A summary of subject disposition for all treated subjects is provided in Table 1. In the 16 mg/kg group, 90 of 106 subjects (85%) discontinued treatment; the majority of treatment discontinuations (82 subjects; 77%) were due to progressive disease. Five subjects (5%) discontinued from treatment due to a TEAE.

| Table : Subject Disposition - Treatment; All Treated Analysis Set (Study 54767414MMY2002) | | | |
| --- | --- | --- | --- |
|  | 8 mg/kg | 16 mg/kg | Total |
| Analysis set: all treated | 18 | 106 | 124 |
| **Discontinued from treatment** | **16 (88.9%)** | **90 (84.9%)** | **106 (85.5%)** |
| Progressive disease | 16 (88.9%) | 82 (77.4%) | 98 (79.0%) |
| Adverse event | 0 | 5 (4.7%) | 5 (4.0%) |
| Withdrawal of consent | 0 | 3 (2.8%) | 3 (2.4%) |
| Death | 0 | 0 | 0 |
| Percentages are calculated with the number of subjects in each group as denominator. | | | |
| Modified from Attachment TSIDS01 | | | |

The median age of all treated subjects was 64 years, and 52% were male. Most (82%) subjects were white, 12% of subjects were black or African American.

In the 16 mg/kg group the median age was 63.5 years; 51% of subjects were female. Most subjects (79%) were white, and 14% were black or African American. A baseline ECOG performance status score of 1 was reported for 65% of subjects and a score of 2 was reported for 8% of subjects.

| Table : Demographics; All Treated Analysis Set (Study 54767414MMY2002) | | | | | |
| --- | --- | --- | --- | --- | --- |
|  | | 16 mg/kg | | |  |
|  | 8 mg/kg | Part 1 | Part 2 | Total | Total |
| Analysis set: all treated | 18 | 41 | 65 | 106 | 124 |
|  |  |  |  |  |  |
| Age (years) |  |  |  |  |  |
| N | 18 | 41 | 65 | 106 | 124 |
| Category, n (%) |  |  |  |  |  |
| 18 - < 65 | 8 (44.4%) | 23 (56.1%) | 35 (53.8%) | 58 (54.7%) | 66 (53.2%) |
| 65 - < 75 | 8 (44.4%) | 13 (31.7%) | 23 (35.4%) | 36 (34.0%) | 44 (35.5%) |
| ≥ 75 | 2 (11.1%) | 5 (12.2%) | 7 (10.8%) | 12 (11.3%) | 14 (11.3%) |
| Mean (SD) | 64.2 (7.72) | 62.6 (10.39) | 63.1 (9.82) | 62.9 (10.00) | 63.1 (9.68) |
