨折 | 0 | 1 (0.3%) |
| 筋断裂 | 0 | 1 (0.3%) |
| 骨盤骨折 | 0 | 1 (0.3%) |
| 中毒 | 0 | 1 (0.3%) |
| 処置後血腫 | 0 | 1 (0.3%) |
| 皮膚損傷 | 0 | 1 (0.3%) |
| 脾臓損傷 | 0 | 1 (0.3%) |
| ストレス骨折 | 0 | 1 (0.3%) |
| 腱断裂 | 0 | 1 (0.3%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 33）**

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

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 34）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 血中カリウム減少 | 5 | (1.3%) | 4 | (1.0%) |
| 血中尿酸増加 | 5 | (1.3%) | 1 | (0.3%) |
| 国際標準比増加 | 5 | (1.3%) | 8 | (2.1%) |
| 血中リン減少 | 4 | (1.0%) | 4 | (1.0%) |
| 白血球数減少 | 4 | (1.0%) | 6 | (1.5%) |
| 血中クレアチンホスホキナーゼ増加 | 3 | (0.8%) | 0 | |
| 血圧上昇 | 3 | (0.8%) | 3 | (0.8%) |
| 血中尿素増加 | 3 | (0.8%) | 1 | (0.3%) |
| 眼圧上昇 | 3 | (0.8%) | 3 | (0.8%) |
| 体重増加 | 3 | (0.8%) | 0 | |
| 血中クロール増加 | 2 | (0.5%) | 0 | |
| 血中マグネシウム減少 | 2 | (0.5%) | 3 | (0.8%) |
| 心電図 QT 延長 | 2 | (0.5%) | 1 | (0.3%) |
| 肝酵素上昇 | 2 | (0.5%) | 1 | (0.3%) |
| A 型インフルエンザウイルス検査陽性 | 2 | (0.5%) | 0 | |
| 前立腺特異性抗原増加 | 2 | (0.5%) | 1 | (0.3%) |
| RS ウイルス検査陽性 | 2 | (0.5%) | 0 | |
| 抱合ビリルビン増加 | 1 | (0.3%) | 0 | |
| 血中ビリルビン異常 | 1 | (0.3%) | 0 | |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 35）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 血中カルシウム減少 | 1 | (0.3%) | 1 | (0.3%) |
| 血中カルシウム増加 | 1 | (0.3%) | 0 | |
| 血中コレステロール増加 | 1 | (0.3%) | 0 | |
| 血中クレアチン増加 | 1 | (0.3%) | 0 | |
| 血中鉄減少 | 1 | (0.3%) | 0 | |
| 血中乳酸脱水素酵素減少 | 1 | (0.3%) | 0 | |
| 血中カリウム増加 | 1 | (0.3%) | 1 | (0.3%) |
| 血中テストステロン減少 | 1 | (0.3%) | 0 | |
| 血中尿素減少 | 1 | (0.3%) | 0 | |
| カンピロバクター検査陽性 | 1 | (0.3%) | 0 | |
| カンジダ検査陽性 | 1 | (0.3%) | 0 | |
| 二酸化炭素減少 | 1 | (0.3%) | 0 | |
| 心雑音 | 1 | (0.3%) | 1 | (0.3%) |
| 心臓負荷試験異常 | 1 | (0.3%) | 0 | |
| 全身健康状態異常 | 1 | (0.3%) | 1 | (0.3%) |
| 糸球体濾過率減少 | 1 | (0.3%) | 1 | (0.3%) |
| グリコヘモグロビン増加 | 1 | (0.3%) | 0 | |
| ヘマトクリット減少 | 1 | (0.3%) | 0 | |
| 心拍数不整 | 1 | (0.3%) | 0 | |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 36）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 打聴診音減弱 | 1 | (0.3%) | 0 | |
| Ｂ型インフルエンザウイルス検査陽性 | 1 | (0.3%) | 0 | |
| 眼圧検査 | 1 | (0.3%) | 0 | |
| 肝機能検査異常 | 1 | (0.3%) | 3 | (0.8%) |
| 平均赤血球容積増加 | 1 | (0.3%) | 1 | (0.3%) |
| モノクローナル免疫グロブリン陽性 | 1 | (0.3%) | 0 | |
| 腎機能検査異常 | 1 | (0.3%) | 0 | |
| 血清フェリチン減少 | 1 | (0.3%) | 1 | (0.3%) |
| レンサ球菌検査陽性 | 1 | (0.3%) | 0 | |
| トランスアミナーゼ上昇 | 1 | (0.3%) | 1 | (0.3%) |
| トロポニン増加 | 1 | (0.3%) | 1 | (0.3%) |
| トロポニンＴ増加 | 1 | (0.3%) | 0 | |
| ウイルス検査陽性 | 1 | (0.3%) | 1 | (0.3%) |
| 血中アルブミン減少 | 0 | | 2 | (0.5%) |
| 血中重炭酸塩増加 | 0 | | 1 | (0.3%) |
| 血中フィブリノゲン増加 | 0 | | 1 | (0.3%) |
| 血中免疫グロブリンＧ減少 | 0 | | 1 | (0.3%) |
| 血圧低下 | 0 | | 1 | (0.3%) |
| 尿中血陽性 | 0 | | 2 | (0.5%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 37）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 呼吸音異常 | 0 | 1 (0.3%) |
| 心電図 ST－T 部分異常 | 0 | 1 (0.3%) |
| 心電図異常 T 波 | 0 | 1 (0.3%) |
| 心拍数増加 | 0 | 1 (0.3%) |
| リンパ球数減少 | 0 | 2 (0.5%) |
| 単球数増加 | 0 | 1 (0.3%) |
| 便潜血陽性 | 0 | 1 (0.3%) |
| 総蛋白減少 | 0 | 1 (0.3%) |
| ビタミン D 減少 | 0 | 1 (0.3%) |
| 代謝および栄養障害 | 225 (57.4%) | 173 (44.5%) |
| 低カリウム血症 | 108 (27.6%) | 52 (13.4%) |
| 低カルシウム血症 | 63 (16.1%) | 45 (11.6%) |
| 低リン酸血症 | 52 (13.3%) | 29 (7.5%) |
| 高血糖 | 49 (12.5%) | 38 (9.8%) |
| 食欲減退 | 44 (11.2%) | 35 (9.0%) |
| 低マグネシウム血症 | 36 (9.2%) | 25 (6.4%) |
| 高尿酸血症 | 18 (4.6%) | 10 (2.6%) |
| 低ナトリウム血症 | 15 (3.8%) | 9 (2.3%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 38）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 低アルブミン血症 | 9 | (2.3%) | 11 | (2.8%) |
| 高カリウム血症 | 8 | (2.0%) | 6 | (1.5%) |
| 脱水 | 6 | (1.5%) | 3 | (0.8%) |
| 体液貯留 | 6 | (1.5%) | 2 | (0.5%) |
| 高カルシウム血症 | 5 | (1.3%) | 13 | (3.3%) |
| 低血糖症 | 5 | (1.3%) | 2 | (0.5%) |
| 水分過負荷 | 4 | (1.0%) | 0 | |
| 高リン酸塩血症 | 4 | (1.0%) | 0 | |
| アシドーシス | 3 | (0.8%) | 0 | |
| 糖尿病 | 3 | (0.8%) | 11 | (2.8%) |
| 痛風 | 3 | (0.8%) | 5 | (1.3%) |
| 高コレステロール血症 | 3 | (0.8%) | 0 | |
| 鉄欠乏 | 3 | (0.8%) | 2 | (0.5%) |
| 腫瘍崩壊症候群 | 3 | (0.8%) | 0 | |
| コントロール不良の糖尿病 | 2 | (0.5%) | 2 | (0.5%) |
| 高脂血症 | 2 | (0.5%) | 3 | (0.8%) |
| 低蛋白血症 | 2 | (0.5%) | 1 | (0.3%) |
| 低尿酸血症 | 2 | (0.5%) | 0 | |
| 乳酸アシドーシス | 2 | (0.5%) | 0 | |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 39）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 代謝性アシドーシス | 2 (0.5%) | 1 (0.3%) |
| ビタミン B12 欠乏 | 2 (0.5%) | 1 (0.3%) |
| ビタミン D 欠乏 | 2 (0.5%) | 1 (0.3%) |
| 糖尿病性ケトアシドーシス | 1 (0.3%) | 0 |
| 電解質失調 | 1 (0.3%) | 1 (0.3%) |
| 高アルブミン血症 | 1 (0.3%) | 0 |
| 高クレアチニン血症 | 1 (0.3%) | 0 |
| 高マグネシウム血症 | 1 (0.3%) | 0 |
| 高ナトリウム血症 | 1 (0.3%) | 1 (0.3%) |
| 高トリグリセリド血症 | 1 (0.3%) | 0 |
| 低クロール血症 | 1 (0.3%) | 0 |
| 低鉄血症 | 1 (0.3%) | 0 |
| 鉄過剰 | 1 (0.3%) | 0 |
| 多飲症 | 1 (0.3%) | 0 |
| テタニー | 1 (0.3%) | 0 |
| 2 型糖尿病 | 1 (0.3%) | 2 (0.5%) |
| 脂質異常症 | 0 | 1 (0.3%) |
| 葉酸欠乏 | 0 | 1 (0.3%) |
| 耐糖能障害 | 0 | 1 (0.3%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 40）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 高蛋白血症 | 0 | 1 (0.3%) |
| 無機質欠乏 | 0 | 1 (0.3%) |
| 過体重 | 0 | 1 (0.3%) |
| 1型糖尿病 | 0 | 1 (0.3%) |
| ビタミンK欠乏 | 0 | 1 (0.3%) |
| 筋骨格系および結合組織障害 | 225 (57.4%) | 215 (55.3%) |
| 筋痙縮 | 104 (26.5%) | 82 (21.1%) |
| 背部痛 | 67 (17.1%) | 78 (20.1%) |
| 関節痛 | 49 (12.5%) | 51 (13.1%) |
| 四肢痛 | 46 (11.7%) | 41 (10.5%) |
| 骨痛 | 39 (9.9%) | 36 (9.3%) |
| 筋力低下 | 27 (6.9%) | 22 (5.7%) |
| 筋骨格痛 | 25 (6.4%) | 34 (8.7%) |
| 筋骨格系胸痛 | 23 (5.9%) | 28 (7.2%) |
| 筋肉痛 | 22 (5.6%) | 22 (5.7%) |
| 頚部痛 | 11 (2.8%) | 18 (4.6%) |
| 関節腫脹 | 9 (2.3%) | 3 (0.8%) |
