Form 4003 R2.0: Cellular Therapy Product

Center: CRID:

Key Fields

Sequence Number: _____

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

CIBMTR Center Number: _____

CIBMTR Research ID: _____

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

Cellular Therapy Product Identification

Questions: 1 - 19

1 Name of product

- ○ Tisagenlecleucel (Kymriah®)
- ○ Axicabtagene Ciloleucel (Yescarta®)
- ○ Other product

2 Specify donor

○ Autologous ○ Allogeneic, related ○ Allogeneic, unrelated

3 Did NMDP / Be the Match facilitate the procurement, collection, or transportation of the product?

○ Yes ○ No

4 Was the product a cord blood unit?

○ Yes ○ No

5 NMDP cord blood unit ID: _____

6 NMDP donor ID: _____

7 Non-NMDP unrelated donor ID: *(not applicable for related donor)* _____

8 Non-NMDP cord blood unit ID: *(include related and autologous CBUs)* _____

9 Global Registration Identifier for Donors (GRID) *(optional)* _____

10 Is there an ISBT DIN number associated with the product?

○ Yes ○ No

11 Is the CBU ID also the ISBT DIN number?

○ yes ○ no

12 Specify the ISBT DIN number: _____

13 Registry or UCB Bank ID _____

14 Specify other Registry or UCB Bank: _____

15 Date of birth (donor / infant)

○ Known ○ Unknown

16 Date of birth: (donor / infant) __ __ __ __ - __ __- __ __

17 Age (donor / infant)

○ Known ○ Unknown

18 Age: (donor / infant) _____

- ○ Months (use only if less than 1 year old)
- ○ years

19 Sex (donor / infant)

○ male ○ female

Cell Product Source

Questions: 20 - 21

20 Date of cell product collection

○ Known ○ Unknown

21 Date of cell product collection: __ __ __ __ - __ __- __ __

Collection Procedure

Questions: 22 - 27

22 Did the recipient have more than one mobilization event to acquire cells?

○ yes ○ no

23 Specify the total number of mobilization events performed for this cellular therapy: _____ (regardless of the number of collections or which collections were used)

24 Number of collections: _____

25 Specify the method of product collection

○ Bone marrow aspirate ○ Leukapheresis ○ Byoptic sample ○ Other method

26 Specify other method: _____

Specify all agents used in the mobilization events reported above:

27 Specify agent(s) used in the mobilization events (check all that apply)

- ☐ G-CSF
- ☐ GM-CSF
- ☐ Pegylated G-CSF
- ☐ Plerixafor (Mozobil)
- ☐ Other CXCR4 inhibitor

Cell Product Manipulation

Questions: 28 - 59

28 Were the cells in the infused product selected / modified / engineered prior to infusion?
○ Yes ○ No

29 Specify the portion manipulated
○ Entire product ○ Portion of product

30 Was the unmanipulated portion of the product also infused?
○ Yes ○ No

31 Was the same manipulation method used on the entire product / all portions of the product?
○ Yes ○ No

Specify all methods used to manipulate the product:

32 Specify method(s) used to manipulate the product (check all that apply)

- ☐ Cultured (ex-vivo expansion)
- ☐ Induced cell differentiation
- ☐ Cell selection - positive
- ☐ Cell selection - negative
- ☐ Cell selection based on affinity to a specific antigen
- ☐ Genetic manipulation (gene transfer / transduction)
- ☐ Other cell manipulation

33 Specify other cell manipulation: _____

Specify the type of genetic manipulation:

34 Transfection
○ Yes ○ No

35 Viral transduction
○ Yes ○ No

36 Lentivirus
○ Yes ○ No

37 Retrovirus
○ Yes ○ No

38 Non-viral transfection
○ yes ○ no

39 Transposon
○ Yes ○ No

40 Electroporation
○ Yes ○ No

41 Other non-viral transfection
○ Yes ○ No

42 Specify other non-viral transfection: _____

43 Gene editing
○ Yes ○ No

44 Specify gene

- ○ ABCD1
- ○ CCR5
- ○ Factor IX
- ○ Factor VIII
- ○ Globlin gene
- ○ TCR (T-cell receptor)
- ○ Other gene

45 Specify other gene: _____

46 Were cells engineered to express a non-native protein?
- ○ Yes ○ No

47 Specify the protein inserted into the cellular product
- ○ T-cell receptor
- ○ Chimeric Antigen Receptor (CAR)
- ○ Suicide gene

48 Specify details of the CAR construct (check all that apply)
- ☐ CD3ζ
- ☐ CD27
- ☐ CD28
- ☐ ICOS
- ☐ OX40
- ☐ 4-1BB
- ☐ EGFR
- ☐ Other construct

49 Specify other construct: _____

50 Specify suicide gene: _____

51 Other genetic manipulation
- ○ Yes ○ No

52 Specify other genetic manipulation: _____

53 Was the product manipulated to recognize a specific target/antigen?
- ○ Yes ○ No

54 Specify target (check all that apply)
- ☐ Viral
- ☐ Tumor / cancer antigen
- ☐ Other target

Targets specific to viral infections

55 Specify viral target(s) (check all that apply)
- ☐ Adenovirus
- ☐ BK virus
- ☐ Cytomegalovirus (CMV)
- ☐ Epstein-Barr virus (EBV)
- ☐ Human herpes virus 6
- ☐ Human Immunodeficiency Virus (HIV)
- ☐ Other virus

56 Specify other virus: _____

Targets specific to tumors

57 Specify the tumor / cancer antigen (check all that apply)

- ☐ AFP (alpha fetoprotein)
- ☐ BCMA
- ☐ CD16
- ☐ CD19
- ☐ CD20
- ☐ CD22
- ☐ CD30
- ☐ CD33
- ☐ CD38
- ☐ CD123
- ☐ CD138
- ☐ CD171
- ☐ CS-1 (SLAMF7)
- ☐ HPV-16E6
- ☐ Lewis Y
- ☐ MAGE-A4
- ☐ MAGE-A10
- ☐ MUC16
- ☐ NY-ESO-1
- ☐ PRAME
- ☐ PSCA (prostate stem cell antigen)
- ☐ WT-1
- ☐ Other tumor / cancer antigen

58 Specify tumor / cancer antigen: _____

Other Target

59 Specify other target: _____

Cell Product Analysis

Questions: 60 - 68

60 Was transfection efficiency done? (genetically engineered cells)

○ Yes ○ No ○ Unknown

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

62 Transfection efficiency: _____ %

63 Was transfection efficiency target achieved?

○ Yes ○ No

64 Was viability of cells done?

○ Yes ○ No ○ Unknown

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

66 Viability of cells: _____ %

67 Method of testing cell viability

○ 7-AAD ○ Propidium iodide ○ Trypan blue ○ Other method

68 Specify other method: _____

Product Infusion

Questions: 69 - 69

69 Specify the total number of planned infusions: _____ (of this product) (as part of this course of cellular therapy)

First Name: _____

Last Name: _____

E-mail address: _____

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