| Median | 65.5 | 63.0 | 64.0 | 63.5 | 64.0 |
| Range | (49; 76) | (31; 84) | (32; 84) | (31; 84) | (31; 84) |
|  |  |  |  |  |  |
| Sex, n (%) |  |  |  |  |  |
| N | 18 | 41 | 65 | 106 | 124 |
| Male | 12 (66.7%) | 25 (61.0%) | 27 (41.5%) | 52 (49.1%) | 64 (51.6%) |
| Female | 6 (33.3%) | 16 (39.0%) | 38 (58.5%) | 54 (50.9%) | 60 (48.4%) |
|  |  |  |  |  |  |
| Race, n (%) |  |  |  |  |  |
| N | 18 | 41 | 65 | 106 | 124 |
| White | 17 (94.4%) | 33 (80.5%) | 51 (78.5%) | 84 (79.2%) | 101 (81.5%) |
| Black or African American | 0 | 4 (9.8%) | 11 (16.9%) | 15 (14.2%) | 15 (12.1%) |
| Asian | 0 | 1 (2.4%) | 3 (4.6%) | 4 (3.8%) | 4 (3.2%) |
| Other | 0 | 1 (2.4%) | 0 | 1 (0.9%) | 1 (0.8%) |
| Unknown | 0 | 1 (2.4%) | 0 | 1 (0.9%) | 1 (0.8%) |
| Not reported | 1 (5.6%) | 1 (2.4%) | 0 | 1 (0.9%) | 2 (1.6%) |
|  |  |  |  |  |  |
| Height (cm) |  |  |  |  |  |
| N | 18 | 40 | 64 | 104 | 122 |
| Mean (SD) | 168.44 (15.366) | 170.75 (9.449) | 165.70 (10.858) | 167.64 (10.584) | 167.76 (11.341) |
| Median | 167.55 | 171.35 | 165.05 | 167.60 | 167.60 |
| Range | (137.4; 198.0) | (152.0; 190.5) | (139.0; 196.0) | (139.0; 196.0) | (137.4; 198.0) |
|  |  |  |  |  |  |
| Weight (kg) |  |  |  |  |  |
| N | 18 | 41 | 65 | 106 | 124 |
| Mean (SD) | 81.95 (28.290) | 78.42 (17.505) | 74.09 (19.731) | 75.77 (18.935) | 76.66 (20.529) |
| Median | 78.80 | 78.00 | 73.00 | 75.50 | 76.00 |
| Range | (46.2; 160.2) | (41.0; 116.0) | (38.4; 140.0) | (38.4; 140.0) | (38.4; 160.2) |
|  |  |  |  |  |  |
| Baseline ECOG score, n (%) |  |  |  |  |  |
| N | 18 | 41 | 65 | 106 | 124 |
| 0 | 7 (38.9%) | 9 (22.0%) | 20 (30.8%) | 29 (27.4%) | 36 (29.0%) |
| 1 | 9 (50.0%) | 30 (73.2%) | 39 (60.0%) | 69 (65.1%) | 78 (62.9%) |
| 2 | 2 (11.1%) | 2 (4.9%) | 6 (9.2%) | 8 (7.5%) | 10 (8.1%) |
| Percentages are calculated with the number of subjects in each group with available data as denominator. | | | | | |
| [TSIDEM01.rtf] [JNJ-54767414\MMY2002\DBR\_CSR\RE\_CSR\tsidem01.sas] 13FEB2015, 14:05 | | | | | |