| 顎骨壊死 | 9 (2.3%) | 14 (3.6%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 41）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 顎痛 | 8 | (2.0%) | 8 | (2.1%) |
| 筋骨格不快感 | 7 | (1.8%) | 3 | (0.8%) |
| 変形性関節症 | 7 | (1.8%) | 3 | (0.8%) |
| 関節炎 | 6 | (1.5%) | 2 | (0.5%) |
| 側腹部痛 | 6 | (1.5%) | 5 | (1.3%) |
| ミオパチー | 6 | (1.5%) | 2 | (0.5%) |
| 筋骨格硬直 | 4 | (1.0%) | 2 | (0.5%) |
| 骨壊死 | 4 | (1.0%) | 3 | (0.8%) |
| 変形性脊椎症 | 4 | (1.0%) | 1 | (0.3%) |
| 鼡径部痛 | 3 | (0.8%) | 2 | (0.5%) |
| 四肢不快感 | 3 | (0.8%) | 1 | (0.3%) |
| 病的骨折 | 3 | (0.8%) | 1 | (0.3%) |
| 重感 | 3 | (0.8%) | 1 | (0.3%) |
| 滑液包炎 | 2 | (0.5%) | 2 | (0.5%) |
| 痛風性関節炎 | 2 | (0.5%) | 1 | (0.3%) |
| 椎間板突出 | 2 | (0.5%) | 0 | |
| 関節滲出液 | 2 | (0.5%) | 0 | |
| 筋拘縮 | 2 | (0.5%) | 1 | (0.3%) |
| 肩回旋筋腱板症候群 | 2 | (0.5%) | 1 | (0.3%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 42）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 腱障害 | 2 (0.5%) | 0 |
| 指炎 | 1 (0.3%) | 0 |
| デュプイトラン拘縮 | 1 (0.3%) | 0 |
| 外骨腫 | 1 (0.3%) | 0 |
| 指変形 | 1 (0.3%) | 0 |
| 骨折による偽関節 | 1 (0.3%) | 0 |
| 椎間板圧迫 | 1 (0.3%) | 0 |
| 椎間板変性症 | 1 (0.3%) | 0 |
| 筋萎縮 | 1 (0.3%) | 0 |
| 筋肉内出血 | 1 (0.3%) | 0 |
| 筋緊張 | 1 (0.3%) | 0 |
| 神経障害性関節症 | 1 (0.3%) | 0 |
| 関節周囲炎 | 1 (0.3%) | 0 |
| 足底筋膜炎 | 1 (0.3%) | 0 |
| 軟部組織障害 | 1 (0.3%) | 0 |
| 軟部組織腫瘤 | 1 (0.3%) | 1 (0.3%) |
| 脊柱管狭窄症 | 1 (0.3%) | 1 (0.3%) |
| 滑膜炎 | 1 (0.3%) | 0 |
| 顎関節症候群 | 1 (0.3%) | 0 |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 43）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 腱痛 | 1 (0.3%) | 0 |
| 腱炎 | 1 (0.3%) | 1 (0.3%) |
| 腱鞘炎 | 1 (0.3%) | 0 |
| 骨嚢腫 | 0 | 1 (0.3%) |
| 骨病変 | 0 | 2 (0.5%) |
| ピロリン酸カルシウム結晶性軟骨石灰化症 | 0 | 2 (0.5%) |
| 骨折痛 | 0 | 1 (0.3%) |
| 関節可動域低下 | 0 | 1 (0.3%) |
| 脊柱後弯症 | 0 | 1 (0.3%) |
| 腰部脊柱管狭窄症 | 0 | 1 (0.3%) |
| 運動性低下 | 0 | 1 (0.3%) |
| 単関節炎 | 0 | 1 (0.3%) |
| 筋肉疲労 | 0 | 1 (0.3%) |
| 筋固縮 | 0 | 1 (0.3%) |
| 骨炎 | 0 | 2 (0.5%) |
| 骨減少症 | 0 | 1 (0.3%) |
| 骨粗鬆症 | 0 | 1 (0.3%) |
| リウマチ性多発筋痛 | 0 | 1 (0.3%) |
| 滑液嚢腫 | 0 | 2 (0.5%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 44）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） | 30 | (7.7%) | 28 | (7.2%) |
| 基底細胞癌 | 5 | (1.3%) | 4 | (1.0%) |
| 形質細胞腫 | 3 | (0.8%) | 2 | (0.5%) |
| 急性骨髄性白血病 | 2 | (0.5%) | 2 | (0.5%) |
| 結腸癌 | 2 | (0.5%) | 0 | |
| 脂肪腫 | 2 | (0.5%) | 0 | |
| 扁平上皮癌 | 2 | (0.5%) | 2 | (0.5%) |
| 皮膚有棘細胞癌 | 2 | (0.5%) | 1 | (0.3%) |
| 腹部新生物 | 1 | (0.3%) | 0 | |
| 膵腺癌 | 1 | (0.3%) | 0 | |
| 骨新生物 | 1 | (0.3%) | 0 | |
| 結腸直腸癌 | 1 | (0.3%) | 0 | |
| 肝の悪性新生物 | 1 | (0.3%) | 1 | (0.3%) |
| 形質細胞性白血病 | 1 | (0.3%) | 0 | |
| 胸膜の悪性新生物 | 1 | (0.3%) | 0 | |
| メラノサイト性母斑 | 1 | (0.3%) | 2 | (0.5%) |
| 骨髄異形成症候群 | 1 | (0.3%) | 3 | (0.8%) |
| 新生物 | 1 | (0.3%) | 0 | |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 45）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 口腔乳頭腫 | 1 (0.3%) | 1 (0.3%) |
| 転移性膵癌 | 1 (0.3%) | 0 |
| 膵新生物 | 1 (0.3%) | 0 |
| 良性副甲状腺腫瘍 | 1 (0.3%) | 1 (0.3%) |
| 前立腺腺腫 | 1 (0.3%) | 0 |
| 皮膚乳頭腫 | 1 (0.3%) | 2 (0.5%) |
| 血管筋脂肪腫 | 0 | 1 (0.3%) |
| 小脳橋角部腫瘍 | 0 | 1 (0.3%) |
| 消化器新生物 | 0 | 1 (0.3%) |
| 消化管間質性腫瘍 | 0 | 1 (0.3%) |
| 肺新生物 | 0 | 1 (0.3%) |
| 悪性黒色腫 | 0 | 1 (0.3%) |
| 多発性骨髄腫 | 0 | 2 (0.5%) |
| 神経鞘腫 | 0 | 1 (0.3%) |
| 非小細胞肺癌 | 0 | 1 (0.3%) |
| 下垂体の良性腫瘍 | 0 | 1 (0.3%) |
| 直腸癌 | 0 | 1 (0.3%) |
| 脂漏性角化症 | 0 | 1 (0.3%) |
| 甲状腺新生物 | 0 | 1 (0.3%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 46）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 移行上皮癌 | 0 | | 1 | (0.3%) |
| 神経系障害 | 187 | (47.7%) | 187 | (48.1%) |
| 頭痛 | 53 | (13.5%) | 31 | (8.0%) |
| 浮動性めまい | 48 | (12.2%) | 44 | (11.3%) |
| 末梢性ニューロパチー | 29 | (7.4%) | 27 | (6.9%) |
| 振戦 | 28 | (7.1%) | 32 | (8.2%) |
| 錯感覚 | 25 | (6.4%) | 23 | (5.9%) |
| 末梢性感覚ニューロパチー | 22 | (5.6%) | 27 | (6.9%) |
| 感覚鈍麻 | 18 | (4.6%) | 13 | (3.3%) |
| 味覚異常 | 13 | (3.3%) | 21 | (5.4%) |
| 多発ニューロパチー | 13 | (3.3%) | 8 | (2.1%) |
| 記憶障害 | 12 | (3.1%) | 5 | (1.3%) |
| 傾眠 | 10 | (2.6%) | 5 | (1.3%) |
| 失神 | 7 | (1.8%) | 14 | (3.6%) |
| 認知障害 | 5 | (1.3%) | 2 | (0.5%) |
| 片頭痛 | 5 | (1.3%) | 0 | |
| 注意力障害 | 4 | (1.0%) | 1 | (0.3%) |
| 異常感覚 | 4 | (1.0%) | 4 | (1.0%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 47）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 神経痛 | 4 | (1.0%) | 7 | (1.8%) |
| 体位性めまい | 3 | (0.8%) | 0 | |
| 坐骨神経痛 | 3 | (0.8%) | 3 | (0.8%) |
| 反射消失 | 2 | (0.5%) | 0 | |
| 灼熱感 | 2 | (0.5%) | 2 | (0.5%) |
| 馬尾症候群 | 2 | (0.5%) | 0 | |
| 脳血管発作 | 2 | (0.5%) | 7 | (1.8%) |
| 錐体外路障害 | 2 | (0.5%) | 0 | |
| 知覚過敏 | 2 | (0.5%) | 3 | (0.8%) |
| 下肢静止不能症候群 | 2 | (0.5%) | 0 | |
| 脊髄圧迫 | 2 | (0.5%) | 3 | (0.8%) |
| 味覚消失 | 1 | (0.3%) | 3 | (0.8%) |
| 異痛症 | 1 | (0.3%) | 0 | |
| 意識変容状態 | 1 | (0.3%) | 0 | |
| 健忘 | 1 | (0.3%) | 7 | (1.8%) |
| 無嗅覚 | 1 | (0.3%) | 2 | (0.5%) |
| 失声症 | 1 | (0.3%) | 2 | (0.5%) |
| 平衡障害 | 1 | (0.3%) | 5 | (1.3%) |
| 脳嚢胞 | 1 | (0.3%) | 0 | |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 48）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 昏睡 | 1 | (0.3%) | 1 | (0.3%) |
| 痙攣 | 1 | (0.3%) | 2 | (0.5%) |
| 認知症 | 1 | (0.3%) | 1 | (0.3%) |
| 労作性めまい | 1 | (0.3%) | 0 | |
| よだれ | 1 | (0.3%) | 0 | |
| 本態性振戦 | 1 | (0.3%) | 0 | |
| 頭蓋内出血 | 1 | (0.3%) | 0 | |
| 水頭症 | 1 | (0.3%) | 0 | |
| 過眠症 | 1 | (0.3%) | 2 | (0.5%) |
| 筋緊張亢進 | 1 | (0.3%) | 0 | |
| 味覚減退 | 1 | (0.3%) | 2 | (0.5%) |
| 意識消失 | 1 | (0.3%) | 1 | (0.3%) |
| 不全対麻痺 | 1 | (0.3%) | 0 | |
| 嗅覚錯誤 | 1 | (0.3%) | 2 | (0.5%) |
| 末梢性運動ニューロパチー | 1 | (0.3%) | 2 | (0.5%) |
| ヘルペス後神経痛 | 1 | (0.3%) | 1 | (0.3%) |
| 失神寸前の状態 | 1 | (0.3%) | 0 | |
| 精神運動亢進 | 1 | (0.3%) | 2 | (0.5%) |
