Mozobil, a hematopoietic stem cell mobilizer, is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin’s lymphoma and multiple myeloma. (1)

DOSEAGE AND ADMINISTRATION

- Initiate Mozobil treatment after the patient has received G-CSF once daily for four days. (2.1)
- Repeat Mozobil dose up to 4 consecutive days. (2.1)
- Dose based on patient weight:
  - ≤ 83 kg: 20 mg dose or select dose based on 0.24 mg/kg actual body weight. (2.1)
  - > 83 kg: select dose based on 0.24 mg/kg actual body weight. (2.1)
- Administer by subcutaneous injection approximately 11 hours prior to initiation of apheresis. (2.1)
- Renal impairment: if creatinine clearance is ≤ 50 mL/min, decrease dose by one-third to 0.16 mg/kg. (2.3)

DOSEAGE FORMS AND STRENGTHS

- Single-use vial containing 1.2 mL of a 20 mg/mL solution. (3)

REFERENCES

Full prescribing information: See full prescribing information for MOZOBIL.

INSTRUCTIONS AND USAGE

Mozobil dose has been calculated based on actual body weight in patients up to 160 kg. When the dose is reduced by one-third in patients with moderate and severe renal impairment, systemic exposure is predicted if the dose is reduced by one-third in patients with moderate and severe renal impairment. For patients with moderate renal impairment, dosing should not exceed 27 mg/day, and for patients with severe renal impairment, dosing should not exceed 40 mg/day. (2.3)

INDICATIONS AND USAGE

Mozobil is indicated for mobilization of hematopoietic stem cells for autologous transplantation in patients with non-Hodgkin's lymphoma and multiple myeloma. (1)

WARNINGS AND PRECAUTIONS

- Anaphylactic shock and serious hypersensitivity reactions have occurred. Monitor patients during and after completion of Mozobil administration. (5.1)
- Tumor cell mobilization in leukemia patients: Mozobil may mobilize leukemic cells and should not be used in leukemia patients. (5.2)
- Hematologic effects: increased circulating leukocytes and decreased platelet counts have been observed. Monitor blood cell counts and platelet counts during Mozobil use. (5.3)
- Potential for Tumor Cell Mobilization: Tumor cells may be released from marrow during HSC mobilization with Mozobil and G-CSF. Effect of reinfusion of tumor cells is unknown. (5.4)
- Splenic Rupture: Evaluate patients who report left upper abdominal and/or scapular or shoulder pain. (5.5)
- Embryo-fetal toxicity: May cause fetal harm. Advise women not to become pregnant when taking Mozobil. (5.6, 8.1)

ADVERSE REACTIONS

Most common adverse reactions (≥ 10%): diarrhea, nausea, fatigue, injection site reactions, headache, arthralgia, dizziness, and vomiting. (6)

To report Suspected Adverse Reactions, contact Genzyme Corporation at 1-877-4MOZOBIL or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

See 17 for Patient Counseling Information

Revised: 12/2017
5 WARNINGS AND PRECAUTIONS

5.1 Anaphylactic Shock and Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening with clinically significant hypotension and shock have occurred in patients receiving Mozobil [see Adverse Reactions (6.2)]. Observe patients for signs and symptoms of hypersensitivity during and after Mozobil administration. If a reaction occurs, discontinue Mozobil and institute appropriate treatment [see Adverse Reactions (6.1)].

5.2 Tumor Cell Mobilization in Leukemia Patients

For the purpose of HSC mobilization, Mozobil may cause mobilization of leukemic cells and subsequent contamination of the apheresis product. Therefore, Mozobil is not intended for HSC mobilization and harvest in patients with leukemia.

5.3 Hematologic Effects

Leukocytosis

Administration of Mozobil in conjunction with G-CSF increases circulating leukocytes as well as HSC populations. Monitor white blood cell counts during Mozobil use [see Adverse Reactions (6.1)].