In the 16 mg/kg group, 37.7% of subjects had ISS Stage II and 37.7% of subjects had ISS Stage III disease. The most frequent type of myeloma was IgG (49 subjects; 46%), IgA (22 subjects; 21%), and light chain (30 subjects; 28%).

In the 16 mg/kg group, translocation t(4,14) was reported in 9 subjects (10%) and deletion 17p13 in 16 subjects (17%).

| Table : Baseline Disease Characteristics; All Treated Analysis Set (Study 54767414MMY2002) | | | | | |
| --- | --- | --- | --- | --- | --- |
|  | | 16 mg/kg | | |  |
|  | 8 mg/kg | Part 1 | Part 2 | Total | Total |
| Analysis set: all treated | 18 | 41 | 65 | 106 | 124 |
|  |  |  |  |  |  |
| Type of myeloma by immunofixation, n (%) |  |  |  |  |  |
| N | 18 | 41 | 65 | 106 | 124 |
| IgG | 11 (61.1%) | 19 (46.3%) | 30 (46.2%) | 49 (46.2%) | 60 (48.4%) |
| IgA | 3 (16.7%) | 9 (22.0%) | 13 (20.0%) | 22 (20.8%) | 25 (20.2%) |
| IgM | 0 | 0 | 0 | 0 | 0 |
| IgD | 0 | 2 (4.9%) | 1 (1.5%) | 3 (2.8%) | 3 (2.4%) |
| IgE | 0 | 0 | 0 | 0 | 0 |
| Light chain | 4 (22.2%) | 10 (24.4%) | 20 (30.8%) | 30 (28.3%) | 34 (27.4%) |
| Kappa | 2 (11.1%) | 6 (14.6%) | 11 (16.9%) | 17 (16.0%) | 19 (15.3%) |
| Lambda | 2 (11.1%) | 4 (9.8%) | 9 (13.8%) | 13 (12.3%) | 15 (12.1%) |
| Biclonal | 0 | 0 | 0 | 0 | 0 |
| Serum free light chain onlya | 0 | 1 (2.4%) | 1 (1.5%) | 2 (1.9%) | 2 (1.6%) |
|  |  |  |  |  |  |
| ISS Staging, n (%) |  |  |  |  |  |
| N | 18 | 41 | 65 | 106 | 124 |
| I | 2 (11.1%) | 11 (26.8%) | 15 (23.1%) | 26 (24.5%) | 28 (22.6%) |
| II | 8 (44.4%) | 17 (41.5%) | 23 (35.4%) | 40 (37.7%) | 48 (38.7%) |
| III | 8 (44.4%) | 13 (31.7%) | 27 (41.5%) | 40 (37.7%) | 48 (38.7%) |
|  |  |  |  |  |  |
| Cytogenetics profileb |  |  |  |  |  |
| Nc | 17 | 37 | 58 | 95 | 112 |
| T (4; 14) | 2 (11.8%) | 3 (8.1%) | 6 (10.3%) | 9 (9.5%) | 11 (9.8%) |
| Del17p | 6 (35.3%) | 4 (10.8%) | 12 (20.7%) | 16 (16.8%) | 22 (19.6%) |
| Del13q | 4 (23.5%) | 15 (40.5%) | 15 (25.9%) | 30 (31.6%) | 34 (30.4%) |
| Amp1q21 | 3 (17.6%) | 7 (18.9%) | 16 (27.6%) | 23 (24.2%) | 26 (23.2%) |
| Otherd | 5 (29.4%) | 17 (45.9%) | 26 (44.8%) | 43 (45.3%) | 48 (42.9%) |
|  |  |  |  |  |  |
| Number of lines of prior therapy, n (%) |  |  |  |  |  |
| N | 18 | 41 | 65 | 106 | 124 |
| ≤ 3 Lines | 6 (33.3%) | 8 (19.5%) | 11 (16.9%) | 19 (17.9%) | 25 (20.2%) |
| > 3 Lines | 12 (66.7%) | 33 (80.5%) | 54 (83.1%) | 87 (82.1%) | 99 (79.8%) |
| Mean (SD) | 5.1 (2.35) | 5.3 (2.10) | 5.7 (2.50) | 5.6 (2.35) | 5.5 (2.35) |
| Median | 5.0 | 5.0 | 5.0 | 5.0 | 5.0 |
| Range | (2; 11) | (2; 11) | (2; 14) | (2; 14) | (2; 14) |
|  |  |  |  |  |  |
| Percentages are calculated with the number of subjects in each group with available data as denominator.  anot detected by immunofixation, serum free light chain only.  bCytogenetic abnormalities were detected by FISH and/or karyotyping.  cOnly includes all subjects with cytogenetics data available.  dIncludes other types of abnormality or normal result. Note: For bone marrow % plasma cells, the maximum value from either biopsy or aspirate at baseline is summarized. | | | | | |
| Modified from Attachment TSIDEM02 | | | | | |

A summary of prior multiple myeloma therapy for all treated subjects is provided in Table 4. In the 16 mg/kg group, median number of prior lines of therapy was 5; 82% of subjects had >3 prior lines of therapy (Table 4). All subjects (100%) received prior PI and IMiD. Eighty-five subjects (80%) had a prior ASCT. All except 1 (99%) subject received prior bortezomib.

