Form 2013 R2.0: Chronic Lymphocytic Leukemia(CLL) Pre-HSCT Data

Center: CRID:

Key Fields

Sequence Number: _____

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

CIBMTR Center Number: _____

CIBMTR Recipient ID: _____

Today's Date: __ __ __ __ - __ __- __ __

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

HSCT type (check all that apply):

- Autologous
- Allogeneic, unrelated
- Allogeneic, related
- Syngeneic (identical twin)

Product type (check all that apply):

- Marrow
- PBSC
- Cord blood
- Other product

Specify: _____

This form must be accompanied by Form 2000 – Recipient Baseline Data. All information in the box above, including the date, should be identical with the corresponding Form 2000. Information should come from an actual examination by the Transplant Center physician, or the physician who is following the recipient post-HSCT, or abstraction of the recipient's medical records.

- If this is a report of a second or subsequent transplant, check here and continue with question 138.

Disease Assessment at Diagnosis

Questions: 1 - 25

1 What was the date of diagnosis of Chronic Lymphocytic Leukemia? __ __ __ __ - __ __- __ __

2 What was the disease histology at diagnosis?

- chronic lymphocytic leukemia (CLL)
- prolymphocytic leukemia (PLL)

3 Is a copy of the pathology report used for diagnosis attached?

- yes
- no

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

- yes
- no

5 Date of transformation: __ __ __ __ - __ __- __ __

6 New histology:

- prolymphocytic leukemia (PLL)
- Richter syndrome (diffuse large cell lymphoma)
- other histology

7 Specify histology: _____

8 Is a copy of the pathology report attached?

- yes
- no

Autoimmune disorder(s) at diagnosis:

9 Immune hemolytic anemia

yes no Unknown

10 Immune thrombocytopenia

yes no Unknown

11 Positive Coombs' test

yes no Unknown

12 Other

yes no Unknown

13 Specify other autoimmune disorder: _____

14 What was the Rai stage at diagnosis?

low risk - stage 0 - lymphocytosis (>15,000 x 10^9/L) in blood or bone marrow only

intermediate risk - stage I- lymphocytosis plus enlarged lymph nodes (lymphadenopathy)

intermediate risk - stage II - lymphocytosis plus enlarged liver or spleen with or without lymphadenopathy

high risk - stage III - lymphocytosis plus anemia (Hgb < 11 g/dL) with or without enlarged liver, spleen, or lymph nodes

high risk - IV - lymphoctyosis plus thrombocytopenia (platelet count < 100 x 10^9/L) with or without anemia or enlarged liver, spleen, or lymph nodes

Unknown

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 lymphiod 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)

Unknown

16 What were the disease symptoms at diagnosis?

A - none of the symptoms listed in B below

B - unexplained weight loss of >10% of body weight in six months before treatment; unexplained fever > 38°C; or, night sweats

Unknown

17 Was there extramedullary and/or extranodal involvement at diagnosis?

yes no Unknown

Specify site(s) of involvement:

18 Central nervous system (CNS)

yes no

19 Liver

yes no

20 Lung

yes no

21 Spleen

yes no

22 Specify centimeters below costal margin: _____

23 Other site:

yes no

24 Specify: _____

If the recipient is 16 years of age or older, complete the Karnofsky Scale. If the recipient is younger than 16 years of age, complete the Lansky Scale.

25 Enter age-appropriate Karnofsky or Lansky score at diagnosis: _____

Laboratory Studies at Diagnosis

Questions: 26 - 80

26 Lymphocytes in bone marrow:

Known Not known

27 _____ %

Peripheral Blood Studies at Diagnosis

28 WBC:

Known Not known

29 _____ x 10^9/L (x 10^3/mm^3)

x 10^6/L

30 Lymphocytes:

Known Not known

31 _____ %

32 Prolymphoctyes:

Known Not known

33 _____ %

34 LDH:

Known Not known

35 _____ U/L μkat/L

36 Upper limit of normal for LDH: _____

37 β^2 microglobulin:

Known Not known

38 _____ μg/dL mg/L nmol/L

39 Upper limit of normal for β^2: _____

40 IgG:

Known Not known

41 _____ mg/dL g/dL g/L

42 Lower limit of normal for IgG: _____

43 IgA:

Known Not known

44 _____ mg/dL g/dL g/L

45 Lower limit of normal for IgA: _____

46 IgM:

Known Not known

47 _____ mg/dL g/dL g/L

48 Lower limit of normal for IgM: _____

49 Leukemia cell type: (may be determined at any time after diagnosis)

B cell T cell Unknown

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

50 CD5+

yes no Unknown

51 CD19+

yes no Unknown

52 CD20+

yes no Unknown

53 CD23+

yes no Unknown

54 CD38+

yes no Unknown

55 slg weakly expressed

yes no Unknown

56 Did hypercalcemia occur at any time?

yes no

57 Were cytogenetics tested (conventional or FISH)?

yes no Unknown

58 Results of tests at diagnosis:

Yes abnormalities identified

No evaluable metaphases

No abnormalities

Specify cytogenetic abnormalities identified at diagnosis:

Trisomy

59 +12

yes no

Translocation

60 t(11;14)

yes no

61 any translocation of 14

yes no

Deletion

62 del(11q)/11q- (ATM)

yes no

63 del(13q)/13q-

yes no

64 del(17p)/17(p53)-

yes no

Other

65 abnormal 6

yes no

66 abnormal 8

yes no

67 Other abnormality

yes no

68 Specify other abnormality: _____

69 Results of tests after diagnosis to prior to preparative regimen:

Yes abnormalities identified

No evaluable metaphases

No abnormalities on any tests after diagnosis and before the preparative regimen

Specify any test result between diagnosis and preparative regimen:

Trisomy

70 +12

yes no

Translocation

71 t(11;14)

yes no

72 any translocation of 14

yes no

Deletion

73 del(11q)/11q- (ATM)

yes no

74 del(13q)/13q-

yes no

75 del(17q)/17(p53)-

yes no

Other

76 abnormal 6

yes no

77 abnormal 8

yes no

78 Other abnormality

yes no

79 Specify other abnormality:

_____

80 Is a copy of the cytogenetic or FISH report attached?

yes no

Pre-HSCT Treatment for CLL

Questions: 81 - 122

81 Was therapy given between diagnosis and the start of the preparative regimen?

yes no Unknown

Line(s) of Therapy (1)

Questions: 82 - 122

Line of Therapy

82 Systemic Therapy

yes no

83 Date therapy started: __ __ __ __ - __ __- __ __

84 Date therapy stopped: __ __ __ __ - __ __- __ __

85 Number of cycles _____ Number of cycles unknown/not applicable

Monoclonal antibodies:

86 Alemtuzumab (Campath)

yes no

87 ibritumomab tiuxetan (Zevalin)

yes no

88 Rituximab (anti-CD20, Rituxan)

yes no

89 tositumomab (Bexxar)

yes no

90 other monoclonal antibody

yes no

91 Specify: _____

92 Chlorambucil (Leukeran)

yes no

93 Cladribine (2-CdA, Leustatin)

yes no

94 Corticosteroids

yes no

95 Cyclophosphamide (Cytoxan)

yes no

96 Cytarabine (Ara-C)

yes no

97 Doxorubicin (Adriamycin)

yes no

98 Etoposide (VP-16, VePesid)

yes no

99 Fludarabine (Fludara)

yes no

100 Gemcitabine (Gemzar)

yes no

101 Ifosfamide (Ifex)

yes no

102 nitrogen mustard (mustine)

yes no

103 Pentostatin (Nipent)

yes no

104 Vincristine (VCR, Oncovin)

yes no

105 other treatment

yes no

106 Specify: _____

107 Radiation Therapy:

yes no

108 Date therapy started: __ __ __ __ - __ __- __ __

109 Date therapy stopped: __ __ __ __ - __ __- __ __

110 Mediastinum

yes no

111 other sites(s)

yes no

112 Specify: _____

113 Surgery:

yes no

114 Date of surgery: __ __ __ __ - __ __- __ __

115 splenectomy

yes no

116 other site(s)

yes no

117 Specify other site(s) _____

118 Was this line of therapy given for stem cell priming?

yes no

119 Best response to line of therapy

CR Complete response (CR) — no lymphadenopathy; no organomegaly; neutrophils > 1.5 x 10^9/L; platelets > 100 x 10^9/L; hemogloblin > 11g/dL; lymphocytes < 4 x 10^9/L; bone marrow < 30% lymphocytes; absence of constitutional symptoms

NPR Nodular partial response (NPR)-complete response with persistent lymphoid nodules in bone marrow

PR Partial response (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, hemogobin > 11g/dL or 50% improvement over baseline

