Form 2565 R2.0: Sanofi Mozobil Supplemental Data Collection

Center: CRID:

Key Fields

Sequence Number: _____

Date Received: __ __ __ __ - __ __- __ __

CIBMTR Center Number: _____

CIBMTR Research ID: _____

Event date: __ __ __ __ - __ __- __ __

Mobilization

Questions: 1 - 3

1 Did the recipient stay at a temporary location closer to the collection center for mobilization? (e.g. hotel)

○ Yes ○ No

2 Specify number of days: _____

Indicate the intended method of mobilization for the recipient. If at the time of mobilization the method was modified or an alternate method was used, report the actual method of mobilization in the Mobilization Agents section.

3 What was the intended method of stem cell mobilization for this recipient?

○ Mobilization with G-CSF (including biosimilars or peg-filgrastim) alone (plerixafor NOT used during initial mobilization attempt with G-CSF alone)

○ Mobilization with G-CSF + plerixafor

○ Mobilization with G-CSF + as needed plerixafor rescue (plerixafor given only if patients met criteria for mobilization failure)

○ Chemomobilization

Pre-Collection Therapy Given to Enhance Product Collection

Questions: 4 - 56

4 Was pre-collection chemotherapy given to enhance product collection?

○ Yes ○ No

5 Specify where chemotherapy was administered

○ Inpatient ○ Outpatient

6 Did the recipient receive antibacterial drugs(s) for infection prophylaxis during chemomobilization?

○ Yes ○ No

Antibiotic Prophylaxis (1)

Questions: 7 - 11

7 Specify antibiotic

○ Amoxicillin clavulanate oral (Augmentin)

○ Cefdinir oral (Omnicef)

○ Cefpodoxime oral (Vantin)

○ Ciprofloxacin IV or oral (Cipro)

○ Ertapenem IV

○ Levofloxacin IV or oral (Levaquin)

○ Moxifloxacin IV or oral (Avelox)

○ Vancomycin IV

○ Other antibacterial drug

8 Specify other antibacterial drug: _____

9 Total daily dose: _____ mg

10 Date started: __ __ __ __ - __ __- __ __

11 Date stopped: __ __ __ __ - __ __- __ __

12 Why was chemotherapy used for mobilization?

○ Center's standard mobilization approach

○ Treatment of primary disease

○ Indicated as part of a clinical trial

○ Other

13 Specify the ClinicalTrials.gov identification number: _____

14 Specify other reason for which chemotherapy was used for mobilization: _____

Specify chemotherapy agents given:

15 Cyclophosphamide (Cytoxan)

○ yes ○ no

16 Total daily dose: _____ mg

17 Number of days: _____

18 Date started: __ __ __ __ - __ __- __ __

Indicate if mesna was given with cyclophosphamide:

19 Mesna
○ Yes ○ No

20 Total daily dose: _____ mg
21 Number of days: _____
22 Date started: __ __ __ __ - __ __- __ __

23 DPACE / DCEP (dexamethasone, cisplatin, doxorubicin, cyclophosphamide and etoposide / dexamethasone, cyclophosphamide, etoposide, cisplatin)
○ Yes ○ No

Specify the dose, number of days, and start date for each drug:

Dexamethasone (given as part of DPACE / DCEP)

24 Total daily dose: (Dexamethasone) _____ mg
25 Number of days: _____
26 Date started: __ __ __ __ - __ __- __ __

Cisplatin (given as part of DPACE / DCEP)

27 Total daily dose: (Cisplatin) _____ mg
28 Number of days: _____
29 Date started: __ __ __ __ - __ __- __ __

Doxorubicin (given as part of DPACE / DCEP)

30 Total daily dose: (Doxorubicin) _____ mg
31 Number of days: _____
32 Date started: __ __ __ __ - __ __- __ __

Cyclophosphamide (Cytoxan) (given as part of DPACE / DCEP)

33 Total daily dose: (Cyclophosphamide) _____ mg
34 Number of days: _____
35 Date started: __ __ __ __ - __ __- __ __

Etoposide (VP-16, VePesid) (given as part of DPACE / DCEP)

36 Total daily dose: (Etoposide) _____ mg
37 Number of days: _____
38 Date started: __ __ __ __ - __ __- __ __

39 Etoposide (VP-16, VePesid)
○ yes ○ no

40 Total daily dose: _____ mg
41 Number of days: _____
42 Date started: __ __ __ __ - __ __- __ __

43 Other drug
○ yes ○ no

44 Total daily dose: _____ mg
45 Number of days: _____
46 Date started: __ __ __ __ - __ __- __ __
47 Specify other drug: _____

