Form 2118 R4.0: Hodgkin and Non-Hodgkin Lymphoma (LYM) Post-Infusion Data

Center: CRID:

Key Fields

Sequence Number: _____

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

CIBMTR Center Number: _____

CIBMTR Research ID: _____

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

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 - 20

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 or post-cellular therapy. When determining the best response to HCT or cellular therapy, compare the post-HCT or post-cellular therapy disease status to the status immediately prior to the preparative regimen or infusion, regardless of time since HCT or cellular therapy. 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 indicate that the date was previously reported.

1 What was the best response by CT (radiographic) criteria to HCT or cellular therapy since the date of the last report? (Include response to any therapy given for post-HCT / post-infusion maintenance, consolidation or persistence, but exclude any therapy given for relapsed or progressive disease.)

- ○ Continued complete remission (CCR) (for patients transplanted in CR)
- ○ Complete remission (CR)
- ○ Partial remission (PR)
- ○ No response (NR) / Stable disease (SD)
- ○ Progressive disease (PD)
- ○ Not assessed

2 Was the date of best response previously reported?

○ yes ○ no

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

4 What was the best response by PET (metabolic) criteria to HCT or cellular therapy since the date of the last report? (Include response to any therapy given for post-HCT / post-infusion maintenance, consolidation or persistence, but exclude any therapy given for relapsed or progressive disease.)

- ○ Continued complete remission (CCR) (for patients transplanted in CR)
- ○ Complete remission (CR)
- ○ Partial remission (PR)
- ○ No response (NR) / Stable disease (SD)
- ○ Progressive disease (PD)
- ○ Not assessed

5 Was the date of best response previously reported?

○ yes ○ no

6 Date assessed: __ __ __ __ - __ __- __ __

7 Was minimal residual disease (MRD) assessed at the time of best response? (report only bone marrow or blood results)

○ Yes ○ No ○ Unknown

Specify methods of assessment and results:

8 Flow cytometry

○ Positive ○ Negative ○ Not done

9 Sample source

○ Blood ○ Bone marrow ○ Other

10 Specify other sample source: _____

11 Date sample collected: __ __ __ __ - __ __- __ __

12 PCR

○ Positive ○ Negative ○ Not done

13 Sample source

○ Blood ○ Bone marrow ○ Other

14 Specify other sample source: _____

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

16 Next generation sequencing (NGS, 3rd gen)

○ Positive ○ Negative ○ Not done

17 Sample source

○ Blood ○ Bone marrow ○ Other

18 Specify other sample source: _____

Center: CRID:

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

20 Was documentation submitted to the CIBMTR? (e.g. path report)

○ Yes ○ No

Post-HCT or Post-Infusion Therapy

Questions: 21 - 35

21 Was therapy given since the date of the last report for reasons other than relapse or progressive disease? (Include any maintenance and consolidation therapy and therapy for persistent disease.)

○ yes ○ no

Therapies (1)

Questions: 22 - 35

Specify therapy given:

22 Systemic therapy

○ yes ○ no

Specify systemic therapy given:

23 Date therapy started

○ Known

○ Unknown

○ Not applicable (continued from prior reporting period)

24 Date started: __ __ __ __ - __ __ - __ __

25 Date therapy stopped

○ Known

○ Unknown

○ Not applicable (still receiving therapy)

26 Date stopped: __ __ __ __ - __ __ - __ __

27 Specify therapy given

○ Brentuximab vedotin

○ Ibrutinib (Imbruvica)

○ Lenalidomide (Revlimid)

○ Nivolumab

○ Pembrolizumab

○ Rituximab (Rituxan, MabThera)