| Table : Type of Prior Multiple Myeloma Therapy; All Treated Analysis Set (Study 54767414MMY2002) | | | | | |
| --- | --- | --- | --- | --- | --- |
|  | | 16 mg/kg | | |  |
|  | 8 mg/kg | Part 1 | Part 2 | Total | Total |
| Analysis set: all treated | 18 | 41 | 65 | 106 | 124 |
| Number of lines of prior therapy, n (%) |  |  |  |  |  |
| ≤ 3 | 6 (33.3%) | 8 (19.5%) | 11 (16.9%) | 19 (17.9%) | 25 (20.2%) |
| > 3 | 12 (66.7%) | 33 (80.5%) | 54 (83.1%) | 87 (82.1%) | 99 (79.8%) |
| Mean (SD) | 5.1 (2.35) | 5.3 (2.10) | 5.7 (2.50) | 5.6 (2.35) | 5.5 (2.35) |
| Median | 5.0 | 5.0 | 5.0 | 5.0 | 5.0 |
| Range | (2; 11) | (2; 11) | (2; 14) | (2; 14) | (2; 14) |
|  |  |  |  |  |  |
| Prior PI | 18 (100.0%) | 41 (100.0%) | 65 (100.0%) | 106 (100.0%) | 124 (100.0%) |
| Bortezomib | 18 (100.0%) | 41 (100.0%) | 64 (98.5%) | 105 (99.1%) | 123 (99.2%) |
| Carfilzomib | 6 (33.3%) | 19 (46.3%) | 34 (52.3%) | 53 (50.0%) | 59 (47.6%) |
|  |  |  |  |  |  |
| Prior IMiD | 18 (100.0%) | 41 (100.0%) | 65 (100.0%) | 106 (100.0%) | 124 (100.0%) |
| Lenalidomide | 18 (100.0%) | 41 (100.0%) | 64 (98.5%) | 105 (99.1%) | 123 (99.2%) |
| Pomalidomide | 9 (50.0%) | 26 (63.4%) | 41 (63.1%) | 67 (63.2%) | 76 (61.3%) |
| Thalidomide | 6 (33.3%) | 14 (34.1%) | 33 (50.8%) | 47 (44.3%) | 53 (42.7%) |
|  |  |  |  |  |  |
| Prior PI+IMiDa | 18 (100.0%) | 41 (100.0%) | 65 (100.0%) | 106 (100.0%) | 124 (100.0%) |
| Prior PI+IMiD+ALKYa | 18 (100.0%) | 41 (100.0%) | 65 (100.0%) | 106 (100.0%) | 124 (100.0%) |
| Prior BORT+LENa | 18 (100.0%) | 41 (100.0%) | 63 (96.9%) | 104 (98.1%) | 122 (98.4%) |
| Prior CARF+POMa | 3 (16.7%) | 15 (36.6%) | 24 (36.9%) | 39 (36.8%) | 42 (33.9%) |
| Prior BORT+LEN+CARFa | 6 (33.3%) | 19 (46.3%) | 33 (50.8%) | 52 (49.1%) | 58 (46.8%) |
| Prior BORT+LEN+POMa | 9 (50.0%) | 26 (63.4%) | 41 (63.1%) | 67 (63.2%) | 76 (61.3%) |
| Prior BORT+LEN+CARF+POMa | 3 (16.7%) | 15 (36.6%) | 24 (36.9%) | 39 (36.8%) | 42 (33.9%) |
| Prior BORT+LEN+CARF+POM+THALa | 3 (16.7%) | 6 (14.6%) | 12 (18.5%) | 18 (17.0%) | 21 (16.9%) |
|  |  |  |  |  |  |
| Prior steroids | 18 (100.0%) | 41 (100.0%) | 65 (100.0%) | 106 (100.0%) | 124 (100.0%) |
| Dexamethasone | 18 (100.0%) | 41 (100.0%) | 65 (100.0%) | 106 (100.0%) | 124 (100.0%) |
| Prednisone | 7 (38.9%) | 10 (24.4%) | 29 (44.6%) | 39 (36.8%) | 46 (37.1%) |
|  |  |  |  |  |  |
| Prior chemotherapy | 18 (100.0%) | 41 (100.0%) | 65 (100.0%) | 106 (100.0%) | 124 (100.0%) |
| Alkylating agentsb | 18 (100.0%) | 41 (100.0%) | 65 (100.0%) | 106 (100.0%) | 124 (100.0%) |
| Anthracyclines | 12 (66.7%) | 16 (39.0%) | 39 (60.0%) | 55 (51.9%) | 67 (54.0%) |
|  |  |  |  |  |  |
| Prior ASCT | 17 (94.4%) | 34 (82.9%) | 51 (78.5%) | 85 (80.2%) | 102 (82.3%) |
|  |  |  |  |  |  |
| Prior radiotherapy | 3 (16.7%) | 18 (43.9%) | 19 (29.2%) | 37 (34.9%) | 40 (32.3%) |
| Keys: PI = proteasome inhibitor; IMiD = Immunomodulatory drug; ASCT = autologous stem cell transplant; BORT = bortezomib; LEN = lenalidomide; CARF = carfilzomib; POM = pomalidomide; THAL = thalidomide; ALKY = alkylating agents, including autologous stem cell transplant.  a Subject may have received these agents in different treatment regimens.  bIncludes either alkylating agents or autologous stem cell transplant. Note: PI includes bortezomib, carfilzomib, MLN9708, marizomib, and oprozomib; IMiD includes thalidomide, lenalidomide, and pomalidomide. Percentages are calculated with the number of subjects in each group as denominator. | | | | | |
| Modified from Attachment TSIPM01 | | | | | |

