Form 2013 R3.0: Chronic Lymphocytic Leukemia (CLL) Pre-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: _____

Subsequent Transplant or Cellular Therapy

If this is a report of a second or subsequent transplant or cellular therapy for the same disease subtype and this baseline disease insert has not been completed for the previous transplant or cellular therapy (e.g. patient was on TED track for the prior HCT, prior HCT was autologous with no consent, prior cellular therapy was not reported to the CIBMTR), begin the form at question one.

If this is a report of a second or subsequent transplant or cellular therapy for a <u>different</u> disease, begin the form at question one.

Is this the report of a second or subsequent transplant or cellular therapy for the same disease?

○ Yes ○ No

Disease Assessment at Diagnosis

Questions: 1 - 21

1 What was the date of diagnosis? __ __ __ __ - __ __- __ __

2 Was documentation submitted to the CIBMTR? (e.g. pathology report used for diagnosis)

○ Yes ○ No

3 Did a histologic transformation occur at any time after CLL diagnosis?

○ yes ○ no

4 Date of transformation: __ __ __ __ - __ __- __ __

5 Specify the disease classification after transformation

- ○ Diffuse large B-cell lymphoma (Richter syndrome) **Also complete CIBMTR form 2018 - LYM**
- ○ Other disease classification

6 Specify other disease classification: _____

7 Was documentation submitted to the CIBMTR? (e.g. pathology report at transformation)

○ Yes ○ No

Autoimmune disorder(s) at diagnosis:

8 Immune hemolytic anemia

○ Yes ○ No ○ Unknown

9 Immune thrombocytopenia

○ Yes ○ No ○ Unknown

10 Other

○ Yes ○ No ○ Unknown

11 Specify other autoimmune disorder: _____

12 Rai stage (at diagnosis)

○ Known ○ Unknown

13 What was the Rai stage? (at diagnosis)

- ○ Stage 0 - Low risk - lymphocytosis (> 15,000 x 10^9/L) in blood or bone marrow only without lymphadenopathy, hepatosplenomegaly, anemia or thrombocytopenia
- ○ Stage I - Intermediate risk - lymphocytosis plus enlarged lymph nodes (lymphadenopathy) without hepatosplenomegaly, anemia or thrombocytopenia
- ○ Stage II - Intermediate risk - lymphocytosis plus enlarged liver or spleen with or without lymphadenopathy
- ○ Stage III - High risk - lymphocytosis plus anemia (Hgb < 11.0 g/dL) with or without enlarged liver, spleen, or lymph nodes
- ○ Stage IV - High risk - lymphocytosis plus thrombocytopenia (platelet count < 100 x 10^9/L) with or without anemia or enlarged liver, spleen, or lymph nodes

14 Binet stage (at diagnosis)

○ Known ○ Unknown

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15 What was the Binet stage? (at diagnosis) (Five lymphoid bearing areas are possible: axillary, cervical, inguino-femoral, liver, and spleen.)

- Stage A - two or fewer lymphoid bearing areas enlarged, without anemia or thrombocytopenia
- Stage B - three or more lymphoid bearing areas enlarged, without anemia or thrombocytopenia
- Stage C - presence of anemia (Hgb < 10.0 g/dL) or thrombocytopenia (platelet count < 100 x 10^9/L)

16 Were systemic symptoms (B symptoms) present? (unexplained fever > 38° C; or night sweats; unexplained weight loss > 10% of body weight in six months before diagnosis)

yes no Unknown

17 Was extranodal disease present?

Yes No

Specify site(s) of disease:

18 Central nervous system (CNS)

Yes No

19 Lung

yes no

20 Other site

yes no

21 Specify other site: _____

Laboratory Studies at Diagnosis

Questions: 22 - 73

22 WBC

Known Unknown

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

24 Hemoglobin (untransfused)

Known Unknown

25 _____ g/dL g/L mmol/L

26 Platelets (untransfused)

Known Unknown

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

28 Lymphocytes

Known Unknown

29 _____ %

30 Prolymphocytes

Known Unknown

31 _____ %

32 LDH

Known Unknown

33 _____ U/L µkat/L

34 Upper limit of normal for LDH: _____ U/L µkat/L

35 Serum β2 microglobulin

Known Unknown

36 _____ µg/dL mg/L nmol/L

37 Upper limit of normal for serum ß2 microglobulin: _____ µg/dL mg/L nmol/L

38 Lymphocytes in bone marrow

Known Unknown

39 _____ %

40 Leukemia cell type *(may be determined at any time after diagnosis)*

B-cell T-cell Unknown

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

yes no Unknown

42 Date sample collected: __ __ __ __ - __ __- __ __

43 Immunoglobulin heavy chain variable (IGHV) mutation

Positive Negative Not done

44 Specify method used

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

45 Specify other method: _____

46 NOTCH 1 mutation

Positive Negative Not done

47 P53 mutation

Positive Negative Not done

48 SF3B1 mutation

Positive Negative Not done

49 Other molecular marker

Positive Negative Not Done

50 Specify other molecular marker: _____

51 Was documentation submitted to the CIBMTR?

Yes No

Immunophenotype: ***(may be determined at any time after diagnosis)***

52 Was flow cytometry (immunophenotyping) performed?

yes no Unknown

53 CD5+

Positive Negative Not Done

54 CD19+

Positive Negative Not Done

55 CD20+

Positive Negative Not Done

56 CD23+

Positive Negative Not Done

57 CD38+

Positive Negative Not done

58 Specify percent positivity

≥30% positivity <30% positivity

59 SIg

Positive Negative Not done

60 ZAP-70 - mutated

Positive Negative Not done

61 Were cytogenetics tested (karyotyping or FISH)?

yes no Unknown

62 Results of tests

- Abnormalities identified
- No evaluable metaphases
- No abnormalities

Specify cytogenetic abnormalities identified at diagnosis:

Trisomy

63 +12

Yes No

Translocation

64 t(11;14)

yes no

65 Any other translocation of 14

Yes No

Deletion

66 del(11q) / 11q–

yes no

67 del(13q) / 13q-

yes no

68 del (17p) / 17p-
yes no

Other

69 Chromosome 6 abnormalities
Yes No

70 Chromosome 8 abnormalities
Yes No

71 Other abnormality
yes no

72 Specify other abnormality: _____

73 Was documentation submitted to the CIBMTR? (e.g. cytogenetic or FISH report)
Yes No

Pre-HCT or Pre-Infusion Therapy

Questions: 74 - 148

74 Was therapy given?
yes no Unknown

Line of Therapy (1)

Questions: 75 - 148

75 Systemic therapy
yes no

76 Date therapy started
Known Unknown

77 Date started: __ __ __ __ - __ __- __ __

78 Date therapy stopped
Known Unknown

79 Date stopped: __ __ __ __ - __ __- __ __

80 Number of cycles
Known Unknown

81 Number of cycles: _____

82 Alemtuzumab (Campath)
yes no

83 Bendamustine
yes no

84 Chlorambucil (Leukeran)
yes no

85 Cladribine (2-CdA, Leustatin)
yes no

86 Corticosteroids
yes no

87 Cyclophosphamide (Cytoxan)
yes no

88 Cytarabine (Ara-C)
yes no

89 Doxorubicin (Adriamycin)
yes no

90 Etoposide (VP-16, VePesid)
yes no

91 Fludarabine (Fludara)
yes no

92 Gemcitabine (Gemzar)
yes no

93 Ibrutinib (Imbruvica)
Yes No

94 Idelalisib (Zydelig)
Yes No

95 Ifosfamide (Ifex)
yes no

96 Lenalidomide (Revlimid)
yes no

97 Nelarabine
Yes No

98 Nitrogen mustard (mustine)
yes no

99 Obinutuzumab
Yes No

100 Oblimersen
Yes No

101 Ofatumumab (Arzerra, HuMAX-CD20)
yes no

102 Pentostatin (Nipent)
yes no

103 Rituximab (anti-CD20, Rituxan)
yes no

104 Venetoclax
Yes No

105 Vincristine (VCR, Oncovin)
yes no

106 Other systemic therapy
yes no

107 Specify other systemic therapy: _____

108 Was this line of therapy given for stem cell mobilization (priming)?
yes no

109 Radiation therapy
yes no

110 Date therapy started
Known Unknown

111 Date started: __ __ __ __ - __ __- __ __

112 Date therapy stopped
Known Unknown

113 Date stopped: __ __ __ __ - __ __- __ __

Specify site(s) of radiation therapy:

