Form 2114 R3.0: Myelodysplasia/Myeloproliferative Neoplasms (MDS/MPN) Post-HCT Data

Center: CRID:

Key Fields

Sequence Number: _____

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

CIBMTR Center Number: _____

CIBMTR Recipient ID: _____

Date of HCT for which this form is being completed: __ __ __ __ - __ __- __ __

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: _____

Visit

☐ 100 day ☐ 6 months ☐ 1 year ☐ 2 years ☐ > 2 years,

Specify: _____

Disease Assessment at the Time of Best Response to HCT

Questions: 1 - 20

1 Compared to the disease status prior to the preparative regimen, what was the best response to HCT since the date of the last report?

(Include response to any therapy given for post-HCT maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease.)

☐ Continued complete remission (CCR) -for patients transplant in CR

☐ Complete remission (CR) -requires all of the following, maintained for ≥ 4 weeks: *bone marrow evaluation: <5% myeloblasts with normal maturation of all cell lines *peripheral blood evaluation: hemoglobin ≥ 11g/dL untransfused and without erythropoietin support; ANC ≥ 1000/mm^3 without myeloid growth factor support; platelets ≥ 100 x $10^{9/L}$ without thrombopoietic support; 0% blasts

☐ Hematologic improvement (HI) -requires one measurement of the following, maintained for ≥ 8 weeks without ongoing cytotoxic therapy; specify which cell line was measured to determine HI response: * HI-E hemoglobin increase of ≥ 1.5 g/dL untransfused; for RBC transfusions performed for Hgb ≤ 9.0, reduction in RBC units transfused in 8 weeks by ≥ 4 units compared to the pre-treatment transfusion number in 8 weeks *HI-P for pre-treatment platelet count of > 20 x 10^9 L, platelet absolute increase of ≥ 30 x 10^9 L; for pre-treatment platelet count of < 20 x 10^9 L, platelet absolute increase of ≥ 20 x 10^9 L and ≥ 100% from pre-treatment level *HI-N neutrophil count increase of ≥ 100% from pre-treatment level and an absolute increase of ≥ 500/mm^3

☐ No response (NR) / stable disease (SD) -does not meet the criteria for at least HI, but no evidence of disease progression

☐ Progression from hematologic improvement (Prog from HI) -requires at least one of the following, in the absence of another explanation (e.g., infection, bleeding, ongoing chemotherapy, etc.): * ≥ 50% reduction from maximum response levels in granulocytes or platelets *reduction in hemoglobin by ≥1.5 g/dL *transfusion dependence

☐ Relapse from complete remission (rel from CR) -requires at least one of the following: *return to pre-treatment bone marrow blast percentage *decrease of ≥ 50% from maximum response levels in granulocytes or platelets *transfusion dependence, or hemoglobin level ≥ 1.5 g/dL lower than prior to therapy

☐ Progression to AML -≥20% blasts in the blood or bone marrow

2 Was the date of best response previously reported?

☐ yes ☐ no

3 Date assessed: __ __ __ __ - __ __- __ __

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4 Was the disease status assessed by molecular testing (e.g. PCR)?

☐ yes ☐ no

5 Date assessed: __ __ __ __ - __ __ - __ __

6 Was disease detected?

☐ yes ☐ no

7 Was the status considered a disease relapse or progression?

☐ yes ☐ no

8 Was the disease status assessed via flow cytometry?

☐ yes ☐ no

9 Date assessed: __ __ __ __ - __ __ - __ __

10 Was disease detected?

☐ yes ☐ no

11 Was the status considered a disease relapse or progression?

☐ yes ☐ no

12 Was the disease status assessed by cytogenetic testing (conventional or FISH)?

☐ yes ☐ no

13 Was the disease status assessed via FISH?

☐ yes ☐ no

14 Date assessed: __ __ __ __ - __ __ - __ __

15 Was disease detected?

☐ yes ☐ no

16 Was the status considered a disease relapse or progression?

☐ yes ☐ no

17 Was the disease status assessed via conventional cytogenetics?

☐ yes ☐ no

18 Date assessed: __ __ __ __ - __ __ - __ __

19 Was disease detected?

☐ yes ☐ no

20 Was the status considered a disease relapse or progression?

☐ yes ☐ no

Disease Relapse or Progression Post-HCT

Questions: 21 - 31

21 Was a disease relapse or progression detected by molecular testing (e.g. PCR)?

☐ yes ☐ no

22 Date assessed: __ __ __ __ - __ __ - __ __

23 Was a disease relapse or progression detected via flow cytometry?

☐ yes ☐ no

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24 Date assessed: __ __ __ __ - __ __- __ __