| 感覚運動障害 | 1 | (0.3%) | 0 | |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 49）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 感覚消失 | 1 (0.3%) | 0 |
| 中毒性ニューロパチー | 1 (0.3%) | 0 |
| 三叉神経痛 | 1 (0.3%) | 0 |
| 第７脳神経麻痺 | 1 (0.3%) | 0 |
| 筋萎縮性側索硬化症 | 0 | 1 (0.3%) |
| 運動失調 | 0 | 1 (0.3%) |
| 自律神経ニューロパチー | 0 | 1 (0.3%) |
| 脳出血 | 0 | 1 (0.3%) |
| 頚髄神経根痛 | 0 | 1 (0.3%) |
| 構語障害 | 0 | 1 (0.3%) |
| ジスキネジー | 0 | 1 (0.3%) |
| 頭部動揺 | 0 | 1 (0.3%) |
| 低酸素性虚血性脳症 | 0 | 1 (0.3%) |
| 肋間神経痛 | 0 | 1 (0.3%) |
| 嗜眠 | 0 | 1 (0.3%) |
| 精神的機能障害 | 0 | 1 (0.3%) |
| 筋痙直 | 0 | 1 (0.3%) |
| 粘液水腫性昏睡 | 0 | 1 (0.3%) |
| 神経圧迫 | 0 | 1 (0.3%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 50）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 眼振 | 0 | 1 (0.3%) |
| 末梢神経不全麻痺 | 0 | 1 (0.3%) |
| 腓骨神経麻痺 | 0 | 1 (0.3%) |
| 神経根痛 | 0 | 1 (0.3%) |
| 鎮静 | 0 | 1 (0.3%) |
| 会話障害 | 0 | 1 (0.3%) |
| 一過性脳虚血発作 | 0 | 2 (0.5%) |
| 第６脳神経麻痺 | 0 | 1 (0.3%) |
| 声帯麻痺 | 0 | 1 (0.3%) |
| 精神障害 | 131 (33.4%) | 111 (28.5%) |
| 不眠症 | 75 (19.1%) | 63 (16.2%) |
| 不安 | 31 (7.9%) | 15 (3.9%) |
| うつ病 | 15 (3.8%) | 13 (3.3%) |
| 激越 | 11 (2.8%) | 10 (2.6%) |
| 錯乱状態 | 10 (2.6%) | 11 (2.8%) |
| 気分変化 | 9 (2.3%) | 14 (3.6%) |
| 落ち着きのなさ | 8 (2.0%) | 4 (1.0%) |
| 睡眠障害 | 6 (1.5%) | 6 (1.5%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 51）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 抑うつ気分 | 4 (1.0%) | 3 (0.8%) |
| 失見当識 | 4 (1.0%) | 0 |
| 神経過敏 | 3 (0.8%) | 6 (1.5%) |
| 幻覚 | 2 (0.5%) | 1 (0.3%) |
| 人格変化 | 2 (0.5%) | 0 |
| 異常行動 | 1 (0.3%) | 0 |
| 感情障害 | 1 (0.3%) | 0 |
| 自殺既遂 | 1 (0.3%) | 0 |
| 転導性 | 1 (0.3%) | 0 |
| 多幸気分 | 1 (0.3%) | 0 |
| 表出性言語障害 | 1 (0.3%) | 0 |
| リビドー減退 | 1 (0.3%) | 0 |
| リビドー亢進 | 1 (0.3%) | 0 |
| 躁病 | 1 (0.3%) | 1 (0.3%) |
| 精神状態変化 | 1 (0.3%) | 1 (0.3%) |
| 気分動揺 | 1 (0.3%) | 3 (0.8%) |
| パニック発作 | 1 (0.3%) | 0 |
| 精神的機能代償不全 | 1 (0.3%) | 0 |
| 精神病性障害 | 1 (0.3%) | 0 |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 52）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| ストレス | 1 (0.3%) | 1 (0.3%) |
| 適応障害 | 0 | 1 (0.3%) |
| 攻撃性 | 0 | 1 (0.3%) |
| 怒り | 0 | 1 (0.3%) |
| 不安障害 | 0 | 1 (0.3%) |
| 睡眠時驚愕 | 0 | 1 (0.3%) |
| 腎および尿路障害 | 60 (15.3%) | 53 (13.6%) |
| 急性腎不全 | 15 (3.8%) | 11 (2.8%) |
| 腎不全 | 10 (2.6%) | 7 (1.8%) |
| 腎機能障害 | 10 (2.6%) | 9 (2.3%) |
| 排尿困難 | 9 (2.3%) | 4 (1.0%) |
| 夜間頻尿 | 5 (1.3%) | 1 (0.3%) |
| 頻尿 | 5 (1.3%) | 6 (1.5%) |
| 慢性腎不全 | 5 (1.3%) | 4 (1.0%) |
| 尿閉 | 5 (1.3%) | 2 (0.5%) |
| 血尿 | 4 (1.0%) | 2 (0.5%) |
| 腎嚢胞 | 3 (0.8%) | 1 (0.3%) |
| 高窒素血症 | 1 (0.3%) | 1 (0.3%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 53）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 膀胱不快感 | 1 (0.3%) | 0 |
| 糖尿 | 1 (0.3%) | 0 |
| 排尿回数減少 | 1 (0.3%) | 0 |
| 尿意切迫 | 1 (0.3%) | 2 (0.5%) |
| ネフローゼ症候群 | 1 (0.3%) | 0 |
| 乏尿 | 1 (0.3%) | 0 |
| 腎仙痛 | 1 (0.3%) | 0 |
| 腎尿細管壊死 | 1 (0.3%) | 0 |
| 有痛性排尿困難 | 1 (0.3%) | 1 (0.3%) |
| 尿路痛 | 1 (0.3%) | 0 |
| 無尿 | 0 | 1 (0.3%) |
| 膀胱憩室 | 0 | 1 (0.3%) |
| 尿管結石 | 0 | 1 (0.3%) |
| 着色尿 | 0 | 1 (0.3%) |
| 尿路出血 | 0 | 2 (0.5%) |
| 腎症 | 0 | 1 (0.3%) |
| 中毒性ネフロパシー | 0 | 1 (0.3%) |
| 多尿 | 0 | 3 (0.8%) |
| 腎前性腎不全 | 0 | 1 (0.3%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 54）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 腎腫瘤 | 0 | | 1 | (0.3%) |
| 尿失禁 | 0 | | 2 | (0.5%) |
| 生殖系および乳房障害 | 21 | (5.4%) | 9 | (2.3%) |
| 良性前立腺肥大症 | 4 | (1.0%) | 1 | (0.3%) |
| 勃起不全 | 4 | (1.0%) | 1 | (0.3%) |
| 骨盤痛 | 4 | (1.0%) | 2 | (0.5%) |
| 前立腺炎 | 3 | (0.8%) | 0 | |
| 精巣上体炎 | 2 | (0.5%) | 0 | |
| 外陰腟そう痒症 | 2 | (0.5%) | 0 | |
| 乳房痛 | 1 | (0.3%) | 0 | |
| 卵巣嚢胞 | 1 | (0.3%) | 0 | |
| 陰茎出血 | 1 | (0.3%) | 0 | |
| 前立腺異形成 | 1 | (0.3%) | 0 | |
| 前立腺痛 | 1 | (0.3%) | 0 | |
| 前立腺症 | 1 | (0.3%) | 1 | (0.3%) |
| 女性化乳房 | 0 | | 1 | (0.3%) |
| 子宮脱 | 0 | | 1 | (0.3%) |
| 外陰腟不快感 | 0 | | 1 | (0.3%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 55）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 外陰腟乾燥 | 0 | 1 (0.3%) |
| 呼吸器、胸郭および縦隔障害 | 217 (55.4%) | 162 (41.6%) |
| 咳嗽 | 113 (28.8%) | 67 (17.2%) |
| 呼吸困難 | 76 (19.4%) | 58 (14.9%) |
| 口腔咽頭痛 | 28 (7.1%) | 21 (5.4%) |
| 労作性呼吸困難 | 21 (5.4%) | 17 (4.4%) |
| 発声障害 | 19 (4.8%) | 11 (2.8%) |
| 鼻出血 | 19 (4.8%) | 16 (4.1%) |
| 湿性咳嗽 | 18 (4.6%) | 12 (3.1%) |
| 肺塞栓症 | 14 (3.6%) | 9 (2.3%) |
| 鼻漏 | 13 (3.3%) | 8 (2.1%) |
| 鼻閉 | 10 (2.6%) | 4 (1.0%) |
| しゃっくり | 9 (2.3%) | 5 (1.3%) |
| 胸水 | 6 (1.5%) | 4 (1.0%) |
| 慢性閉塞性肺疾患 | 5 (1.3%) | 5 (1.3%) |
| アレルギー性鼻炎 | 5 (1.3%) | 3 (0.8%) |
| 肺障害 | 4 (1.0%) | 4 (1.0%) |
| 肺水腫 | 4 (1.0%) | 3 (0.8%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 56）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 気道うっ血 | 4 (1.0%) | 3 (0.8%) |
| 急性呼吸窮迫症候群 | 3 (0.8%) | 0 |
| 低酸素症 | 3 (0.8%) | 2 (0.5%) |
| 呼吸不全 | 3 (0.8%) | 6 (1.5%) |
| 慢性気管支炎 | 2 (0.5%) | 1 (0.3%) |
| 気管支痙攣 | 2 (0.5%) | 2 (0.5%) |
| 副鼻腔分泌過多 | 2 (0.5%) | 0 |
| 誤嚥性肺炎 | 2 (0.5%) | 0 |
| 肺臓炎 | 2 (0.5%) | 1 (0.3%) |
| 肺高血圧症 | 2 (0.5%) | 1 (0.3%) |
| ラ音 | 2 (0.5%) | 1 (0.3%) |
| 副鼻腔うっ血 | 2 (0.5%) | 4 (1.0%) |
| 急性肺水腫 | 1 (0.3%) | 0 |
| 急性呼吸不全 | 1 (0.3%) | 1 (0.3%) |
| アデノイド肥大 | 1 (0.3%) | 0 |
| アレルギー性気管支炎 | 1 (0.3%) | 0 |
| 胞隔炎 | 1 (0.3%) | 1 (0.3%) |
| 誤嚥 | 1 (0.3%) | 0 |
| 喘息 | 1 (0.3%) | 2 (0.5%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 57）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 気管支肺症 | 1 | (0.3%) | 0 | |
| 肺気腫 | 1 | (0.3%) | 0 | |
| 好酸球性肺炎 | 1 | (0.3%) | 0 | |
| 喀血 | 1 | (0.3%) | 1 | (0.3%) |
| 低換気 | 1 | (0.3%) | 0 | |
| 間質性肺疾患 | 1 | (0.3%) | 1 | (0.3%) |
| 喉頭浮腫 | 1 | (0.3%) | 0 | |
| 鼻部不快感 | 1 | (0.3%) | 0 | |
| 鼻の炎症 | 1 | (0.3%) | 0 | |
| 鼻粘膜障害 | 1 | (0.3%) | 1 | (0.3%) |
| 鼻潰瘍 | 1 | (0.3%) | 1 | (0.3%) |