48 Were there complications from chemotherapy?
○ Yes ○ No

49 Specify complications from chemotherapy (check all that apply)
- ☐ Hospitalization (post-chemotherapy administration)
- ☐ Infection
- ☐ Non-neutropenic fever
- ☐ Neutropenic fever
- ☐ Nausea
- ☐ Vomiting
- ☐ Anemia requiring blood transfusion(s)
- ☐ Thrombocytopenia requiring platelet transfusion(s)
- ☐ Hypocalcemia
- ☐ Bleeding
- ☐ Other

50 Specify date of admission: __ __ __ __ - __ __- __ __
51 Was the recipient discharged prior to conditioning?
○ Yes ○ No

52 Specify date of discharge: __ __ __ __ - __ __- __ __

Center: CRID:

53 Specify where the recipient was hospitalized
- ○ Transplant center ○ Local hospital

54 Specify number of units transfused: (blood) _____

55 Specify number of units transfused: (platelets) _____

56 Specify other complication: _____

Mobilization Agents
Questions: 57 - 78

Specify mobilization agents used:

57 G-CSF
- ○ yes ○ no

G-CSF Types (1)
Questions: 58 - 62

58 Specify type of G-CSF
- ○ Filgrastim
- ○ Peg-filgrastim
- ○ Filgrastim-sndz (Zarxio)
- ○ TBO filgrastim (Granix)
- ○ Other

59 Specify other type of G-CSF: _____

60 Total daily dose: _____ mg

61 Number of days: _____

62 Date started: __ __ __ __ - __ __- __ __

Plerixafor (Mozobil)

63 Plerixafor (Mozobil)
- ○ yes ○ no

64 Total daily dose: _____ mg

65 Number of days: _____

66 Date started: __ __ __ __ - __ __- __ __

67 Indicate the reason for which plerixafor was given
- ○ Planned per protocol
- ○ Recipient at risk of mobilization failure

68 Specify the reason recipient was at risk of mobilization failure
- ○ Low peripheral blood CD34 count
- ○ Low collection on day 1
- ○ Low collection on days 1 and 2
- ○ Other reason

69 Specify other reason: _____

Other mobilization agent

70 Other mobilization agent
- ○ Yes ○ No

71 Specify other mobilization agent: _____

72 Total daily dose: _____ mg

73 Number of days: _____

74 Date started: __ __ __ __ - __ __- __ __

75 Did the recipient receive blood transfusions (RBCs) during this apheresis collection?
- ○ Yes ○ No

76 Specify number of units: _____

77 Did the recipient receive platelets during this apheresis collection?
- ○ Yes ○ No

78 Specify number of units: _____

Apheresis Collection
Questions: 79 - 100

79 Was peripheral blood CD34+ checked the day prior to collection?
- ○ Yes ○ No

80 _____ cells/µL

81 Specify the total number of apheresis collection days for this mobilization: _____

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Center: CRID:

82 Was there a planned hospitalization for collection?

○ Yes ○ No

83 Number of days: _____

Day of Collection (1) **Questions: 84 - 97**

84 Date of collection: __ __ __ __ - __ __ - __ __

85 Was there central venous access during collection? (i.e. central venous line (CVL))

○ yes ○ no

86 Specify the type of central venous access

○ Planned temporary CVL (for collection)

○ Permanent CVL

○ Unplanned CVL (placed after beginning collection)

87 Was the CVL removed after collection but prior to transplant?

○ Yes ○ No

Labs on this date of collection:

88 Peripheral blood CD34+ cells

○ Known ○ Unknown

89 _____ cells/µL

90 Absolute neutrophil count (ANC)

○ Known ○ Unknown

91 _____ ○ x 10^9/L (x 10^3/mm^3)

○ x 10^6/L

92 Platelets

○ Known ○ Unknown

93 _____ ○ x 10^9/L (x 10^3/mm^3)

○ x 10^6/L

94 Were platelets transfused ≤ 7 days before date of test?

○ Yes ○ No

95 Blood volume processed

○ Known ○ Unknown

96 Total blood volume processed on this day of collection: _____ ○ Blood volumes ○ Liters

Specify the total number of CD34+ cells collected on this date of collection:

97 Total CD34+ collected: (on this day of collection) _____ x 10 _____ cells/kg

98 Number of bags cryopreserved: _____

99 Was this mobilization episode considered successful?

○ Yes ○ No

100 Was remobilization done as a result?

○ Yes ○ No

First Name: _____ Last Name: _____

E-mail address: _____ Date: __ __ __ __ - __ __ - __ __