Thrombocytopenia

Thrombocytopenia has been observed in patients receiving Mozobil. Monitor platelet counts in all patients who receive Mozobil and then undergo apheresis.

5.4 Potential for Tumor Cell Mobilization

When Mozobil is used in combination with G-CSF for HSC mobilization, tumor cells may be released from the marrow and subsequently collected in the leukapheresis product. The effect of potential reinfection of tumor cells has not been well-studied.

5.5 Splenic Enlargement and Rupture

Higher absolute and relative spleen weights associated with extramedullary hematopoiesis were observed following prolonged (2 to 4 weeks) daily plerixafor SC administration in rats at doses approximately 4-fold higher than the recommended human dose based on body surface area. The effect of Mozobil on spleen size in patients was not specifically evaluated in clinical studies. Cases of splenic enlarging or rupture have been reported following the administration of Mozobil in conjunction with growth factor G-CSF. Evaluate individuals receiving Mozobil in combination with G-CSF who report left upper abdominal pain and/or scapular or shoulder pain for splenic integrity.

5.6 Embryo-fetal Toxicity

Mozobil may cause fetal harm when administered to a pregnant woman. Plerixafor is teratogenic in animals. There are no adequate and well-controlled studies in pregnant women using Mozobil. Advise women of childbearing potential to avoid becoming pregnant while receiving treatment with Mozobil. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus [see Use in Specific Populations (8.1)].

6 ADVERSE REACTIONS

The following serious adverse reactions are discussed elsewhere in the labeling:

- Anaphylactic shock and hypersensitivity reactions [see Warnings and Precautions (5.1)]
- Potential for tumor cell mobilization in leukemia patients [see Warnings and Precautions (5.2)]
- Increased circulating leukocytes and decreased platelet counts [see Warnings and Precautions (5.3)]
- Potential for tumor cell mobilization [see Warnings and Precautions (5.4)]
- Splenic enlargement [see Warnings and Precautions (5.5)]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The most common adverse reactions (≥10%) reported in patients who received Mozobil in conjunction with G-CSF regardless of causality and more frequent with Mozobil than placebo during HSC mobilization and apheresis were diaphoresis, nausea, fatigue, injection site reactions, headache, arthralgia, dizziness, and vomiting.

Safety data for Mozobil in combination with G-CSF were obtained from two randomized placebo-controlled studies (301 patients) and 10 uncontrolled studies (242 patients). Patients were primarily treated with Mozobil at daily doses of 0.24 mg/kg SC. Median exposure to Mozobil in these studies was 2 days (range 1 to 7 days).

In the two randomized studies in patients with NHL and MM, a total of 301 patients were treated in the Mozobil and G-CSF group and 292 patients were treated in the placebo and G-CSF group. Patients received daily morning doses of G-CSF 10 micrograms/kg for 4 days prior to the first dose of Mozobil 0.24 mg/kg SC or placebo and on each morning prior to apheresis. The adverse reactions that occurred in ≥5% of the patients who received Mozobil regardless of causality and were more frequent with Mozobil than placebo during HSC mobilization and apheresis are shown in Table 2.

Table 2: Adverse Reactions in ≥5% of Non-Hodgkin’s Lymphoma and Multiple Myeloma Patients Receiving Mozobil® and More Frequent than Placebo during HSC Mobilization and Apheresis

<table>
<thead>
<tr>
<th>Percent of Patients (%)</th>
<th>Mozobil® and G-CSF (n=301)</th>
<th>Placebo and G-CSF (n=292)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Grades</td>
<td>Grade 3</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>37</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Nausea</td>
<td>34</td>
<td>0</td>
</tr>
<tr>
<td>Vomiting</td>
<td>10</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Flatulence</td>
<td>7</td>
<td>0</td>
</tr>
</tbody>
</table>

In the randomized studies, 34% of patients with NHL or MM had mild to moderate injection site reactions at the site of subcutaneous administration of Mozobil. These included erythema, hemorrhage, induration, inflammation, irritation, pain, paresthesia, pruritus, rash, swelling, and urticaria. Mild to moderate allergic reactions were observed in less than 1% of patients within approximately 30 min after Mozobil administration, including one or more of the following: urticaria (n=2), pruritic swelling (n=2), dyspnea (n=1), and hypotension (n=1). Symptoms generally responded to treatments (e.g., antihistamines, corticosteroids, hydration or supplemental oxygen) or resolved spontaneously.