| 呼吸時疼痛 | 1 | (0.3%) | 0 | |
| 咽頭壊死 | 1 | (0.3%) | 0 | |
| 胸膜障害 | 1 | (0.3%) | 0 | |
| 胸膜線維症 | 1 | (0.3%) | 0 | |
| 胸膜炎 | 1 | (0.3%) | 0 | |
| 胸膜痛 | 1 | (0.3%) | 0 | |
| 呼吸障害 | 1 | (0.3%) | 1 | (0.3%) |
| 低音性連続性ラ音 | 1 | (0.3%) | 0 | |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 58）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| くしゃみ | 1 (0.3%) | 0 |
| いびき | 1 (0.3%) | 0 |
| 頻呼吸 | 1 (0.3%) | 1 (0.3%) |
| 咽喉刺激感 | 1 (0.3%) | 0 |
| 咽喉絞扼感 | 1 (0.3%) | 0 |
| 上気道うっ血 | 1 (0.3%) | 0 |
| 喘鳴 | 1 (0.3%) | 4 (1.0%) |
| 気管支反応性亢進 | 0 | 1 (0.3%) |
| 肺浸潤 | 0 | 1 (0.3%) |
| 口腔咽頭不快感 | 0 | 1 (0.3%) |
| 起坐呼吸 | 0 | 1 (0.3%) |
| 咽頭浮腫 | 0 | 1 (0.3%) |
| 呼気延長 | 0 | 1 (0.3%) |
| 肺うっ血 | 0 | 1 (0.3%) |
| 呼吸性アシドーシス | 0 | 1 (0.3%) |
| 呼吸窮迫 | 0 | 1 (0.3%) |
| 気道の炎症 | 0 | 1 (0.3%) |
| 副鼻腔ポリープ | 0 | 2 (0.5%) |
| 変色痰 | 0 | 1 (0.3%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 59）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 上気道咳症候群 | 0 | | 2 | (0.5%) |
| 皮膚および皮下組織障害 | 151 | (38.5%) | 129 | (33.2%) |
| 発疹 | 52 | (13.3%) | 60 | (15.4%) |
| 紅斑 | 30 | (7.7%) | 12 | (3.1%) |
| そう痒症 | 30 | (7.7%) | 16 | (4.1%) |
| 多汗症 | 26 | (6.6%) | 18 | (4.6%) |
| 皮膚乾燥 | 12 | (3.1%) | 15 | (3.9%) |
| 斑状丘疹状皮疹 | 12 | (3.1%) | 11 | (2.8%) |
| 斑状出血 | 11 | (2.8%) | 0 | |
| 日光性角化症 | 9 | (2.3%) | 0 | |
| 寝汗 | 9 | (2.3%) | 10 | (2.6%) |
| 皮膚病変 | 8 | (2.0%) | 2 | (0.5%) |
| 脱毛症 | 5 | (1.3%) | 7 | (1.8%) |
| 紅斑性皮疹 | 5 | (1.3%) | 3 | (0.8%) |
| 点状出血 | 4 | (1.0%) | 2 | (0.5%) |
| 全身性皮疹 | 4 | (1.0%) | 2 | (0.5%) |
| そう痒性皮疹 | 4 | (1.0%) | 3 | (0.8%) |
| 皮膚変色 | 4 | (1.0%) | 2 | (0.5%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 60）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 皮膚潰瘍 | 4 | (1.0%) | 2 | (0.5%) |
| 皮膚剥脱 | 3 | (0.8%) | 1 | (0.3%) |
| 皮膚色素過剰 | 3 | (0.8%) | 3 | (0.8%) |
| 顔面腫脹 | 3 | (0.8%) | 1 | (0.3%) |
| 水疱 | 2 | (0.5%) | 0 | |
| 冷汗 | 2 | (0.5%) | 0 | |
| 皮膚炎 | 2 | (0.5%) | 1 | (0.3%) |
| アレルギー性皮膚炎 | 2 | (0.5%) | 2 | (0.5%) |
| 紅色症 | 2 | (0.5%) | 0 | |
| 汗腺炎 | 2 | (0.5%) | 1 | (0.3%) |
| 男性型多毛症 | 2 | (0.5%) | 1 | (0.3%) |
| 皮膚毒性 | 2 | (0.5%) | 0 | |
| 蕁麻疹 | 2 | (0.5%) | 2 | (0.5%) |
| ざ瘡 | 1 | (0.3%) | 1 | (0.3%) |
| 急性熱性好中球性皮膚症 | 1 | (0.3%) | 0 | |
| 皮膚嚢腫 | 1 | (0.3%) | 0 | |
| 水疱性皮膚炎 | 1 | (0.3%) | 0 | |
| 薬疹 | 1 | (0.3%) | 1 | (0.3%) |
| 湿疹 | 1 | (0.3%) | 1 | (0.3%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 61）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 湿潤性湿疹 | 1 | (0.3%) | 0 | |
| 毛髪成長異常 | 1 | (0.3%) | 1 | (0.3%) |
| 過角化 | 1 | (0.3%) | 4 | (1.0%) |
| 多毛症 | 1 | (0.3%) | 1 | (0.3%) |
| 内出血発生の増加傾向 | 1 | (0.3%) | 5 | (1.3%) |
| 嵌入爪 | 1 | (0.3%) | 1 | (0.3%) |
| 内方発育毛 | 1 | (0.3%) | 0 | |
| 間擦疹 | 1 | (0.3%) | 0 | |
| 機械性蕁麻疹 | 1 | (0.3%) | 0 | |
| 爪床障害 | 1 | (0.3%) | 0 | |
| 爪破損 | 1 | (0.3%) | 1 | (0.3%) |
| 手掌・足底発赤知覚不全症候群 | 1 | (0.3%) | 0 | |
| アレルギー性そう痒症 | 1 | (0.3%) | 0 | |
| 全身性そう痒症 | 1 | (0.3%) | 2 | (0.5%) |
| 紫斑 | 1 | (0.3%) | 0 | |
| 丘疹性皮疹 | 1 | (0.3%) | 1 | (0.3%) |
| 酒さ | 1 | (0.3%) | 0 | |
| 脂漏性皮膚炎 | 1 | (0.3%) | 1 | (0.3%) |
| 皮膚亀裂 | 1 | (0.3%) | 2 | (0.5%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 62）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 皮膚刺激 | 1 | (0.3%) | 0 | |
| 日光皮膚炎 | 1 | (0.3%) | 0 | |
| 血管性紫斑病 | 1 | (0.3%) | 0 | |
| 急性汎発性発疹性膿疱症 | 0 | | 1 | (0.3%) |
| 血管浮腫 | 0 | | 2 | (0.5%) |
| ざ瘡様皮膚炎 | 0 | | 1 | (0.3%) |
| 接触性皮膚炎 | 0 | | 2 | (0.5%) |
| 爪の障害 | 0 | | 2 | (0.5%) |
| ポードレンジ | 0 | | 1 | (0.3%) |
| 乾癬 | 0 | | 1 | (0.3%) |
| 皮膚萎縮 | 0 | | 1 | (0.3%) |
| 皮膚腫脹 | 0 | | 1 | (0.3%) |
| 皮膚のつっぱり感 | 0 | | 1 | (0.3%) |
| うっ滞性皮膚炎 | 0 | | 1 | (0.3%) |
| 外科および内科処置 | 1 | (0.3%) | 2 | (0.5%) |
| 胆石摘出 | 1 | (0.3%) | 0 | |
| 白内障手術 | 0 | | 1 | (0.3%) |
| 抜歯 | 0 | | 1 | (0.3%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 63）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 血管障害 | 147 | (37.5%) | 97 | (24.9%) |
| 高血圧 | 56 | (14.3%) | 27 | (6.9%) |
| 深部静脈血栓症 | 26 | (6.6%) | 15 | (3.9%) |
| 低血圧 | 25 | (6.4%) | 23 | (5.9%) |
| 潮紅 | 13 | (3.3%) | 4 | (1.0%) |
| 静脈炎 | 12 | (3.1%) | 4 | (1.0%) |
| 表在性血栓性静脈炎 | 11 | (2.8%) | 6 | (1.5%) |
| ほてり | 10 | (2.6%) | 1 | (0.3%) |
| 血栓性静脈炎 | 8 | (2.0%) | 3 | (0.8%) |
| 血栓症 | 6 | (1.5%) | 5 | (1.3%) |
| 四肢静脈血栓症 | 6 | (1.5%) | 0 | |
| 血腫 | 5 | (1.3%) | 12 | (3.1%) |
| 起立性低血圧 | 4 | (1.0%) | 4 | (1.0%) |
| 塞栓症 | 3 | (0.8%) | 1 | (0.3%) |
| 血栓後症候群 | 3 | (0.8%) | 0 | |
| 大動脈瘤 | 2 | (0.5%) | 0 | |
| 動脈硬化症 | 2 | (0.5%) | 0 | |
| 循環虚脱 | 2 | (0.5%) | 0 | |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 64）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 高血圧クリーゼ | 2 | (0.5%) | 1 | (0.3%) |
| 末梢冷感 | 2 | (0.5%) | 0 | |
| 表在性静脈炎 | 2 | (0.5%) | 0 | |
| 静脈瘤 | 2 | (0.5%) | 0 | |
| 大動脈硬化症 | 1 | (0.3%) | 1 | (0.3%) |
| 動脈炎 | 1 | (0.3%) | 0 | |
| 青趾症候群 | 1 | (0.3%) | 0 | |
| 出血 | 1 | (0.3%) | 1 | (0.3%) |
| リンパ浮腫 | 1 | (0.3%) | 1 | (0.3%) |
| 末梢動脈狭窄 | 1 | (0.3%) | 0 | |
| 収縮期高血圧 | 1 | (0.3%) | 0 | |
| 静脈血栓症 | 1 | (0.3%) | 4 | (1.0%) |
| 血圧変動 | 0 | | 1 | (0.3%) |
| 間欠性跛行 | 0 | | 1 | (0.3%) |
| 蒼白 | 0 | | 1 | (0.3%) |
| 骨盤静脈血栓症 | 0 | | 1 | (0.3%) |
| 末梢動脈瘤 | 0 | | 1 | (0.3%) |
| 末梢血管障害 | 0 | | 1 | (0.3%) |
| レイノー現象 | 0 | | 1 | (0.3%) |

**表 2.7.6.18.2-4　有害事象の MedDRA SOC 別，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 65）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 鎖骨下動脈狭窄 | 0 | 1 (0.3%) |
| 血管炎 | 0 | 1 (0.3%) |
| Uncoded | 0 | 1 (0.3%) |
| Feeling of Preposession | 0 | 1 (0.3%) |

CRd = Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm; Rd = Revlimid (lenalidomide)/dexamethasone arm.
