Form 4003 R1.0: Cellular Therapy Product

Key Fields

Sequence Number: ____________________
Date Received: __ __ __ __ - __ __- __ __
CIBMTR Center Number: ____________________
CIBMTR Research ID: ____________________
Event date: ____________________

Cellular Therapy Product Identification

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

19 Date of cell product collection
   - Known
   - Unknown

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

Collection Procedure

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:

23 Number of collections: ____________________

24 Specify the method of product collection
   - Bone marrow aspirate
   - Leukapheresis
   - Byoptic sample
   - Other method

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### Cell Product Manipulation

#### Questions: 25 - 58

**25** Specify other method: __________________________________________________________________________

**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

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>27</td>
<td>Were the cells in the infused product selected / modified / engineered prior to infusion?</td>
</tr>
<tr>
<td>28</td>
<td>Specify the portion manipulated</td>
</tr>
<tr>
<td>29</td>
<td>Was the unmanipulated portion of the product also infused?</td>
</tr>
<tr>
<td>30</td>
<td>Was the same manipulation method used on the entire product / all portions of the product?</td>
</tr>
<tr>
<td>31</td>
<td>Specify method(s) used to manipulate the product (check all that apply)</td>
</tr>
<tr>
<td>32</td>
<td>Specify other cell manipulation: ______________________________________________________________________</td>
</tr>
<tr>
<td>33</td>
<td>Transfection</td>
</tr>
<tr>
<td>34</td>
<td>Viral transduction</td>
</tr>
<tr>
<td>35</td>
<td>Lentivirus</td>
</tr>
<tr>
<td>36</td>
<td>Retrovirus</td>
</tr>
<tr>
<td>37</td>
<td>Non-viral transfection</td>
</tr>
<tr>
<td>38</td>
<td>Transposon</td>
</tr>
<tr>
<td>39</td>
<td>Electroporation</td>
</tr>
<tr>
<td>40</td>
<td>Other non-viral transfection</td>
</tr>
<tr>
<td>41</td>
<td>Specify other non-viral transfection: ______________________________________________________________________</td>
</tr>
<tr>
<td>42</td>
<td>Gene editing</td>
</tr>
</tbody>
</table>

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**CIBMTR Form 4003 R1.0: Cellular Therapy Product**

Center: ______

CRID: ______

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**ERROR CORRECTION FORM**

Sequence Number: ______

CIBMTR Recipient ID: ______

Initials: ______

Today's Date: Month Day Year

Infusion Date: Month Day Year

CIBMTR Center Number: ______

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43 Specify gene
- ABCD1
- CCR5
- Factor IX
- Factor VIII
- Globin 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)
- CD3ζ
- 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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Center: CRID:

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: ____________________________
**CIBMTR Form 4003 R1.0: Cellular Therapy Product**

**Center:**

**CRID:**

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**Date:** 

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**Cell Product Manipulation**

<table>
<thead>
<tr>
<th>Event date</th>
<th>Date of cell product collection</th>
<th>Was viability of cells done?</th>
<th>Was the product manipulated to recognize a specific target/antigen?</th>
<th>Did the recipient have more than one mobilization event to acquire cells?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

**Number of collections**

<table>
<thead>
<tr>
<th>Number of collections</th>
<th>Method of testing cell viability</th>
<th>Date of cell product collection:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Specify all methods used to manipulate the product**

- Gene editing
- Retrovirus
- Viral transduction
- Non-viral transfection
- Transfection efficiency

**Specify all agent(s) used in the mobilization events reported above:**

- GM-CSF
- Pegylated G-CSF

**Specify all methods used to manipulate the product:**

- Electroporation
- Transposon
- Transfection efficiency

**Specify the total number of mobilization events performed for this cellular therapy:**

<table>
<thead>
<tr>
<th>Total number of mobilization events</th>
<th>Date of mobilization event:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Specify agent(s) used in the mobilization events**

- GM-CSF
- Pegylated G-CSF
- Plerixafor (Mozobil)

**Specify the portion manipulated**

- Entire product
- Unmanipulated portion

**Was unmanipulated portion of the product also infused?**

- Yes
- No

**Specify other Registry or UCB Bank:**

- Non-NMDP unrelated donor ID
- NMDP donor ID
- NMDP cord blood unit ID

**Specify the type of genetic manipulation:**

- Gene editing
- Retrovirus
- Viral transduction
- Non-viral transfection

**Specify gene**

- Other gene
- Factor IX
- ABCD1
- Factor VIII

**Specify other non-viral transfection:**

- Electroporation
- Transposon
- Recombinant DNA

**Specify other target:**

- Other virus
- Human Immunodeficiency Virus (HIV)
- Epstein-Barr virus (EBV)
- Cytomegalovirus (CMV)
- Adenovirus

**Specify the tumor / cancer antigen**

- Other virus
- Human Immunodeficiency Virus (HIV)
- Epstein-Barr virus (EBV)
- Cytomegalovirus (CMV)
- Adenovirus

**Specify the protein inserted into the cellular product**

- Other protein
- Tisagenlecleucel
- Yescarta®
- Kymriah®

**Specify the total number of planned infusions**

- Known
- Unknown

**Specify other infusion:**

- Other method

**Specify the tumor / cancer antigen**

- Other virus
- Human Immunodeficiency Virus (HIV)
- Epstein-Barr virus (EBV)
- Cytomegalovirus (CMV)
- Adenovirus

**Specify the protein inserted into the cellular product**

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- Tisagenlecleucel
- Yescarta®
- Kymriah®

**Specify the portion manipulated**

- Entire product
- Unmanipulated portion

**Was unmanipulated portion of the product also infused?**

- Yes
- No

**Specify other non-viral transfection:**

- Electroporation
- Transposon
- Recombinant DNA

**Specify other target:**

- Other virus
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