6.2 Postmarketing Experience

In addition to adverse reactions reported from clinical trials, the following adverse reactions have been reported from postmarketing experience with Mozobil. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

6.3 Drug Interactions

Based on in vitro data, plerixafor is not a substrate, inhibitor or inducer of human cytochrome P450 isoenzymes. Plerixafor is not likely to be implicated in in vivo drug-drug interactions involving cytochrome P450s. At concentrations similar to what are seen clinically, plerixafor did not act as a substrate or inhibitor of P-glycoprotein in an in vitro study [see Clinical Pharmacology (12.3)].

6.4 Use in Specific Populations

8.1 Pregnancy

Pregnancy Category D

Risk Summary

Mozobil may cause fetal harm when administered to a pregnant woman. Plerixafor is teratogenic in animals.

Animal Data

Plerixafor administered to pregnant rats induced embryo-fetal toxicities including fetal death, increased resorptions and postimplantation loss, decreased fetal weights, anophthalmia, shortened digits, cardiac interventricular septal defect, ringed aorta, globular heart, hydrocephaly, dilatation of olfactory ventricles, and retarded skeletal development. Embryo-fetal toxicities occurred mainly at a dose of 90 mg/m² (approximately 10 times the recommended human dose of 0.24 mg/kg when compared on a mg/m² basis or 10 times the AUC in subjects with normal renal function who received a single dose of 0.24 mg/kg).

8.2 Nursing Mothers

It is not known whether plerixafor is excreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from Mozobil, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.
Plerixafor is a hematopoietic stem cell mobilizer with a chemical name 1, 1′-[1,4-phenylenebis(methylene)]-bis-1,4,8,11-tetraazacyclotetradecane. It has the molecular formula C₅₅H₇₆N₄O₂. Plerixafor is a hematopoietic stem cell mobilizer with a chemical name 1, 1′-[1,4-phenylenebis(methylene)]-bis-1,4,8,11-tetraazacyclotetradecane. It has the molecular formula C₅₅H₇₆N₄O₂.

In pharmacodynamic studies of Mozobil in healthy volunteers, peak mobilization of CD34+ cells/kg than the mg/kg-based dose. However, the median time to reach 25 × 10⁶CD34+ cells/kg was 3 days for both treatment groups, and the safety profile between the groups was similar. Based on these results, further analysis was conducted by FDA reviewers and a body weight of 83 kg was selected as an appropriate cut-off point to transition patients from fixed to weight based dosing.

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Geometric Mean AUC</th>
<th>Ratio (90% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fixed 20 mg (n=30)</td>
<td>3991.2</td>
<td>1.43 (1.32,1.54)</td>
</tr>
<tr>
<td>0.24 mg/kg (n=31)</td>
<td>2792.7</td>
<td></td>
</tr>
</tbody>
</table>

There is limited experience with the 0.24 mg/kg dose of plerixafor in patients weighing above 160 kg. Therefore, the dose should not exceed that of a 160 kg patient (i.e., 40 mg/day if CLcr is <50 mL/min and 27 mg/day if CLcr is ≥50 mL/min) [see Dosage and Administration (2.1, 2.3)].

### 12.2 Pharmacodynamics

Data on the fold increase in peripheral blood CD34+ cell count (cells/ml) by apheresis day were evaluated in two placebo-controlled clinical studies in patients with NHL and MM (Study 1 and Study 2, respectively). The fold increase in CD34+ cell count (cells/ml) over the 24-hour period starting from the day prior to the first apheresis and ending the next morning just before the first apheresis is summarized in Table 3. During this 24-hour period, a single dose of Mozobil or placebo was administered 10 to 11 hours prior to apheresis.