For subjects in both treatment groups, the median hemoglobin laboratory value at baseline was 100 g/L (16 mg/kg group: 99.5 g/L). For subjects in both treatment groups, the median platelet count at baseline was 149.5 x109/L (16 mg/kg group: 154.0 x109/L).

| Table : Disease-related Laboratory Values at Baseline; All Treated Analysis Set (Study 54767414MMY2002) | | | |
| --- | --- | --- | --- |
|  | 8 mg/kg | 16 mg/kg | Total |
| Analysis set: all treated | 18 | 106 | 124 |
| Hemoglobin (g/L) |  |  |  |
| N | 18 | 106 | 124 |
| Category, n (%) |  |  |  |
| <80 | 1 (5.6%) | 8 (7.5%) | 9 (7.3%) |
| 80 - 100 | 7 (38.9%) | 47 (44.3%) | 54 (43.5%) |
| >100 | 10 (55.6%) | 51 (48.1%) | 61 (49.2%) |
| Mean (SD) | 102.17 (15.648) | 100.92 (15.483) | 101.10 (15.449) |
| Median | 104.50 | 99.50 | 100.00 |
| Range | (71.0; 129.0) | (62.0; 139.0) | (62.0; 139.0) |
| Platelet count (10^9/L) |  |  |  |
| N | 18 | 106 | 124 |
| Category, n (%) |  |  |  |
| < 75 | 5 (27.8%) | 7 (6.6%) | 12 (9.7%) |
| ≥ 75 | 13 (72.2%) | 99 (93.4%) | 112 (90.3%) |
| Mean (SD) | 130.28 (60.076) | 161.10 (71.983) | 156.63 (70.999) |
| Median | 123.50 | 154.00 | 149.50 |
| Range | (29.0; 248.0) | (37.0; 454.0) | (29.0; 454.0) |
| Calcium (mmol/L) |  |  |  |
| N | 18 | 106 | 124 |
| Category, n (%) |  |  |  |
| > ULN | 0 | 15 (14.2%) | 15 (12.1%) |
| ≤ ULN | 18 (100.0%) | 91 (85.8%) | 109 (87.9%) |
| Mean (SD) | 2.32 (0.108) | 2.37 (0.216) | 2.37 (0.204) |
| Median | 2.32 | 2.32 | 2.32 |
| Range | (2.1; 2.5) | (1.9; 3.1) | (1.9; 3.1) |
| Keys: ULN = upper limit normal. Percentages are calculated with the number of subjects in each group with available data as denominator. | | | |
| [TSILB01.rtf] [JNJ-54767414\MMY2002\DBR\_CSR\RE\_CSR\tsilb01.sas] 13FEB2015, 14:11 | | | |

Major protocol deviations based on sponsor medical review are presented in Table 6. Eleven subjects (9%) had major protocol deviations. Seven (6%) subjects entered the study but did not satisfy the inclusion/exclusion criteria (see brief narratives below). Three subjects (2%) received wrong treatment. One subject, in the 16 mg/kg group was considered to have had a major protocol deviation captured as “other” for not having an ECG completed at screening.