Notes: MedDRA version 15.1 was used for coding.
Subjects were counted only once for each System Organ Class and each Preferred Term.
出典［総括報告書 5.3.5.1-1（PX-171-009），Table 14.3.2.1］

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| Number of Subjects with at Least One Treatment-Related Event | 332 (84.7%) | 329 (84.6%) |
| 血液およびリンパ系障害 | 189 (48.2%) | 185 (47.6%) |
| 好中球減少症 | 134 (34.2%) | 114 (29.3%) |
| 貧血 | 100 (25.5%) | 92 (23.7%) |
| 血小板減少症 | 88 (22.4%) | 70 (18.0%) |
| 白血球減少症 | 20 (5.1%) | 19 (4.9%) |
| 発熱性好中球減少症 | 11 (2.8%) | 4 (1.0%) |
| リンパ球減少症 | 11 (2.8%) | 11 (2.8%) |
| 溶血 | 1 (0.3%) | 0 |
| 溶血性貧血 | 1 (0.3%) | 1 (0.3%) |
| 白血球増加症 | 1 (0.3%) | 0 |
| 好中球増加症 | 1 (0.3%) | 0 |
| 汎血球減少症 | 1 (0.3%) | 5 (1.3%) |
| 好酸球増加症 | 0 | 1 (0.3%) |
| リンパ節症 | 0 | 1 (0.3%) |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 1）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 心臓障害 | 22 | (5.6%) | 32 | (8.2%) |
| 動悸 | 8 | (2.0%) | 4 | (1.0%) |
| 狭心症 | 3 | (0.8%) | 3 | (0.8%) |
| うっ血性心不全 | 3 | (0.8%) | 3 | (0.8%) |
| 心房細動 | 2 | (0.5%) | 11 | (2.8%) |
| 頻脈 | 2 | (0.5%) | 3 | (0.8%) |
| 大動脈弁石灰化 | 1 | (0.3%) | 0 | |
| 心房粗動 | 1 | (0.3%) | 0 | |
| 徐脈 | 1 | (0.3%) | 4 | (1.0%) |
| 心停止 | 1 | (0.3%) | 0 | |
| 左室機能不全 | 1 | (0.3%) | 0 | |
| 洞性徐脈 | 1 | (0.3%) | 0 | |
| 上室性期外収縮 | 1 | (0.3%) | 2 | (0.5%) |
| 心室性不整脈 | 1 | (0.3%) | 0 | |
| 心室性期外収縮 | 1 | (0.3%) | 1 | (0.3%) |
| 急性冠動脈症候群 | 0 | | 1 | (0.3%) |
| 急性心筋梗塞 | 0 | | 1 | (0.3%) |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 2）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 不安定狭心症 | 0 | 1 (0.3%) |
| 左脚ブロック | 0 | 1 (0.3%) |
| 右脚ブロック | 0 | 1 (0.3%) |
| 心障害 | 0 | 1 (0.3%) |
| 心不全 | 0 | 1 (0.3%) |
| 伝導障害 | 0 | 1 (0.3%) |
| 心筋梗塞 | 0 | 1 (0.3%) |
| 心嚢液貯留 | 0 | 1 (0.3%) |
| 肺動脈弁閉鎖不全症 | 0 | 1 (0.3%) |
| 耳および迷路障害 | 8 (2.0%) | 9 (2.3%) |
| 回転性めまい | 8 (2.0%) | 6 (1.5%) |
| 難聴 | 0 | 1 (0.3%) |
| 聴覚障害 | 0 | 1 (0.3%) |
| 耳鳴 | 0 | 1 (0.3%) |
| 内分泌障害 | 11 (2.8%) | 7 (1.8%) |
| クッシング様 | 4 (1.0%) | 2 (0.5%) |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 3）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 副腎機能不全 | 3 (0.8%) | 2 (0.5%) |
| クッシング症候群 | 2 (0.5%) | 0 |
| アジソン病 | 1 (0.3%) | 0 |
| 甲状腺障害 | 1 (0.3%) | 0 |
| 甲状腺機能低下症 | 0 | 3 (0.8%) |
| ステロイド離脱症候群 | 0 | 1 (0.3%) |
| 眼障害 | 53 (13.5%) | 41 (10.5%) |
| 白内障 | 17 (4.3%) | 12 (3.1%) |
| 霧視 | 11 (2.8%) | 12 (3.1%) |
| 眼乾燥 | 7 (1.8%) | 5 (1.3%) |
| 視力障害 | 7 (1.8%) | 4 (1.0%) |
| 結膜炎 | 3 (0.8%) | 1 (0.3%) |
| 失明 | 2 (0.5%) | 0 |
| 眼刺激 | 2 (0.5%) | 0 |
| 眼窩浮腫 | 2 (0.5%) | 0 |
| 硝子体浮遊物 | 2 (0.5%) | 0 |
| 眼瞼浮腫 | 1 (0.3%) | 3 (0.8%) |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 4）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 緑内障 | 1 (0.3%) | 1 (0.3%) |
| 角膜炎 | 1 (0.3%) | 0 |
| 流涙増加 | 1 (0.3%) | 0 |
| 夜盲 | 1 (0.3%) | 0 |
| 視神経乳頭浮腫 | 1 (0.3%) | 0 |
| 網膜剥離 | 1 (0.3%) | 0 |
| 暗点 | 1 (0.3%) | 0 |
| 視力低下 | 1 (0.3%) | 2 (0.5%) |
| 眼の異常感 | 0 | 1 (0.3%) |
| 複視 | 0 | 1 (0.3%) |
| 水晶体混濁 | 0 | 1 (0.3%) |
| 近視 | 0 | 1 (0.3%) |
| 眼窩周囲浮腫 | 0 | 1 (0.3%) |
| 網膜血管障害 | 0 | 1 (0.3%) |
| 網膜静脈閉塞 | 0 | 1 (0.3%) |
| | | |
| 胃腸障害 | 146 (37.2%) | 126 (32.4%) |
| 下痢 | 73 (18.6%) | 63 (16.2%) |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 5）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 悪心 | 37 | (9.4%) | 25 | (6.4%) |
| 便秘 | 36 | (9.2%) | 38 | (9.8%) |
| 上腹部痛 | 14 | (3.6%) | 5 | (1.3%) |
| 嘔吐 | 14 | (3.6%) | 9 | (2.3%) |
| 消化不良 | 11 | (2.8%) | 16 | (4.1%) |
| 腹痛 | 10 | (2.6%) | 6 | (1.5%) |
| 口内炎 | 8 | (2.0%) | 1 | (0.3%) |
| 腹部不快感 | 7 | (1.8%) | 5 | (1.3%) |
| 腹部膨満 | 7 | (1.8%) | 5 | (1.3%) |
| 口内乾燥 | 5 | (1.3%) | 3 | (0.8%) |
| 鼓腸 | 5 | (1.3%) | 3 | (0.8%) |
| 胃炎 | 5 | (1.3%) | 4 | (1.0%) |
| 胃腸障害 | 4 | (1.0%) | 1 | (0.3%) |
| 胃食道逆流性疾患 | 4 | (1.0%) | 7 | (1.8%) |
| 心窩部不快感 | 2 | (0.5%) | 1 | (0.3%) |
| 胃腸毒性 | 2 | (0.5%) | 1 | (0.3%) |
| 胃排出不全 | 2 | (0.5%) | 0 | |
| 食道炎 | 2 | (0.5%) | 0 | |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 6）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 口腔内不快感 | 2 (0.5%) | 0 |
| 下腹部痛 | 1 (0.3%) | 0 |
| 腹部圧痛 | 1 (0.3%) | 1 (0.3%) |
| アフタ性口内炎 | 1 (0.3%) | 0 |
| 便習慣変化 | 1 (0.3%) | 0 |
| 大腸炎 | 1 (0.3%) | 0 |
| 嚥下障害 | 1 (0.3%) | 0 |
| 変色便 | 1 (0.3%) | 1 (0.3%) |
| 排便回数増加 | 1 (0.3%) | 0 |
| 歯肉腫脹 | 1 (0.3%) | 0 |
| 血便排泄 | 1 (0.3%) | 0 |
| 痔核 | 1 (0.3%) | 0 |
| 排便回数減少 | 1 (0.3%) | 0 |
| 大腸穿孔 | 1 (0.3%) | 0 |
| 口唇乾燥 | 1 (0.3%) | 0 |
| 口唇腫脹 | 1 (0.3%) | 0 |
| 下部消化管出血 | 1 (0.3%) | 0 |
| 好中球減少性大腸炎 | 1 (0.3%) | 0 |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 7）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 急性膵炎 | 1 (0.3%) | 0 |
| 口の錯感覚 | 1 (0.3%) | 1 (0.3%) |
| 吐き戻し | 1 (0.3%) | 0 |
| 歯痛 | 1 (0.3%) | 2 (0.5%) |
| 胃出血 | 0 | 1 (0.3%) |
| 胃腸出血 | 0 | 3 (0.8%) |
| 消化器痛 | 0 | 1 (0.3%) |
| 歯肉出血 | 0 | 1 (0.3%) |
| 歯肉痛 | 0 | 1 (0.3%) |
| 舌痛 | 0 | 1 (0.3%) |
| 口の感覚鈍麻 | 0 | 1 (0.3%) |
| 口腔内痛 | 0 | 1 (0.3%) |
| 膵炎 | 0 | 1 (0.3%) |
| 歯周病 | 0 | 1 (0.3%) |
| 直腸炎 | 0 | 1 (0.3%) |
| 小腸閉塞 | 0 | 1 (0.3%) |
| 小腸穿孔 | 0 | 1 (0.3%) |
| 舌苔 | 0 | 1 (0.3%) |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 8）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 舌潰瘍 | 0 | 1 (0.3%) |
| 一般・全身障害および投与部位の状態 | 173 (44.1%) | 139 (35.7%) |
| 疲労 | 88 (22.4%) | 83 (21.3%) |
| 無力症 | 41 (10.5%) | 32 (8.2%) |
| 末梢性浮腫 | 40 (10.2%) | 35 (9.0%) |
| 発熱 | 30 (7.7%) | 20 (5.1%) |
| 悪寒 | 9 (2.3%) | 1 (0.3%) |
| 浮腫 | 9 (2.3%) | 8 (2.1%) |
| 易刺激性 | 8 (2.0%) | 4 (1.0%) |
| 粘膜の炎症 | 7 (1.8%) | 2 (0.5%) |
| 注入部位疼痛 | 5 (1.3%) | 0 |
| 倦怠感 | 5 (1.3%) | 3 (0.8%) |
| 疼痛 | 5 (1.3%) | 2 (0.5%) |
| 顔面浮腫 | 4 (1.0%) | 3 (0.8%) |
| 胸痛 | 3 (0.8%) | 1 (0.3%) |