114 Mediastinum
Yes No

115 Other site
yes no

116 Specify other site: _____

117 Surgery
yes no

118 Date of surgery: __ __ __ __ - __ __- __ __

119 Splenectomy
yes no

120 Other site
yes no

121 Specify other site: _____

122 Best response to line of therapy

- 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 the sum of the 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
- Unknown

123 Date assessed: __ __ __ __ - __ __- __ __

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

125 Date sample collected: __ __ __ __ - __ __- __ __

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

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

128 Specify other method: _____

129 NOTCH 1 mutation
- Positive
- Negative
- Not done

130 P53 mutation
- Positive
- Negative
- Not done

131 SF3B1 mutation
- Positive
- Negative
- Not done

132 Other molecular marker
- Positive
- Negative
- Not Done

133 Specify other molecular marker: _____

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

135 Date sample collected: __ __ __ __ - __ __- __ __

136 Was disease detected?
- yes
- no

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

138 Was the disease status assessed via FISH?
- yes
- no

139 Date sample collected: __ __ __ __ - __ __- __ __

140 Was disease detected?
- yes
- no

141 Was the disease status assessed via karyotyping?
- Yes
- No

142 Date sample collected: __ __ __ __ - __ __- __ __

143 Was disease detected?
- yes
- no

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

145 Date assessed: __ __ __ __ - __ __- __ __

146 Was disease detected?
- yes
- no

147 Did disease relapse/progress following this line of therapy?
- yes
- no

148 Date of relapse/progression: __ __ __ __ - __ __- __ __

Disease Assessment at Last Evaluation Prior to the Start of the Preparative Regimen / Infusion

Questions: 149 - 191

149 Did the recipient have known nodal involvement?
- yes
- no

150 Specify the size of the largest nodal mass: _____ cm x _____ cm

151 Was extranodal disease present?
- Yes
- No

Specify site(s) of involvement:

152 Central nervous system (CNS)
- Yes
- No

153 Lung
- yes
- no

154 Other site
- yes
- no

155 Specify other site: _____

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Center: CRID:

156 Prolymphocytes
- ○ Known ○ Unknown

157 _____ %

158 Serum β2 microglobulin
- ○ Known ○ Unknown

159 _____ ○ µg/dL ○ mg/L ○ nmol/L

160 Upper limit of normal for serum ß2 microglobulin: _____ ○ µg/dL ○ mg/L ○ nmol/L

161 Lymphocytes in bone marrow
- ○ Known ○ Unknown

162 _____ %

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

164 Date sample collected: __ __ __ __ - __ __- __ __

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

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

167 Specify other method: _____

168 NOTCH 1 mutation
- ○ Positive ○ Negative ○ Not done

169 P53 mutation
- ○ Positive ○ Negative ○ Not done

170 SF3B1 mutation
- ○ Positive ○ Negative ○ Not done

171 Other molecular marker
- ○ Positive ○ Negative ○ Not Done

172 Specify other molecular marker: _____

173 Was documentation submitted to the CIBMTR?
- ○ Yes ○ No

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

175 Date sample collected: __ __ __ __ - __ __- __ __

176 Was disease detected?
- ○ yes ○ no

177 Were cytogenetics tested (karyotyping or FISH)?
- ○ yes ○ no ○ Unknown

178 Results of tests
- ○ Abnormalities identified
- ○ No evaluable metaphases
- ○ No abnormalities

Specify cytogenetic abnormalities detected at last evaluation prior to the start of the preparative regimen / infusion:

Trisomy

179 +12
- ○ Yes ○ No

Translocation

180 t(11;14)
- ○ yes ○ no

181 Any other translocation of 14
- ○ Yes ○ No

Deletion

182 del(11q) / 11q–
- ○ yes ○ no

183 del(13q) / 13q-
- ○ yes ○ no

184 del (17p) / 17p-

yes no

Other

185 Chromosome 6 abnormalities

Yes No

186 Chromosome 8 abnormalities

Yes No

187 Other abnormality

yes no

188 Specify other abnormality: _____

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

yes no

190 Date assessed: __ __ __ __ - __ __- __ __

191 Was disease detected?

yes no

Disease Status at the Last Evaluation Prior to the Start of the Preparative Regimen / Infusion

Questions: 192 - 193

192 What was the 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
- 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 the sum of the 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
- Untreated - no chemotherapy given in the 6 months prior to HCT
- Not assessed

193 Date assessed: __ __ __ __ - __ __- __ __

First Name: _____

Last Name: _____

E-mail address: _____

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