| Table : Subjects with Major Protocol Deviation; All Treated Analysis Set (Study 54767414MMY2002) | | | |
| --- | --- | --- | --- |
|  | 8 mg/kg | 16 mg/kg | Total |
| Analysis set: all treated | 18 | 106 | 124 |
|  |  |  |  |
| **Subjects with major protocol deviation** | **2 (11.1%)** | **9 (8.5%)** | **11 (8.9%)** |
| Received wrong treatment or incorrect dose | 0 | 3 (2.8%) | 3 (2.4%) |
| Received a disallowed concomitant treatment | 0 | 0 | 0 |
| Entered but did not satisfy criteria | 2 (11.1%) | 5 (4.7%) | 7 (5.6%) |
| Developed withdrawal criteria but not withdrawn | 0 | 0 | 0 |
| Efficacy assessment deviation | 0 | 0 | 0 |
| Safety assessment deviation | 0 | 0 | 0 |
| Other\* | 0 | 1 (0.9%) | 1 (0.8%) |
| \* Screening ECG was not done for this subject.  Percentages are calculated with the number of subjects in each group as denominator. | | | |
| Modified from Attachment TSIPD01 | | | |

As of the clinical cut-off date, the median duration of treatment for the 16 mg/kg group was 2.8 months, with the longest treatment duration being 14.2 months (Table 7). The median number of treatment cycles received was 4.0 cycles (1 cycle = 28 days). Forty subjects (38%) received at least 6 cycles of daratumumab treatment. For all treated subjects, the median relative dose intensity was 100% of the target dose for both treatment groups (8 and 16 mg/kg).

| Table : Daratumumab Infusions; All Treated Analysis Set (Study 54767414MMY2002) | | | |
| --- | --- | --- | --- |
|  | 8 mg/kg | 16 mg/kg | Total |
| Analysis set: all treated | 18 | 106 | 124 |
|  |  |  |  |
| Duration of treatment (months) |  |  |  |
| N | 18 | 106 | 124 |
| Mean (SD) | 3.745 (4.5922) | 4.252 (3.3556) | 4.178 (3.5439) |
| Median | 1.873 | 2.825 | 2.793 |
| Range | (0.03; 13.90) | (0.03; 14.19) | (0.03; 14.19) |
|  |  |  |  |
| Number of treatment cycles |  |  |  |
| N | 18 | 106 | 124 |
| At least 1 cycle | 18 (100.0%) | 106 (100.0%) | 124 (100.0%) |
| At least 2 cycles | 16 (88.9%) | 96 (90.6%) | 112 (90.3%) |
| At least 3 cycles | 10 (55.6%) | 79 (74.5%) | 89 (71.8%) |
| At least 4 cycles | 8 (44.4%) | 61 (57.5%) | 69 (55.6%) |
| At least 5 cycles | 4 (22.2%) | 45 (42.5%) | 49 (39.5%) |
| At least 6 cycles | 4 (22.2%) | 40 (37.7%) | 44 (35.5%) |
| At least 7 cycles | 4 (22.2%) | 34 (32.1%) | 38 (30.6%) |
| Mean (SD) | 5.0 (4.95) | 5.3 (3.73) | 5.3 (3.91) |
| Median | 3.0 | 4.0 | 4.0 |
| Range | (1; 16) | (1; 16) | (1; 16) |
|  |  |  |  |
| Total dose received (mg/kg) |  |  |  |
| N | 18 | 106 | 124 |
| Mean (SD) | 51.96 (65.056) | 198.63 (97.009) | 177.34 (106.346) |
| Median | 24.26 | 176.01 | 163.33 |
| Range | (7.7; 216.1) | (1.9; 416.8) | (1.9; 416.8) |
|  |  |  |  |
| Total number of Daratumumab infusions |  |  |  |
| N | 18 | 106 | 124 |
| Mean (SD) | 5.2 (5.23) | 12.4 (6.06) | 11.4 (6.46) |
| Median | 3.0 | 11.0 | 11.0 |
| Range | (1; 16) | (1; 26) | (1; 26) |
|  |  |  |  |
| Relative dose intensity (%) |  |  |  |
| N | 18 | 106 | 124 |
| Mean (SD) | 97.48 (9.995) | 99.15 (8.669) | 98.90 (8.849) |
| Median | 99.96 | 100.02 | 100.01 |
| Range | (58.1; 103.6) | (11.7; 103.5) | (11.7; 103.6) |
| Note: 3 subjects in the 8 mg/kg group crossed to the 16 mg/kg group and results for these 3 subjects are included in the 8 mg/kg treatment group. Percentages are calculated with the number of subjects in each group as denominator. A subject is considered as treated in a cycle if he/she received any nonzero dose of Daratumumab in that cycle. | | | |
| Modified from Attachment TSIEXP01 | | | |

