Form 2113 R3.0: Chronic Lymphocytic Leukemia (CLL) Post-Infusion 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: _____

Visit

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

Specify: _____

Disease Assessment at the Time of Best Response to HCT or Cellular Therapy

Questions: 1 - 3

Best response is based on response to the HCT or cellular therapy, but does NOT include response to any therapy given for disease relapse or progression post-HCT / post-infusion. When determining the best response, compare the post-HCT / post-infusion disease status to the status immediately prior to the preparative regimen or cellular therapy, regardless of time since HCT or infusion. This comparison is meant to capture the BEST disease status in response to HCT or cellular therapy that occurred in the reporting interval, even if a subsequent disease relapse or progression occurred during the same reporting interval. If a recipient already achieved their best response in a previous reporting interval, confirm the best response and check "yes" to indicate "date previously reported."

1 Compared to the disease status prior to the preparative regimen, what was the best response to HCT or cellular therapy 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.)

- ○ Complete remission (CR) - no lymphadenopathy; no organomegaly; neutrophils ≥ 1.5 x 10^9/L; platelets > 100 x 10^9/L; hemoglobin > 11.0 g/dL; lymphocytes < 4 x 10^9/L; bone marrow < 30% lymphocytes; absence of constitutional symptoms
- ○ Partial remission (PR) - ≥50% decrease in peripheral blood lymphocyte count from pretreatment value; ≥ 50% reduction in lymphadenopathy if present pretreatment; ≥ 50% reduction in liver and spleen size if enlarged pretreatment; one or more of the following: neutrophils ≥ 1.5 x 10^9/L or 50% improvement over baseline, platelets > 100 x 10^9/L or 50% improvement over baseline, hemoglobin > 11.0 g/dL or 50% improvement over baseline
- ○ Stable disease (SD) - no change; not complete remission, partial remission, nor progressive disease
- ○ Progressive disease (Prog) - one or more of the following: ≥ 50% increase in sum of products of ≥ 2 lymph nodes (≥ 1 node must be ≥ 2 cm) or new nodes; ≥ 50% increase in liver or spleen size or new hepatomegaly or splenomegaly; ≥ 50% increase in absolute lymphocyte count to ≥ 5 x 10^9/L; transformation to a more aggressive histology
- ○ Not assessed

2 Was the date of best response previously reported?

○ yes ○ no

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

Disease Assessment at the Time of Best Response

Questions: 4 - 26

4 Were tests for molecular markers performed (e.g. PCR)?

○ yes ○ no ○ Unknown

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

6 Immunoglobulin heavy chain variable (IGHV) mutation

○ Positive ○ Negative ○ Not done

7 Specify method used

- ○ ASO IGHV RQ-PCR
- ○ Consensus IGHV PCR
- ○ Consensus IGHV PCR using HTS
- ○ Nested ASO IGHV PCR
- ○ Other method

8 Specify other method: _____

9 NOTCH 1 mutation

○ Positive ○ Negative ○ Not done

10 P53 mutation

○ Positive ○ Negative ○ Not done

11 SF3B1 mutation
Positive Negative Not done

12 Other molecular marker
Positive Negative Not Done

13 Specify other molecular marker: _____

14 Was the disease status assessed via flow cytometry? (minimum 4-color flow) (immunophenotyping)
yes no

15 Date sample collected: __ __ __ __ - __ __- __ __

16 Was disease detected?
yes no

17 Was the disease status assessed by cytogenetic testing (karyotyping or FISH)?
yes no

18 Was the disease status assessed via FISH?
yes no

19 Date sample collected: __ __ __ __ - __ __- __ __

20 Was disease detected?
yes no

21 Was the disease status assessed via karyotyping?
Yes No

22 Date sample collected: __ __ __ __ - __ __- __ __

23 Was disease detected?
yes no

24 Was the disease status assessed by clinical / hematologic assessment?
yes no

25 Date assessed: __ __ __ __ - __ __- __ __

26 Was disease detected?
yes no

Post-HCT / Post-Infusion Planned Therapy

Questions: 27 - 42

27 Was therapy given since the date of the last report for reasons other than relapse or progressive disease? (Include any maintenance and consolidation therapy.)
yes no

Specify the therapy(s) given:

28 Systemic therapy
yes no

29 Chemotherapy
yes no

30 Immune therapy / monoclonal antibody (mAb)
Yes No

Specify therapy(s) given:

31 Aldesleukin (interleukin-2, IL-2)
yes no

32 Alemtuzumab (Campath)
yes no

33 Ibrutinib (Imbruvica)
Yes No

34 Rituximab (anti-CD20, Rituxan)
yes no

35 Other mAb
yes no

36 Specify other mAb: _____

37 Other immune therapy
Yes No

38 Specify other immune therapy: _____

39 Radiation therapy
yes no

40 Cellular therapy
yes no

41 Other therapy
yes no

42 Specify other therapy: _____

Disease Relapse or Progression Post-HCT / Post-Infusion

Questions: 43 - 88

43 Was a disease relapse or progression detected since the date of last report?
yes no

44 Was a disease relapse or progression detected by molecular testing (e.g. PCR)?
yes no

45 Date sample collected: __ __ __ __ - __ __- __ __

46 Was a disease relapse or progression detected via flow cytometry?
yes no

47 Date sample collected: __ __ __ __ - __ __- __ __

48 Was a disease relapse or progression detected by cytogenetic testing (karyotyping or FISH)?
yes no

49 Was a disease relapse or progression detected via FISH?
yes no

50 Date sample collected: __ __ __ __ - __ __- __ __

51 Was a disease relapse or progression detected via karyotyping?
Yes No

52 Date sample collected: __ __ __ __ - __ __- __ __

53 Was a disease relapse or progression detected by clinical / hematologic assessment?
yes no

54 Date assessed: __ __ __ __ - __ __- __ __

55 Was any therapy given for relapse or progressive disease since the date of last report?
yes no

56 Date started: __ __ __ __ - __ __- __ __

Specify if any of the following were given:

57 Systemic therapy
yes no

58 Alemtuzumab (Campath)
yes no

59 Bendamustine
yes no

60 Chlorambucil (Leukeran)
yes no

61 Cladribine (2-CdA, Leustatin)
yes no

62 Corticosteroids
yes no

63 Cyclophosphamide (Cytoxan)
yes no

64 Cytarabine (Ara-C)
yes no

65 Doxorubicin (Adriamycin)
yes no

66 Etoposide (VP-16, VePesid)
yes no

67 Fludarabine (Fludara)
yes no

68 Gemcitabine (Gemzar)
yes no

69 Ibrutinib (Imbruvica)
Yes No

70 Idelalisib (Zydelig)
Yes No

71 Ifosfamide (Ifex)
yes no

72 Lenalidomide (Revlimid)
yes no

73 Nelarabine
- Yes
- No

74 Nitrogen mustard (mustine)
- yes
- no

75 Obinutuzumab
- Yes
- No

76 Oblimersen
- Yes
- No

77 Ofatumumab (Arzerra, HuMAX-CD20)
- yes
- no

78 Pentostatin (Nipent)
- yes
- no

79 Rituximab (anti-CD20, Rituxan)
- yes
- no

80 Venetoclax
- Yes
- No

81 Vincristine (VCR, Oncovin)
- yes
- no

82 Other systemic therapy
- yes
- no

83 Specify other systemic therapy: _____

84 Radiation therapy
- yes
- no

85 Cellular therapy
- yes
- no

86 Withdrawal of immunosuppression
- Yes
- No

87 Other therapy
- yes
- no

88 Specify other therapy: _____

Disease Status at the Time of Evaluation for This Reporting Period

Questions: 89 - 113

89 Were tests for molecular markers performed (e.g. PCR)?
- yes
- no
- Unknown

90 Date sample collected: __ __ __ __ - __ __- __ __

91 Immunoglobulin heavy chain variable (IGHV) mutation
- Positive
- Negative
- Not done

92 Specify method used
- ASO IGHV RQ-PCR
- Consensus IGHV PCR
- Consensus IGHV PCR using HTS
- Nested ASO IGHV PCR
- Other method

93 Specify other method: _____

94 NOTCH 1 mutation
- Positive
- Negative
- Not done

95 P53 mutation
- Positive
- Negative
- Not done

96 SF3B1 mutation
- Positive
- Negative
- Not done

97 Other molecular marker
- Positive
- Negative
- Not Done

98 Specify other molecular marker: _____

99 Was the disease status assessed via flow cytometry? (minimum 4-color flow) (immunophenotyping)
- yes
- no

100 Date sample collected: __ __ __ __ - __ __- __ __

101 Was disease detected?
- yes
- no

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102 Was the disease status assessed by cytogenetic testing (karyotyping or FISH)?

○ yes ○ no

103 Was the disease status assessed via FISH?

○ yes ○ no

104 Date sample collected: __ __ __ __ - __ __- __ __

105 Was disease detected?

○ yes ○ no

106 Was the disease status assessed via karyotyping?

○ Yes ○ No

107 Date sample collected: __ __ __ __ - __ __- __ __

108 Was disease detected?

○ yes ○ no

109 Was the disease status assessed by clinical / hematologic assessment?

○ yes ○ no

110 Date assessed: __ __ __ __ - __ __- __ __

111 Was disease detected?

○ yes ○ no

112 What is the current disease status?

- ○ Complete remission (CR) - no lymphadenopathy; no organomegaly; neutrophils ≥ 1.5 x 10^9/L; platelets > 100 x 10^9/L; hemoglobin > 11.0 g/dL; lymphocytes < 4 x 10^9/L; bone marrow < 30% lymphocytes; absence of constitutional symptoms
- ○ Partial remission (PR) - ≥ 50% decrease in peripheral blood lymphocyte count from pretreatment value; ≥ 50% reduction in lymphadenopathy if present pretreatment; ≥ 50% reduction in liver and spleen size if enlarged pretreatment; one or more of the following: neutrophils ≥ 1.5 x 10^9/L or 50% improvement over baseline, platelets > 100 x 10^9/L or 50% improvement over baseline, hemoglobin > 11.0 g/dL or 50% improvement over baseline
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- ○ Not assessed

113 Date assessed: __ __ __ __ - __ __- __ __

First Name: _____

Last Name: _____

E-mail address: _____

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