### 12.3 Pharmacokinetics

The single-dose pharmacokinetics of plerixafor 0.24 mg/kg were evaluated in patients with NHL and MM following pretreatment with G-CSF (10 micrograms/kg once daily for 4 consecutive days). Plerixafor exhibits linear kinetics between the 0.04 mg/kg to 0.24 mg/kg dose range. The pharmacokinetics of plerixafor was similar across clinical studies in healthy subjects who received plerixafor alone and NHL and MM patients who received plerixafor in combination with G-CSF.

A population pharmacokinetic analysis incorporated plerixafor data from 63 subjects (NHL patients, MM patients, subjects with varying degrees of renal impairment, and healthy subjects) who received a single SC dose (0.04 mg/kg to 0.24 mg/kg) of plerixafor. A two-compartment disposition model with first order absorption and elimination was found to adequately describe the plerixafor concentration-time profile. Significant relationships between clearance and creatinine clearance (CLcr), as well as between central volume of distribution and body weight were observed. The distribution half-life (t1/2α) was estimated to be 0.3 hours and the terminal population half-life (t1/2β) was 5.3 hours in patients with normal renal function.

The population pharmacokinetic analysis showed that the mg/kg-based dosage results in an increased plerixafor exposure (AUC0-24h) with increasing body weight. In order to compare the pharmacokinetics and pharmacodynamics of plerixafor following 0.24 mg/kg-based and fixed (20 mg) doses, a follow-up trial was conducted in patients with NHL (N=61) who were treated with 0.24 mg/kg or 20 mg of plerixafor. The trial was conducted in patients weighing 70 kg or less. The fixed 20 mg dose showed 1.43-fold higher exposure (AUC0-24h) than the 0.24 mg/kg dose (Table 4). The fixed 20 mg dose also showed numerically higher response rate (5.2% [80.0% vs 54.8%] based on the local lab data and 11.7% [63.3% vs 51.6%] based on the central lab data) in attaining the target of ≥5 × 10⁶ CD34+cells/kg than the mg/kg-based dose. However, the median time to reach ≥5 × 10⁶ CD34+ cells/kg was 3 days for both treatment groups, and the safety profile between the groups was similar. Based on these results, further analysis was conducted by FDA reviewers and a body weight of 83 kg was selected as an appropriate cut-off point to transition patients from fixed to weight based dosing.

### Table 4: Systemic Exposure (AUC0-24h) Comparisons of Fixed and Weight-Based Regimens

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Geometric Mean AUC</th>
<th>Ratio (90% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fixed 20 mg (n=30)</td>
<td>3991.2</td>
<td>1.43 (1.32,1.54)</td>
</tr>
<tr>
<td>0.24 mg/kg (n=31)</td>
<td>2792.7</td>
<td></td>
</tr>
</tbody>
</table>

### 12.4 Pediatric Use

The safety and efficacy of Mozobil in pediatric patients have not been established in controlled clinical studies.

### 8.4 Pediatric Use

The safety and efficacy of Mozobil in pediatric patients have not been established in controlled clinical studies.

### 8.5 Geriatric Use

Of the total number of subjects in controlled clinical studies of Mozobil, 24% were 65 and over, while 0.8% were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Since plerixafor is mainly excreted by the kidney, no dose modifications are necessary in elderly individuals with normal renal function. In general, care should be taken in dose selection for elderly patients due to the greater frequency of decreased renal function with advanced age. Dosage adjustment in elderly patients with CLcr <50 mL/min is recommended [see Dosage and Administration (2.3) and Clinical Pharmacology (12.3)].

