Form 2556 R1.0: Myelofibrosis CMS Study Supplemental Pre-HCT Data

Center: CRID:

Key Fields

Sequence Number: _____

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

CIBMTR Center Number: _____

CIBMTR Research ID: _____

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

HCT type: (check all that apply)

- ☐ Autologous
- ☐ Allogeneic, unrelated
- ☐ Allogeneic, related

Product type: (check all that apply)

- ☐ Bone marrow
- ☐ PBSC
- ☐ Single cord blood unit
- ☐ Multiple cord blood units
- ☐ Other product

Specify: _____

DIPSS Prognosis Score

Questions: 1 - 17

1 Specify the maximum DIPSS score the patient ever achieved: _____

2 Specify when maximum DIPSS score was documented

- ○ At diagnosis
- ○ Between diagnosis and the preparative regimen
- ○ At last evaluation prior to the start of the preparative regimen

Report the clinical and laboratory assessments used to determine the maximum DIPSS score:

3 WBC

○ Known ○ Unknown

4 _____ ○ x 10^9/L (x 10^3/mm^3) ○ x 10^6/L

5 Date sample collected: __ __ __ __ - __ __- __ __

6 Hemoglobin

○ Known ○ Unknown

7 _____ ○ g/dL ○ g/L ○ mmol/L

8 Date sample collected: __ __ __ __ - __ __- __ __

9 Was RBC transfused ≤ 30 days before date of test?

○ Yes ○ No

10 Platelets

○ Known ○ Unknown

11 _____ ○ x 10^9/L (x 10^3/mm^3) ○ x 10^6/L

12 Date sample collected: __ __ __ __ - __ __- __ __

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

○ Yes ○ No

14 Blasts in blood

○ Known ○ Unknown

15 _____ %

16 Date sample collected: __ __ __ __ - __ __- __ __

17 Did the recipient have constitutional symptoms? (> 10% weight loss in 6 months, night sweats, unexplained fever higher than 37.5°C)

○ Yes ○ No

Pre-HCT JAK1 and JAK2 Inhibitor Therapy

Questions: 18 - 33

18 Did the recipient receive JAK1 or JAK2 inhibitor therapy? (pre-HCT)

○ Yes ○ No

Pre-HCT JAK1 and JAK2 Inhibitor Therapy (1)

Questions: 19 - 31

Specify therapy given:

19 Ruxolitinib (Jakafi)

yes no

20 Date therapy started

Known Unknown

21 Date started: __ __ __ __ - __ __- __ __

22 Date therapy stopped

Known Unknown

23 Date stopped: __ __ __ __ - __ __- __ __

24 Specify the reason therapy stopped

- Toxicity (e.g.cytopenisa)
- Not tolerable
- Lack of response
- Disease progression
- Other
- Unknown

25 Specify other reason: _____

26 Other JAK1 or JAK2 inhibitor

Yes No

27 Specify other JAK1 or JAK2 inhibitor: _____

28 Date therapy started

Known Unknown

29 Date started: __ __ __ __ - __ __- __ __

30 Date therapy stopped

Known Unknown

31 Date stopped: __ __ __ __ - __ __- __ __

32 Response to therapy

- Clinical improvement : defined as 50% improvement in palpable spleen length for spleen palpable by 10 cm, or complete resolution of splenomegaly for palpable spleen <10 cm
- Stable disease
- Non-splenic disease progression : increase in blasts to 10% to 19%, intolerance to treatment due to hematologic/non-hematologic side effects, or new onset transfusion-requiring anemia
- Splenic disease progression : appearance of new splenomegaly palpable 5 cm below costal margin (BCM) or 100% increase in palpable distance BCM for baseline splenomegaly of 5 cm to 10 cm BCM, 50% increase in palpable distance BCM for baseline splenomegaly of 10 cm BCM, loss of spleen response, or symptomatic splenomegaly requiring splenectomy
- Transformation to leukemia : peripheral blood or bone marrow blast count of 20%