Table 8 summarizes treatment modifications including incidence and reasons for all treated subjects. In the 16 mg/kg dose group, 19 subjects (18%) experienced a cycle delay; delays for 11 subjects (10%) were due to an AE. Ten (9%) subjects had dose delays attributed to “other” (eg, various IV administration issues). Prior to the start of the infusion, a decision was made to skip the infusion for 12 subjects (11%), mostly due to an ongoing AE (11 subjects; 10%). During the infusion, 38 subjects (36%) had dose interruptions. Most interruptions (34 subjects; 32%) were due to an AE. The infusion rate was decreased for 11 subjects (10%), and for 10 subjects (9%), it was due to an AE.

| Table : Treatment Modification: Incidence and Reasons; All Treated Analysis Set (Study 54767414MMY2002) | | | |
| --- | --- | --- | --- |
|  | 8 mg/kg | 16 mg/kg | Total |
| Analysis set: all treated | 18 | 106 | 124 |
|  |  |  |  |
| Cycle delay | 3 (16.7%) | 19 (17.9%) | 22 (17.7%) |
| Adverse event | 2 (11.1%) | 11 (10.4%) | 13 (10.5%) |
| Other | 1 (5.6%) | 10 (9.4%) | 11 (8.9%) |
|  |  |  |  |
| Action planned prior to infusion start Infusion skipped | 1 (5.6%) | 12 (11.3%) | 13 (10.5%) |
| Adverse event | 1 (5.6%) | 11 (10.4%) | 12 (9.7%) |
| Other | 0 | 1 (0.9%) | 1 (0.8%) |
| Infusion delayed within a cycle | 1 (5.6%) | 4 (3.8%) | 5 (4.0%) |
| Adverse event | 1 (5.6%) | 4 (3.8%) | 5 (4.0%) |
| Study drug permanently discontinued | 0 | 2 (1.9%) | 2 (1.6%) |
| Adverse event | 0 | 0 | 0 |
| Other | 0 | 2 (1.9%) | 2 (1.6%) |
|  |  |  |  |
| Action taken during infusion Infusion interrupted | 7 (38.9%) | 38 (35.8%) | 45 (36.3%) |
| Adverse event | 7 (38.9%) | 34 (32.1%) | 41 (33.1%) |
| Other | 0 | 4 (3.8%) | 4 (3.2%) |
| Infusion rate decreased | 3 (16.7%) | 11 (10.4%) | 14 (11.3%) |
| Adverse event | 3 (16.7%) | 10 (9.4%) | 13 (10.5%) |
| Other | 0 | 1 (0.9%) | 1 (0.8%) |
| Infusion aborted | 1 (5.6%) | 4 (3.8%) | 5 (4.0%) |
| Adverse event | 1 (5.6%) | 3 (2.8%) | 4 (3.2%) |
| Other | 0 | 1 (0.9%) | 1 (0.8%) |
| Percentages are calculated with the number of subjects in each group as denominator. | | | |
| [TSIEXP02.rtf] [JNJ-54767414\MMY2002\DBR\_CSR\RE\_CSR\tsiexp02.sas] 13FEB2015, 14:07 | | | |