### 8.5 Geriatric Use

Of the total number of subjects in controlled clinical studies of Mozobil, 24% were 65 and over, while 0.8% were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Since plerixafor is mainly excreted by the kidney, no dose modifications are necessary in elderly individuals with normal renal function. In general, care should be taken in dose selection for elderly patients due to the greater frequency of decreased renal function with advanced age. Dosage adjustment in elderly patients with CLcr <50 mL/min is recommended [see Dosage and Administration (2.3) and Clinical Pharmacology (12.3)].

### 10 OVERDOSAGE

### 10 OVERDOSAGE

### 11 DESCRIPTION

Mozobil (plerixafor) injection is a sterile, preservative-free, clear, colorless to pale-yellow, isotonic solution for subcutaneous injection. Each mL of the sterile solution contains 20 mg of plerixafor. Each single-use vial is filled to deliver 1.2 mL of the sterile solution that contains 24 mg of plerixafor and 5.9 mg of sodium chloride in Water for Injection adjusted to a pH of 6.0 to 7.5 with hydrochloric acid and with sodium hydroxide, if required.

### 12 CLINICAL PHARMACOLOGY

#### 12.1 Mechanism of Action

Plerixafor is an inhibitor of the CXCR4 chemokine receptor and blocks binding of its cognate ligand, stromal cell-derived factor-1α (SDF-1α). SDF-1α and CXCR4 are recognized to play a role in the trafficking and homing of human hematopoietic stem cells (HSCs) to the marrow compartment. Once in the marrow, stem cell CXCR4 can act to help anchor these cells to the marrow matrix, either directly via SDF-1α or through the induction of other adhesion molecules. Treatment with plerixafor resulted in leukocytosis and elevations in circulating hematopoietic progenitor cells in mice, dogs, and humans. CD34+ cells mobilized by plerixafor were capable of engraftment with long-term repopulating capacity up to one year in canine transplantation models.

#### 12.2 Pharmacodynamics

Data on the fold increase in peripheral blood CD34+ cell count (cells/ml) by apheresis day were evaluated in two placebo-controlled clinical studies in patients with NHL and MM (Study 1 and Study 2, respectively). The fold increase in CD34+ cell count (cells/ml) over the 24-hour period starting from the day prior to the first apheresis and ending the next morning just before the first apheresis is summarized in Table 3. During this 24-hour period, a single dose of Mozobil or placebo was administered 10 to 11 hours prior to apheresis.

#### Table 3: Fold Increase in Peripheral Blood CD34+ Cell Count Following Pretreatment with G-CSF and Administration of Plerixafor

<table>
<thead>
<tr>
<th>Study</th>
<th>Mozobil® and G-CSF</th>
<th>Placebo and G-CSF</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Study 1</td>
<td>5.0</td>
<td>6.1 (5.4)</td>
</tr>
<tr>
<td>Study 2</td>
<td>4.8</td>
<td>6.4 (6.8)</td>
</tr>
</tbody>
</table>

In pharmacodynamic studies of Mozobil in healthy volunteers, peak mobilization of CD34+ cells was observed between 6 and 9 hours after administration. In pharmacodynamic studies of Mozobil in conjunction with G-CSF, in healthy volunteers, a sustained elevation in the peripheral blood CD34+ count was observed from 4 to 18 hours after plerixafor administration with a peak CD34+ count between 10 and 14 hours.

### QT/QTc Prolongation

There is no indication of a QT/QTc prolonging effect of Mozobil in single doses up to 0.40 mg/kg. In a randomized, double-blind, crossover study, 48 healthy subjects were administered a single subcutaneous dose of plerixafor (0.24 mg/kg and 0.40 mg/kg) and placebo. Peak concentrations for 0.40 mg/kg Mozobil were approximately 1.8-fold higher than the peak concentrations following the 0.24 mg/kg single subcutaneous dose.
The median number of days to reach CD34+ cells/kg by apheresis day in NHL Patients Table 5: Study 1 Efficacy Results - CD34+ Cell Mobilization in NHL Patients

