Form 2124 R2.0: Sarcoma Post-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: _____

Visit:

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

Specify: _____

Disease Assessment at the Time of Best Response to HSCT

Questions: 1 - 5

Best response is based on response to the HSCT, but does NOT include response to any therapy given for disease relapse or progression post-HSCT. When determining the best response to HSCT, compare the post-HSCT disease status to the status immediately prior to the preparative regimen, regardless of time since HSCT. This comparison is meant to capture the BEST disease status in response to HSCT 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 the box to indicate "date previously reported."

1 Compared to the disease status prior to the preparative regimen, what was the best response to HSCT since the date of the last report? (Include response to planned post-HSCT tretament.)

- CR - disappearance of all target lesions for a period of at least one month
- CRU - Complete response with persistent imaging abnormalities of unknown significance.
- PR - at least 30% decrease in the sum of the longest diameter of measured lesions (target lesions) taking as reference the baseline sum of longest diameters
- SD - neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD, taking as reference the smallest sum of the longest diameters since the treatment started
- PD - at least a 20% increase in the sum of the longest diameter of measured lesions (target lesions), taking as reference the smallest sum of the longest diameters recorded since the treatment started or the appearance of one or more new lesions
- NA - Not assessed
- NETD - Not evaluable, toxic death

2 Date the best response first began: __ __ __ __ - __ __- __ __ date of the best response previously reported

3 Was the best response documented surgically?

yes | no | Unknown

4 Specify type of surgery:

- biopsy only
- partial resection
- gross total resection with involved margins
- total resection with clean margins < 2 cm
- total resection with clean margins > 2 cm
- Other surgery

5 Specify surgery: _____

Relapse or progression Post-HSCT

Questions: 6 - 20

6 Has the disease relapsed or progressed since the date of the last report?

yes no Unknown

7 Date of progression/relapse: __ __ __ __ - __ __- __ __ Date unknown

8 *Allogeneic HSCTs only*: Was there subsequent disease stability or regression without further therapy (so-called graft-verses-tumor effect)?

yes no Unknown

9 Did this change in disease status qualify as a partial response or better if compared to a post-HSCT imaging study? (*see page 1 for criteria to define partial response*)

yes no

10 Date of response: __ __ __ __ - __ __- __ __ Date unknown

Specify site(s) of disease progression / recurrence

11 Abdominal - diffuse

yes no Unknown

12 Bone marrow

yes no Unknown

13 Central nervous system (CNS)

yes no Unknown

14 Liver

yes no Unknown

15 Lungs

yes no Unknown

16 Lymph nodes - distant

yes no Unknown

17 Lymph nodes - regional

yes no Unknown

18 Skin

yes no Unknown

19 Other site:

yes no Unknown

20 Specify site: _____

Post-HSCT Treatment for Sarcoma

Questions: 21 - 62

21 Was any treatment given for persistent, relapsed or progressive disease since the date of the last report?

yes no

Line of Therapy (1)

Questions: 22 - 62

22 Was therapy planned?

yes no

23 Systemic Therapy:

yes no

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

25 Date therapy stopped: __ __ __ __ - __ __- __ __

26 Number of cycles _____ Unknown/not applicable

27 Cisplatin (Platinol, CDDP)

yes no

28 Cyclophosphamide (Cytoxan)

yes no

29 dactinomycin (Actinomycin D)

yes no

30 dacarbazine (DTIC)

yes no

31 Doxorubicin (Adriamycin)

yes no

32 Etoposide (VP-16, VePesid)

yes no

33 Ifosfamide (Ifex)

yes no

34 imatinib (Gleevec)

yes no

35 melphalan (L-PAM, Alkeran)

yes no

36 sunitinib (Sutent, SU11248)

yes no

37 topotecan (Hycamtin)

yes no

38 Vincristine (VCR, Oncovin)

yes no

39 Other systemic therapy

yes no

40 Specify other therapy: _____

41 Radiation Therapy:

yes no

42 Date therapy started: __ __ __ __ - __ __- __ __

43 Date therapy stopped: __ __ __ __ - __ __- __ __

44 Local / regional

yes no

45 Specify total dose _____

46 Sites of non-contiguous metastases

yes no

47 Specify total dose _____

48 Other radiation therapy site

yes no

49 Specify other radiation site _____

50 Specify total dose _____

51 Surgical Biopsy/Resection:

yes no

52 Date of surgery: __ __ __ __ - __ __- __ __

53 Type of surgery _____

54 Specify other surgery: _____

55 Site of surgery:

primary lesion metastatic lesion Both

56 Was the extent of resection radiographically confirmed?

yes no

57 Was any persistent, viable tumor detected?

yes no Unknown

58 Best response to line of therapy:

CR - disappearance of all target lesions for a period of at least one month

CRU - Complete response with persistent imaging abnormalities of unknown significance.

PR - at least 30% decrease in the sum of the longest diameter of measured lesions (target lesions) taking as reference the baseline sum of longest diameters

SD - neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD, taking as reference the smallest sum of the longest diameters since the treatment started

PD - at least 20% increase in the sum of the longest diameter of measured lesions (target lesions), taking as reference the smallest sum of the longest diameters recorded since the treatment started or the appearance of one or more new lesions

NA - not assessed

NETD - not evaluable, toxic death

59 Date response evaluated: __ __ __ __ - __ __- __ __

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

yes no

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

62 Specify site(s) of relapse: _____

Disease Status at the Time of Assessment for This Reporting Period

Questions: 63 - 64

63 What is the current disease status?

- complete remission
- Not in complete remission

64 Date the current disease status was established in this reporting period: __ __ __ __ - __ __- __ __

First Name: _____ Last Name: _____

Phone: _____ Fax: _____

E-mail address: _____