SD Stable disease (SD)-no change; not complete response, partial response, nor progressive disease

Prog 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

NA Not assessed (NA)

Unknown

120 Date response established: __ __ __ __ - __ __- __ __

121 Did disease relapse/progress following this line of therapy?

yes no

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

Most Recent Disease Assessment Prior to the Start of the Preparative Regimen

Questions: 123 - 137

123 What was the Rai stage immediately prior to the preparative regimen?

Complete Remission

low risk - stage 0 - lymphocytosis (>15,000 x 10^9/L) in blood or bone marrow only

intermediate risk - stage I- lymphocytosis plus enlarged lymph nodes (lymphadenopathy)

intermediate risk - stage II - lymphocytosis plus enlarged liver or spleen with or without lymphadenopathy

high risk - stage III - lymphocytosis plus anemia (Hgb < 11 g/dL) with or without enlarged liver, spleen, or lymph nodes

high risk - IV - lymphoctyosis plus thrombocytopenia (platelet count < 100 x 10^9/L) with or without anemia or enlarged liver, spleen, or lymph nodes

Unknown

124 What was the Binet stage immediately prior to the preparative regimen? (Five lymphoid bearing areas are possible: axillary, cervical, inguino-femoral, liver, and spleen.)

Complete Remission

stage A - two or fewer lymphiod 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)

Unknown

125 Did the recipient have known nodal involvement immediately prior to the preparative regimen?

yes no

126 Specify the total number of nodes involved:

one node two or more nodes

127 Specify the size of the largest nodal mass: _____ cm X _____ cm

128 Did the recipient have known extramedullary and/or extranodal involvement immediately prior to the preparative regimen?

yes no

Specify site(s) of involvement:

129 Cental nervous system (CNS)

yes no

130 Liver

yes no

131 Lung

yes no

132 Spleen

yes no

133 Specify centimeters below costal margin: _____

134 Other site:

yes no

135 Specify site: _____

136 Was a direct or indirect Coomb's test performed?

yes no

137 Specify the Coomb's test results:

negative (normal, no agglutination)

postive (abnormal, antibodies present)

Laboratory Studies Prior to the Start of the Preparative Regimen

Questions: 138 - 161

138 Lymphocytes in bone marrow:

Known Not known

139 _____ %

140 LDH:

Known Not known

141 _____ U/L μkat/L

142 Upper limit of normal for LDH: _____

143 β^2 microglobulin:

Known Not known

144 _____ μg/dL mg/L nmol/L

145 Upper limit of normal for β^2: _____

146 IgG:

Known Not known

147 _____ mg/dL g/dL g/L

148 Lower limit of normal for IgG: _____

149 IgA: Known Not known

150 _____ mg/dL g/dL g/L

151 Lower limit of normal for IgA: _____

152 IgM:

Known Not known

153 _____ mg/dL g/dL g/L

154 Lower limit of normal for IgM: _____

155 Was molecular testing/immunophenotyping performed at the time of disease assessment prior to the preparative regimen?

yes no

Specify the testing method(s) used:

156 Immunophenotyping (4 color flow cytometry)

yes no

157 Specify the date immunophenotyping was performed: __ __ __ __ - __ __- __ __

158 Was disease detected?

yes no

159 Heavy chain gene rearrangement (ASO-PCR)

yes no

160 Specify the date the heavy chain gene rearrangement testing was performed: __ __ __ __ - __ __- __ __

161 Was disease detected?

yes no

Disease Status at the Last Assessment Prior to the Preparative Regimen

Questions: 162 - 164

162 What was the disease status at the last evaluation prior to the preparative regimen?

complete response (CR) - no lymphadenopathy; no organomegaly; neutrophils >1.5 x 10^9/L; platelets > 100 x 10^9/L; hemoglobin > 11g/dL; lymphocytes < 4 x 10^9/L; bone marrow < 30% lymphocytes; absense of constitutional symptoms

nodular partial response (NPR) - complete response with persistent lymphoid nodules in bone marrow

partial response (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 response; partial reponse; 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 lymphoctye count to ≥ 5 x 10^9/L; transfromation to a more aggressive histology

untreated - no chemotherapy given in the 6 months prior to HSCT

Not assessed

163 Date of most recent assessment for disease status prior to the preparative regimen: __ __ __ __ - __ __- __ __

First Name: _____ Last Name: _____

Phone number: _____ Fax number: _____

164 E-mail address: _____