33 Date assessed: __ __ __ __ - __ __- __ __

Laboratory Studies Prior to Therapy

Questions: 34 - 71

Specify the laboratory values immediately prior to JAK1 / JAK2 inhibitor therapy. If no JAK1 / JAK2 inhibitor therapy was given, report results at last evaluation prior to the start of the preparative regimen:

34 Was presence of somatic mutations tested? (immediately prior to JAK2 inhibitor therapy initiation)

Yes No Unknown

35 Date sample collected: __ __ __ __ - __ __- __ __

36 Specify the cell source

Bone marrow Peripheral blood

37 JAK 2

Positive Negative Not done

38 CALR1

Positive Negative Not done

39 CALR2

Positive Negative Not done

40 MPL

Positive Negative Not done

41 ASXL1

Positive Negative Not done

42 SRSF2

Positive Negative Not done

43 EZH2

Positive Negative Not Done

44 IDH1
Positive Negative Not done

45 IDH2
Positive Negative Not done

46 LNK
Positive Negative Not done

47 CBL
Positive Negative Not done

48 TET2
Positive Negative Not done

49 IKZF1
Positive Negative Not done

50 DNMT3A
Positive Negative Not done

51 TP53
Positive Negative Not done

52 SF3B1
Positive Negative Not done

53 U2AF1
Positive Negative Not done

54 FLT3
Positive Negative Not done

Laboratory Studies Prior to Therapy (1) — Questions: 55 - 56

55 Other gene mutation
Positive Negative Not done

56 Specify other gene mutation: _____

57 WBC
Known Unknown

58 _____ x 10^9/L (x 10^3/mm^3) x 10^6/L

59 Date sample collected: __ __ __ __ - __ __- __ __

60 Hemoglobin
Known Unknown

61 _____ g/dL g/L mmol/L

62 Date sample collected: __ __ __ __ - __ __- __ __

63 Was RBC transfused ≤ 30 days before date of test?
Yes No

64 Platelets
Known Unknown

65 _____ x 10^9/L (x 10^3/mm^3) x 10^6/L

66 Date sample collected: __ __ __ __ - __ __- __ __

67 Were platelets transfused ≤ 7 days before date of test?
Yes No

68 Blasts in blood
Known Unknown

69 _____ %

70 Date sample collected: __ __ __ __ - __ __- __ __

71 Did the recipient have constitutional symptoms? (> 10% weight loss in 6 months, night sweats, unexplained fever higher than 37.5°C)
Yes No

Laboratory Studies at Last Evaluation Prior to HCT — Questions: 72 - 76

72 Total serum ferritin
Known Unknown

73 _____ ng/mL (µg/L)

74 Date sample collected: __ __ __ __ - __ __- __ __

75 CD34+ cells (peripheral blood)

○ Known ○ Unknown

76 _____ x 10 _____

Disease Assessment at the Time of HCT

Questions: 77 - 90

77 Did the recipient have evidence of pulmonary hypertension at HCT?

○ Yes ○ No ○ Unknown

78 Did the recipient have evidence of portal hypertension at HCT?

○ Yes ○ No ○ Unknown

Specify if the recipient had any of the following at the time of HCT:

79 Hepatomegaly

○ yes ○ no

80 Specify the liver size: _____ centimeters below right costal margin

81 Specify the method used to measure liver size:

○ Physical assessment ○ Ultrasound ○ CT

82 Spleen size

○ Known

○ Unknown

○ Not applicable (splenectomy)

83 Specify the spleen size: _____ centimeters below right costal margin

84 Iron overload

○ Yes ○ No

Indicate how the iron overload diagnosis was made:

85 Serum ferritin

○ Yes ○ No

86 Liver MRI

○ Yes ○ No

87 Other method

○ Yes ○ No

88 Specify other method: _____

Specify therapy given for iron overload:

89 Iron chelation therapy

○ Yes ○ No

90 Phlebotomy

○ Yes ○ No

First Name: _____ Last Name: _____

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