25 Was a disease relapse or progression detected by cytogenetic testing (conventional or FISH)?

☐ yes ☐ no

26 Was a disease relapse or progression detected via FISH?

☐ yes ☐ no

27 Date assessed: __ __ __ __ - __ __- __ __

28 Was a disease relapse or progression detected via conventional cytogenetics?

☐ yes ☐ no

29 Date assessed: __ __ __ __ - __ __- __ __

30 Was a disease relapse or progression detected by clinical / hematologic assessment?

☐ yes ☐ no

31 Date assessed: __ __ __ __ - __ __- __ __

Laboratory Studies at the Time of Evaluation for this Reporting Period

Questions: 32 - 37

32 Was the bone marrow examined (post-HCT) since the date of the last report?

☐ yes ☐ no ☐ Unknown

33 Date sample collected: __ __ __ __ - __ __- __ __

34 Blasts in bone marrow

☐ Known ☐ Unknown

35 _____ %

36 Did the recipient have myelofibrosis since the date of the last report?

☐ yes ☐ no ☐ Unknown

37 Specify the status of marrow fibrosis since the date of the last report _____

Disease Status at the Time of Evaluation for this Reporting Period

Questions: 38 - 41

38 What is the current disease status?

☐ Complete remission (CR) — requires all of the following, maintained for ≥ 4 weeks: * bone marrow evaluation: < 5% myeloblasts with normal maturation of all cell lines * peripheral blood evaluation: hemoglobin ≥ 11 g/dL untransfused and without erythropoietin support; ANC ≥ 1000 / mm^3 without myeloid growth factor support; platelets ≥ 100 x 10^9 /L without thrombopoietic support; 0% blasts

☐ Hematologic improvement (HI) — requires one measurement of the following, maintained for ≥ 8 weeks without ongoing cytotoxic therapy; specify which cell line was measured to determine HI response: * HI-E – hemoglobin increase of ≥ 1.5 g/dL untransfused; for RBC transfusions performed for Hgb ≤ 9.0, reduction in RBC units transfused in 8 weeks by ≥ 4 units compared to the pre-treatment transfusion number in 8 weeks * HI-P – for pre-treatment platelet count of > 20 x 10^9/L, platelet absolute increase of ≥ 30 x 10^9/L; for pre-treatment platelet count of < 20 x 10^9/L, platelet absolute increase of ≥ 20 x 10^9/L and ≥ 100% from pre-treatment level * HI-N – neutrophil count increase of ≥ 100% from pre-treatment level and an absolute increase of ≥ 500 / mm^3

☐ No response (NR) / stable disease (SD) — does not meet the criteria for at least HI, but no evidence of disease progression

☐ Progression from hematologic improvement (Prog from HI) — requires at least one of the following, in the absence of another explanation (e.g., infection, bleeding, ongoing chemotherapy, etc.): * ≥ 50% reduction from maximum response levels in granulocytes or platelets * reduction in hemoglobin by ≥ 1.5 g/dL *transfusion dependence

☐ Relapse from complete remission (Rel from CR) — requires at least one of the following: * return to pre-treatment bone marrow blast percentage * decrease of ≥ 50% from maximum response levels in granulocytes or platelets * transfusion dependence, or hemoglobin level ≥ 1.5 g/dL lower than prior to therapy

☐ Progression to AML — ≥ 20% blasts in the blood or bone marrow

☐ Not assessed

39 Was the recipient in molecular remission?

☐ Yes ☐ No ☐ Unknown ☐ Not applicable

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40 Was the recipient in cytogenetic remission?

☐ Yes ☐ No ☐ Unknown ☐ Not applicable

41 Date assessed: __ __ __ __ - __ __- __ __

First Name: _____

Last Name: _____

E-mail address: _____

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

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