○ Other systemic therapy

28 Specify other systemic therapy: _____

29 Reason systemic therapy stopped

○ Relapse / progression

○ Did not tolerate therapy

○ Therapy considered complete

○ Other

○ Unknown

30 Was therapy given as part of clinical trial?

○ Yes ○ No ○ Unknown

31 Specify the ClinicalTrials.gov identification number: _____

32 Radiation therapy

○ yes ○ no

33 Cellular therapy (e.g. CAR-T cells)

○ yes **- Also complete Pre-CTED Form 4000**

○ no

34 Other therapy

○ yes ○ no

35 Specify other therapy: _____

Disease Relapse or Progression Since the Date of Last Report

Questions: 36 - 86

36 Did the recipient experience a relapse or progression since the date of the last report? (by any method)

○ Yes ○ No ○ Unknown

37 Was disease detected by molecular testing? (e.g. PCR)

○ Yes ○ No ○ Not done

38 Date sample collected: __ __ __ __ - __ __- __ __

39 Was disease detected by cytogenetic testing? (karyotyping or FISH)

○ Yes ○ No ○ Not done

40 Was disease detected via FISH?

○ Yes ○ No

41 Date sample collected: __ __ __ __ - __ __- __ __

42 Was disease detected via karyotyping?

○ Yes ○ No

43 Date sample collected: __ __ __ __ - __ __- __ __

44 Was disease detected by radiological assessment? (e.g. PET, MRI, CT)

○ Yes ○ No ○ Not done

45 Date assessed: __ __ __ __ - __ __- __ __

46 Was disease detected by clinical / hematologic assessment?

○ Yes ○ No ○ Not done

47 Date assessed: __ __ __ __ - __ __- __ __

48 Did the recipient have known nodal involvement?

○ Yes ○ No ○ Unknown

49 Was there any known extranodal or splenic involvement?

○ yes ○ no ○ Unknown

Specify site(s) of extranodal involvement:

50 Specify site(s) of involvement (check all that apply)

- ☐ Adrenal
- ☐ Bone
- ☐ Bone marrow
- ☐ Brain
- ☐ Cerebrospinal fluid (CSF)
- ☐ Epidural space
- ☐ Gastrointestinal (GI) tract
- ☐ Heart
- ☐ Kidney
- ☐ Leptomeningeal involvement
- ☐ Liver
- ☐ Lung
- ☐ Pericardium
- ☐ Pleura
- ☐ Skin
- ☐ Spleen
- ☐ Other site

51 Specify other site: _____

52 Was a biopsy performed to confirm relapse / progression?

○ Yes ○ No ○ Unknown

53 Was documentation submitted to the CIBMTR? (e.g. path report)

○ Yes ○ No

54 Was intervention given for relapsed disease, progressive disease, or minimal residual disease? (since the date of the last report)

○ Yes ○ No

Other Therapy (1) — Questions: 55 - 86

55 Specify reason for which therapy was given

- ○ Relapsed disease
- ○ Progressive disease
- ○ Minimal residual disease (MRD)

Specify therapy given:

56 Systemic therapy

○ yes ○ no

57 Date therapy started

- ○ Known
- ○ Unknown
- ○ Not applicable (continued from prior reporting period)

58 Date started: __ __ __ __ - __ __- __ __

59 Date therapy stopped

- ○ Known
- ○ Unknown
- ○ Not applicable (still receiving therapy)

60 Date stopped: __ __ __ __ - __ __- __ __

61 Specify therapy given (check all drugs given as part of this line of therapy)

- ☐ Acalabrutinib (Calquence)
- ☐ Alemtuzumab (Campath)
- ☐ Bendamustine (Trenda)
- ☐ Bexarotene (Targretin)
- ☐ Bleomycin (BLM, Blenoxane)
- ☐ Bortezomib (Velcade)
- ☐ Brentuximab vedotin
- ☐ Carboplatin
- ☐ Carmustine (BCNU, Gliadel)
- ☐ Cisplatin (Platinol, CDDP)
- ☐ Cladribine (2-CdA, Leustatin)
- ☐ Copanlisib
- ☐ Corticosteroids
- ☐ Cyclophosphamide (Cytoxan)
- ☐ Cytarabine (Ara-C)
- ☐ High dose Cytarabine (Ara-C)
- ☐ Dacarbazine (DTIC)
- ☐ Doxorubicin (Adriamycin)
- ☐ Doxorubicin liposomal (Doxil)
- ☐ Etoposide (VP-16, VePesid)
- ☐ Everolimus (RAD-001)
- ☐ Fludarabine(Fludara)
- ☐ Gemcitabine (Gemzar)
- ☐ Ibritumomab tiuxetan (Zevalin)
- ☐ Ibrutinib (Imbruvica)
- ☐ Idelalisib (Zydelig)
- ☐ Ifosfamide (Ifex)
- ☐ Ipilimumab (Yervoy)
- ☐ Ixazomib (Ninlaro)
- ☐ L-asparaginase
- ☐ PEG-asparaginase
- ☐ Lenalidomide (Revlimid)
- ☐ Methotrexate (MTX)
- ☐ High dose Methotrexate (defined as IV doses ≥ 2.5 gm/m2)
- ☐ Mitoxantrone (Novantrone)
- ☐ Mogamulizumab
- ☐ Nivolumab (Opdivo)
- ☐ Obinutuzumab (Gazyva)
- ☐ Ofatumumab (Arzerra, HuMAX-CD20)
- ☐ Pembrolizumab (Keytruda)
- ☐ Pentostatin (Nipent)
- ☐ Pralatrexate (Folotyn)
- ☐ Procarbazine (Matulane)
- ☐ Rituximab (Rituxan, MabThera)