| インフルエンザ様疾患 | 3 (0.8%) | 2 (0.5%) |
| 歩行障害 | 2 (0.5%) | 3 (0.8%) |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 9）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 全身性浮腫 | 2 (0.5%) | 1 (0.3%) |
| 非心臓性胸痛 | 2 (0.5%) | 2 (0.5%) |
| 医薬品副作用 | 1 (0.3%) | 2 (0.5%) |
| 胸部不快感 | 1 (0.3%) | 0 |
| 早期満腹 | 1 (0.3%) | 0 |
| 異常感 | 1 (0.3%) | 1 (0.3%) |
| 熱感 | 1 (0.3%) | 0 |
| ぴくぴく感 | 1 (0.3%) | 0 |
| 全身健康状態低下 | 1 (0.3%) | 4 (1.0%) |
| 炎症 | 1 (0.3%) | 1 (0.3%) |
| 注入部位血管外漏出 | 1 (0.3%) | 0 |
| 注入部位硬結 | 1 (0.3%) | 0 |
| 注入部位炎症 | 1 (0.3%) | 0 |
| 注入部位腫脹 | 1 (0.3%) | 0 |
| 注入部位小水疱 | 1 (0.3%) | 0 |
| 注射部位反応 | 1 (0.3%) | 0 |
| 限局性浮腫 | 1 (0.3%) | 0 |
| 圧痛 | 1 (0.3%) | 0 |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 10）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 医療機器関連の血栓症 | 1 | (0.3%) | 0 | |
| 腋窩痛 | 0 | | 1 | (0.3%) |
| 顔面痛 | 0 | | 1 | (0.3%) |
| 冷感 | 0 | | 1 | (0.3%) |
| 治癒不良 | 0 | | 1 | (0.3%) |
| 粘膜乾燥 | 0 | | 1 | (0.3%) |
| 肝胆道系障害 | 11 | (2.8%) | 5 | (1.3%) |
| 中毒性肝炎 | 4 | (1.0%) | 0 | |
| 高ビリルビン血症 | 3 | (0.8%) | 1 | (0.3%) |
| 肝細胞損傷 | 2 | (0.5%) | 0 | |
| 肝毒性 | 2 | (0.5%) | 1 | (0.3%) |
| 急性胆嚢炎 | 1 | (0.3%) | 0 | |
| 胆汁うっ滞 | 0 | | 2 | (0.5%) |
| 胆汁うっ滞性肝炎 | 0 | | 1 | (0.3%) |
| 免疫系障害 | 6 | (1.5%) | 5 | (1.3%) |
| 薬物過敏症 | 2 | (0.5%) | 1 | (0.3%) |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 11）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 低γグロブリン血症 | 2 (0.5%) | 0 |
| サイトカイン放出症候群 | 1 (0.3%) | 1 (0.3%) |
| 過敏症 | 1 (0.3%) | 2 (0.5%) |
| アレルギー性浮腫 | 0 | 1 (0.3%) |
| 感染症および寄生虫症 | 118 (30.1%) | 99 (25.4%) |
| 上気道感染 | 38 (9.7%) | 21 (5.4%) |
| 肺炎 | 30 (7.7%) | 21 (5.4%) |
| 気管支炎 | 19 (4.8%) | 13 (3.3%) |
| 鼻咽頭炎 | 14 (3.6%) | 10 (2.6%) |
| 気道感染 | 14 (3.6%) | 12 (3.1%) |
| 副鼻腔炎 | 7 (1.8%) | 6 (1.5%) |
| 尿路感染 | 7 (1.8%) | 5 (1.3%) |
| インフルエンザ | 4 (1.0%) | 1 (0.3%) |
| 下気道感染 | 4 (1.0%) | 2 (0.5%) |
| カンジダ症 | 3 (0.8%) | 2 (0.5%) |
| クロストリジウム・ディフィシレ大腸炎 | 3 (0.8%) | 0 |
| 感染 | 3 (0.8%) | 3 (0.8%) |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 12）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 口腔カンジダ症 | 3 (0.8%) | 3 (0.8%) |
| 敗血症 | 3 (0.8%) | 3 (0.8%) |
| 急性副鼻腔炎 | 2 (0.5%) | 1 (0.3%) |
| 気管支肺炎 | 2 (0.5%) | 1 (0.3%) |
| 蜂巣炎 | 2 (0.5%) | 2 (0.5%) |
| ウイルス性消化管感染 | 2 (0.5%) | 0 |
| 帯状疱疹 | 2 (0.5%) | 3 (0.8%) |
| 肺感染 | 2 (0.5%) | 0 |
| 急性中耳炎 | 2 (0.5%) | 0 |
| 咽頭炎 | 2 (0.5%) | 3 (0.8%) |
| 敗血症性ショック | 2 (0.5%) | 1 (0.3%) |
| ウイルス性上気道感染 | 2 (0.5%) | 2 (0.5%) |
| 創傷感染 | 2 (0.5%) | 0 |
| アデノウイルス感染 | 1 (0.3%) | 0 |
| 細気管支炎 | 1 (0.3%) | 0 |
| 慢性副鼻腔炎 | 1 (0.3%) | 1 (0.3%) |
| クロストリジウム感染 | 1 (0.3%) | 0 |
| 膀胱炎 | 1 (0.3%) | 1 (0.3%) |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 13）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| サイトメガロウイルス感染 | 1 (0.3%) | 0 |
| 丹毒 | 1 (0.3%) | 1 (0.3%) |
| 毛包炎 | 1 (0.3%) | 1 (0.3%) |
| 皮膚真菌感染 | 1 (0.3%) | 2 (0.5%) |
| せつ | 1 (0.3%) | 0 |
| 胃腸炎 | 1 (0.3%) | 1 (0.3%) |
| 消化管感染 | 1 (0.3%) | 0 |
| 歯肉炎 | 1 (0.3%) | 1 (0.3%) |
| 鼠径部膿瘍 | 1 (0.3%) | 0 |
| 感染性嚢腫 | 1 (0.3%) | 0 |
| 喉頭炎 | 1 (0.3%) | 2 (0.5%) |
| 大葉性肺炎 | 1 (0.3%) | 0 |
| 好中球減少性敗血症 | 1 (0.3%) | 0 |
| 食道カンジダ症 | 1 (0.3%) | 0 |
| 爪真菌症 | 1 (0.3%) | 2 (0.5%) |
| 口腔感染 | 1 (0.3%) | 0 |
| 精巣炎 | 1 (0.3%) | 0 |
| 骨髄炎 | 1 (0.3%) | 0 |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 14）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 中耳炎 | 1 (0.3%) | 1 (0.3%) |
| 細菌性中耳炎 | 1 (0.3%) | 0 |
| 細菌性咽頭炎 | 1 (0.3%) | 0 |
| ニューモシスティスジロヴェシ肺炎 | 1 (0.3%) | 0 |
| インフルエンザ性肺炎 | 1 (0.3%) | 0 |
| 進行性多巣性白質脳症 | 1 (0.3%) | 0 |
| ウイルス性気道感染 | 1 (0.3%) | 3 (0.8%) |
| サルモネラ性敗血症 | 1 (0.3%) | 0 |
| 軟部組織感染 | 1 (0.3%) | 0 |
| 白癬感染 | 1 (0.3%) | 0 |
| 歯膿瘍 | 1 (0.3%) | 0 |
| 細菌性上気道感染 | 1 (0.3%) | 1 (0.3%) |
| 尿路性敗血症 | 1 (0.3%) | 0 |
| ウイルス感染 | 1 (0.3%) | 1 (0.3%) |
| 外陰部膣カンジダ症 | 1 (0.3%) | 0 |
| 四肢膿瘍 | 0 | 1 (0.3%) |
| 憩室炎 | 0 | 1 (0.3%) |
| 大腸菌性尿路感染 | 0 | 2 (0.5%) |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 15）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 真菌感染 | 0 | 1 (0.3%) |
| 肝感染 | 0 | 1 (0.3%) |
| 単純ヘルペス | 0 | 1 (0.3%) |
| 播種性帯状疱疹 | 0 | 1 (0.3%) |
| 迷路炎 | 0 | 1 (0.3%) |
| リステリア性敗血症 | 0 | 1 (0.3%) |
| 爪感染 | 0 | 1 (0.3%) |
| 口腔真菌感染 | 0 | 4 (1.0%) |
| 口腔ヘルペス | 0 | 2 (0.5%) |
| 百日咳 | 0 | 1 (0.3%) |
| RS ウイルス感染 | 0 | 1 (0.3%) |
| 鼻炎 | 0 | 1 (0.3%) |
| 皮膚感染 | 0 | 1 (0.3%) |
| レンサ球菌性菌血症 | 0 | 1 (0.3%) |
| 扁桃炎 | 0 | 1 (0.3%) |
| 外陰膣真菌感染 | 0 | 1 (0.3%) |
| 傷害、中毒および処置合併症 | 11 (2.8%) | 6 (1.5%) |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 16）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 挫傷 | 5 (1.3%) | 2 (0.5%) |
| 注入に伴う反応 | 2 (0.5%) | 0 |
| 大腿骨骨折 | 1 (0.3%) | 1 (0.3%) |
| 眼窩周囲出血 | 1 (0.3%) | 0 |
| 皮下血腫 | 1 (0.3%) | 0 |
| 血管確保合併症 | 1 (0.3%) | 0 |
| 転倒 | 0 | 2 (0.5%) |
| 肋骨骨折 | 0 | 1 (0.3%) |
| 臨床検査 | 80 (20.4%) | 62 (15.9%) |
| 好中球数減少 | 13 (3.3%) | 17 (4.4%) |
| 血小板数減少 | 13 (3.3%) | 12 (3.1%) |
| アラニンアミノトランスフェラーゼ増加 | 11 (2.8%) | 8 (2.1%) |
| 血中クレアチニン増加 | 8 (2.0%) | 7 (1.8%) |
| 腎クレアチニン・クリアランス減少 | 7 (1.8%) | 3 (0.8%) |
| アスパラギン酸アミノトランスフェラーゼ増加 | 6 (1.5%) | 2 (0.5%) |
| 血中ビリルビン増加 | 5 (1.3%) | 0 |
| ヘモグロビン減少 | 5 (1.3%) | 2 (0.5%) |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 17）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 体重減少 | 5 (1.3%) | 7 (1.8%) |
| 血中ブドウ糖増加 | 3 (0.8%) | 3 (0.8%) |
| 体重増加 | 3 (0.8%) | 0 |
| 血中クロール増加 | 2 (0.5%) | 0 |
| 血中クレアチンホスホキナーゼ増加 | 2 (0.5%) | 0 |
| 血中乳酸脱水素酵素増加 | 2 (0.5%) | 1 (0.3%) |
| 血圧上昇 | 2 (0.5%) | 1 (0.3%) |
| C－反応性蛋白増加 | 2 (0.5%) | 1 (0.3%) |
| γ－グルタミルトランスフェラーゼ増加 | 2 (0.5%) | 1 (0.3%) |
| 眼圧上昇 | 2 (0.5%) | 3 (0.8%) |
| 白血球数減少 | 2 (0.5%) | 5 (1.3%) |
