

# ERROR CORRECTION FORM

Sequence Number:

CIBMTR Recipient ID:

Initials:

Today's Date:

Month Day Year

Infusion Date:

Month Day Year

CIBMTR Center Number:

## Form 4003 R1.0: 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 - 18

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 Is there an ISBT DIN number associated with the product?

- Yes  No

10 Is the CBU ID also the ISBT DIN number?

- yes  no

11 Specify the ISBT DIN number: \_\_\_\_\_

12 Registry or UCB Bank ID \_\_\_\_\_

13 Specify other Registry or UCB Bank: \_\_\_\_\_

14 Date of birth (donor / infant)

- Known  Unknown

15 Date of birth: (donor / infant) \_\_\_\_-\_\_\_\_-\_\_\_\_

16 Age (donor / infant)

- Known  Unknown

17 Age: (donor / infant) \_\_\_\_\_

Months (use only if less than 1 year old)

years

18 Sex (donor / infant)

- male  female

### Cell Product Source

Questions: 19 - 20

19 Date of cell product collection

- Known  Unknown

20 Date of cell product collection: \_\_\_\_-\_\_\_\_-\_\_\_\_

### Collection Procedure

Questions: 21 - 26

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

- yes  no

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

23 Number of collections: \_\_\_\_\_

24 Specify the method of product collection

- Bone marrow aspirate  Leukapheresis  Byoptic sample  Other method

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25 Specify other method: \_\_\_\_\_

**Specify all agents used in the mobilization events reported above:**

26 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: 27 - 58

27 Were the cells in the infused product selected / modified / engineered prior to infusion?

- Yes  No

28 Specify the portion manipulated

- Entire product  Portion of product

29 Was the unmanipulated portion of the product also infused?

- Yes  No

30 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:**

31 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

32 Specify other cell manipulation: \_\_\_\_\_

**Specify the type of genetic manipulation:**

33 Transfection

- Yes  No

34 Viral transduction

- Yes  No

35 Lentivirus

- Yes  No

36 Retrovirus

- Yes  No

37 Non-viral transfection

- yes  no

38 Transposon

- Yes  No

39 Electroporation

- Yes  No

40 Other non-viral transfection

- Yes  No

41 Specify other non-viral transfection: \_\_\_\_\_

42 Gene editing

- Yes  No

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Center:

CRID:

### 43 Specify gene

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

44 Specify other gene: \_\_\_\_\_

### 45 Were cells engineered to express a non-native protein?

- Yes  No

### 46 Specify the protein inserted into the cellular product

- T-cell receptor
- Chimeric Antigen Receptor (CAR)
- Suicide gene

### 47 Specify details of the CAR construct (check all that apply)

- CD3 $\zeta$
- CD27
- CD28
- ICOS
- OX40
- 4-1BB
- EGFR
- Other construct

48 Specify other construct: \_\_\_\_\_

49 Specify suicide gene: \_\_\_\_\_

### 50 Other genetic manipulation

- Yes  No

51 Specify other genetic manipulation: \_\_\_\_\_

### 52 Was the product manipulated to recognize a specific target/antigen?

- Yes  No

### 53 Specify target (check all that apply)

- Viral
- Tumor / cancer antigen
- Other target

#### Targets specific to viral infections

### 54 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

55 Specify other virus: \_\_\_\_\_

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### Targets specific to tumors

56 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

57 Specify tumor / cancer antigen: \_\_\_\_\_

### Other Target

58 Specify other target: \_\_\_\_\_

## Cell Product Analysis

Questions: 59 - 67

59 Was transfection efficiency done? (genetically engineered cells)

- Yes  No  Unknown

60 Date: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

61 Transfection efficiency: \_\_\_\_\_ %

62 Was transfection efficiency target achieved?

- Yes  No

63 Was viability of cells done?

- Yes  No  Unknown

64 Date: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

65 Viability of cells: \_\_\_\_\_ %

66 Method of testing cell viability

- 7-AAD  Propidium iodide  Trypan blue  Other method

67 Specify other method: \_\_\_\_\_

## Product Infusion

Questions: 68 - 68

68 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: \_\_\_\_\_

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