- [ ] Romidepsin (Istodax)
- [ ] Temozolomide (Temodar)
- [ ] Temsirolimus (Torisel)
- [ ] Tositumomab (Bexxar)
- [ ] Venetoclax
- [ ] Vinblastine (Velban, VLB)
- [ ] Vincristine (VCR, Oncovin)
- [ ] Vinorelbine (Navelbine)
- [ ] Vorinostat (Zolinza)
- [ ] Other systemic therapy

62 Specify other systemic therapy: _____

63 Was therapy given as part of clinical trial?
( ) Yes ( ) No ( ) Unknown

64 Specify the ClinicalTrials.gov identification number: _____

65 Intrathecal therapy
( ) yes ( ) no

66 Date therapy started
( ) Known
( ) Unknown
( ) Not applicable (continued from prior reporting period)

67 Date started: __ __ __ __ - __ __- __ __

68 Date therapy stopped
( ) Known
( ) Unknown
( ) Not applicable (still receiving therapy)

69 Date stopped: __ __ __ __ - __ __- __ __

70 Specify intrathecal therapy
( ) Intrathecal methotrexate
( ) Intrathecal cytarabine
( ) Intrathecal depo-cytarabine
( ) Intrathecal methylprednisolone
( ) Intrathecal rituximab
( ) Other intrathecal therapy

71 Specify other intrathecal therapy: _____

72 Intraocular therapy
( ) Yes ( ) No

73 Date therapy started
( ) Known
( ) Unknown
( ) Not applicable (continued from prior reporting period)

74 Date started: __ __ __ __ - __ __- __ __

75 Date therapy stopped
( ) Known
( ) Unknown
( ) Not applicable (still receiving therapy)

76 Date stopped: __ __ __ __ - __ __- __ __

77 Specify intraocular therapy
( ) Intraocular methotrexate
( ) Intraocular rituximab
( ) Other intraocular therapy

78 Specify other intraocular therapy: _____

79 Radiation therapy
( ) yes ( ) no

80 Cellular therapy (e.g. CAR-T cells)
( ) yes **- Also complete Pre-CTED Form 4000**
( ) no

81 Other therapy
( ) yes ( ) no

Center: CRID:

82 Specify other therapy: _____

83 Best response to line of therapy by CT (radiographic) criteria (for relapse / progressive disease)

- Complete remission (CR)
- Partial remission (PR)
- No response (NR) / Stable disease (SD)
- Progressive disease (PD)
- Not assessed

84 Date assessed: __ __ __ __ - __ __- __ __

85 Best response to line of therapy by PET (metabolic) criteria (for relapse / progressive disease)

- Complete remission (CR)
- Partial remission (PR)
- No response (NR) / Stable disease (SD)
- Progressive disease (PD)
- Not assessed

86 Date assessed: __ __ __ __ - __ __- __ __

Disease Status at the Time of Evaluation for This Reporting Period

Questions: 87 - 90

87 What is the disease status? (by CT (radiographic) criteria)

- Complete remission (CR)
- Partial remission (PR)
- No response (NR) / Stable disease (SD)
- Progressive disease (PD)
- Not assessed

88 Date assessed: __ __ __ __ - __ __- __ __

89 What is the current disease status? (by PET (metabolic) criteria)

- Complete remission (CR)
- Partial remission (PR)
- No response (NR) / Stable disease (SD)
- Progressive disease (PD)
- Not assessed

90 Date assessed: __ __ __ __ - __ __- __ __

First Name: _____

Last Name: _____

E-mail address: _____

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