| 抱合ビリルビン増加 | 1 (0.3%) | 0 |
| 血中アルカリホスファターゼ増加 | 1 (0.3%) | 2 (0.5%) |
| 血中リン減少 | 1 (0.3%) | 1 (0.3%) |
| 血中テストステロン減少 | 1 (0.3%) | 0 |
| 血中尿素減少 | 1 (0.3%) | 0 |
| カンピロバクター検査陽性 | 1 (0.3%) | 0 |
| カンジダ検査陽性 | 1 (0.3%) | 0 |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 18）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 心臓負荷試験異常 | 1 (0.3%) | 0 |
| 心電図 QT 延長 | 1 (0.3%) | 0 |
| 全身健康状態異常 | 1 (0.3%) | 1 (0.3%) |
| グリコヘモグロビン増加 | 1 (0.3%) | 0 |
| 肝酵素上昇 | 1 (0.3%) | 1 (0.3%) |
| 打聴診音減弱 | 1 (0.3%) | 0 |
| 眼圧検査 | 1 (0.3%) | 0 |
| 腎機能検査異常 | 1 (0.3%) | 0 |
| トランスアミナーゼ上昇 | 1 (0.3%) | 1 (0.3%) |
| トロポニン増加 | 1 (0.3%) | 0 |
| 血中フィブリノゲン増加 | 0 | 1 (0.3%) |
| 心電図 STーT 部分異常 | 0 | 1 (0.3%) |
| 心拍数増加 | 0 | 1 (0.3%) |
| リンパ球数減少 | 0 | 2 (0.5%) |
| 総蛋白減少 | 0 | 1 (0.3%) |
| ウイルス検査陽性 | 0 | 1 (0.3%) |
| 代謝および栄養障害 | 124 (31.6%) | 79 (20.3%) |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 19）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 低カリウム血症 | 43 (11.0%) | 17 (4.4%) |
| 高血糖 | 40 (10.2%) | 33 (8.5%) |
| 低リン酸血症 | 28 (7.1%) | 8 (2.1%) |
| 食欲減退 | 21 (5.4%) | 18 (4.6%) |
| 低カルシウム血症 | 18 (4.6%) | 4 (1.0%) |
| 低マグネシウム血症 | 13 (3.3%) | 4 (1.0%) |
| 脱水 | 4 (1.0%) | 1 (0.3%) |
| 体液貯留 | 4 (1.0%) | 2 (0.5%) |
| 糖尿病 | 3 (0.8%) | 7 (1.8%) |
| 低アルブミン血症 | 3 (0.8%) | 0 |
| 腫瘍崩壊症候群 | 3 (0.8%) | 0 |
| 高尿酸血症 | 2 (0.5%) | 1 (0.3%) |
| アシドーシス | 1 (0.3%) | 0 |
| コントロール不良の糖尿病 | 1 (0.3%) | 2 (0.5%) |
| 糖尿病性ケトアシドーシス | 1 (0.3%) | 0 |
| 電解質失調 | 1 (0.3%) | 1 (0.3%) |
| 水分過負荷 | 1 (0.3%) | 0 |
| 痛風 | 1 (0.3%) | 1 (0.3%) |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 20）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 高クレアチニン血症 | 1 | (0.3%) | 0 | |
| 高リン酸塩血症 | 1 | (0.3%) | 0 | |
| 低血糖症 | 1 | (0.3%) | 0 | |
| 低ナトリウム血症 | 1 | (0.3%) | 1 | (0.3%) |
| 低蛋白血症 | 1 | (0.3%) | 0 | |
| 代謝性アシドーシス | 1 | (0.3%) | 1 | (0.3%) |
| テタニー | 1 | (0.3%) | 0 | |
| 2 型糖尿病 | 1 | (0.3%) | 2 | (0.5%) |
| 耐糖能障害 | 0 | | 1 | (0.3%) |
| 高カルシウム血症 | 0 | | 1 | (0.3%) |
| 高カリウム血症 | 0 | | 1 | (0.3%) |
| 高脂血症 | 0 | | 1 | (0.3%) |
| 高ナトリウム血症 | 0 | | 1 | (0.3%) |
| 無機質欠乏 | 0 | | 1 | (0.3%) |
| 過体重 | 0 | | 1 | (0.3%) |
| 1 型糖尿病 | 0 | | 1 | (0.3%) |
| 筋骨格系および結合組織障害 | 104 | (26.5%) | 78 | (20.1%) |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 21）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 筋痙縮 | 72 (18.4%) | 54 (13.9%) |
| 筋力低下 | 22 (5.6%) | 15 (3.9%) |
| 関節痛 | 11 (2.8%) | 6 (1.5%) |
| 四肢痛 | 11 (2.8%) | 4 (1.0%) |
| 筋肉痛 | 6 (1.5%) | 7 (1.8%) |
| ミオパチー | 6 (1.5%) | 2 (0.5%) |
| 骨痛 | 5 (1.3%) | 0 |
| 重感 | 3 (0.8%) | 0 |
| 背部痛 | 2 (0.5%) | 2 (0.5%) |
| 変形性関節症 | 2 (0.5%) | 0 |
| 関節炎 | 1 (0.3%) | 0 |
| 鼡径部痛 | 1 (0.3%) | 0 |
| 関節滲出液 | 1 (0.3%) | 0 |
| 関節腫脹 | 1 (0.3%) | 1 (0.3%) |
| 筋拘縮 | 1 (0.3%) | 0 |
| 筋骨格系胸痛 | 1 (0.3%) | 1 (0.3%) |
| 筋骨格痛 | 1 (0.3%) | 1 (0.3%) |
| 筋骨格硬直 | 1 (0.3%) | 1 (0.3%) |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 22）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 頚部痛 | 1 | (0.3%) | 0 | |
| 骨壊死 | 1 | (0.3%) | 1 | (0.3%) |
| 肩回旋筋腱板症候群 | 1 | (0.3%) | 0 | |
| 腱障害 | 1 | (0.3%) | 0 | |
| 側腹部痛 | 0 | | 1 | (0.3%) |
| 単関節炎 | 0 | | 1 | (0.3%) |
| 筋固縮 | 0 | | 1 | (0.3%) |
| 顎痛 | 0 | | 1 | (0.3%) |
| 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） | 9 | (2.3%) | 7 | (1.8%) |
| 急性骨髄性白血病 | 2 | (0.5%) | 1 | (0.3%) |
| 基底細胞癌 | 2 | (0.5%) | 1 | (0.3%) |
| 結腸癌 | 1 | (0.3%) | 0 | |
| 骨髄異形成症候群 | 1 | (0.3%) | 2 | (0.5%) |
| 転移性膵癌 | 1 | (0.3%) | 0 | |
| 膵新生物 | 1 | (0.3%) | 0 | |
| 良性副甲状腺腫瘍 | 1 | (0.3%) | 0 | |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 23）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 扁平上皮癌 | 1 (0.3%) | 1 (0.3%) |
| 小脳橋角部腫瘍 | 0 | 1 (0.3%) |
| 皮膚乳頭腫 | 0 | 1 (0.3%) |
| 皮膚有棘細胞癌 | 0 | 1 (0.3%) |
| 神経系障害 | 115 (29.3%) | 113 (29.0%) |
| 浮動性めまい | 24 (6.1%) | 21 (5.4%) |
| 末梢性ニューロパチー | 20 (5.1%) | 20 (5.1%) |
| 振戦 | 20 (5.1%) | 27 (6.9%) |
| 頭痛 | 19 (4.8%) | 10 (2.6%) |
| 末梢性感覚ニューロパチー | 18 (4.6%) | 17 (4.4%) |
| 錯感覚 | 16 (4.1%) | 16 (4.1%) |
| 多発ニューロパチー | 13 (3.3%) | 8 (2.1%) |
| 味覚異常 | 11 (2.8%) | 15 (3.9%) |
| 感覚鈍麻 | 8 (2.0%) | 4 (1.0%) |
| 記憶障害 | 5 (1.3%) | 1 (0.3%) |
| 傾眠 | 5 (1.3%) | 1 (0.3%) |
| 注意力障害 | 3 (0.8%) | 0 |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 24）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 異常感覚 | 3 (0.8%) | 1 (0.3%) |
| 灼熱感 | 2 (0.5%) | 2 (0.5%) |
| 認知障害 | 2 (0.5%) | 1 (0.3%) |
| 味覚消失 | 1 (0.3%) | 3 (0.8%) |
| 無嗅覚 | 1 (0.3%) | 2 (0.5%) |
| 失声症 | 1 (0.3%) | 1 (0.3%) |
| 反射消失 | 1 (0.3%) | 0 |
| 馬尾症候群 | 1 (0.3%) | 0 |
| 脳血管発作 | 1 (0.3%) | 4 (1.0%) |
| 体位性めまい | 1 (0.3%) | 0 |
| 本態性振戦 | 1 (0.3%) | 0 |
| 頭蓋内出血 | 1 (0.3%) | 0 |
| 筋緊張亢進 | 1 (0.3%) | 0 |
| 神経痛 | 1 (0.3%) | 6 (1.5%) |
| 不全対麻痺 | 1 (0.3%) | 0 |
| 精神運動亢進 | 1 (0.3%) | 1 (0.3%) |
| 下肢静止不能症候群 | 1 (0.3%) | 0 |
| 失神 | 1 (0.3%) | 5 (1.3%) |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 25）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 中毒性ニューロパチー | 1 (0.3%) | 0 |
| 健忘 | 0 | 3 (0.8%) |
| 運動失調 | 0 | 1 (0.3%) |
| 自律神経ニューロパチー | 0 | 1 (0.3%) |
| 認知症 | 0 | 1 (0.3%) |
| 知覚過敏 | 0 | 2 (0.5%) |
| 過眠症 | 0 | 1 (0.3%) |
| 味覚減退 | 0 | 1 (0.3%) |
| 精神的機能障害 | 0 | 1 (0.3%) |
| 粘液水腫性昏睡 | 0 | 1 (0.3%) |
| 嗅覚錯誤 | 0 | 1 (0.3%) |
| 末梢性運動ニューロパチー | 0 | 2 (0.5%) |
| 鎮静 | 0 | 1 (0.3%) |
| 一過性脳虚血発作 | 0 | 2 (0.5%) |
| 精神障害 | 85 (21.7%) | 75 (19.3%) |
| 不眠症 | 56 (14.3%) | 46 (11.8%) |
| 不安 | 11 (2.8%) | 8 (2.1%) |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 26）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| うつ病 | 9 | (2.3%) | 4 | (1.0%) |
| 激越 | 8 | (2.0%) | 9 | (2.3%) |
| 気分変化 | 8 | (2.0%) | 12 | (3.1%) |
| 落ち着きのなさ | 8 | (2.0%) | 1 | (0.3%) |