<table>
<thead>
<tr>
<th>Efficacy Endpoint</th>
<th>Mozobil® and G-CSF (n=150)</th>
<th>Placebo and G-CSF (n=148)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients achieving ≥5 x 10^6 cells/kg in ≤4 apheresis days</td>
<td>89 (59%)</td>
<td>29 (20%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Patients achieving ≥2 x 10^6 cells/kg in ≤4 apheresis days</td>
<td>130 (87%)</td>
<td>70 (47%)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

*p-value calculated using Pearson's Chi-Squared test

The median number of days to reach ≥5 x 10^6 CD34+ cells/kg was 3 days for the Mozobil group and not evaluable for the placebo group. Table 6 presents the proportion of patients who achieved ≥5 x 10^6 CD34+ cells/kg by apheresis day.

Table 6: Study 1 Efficacy Results – Proportion of Patients Who Achieved ≥5 x 10^6 CD34+ cells/kg by Apheresis Day in NHL Patients

<table>
<thead>
<tr>
<th>Days</th>
<th>Proportion* in Mozobil® and G-CSF (n=147)</th>
<th>Proportion* in Placebo and G-CSF (n=142)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>27.9%</td>
<td>4.2%</td>
</tr>
<tr>
<td>2</td>
<td>49.1%</td>
<td>14.2%</td>
</tr>
<tr>
<td>3</td>
<td>57.7%</td>
<td>21.6%</td>
</tr>
<tr>
<td>4</td>
<td>65.6%</td>
<td>24.2%</td>
</tr>
</tbody>
</table>

*p-value determined by Kaplan Meier method
†n includes all patients who received at least one day of apheresis

In Study 2, 72% of MM patients who were mobilized with Mozobil and G-CSF collected ≥5 x 10^6 CD34+ cells/kg from the peripheral blood in two or fewer apheresis sessions, compared with 34% of patients who were mobilized with placebo and G-CSF (p <0.001). Other CD34+ cell mobilization outcomes showed similar findings (Table 7).

Table 7: Study 2 Efficacy Results – CD34+ Cell Mobilization in Multiple Myeloma Patients

<table>
<thead>
<tr>
<th>Efficacy Endpoint</th>
<th>Mozobil® and G-CSF (n=148)</th>
<th>Placebo and G-CSF (n=154)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients achieving ≥5 x 10^6 cells/kg in ≤3 apheresis days</td>
<td>106 (72%)</td>
<td>53 (34%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Patients achieving ≥6 x 10^6 cells/kg in ≤4 apheresis days</td>
<td>112 (76%)</td>
<td>79 (51%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Patients achieving ≥2 x 10^6 cells/kg in ≤4 apheresis days</td>
<td>141 (85%)</td>
<td>136 (88%)</td>
<td>0.028</td>
</tr>
</tbody>
</table>

*p-value calculated using Pearson's Chi-Squared test

The median number of days to reach ≥5 x 10^6 CD34+ cells/kg was 1 day for the Mozobil group and 4 days for the placebo group. Table 8 presents the proportion of patients who achieved ≥6 x 10^6 CD34+ cells/kg by apheresis day.

Table 8: Study 2 – Proportion of Patients Who Achieved ≥6 x 10^6 CD34+ cells/kg by Apheresis Day in MM Patients

<table>
<thead>
<tr>
<th>Days</th>
<th>Proportion* in Mozobil® and G-CSF (n=154)</th>
<th>Proportion* in Placebo and G-CSF (n=150)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>54.2%</td>
<td>17.3%</td>
</tr>
<tr>
<td>2</td>
<td>77.9%</td>
<td>35.3%</td>
</tr>
<tr>
<td>3</td>
<td>86.6%</td>
<td>48.9%</td>
</tr>
<tr>
<td>4</td>
<td>86.6%</td>
<td>55.9%</td>
</tr>
</tbody>
</table>

*p-values determined by Kaplan Meier method
†n includes all patients who received at least one day of apheresis