| 錯乱状態 | 4 | (1.0%) | 6 | (1.5%) |
| 失見当識 | 3 | (0.8%) | 0 | |
| 睡眠障害 | 3 | (0.8%) | 4 | (1.0%) |
| 神経過敏 | 2 | (0.5%) | 5 | (1.3%) |
| 異常行動 | 1 | (0.3%) | 0 | |
| 感情障害 | 1 | (0.3%) | 0 | |
| 抑うつ気分 | 1 | (0.3%) | 1 | (0.3%) |
| 転導性 | 1 | (0.3%) | 0 | |
| 多幸気分 | 1 | (0.3%) | 0 | |
| 表出性言語障害 | 1 | (0.3%) | 0 | |
| リビドー亢進 | 1 | (0.3%) | 0 | |
| 躁病 | 1 | (0.3%) | 1 | (0.3%) |
| 気分動揺 | 1 | (0.3%) | 3 | (0.8%) |
| 人格変化 | 1 | (0.3%) | 0 | |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 27）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 精神的機能代償不全 | 1 | (0.3%) | 0 | |
| 精神病性障害 | 1 | (0.3%) | 0 | |
| 攻撃性 | 0 | | 1 | (0.3%) |
| 怒り | 0 | | 1 | (0.3%) |
| 腎および尿路障害 | 13 | (3.3%) | 16 | (4.1%) |
| 急性腎不全 | 4 | (1.0%) | 1 | (0.3%) |
| 腎機能障害 | 4 | (1.0%) | 7 | (1.8%) |
| 腎不全 | 3 | (0.8%) | 3 | (0.8%) |
| 高窒素血症 | 1 | (0.3%) | 1 | (0.3%) |
| 夜間頻尿 | 1 | (0.3%) | 0 | |
| 慢性腎不全 | 1 | (0.3%) | 1 | (0.3%) |
| 排尿困難 | 0 | | 1 | (0.3%) |
| 中毒性ネフロパシー | 0 | | 1 | (0.3%) |
| 頻尿 | 0 | | 1 | (0.3%) |
| 多尿 | 0 | | 1 | (0.3%) |
| 有痛性排尿困難 | 0 | | 1 | (0.3%) |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 28）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 生殖系および乳房障害 | 5 (1.3%) | 1 (0.3%) |
| 勃起不全 | 3 (0.8%) | 0 |
| 精巣上体炎 | 1 (0.3%) | 0 |
| 骨盤痛 | 1 (0.3%) | 0 |
| 前立腺炎 | 1 (0.3%) | 0 |
| 外陰膣乾燥 | 0 | 1 (0.3%) |
| 呼吸器、胸郭および縦隔障害 | 90 (23.0%) | 54 (13.9%) |
| 呼吸困難 | 28 (7.1%) | 17 (4.4%) |
| 咳嗽 | 13 (3.3%) | 10 (2.6%) |
| 労作性呼吸困難 | 13 (3.3%) | 5 (1.3%) |
| 発声障害 | 11 (2.8%) | 7 (1.8%) |
| 肺塞栓症 | 11 (2.8%) | 8 (2.1%) |
| しゃっくり | 7 (1.8%) | 3 (0.8%) |
| 鼻出血 | 6 (1.5%) | 2 (0.5%) |
| 口腔咽頭痛 | 6 (1.5%) | 8 (2.1%) |
| 湿性咳嗽 | 3 (0.8%) | 3 (0.8%) |
| 肺水腫 | 3 (0.8%) | 0 |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 29）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 肺障害 | 2 (0.5%) | 1 (0.3%) |
| 呼吸不全 | 2 (0.5%) | 3 (0.8%) |
| 慢性閉塞性肺疾患 | 1 (0.3%) | 0 |
| 好酸球性肺炎 | 1 (0.3%) | 0 |
| 喀血 | 1 (0.3%) | 0 |
| 低酸素症 | 1 (0.3%) | 0 |
| 間質性肺疾患 | 1 (0.3%) | 1 (0.3%) |
| 鼻閉 | 1 (0.3%) | 0 |
| 胸膜障害 | 1 (0.3%) | 0 |
| 胸水 | 1 (0.3%) | 1 (0.3%) |
| 肺臓炎 | 1 (0.3%) | 1 (0.3%) |
| 頻呼吸 | 1 (0.3%) | 0 |
| 咽喉絞扼感 | 1 (0.3%) | 0 |
| 鼻粘膜障害 | 0 | 1 (0.3%) |
| ラ音 | 0 | 1 (0.3%) |
| 鼻漏 | 0 | 5 (1.3%) |
| 副鼻腔うっ血 | 0 | 1 (0.3%) |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 30）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 皮膚および皮下組織障害 | 87 (22.2%) | 78 (20.1%) |
| 発疹 | 25 (6.4%) | 34 (8.7%) |
| 紅斑 | 14 (3.6%) | 8 (2.1%) |
| そう痒症 | 14 (3.6%) | 6 (1.5%) |
| 多汗症 | 11 (2.8%) | 10 (2.6%) |
| 斑状丘疹状皮疹 | 8 (2.0%) | 7 (1.8%) |
| 皮膚乾燥 | 5 (1.3%) | 10 (2.6%) |
| 脱毛症 | 3 (0.8%) | 3 (0.8%) |
| 寝汗 | 3 (0.8%) | 7 (1.8%) |
| 紅斑性皮疹 | 3 (0.8%) | 2 (0.5%) |
| 紅色症 | 2 (0.5%) | 0 |
| 全身性皮疹 | 2 (0.5%) | 1 (0.3%) |
| 皮膚剥脱 | 2 (0.5%) | 0 |
| 皮膚毒性 | 2 (0.5%) | 0 |
| 顔面腫脹 | 2 (0.5%) | 0 |
| 蕁麻疹 | 2 (0.5%) | 1 (0.3%) |
| 日光性角化症 | 1 (0.3%) | 0 |
| 急性熱性好中球性皮膚症 | 1 (0.3%) | 0 |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 31）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 皮膚炎 | 1 (0.3%) | 1 (0.3%) |
| 斑状出血 | 1 (0.3%) | 0 |
| 毛髪成長異常 | 1 (0.3%) | 1 (0.3%) |
| 男性型多毛症 | 1 (0.3%) | 1 (0.3%) |
| 多毛症 | 1 (0.3%) | 1 (0.3%) |
| 内出血発生の増加傾向 | 1 (0.3%) | 3 (0.8%) |
| 間擦疹 | 1 (0.3%) | 0 |
| 機械性蕁麻疹 | 1 (0.3%) | 0 |
| 爪床障害 | 1 (0.3%) | 0 |
| 爪破損 | 1 (0.3%) | 1 (0.3%) |
| 手掌・足底発赤知覚不全症候群 | 1 (0.3%) | 0 |
| 点状出血 | 1 (0.3%) | 0 |
| アレルギー性そう痒症 | 1 (0.3%) | 0 |
| 全身性そう痒症 | 1 (0.3%) | 1 (0.3%) |
| そう痒性皮疹 | 1 (0.3%) | 2 (0.5%) |
| 脂漏性皮膚炎 | 1 (0.3%) | 0 |
| 皮膚変色 | 1 (0.3%) | 1 (0.3%) |
| 皮膚色素過剰 | 1 (0.3%) | 0 |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 32）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 血管性紫斑病 | 1 (0.3%) | 0 |
| ざ瘡 | 0 | 1 (0.3%) |
| 急性汎発性発疹性膿疱症 | 0 | 1 (0.3%) |
| 血管浮腫 | 0 | 2 (0.5%) |
| ざ瘡様皮膚炎 | 0 | 1 (0.3%) |
| アレルギー性皮膚炎 | 0 | 1 (0.3%) |
| 汗腺炎 | 0 | 1 (0.3%) |
| 過角化 | 0 | 1 (0.3%) |
| 爪の障害 | 0 | 1 (0.3%) |
| 丘疹性皮疹 | 0 | 1 (0.3%) |
| 皮膚萎縮 | 0 | 1 (0.3%) |
| 皮膚亀裂 | 0 | 1 (0.3%) |
| 皮膚腫脹 | 0 | 1 (0.3%) |
| 皮膚のつっぱり感 | 0 | 1 (0.3%) |
| 血管障害 | 91 (23.2%) | 47 (12.1%) |
| 高血圧 | 24 (6.1%) | 10 (2.6%) |
| 深部静脈血栓症 | 22 (5.6%) | 14 (3.6%) |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 33）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | | Rd<br>(N=389) | |
|---|---|---|---|---|
| 潮紅 | 9 | (2.3%) | 3 | (0.8%) |
| ほてり | 8 | (2.0%) | 1 | (0.3%) |
| 低血圧 | 7 | (1.8%) | 4 | (1.0%) |
| 表在性血栓性静脈炎 | 7 | (1.8%) | 4 | (1.0%) |
| 静脈炎 | 5 | (1.3%) | 0 | |
| 血栓性静脈炎 | 5 | (1.3%) | 3 | (0.8%) |
| 血栓症 | 5 | (1.3%) | 4 | (1.0%) |
| 四肢静脈血栓症 | 4 | (1.0%) | 0 | |
| 塞栓症 | 3 | (0.8%) | 1 | (0.3%) |
| 起立性低血圧 | 2 | (0.5%) | 1 | (0.3%) |
| 表在性静脈炎 | 2 | (0.5%) | 0 | |
| リンパ浮腫 | 1 | (0.3%) | 0 | |
| 血栓後症候群 | 1 | (0.3%) | 0 | |
| 静脈血栓症 | 1 | (0.3%) | 3 | (0.8%) |
| 血圧変動 | 0 | | 1 | (0.3%) |
| 血腫 | 0 | | 2 | (0.5%) |
| 高血圧クリーゼ | 0 | | 1 | (0.3%) |
| 骨盤静脈血栓症 | 0 | | 1 | (0.3%) |

**表 2.7.6.18.2-5　治験薬との因果関係が否定できない有害事象の MedDRA SOC，PT 別発現頻度（安全性解析対象集団）（PX-171-009）（続き 34）**

| System Organ Class<br>Preferred Term | CRd<br>(N=392) | Rd<br>(N=389) |
|---|---|---|
| 血管炎 | 0 | 1 (0.3%) |
| Uncoded | 0 | 1 (0.3%) |
| Feeling of Preposession | 0 | 1 (0.3%) |

CRd = Carfilzomib/Revlimid (lenalidomide)/dexamethasone arm; Rd = Revlimid (lenalidomide)/dexamethasone arm.
Notes: MedDRA version 15.1 was used for coding.
Treatment-related adverse events are adverse events considered related to at least one study drug by investigator, including those with missing relationship.
Subjects were counted only once for each System Organ Class and each Preferred Term.
出典［総括報告書 5.3.5.1-1（PX-171-009），Table 14.3.3.1］