This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of Investigation Results

CAR-T Cell Products

August 29, 2023

Non-proprietary name

See attachment.

Brand name (marketing authorization holder)

See attachment.

Japanese market launch

See attachment.

Indications or Performance

See attachment.

Summary of revisions

A statement should be added to the Important Precautions section that an explanation on the possibility that the product cannot be provided due to reasons such as not conforming to specifications should be given to patients.

Investigation results and background of the revision

Cases for each CAR-T cell product where the product could not be provided and the relevant descriptions of those cases in the package inserts in Japan and overseas were evaluated. For each CAR-T cell product, it was considered possible that the product cannot be provided due to reasons such as not conforming to specifications. Since it is important to explain such matters to patients, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary as a result of consultation with expert advisors.

This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Attachment

No.	Brand name	Non-proprietary name	Marketing authorization holder	Japanese market launch	Indications or Performance
a.	Yescarta Intravenous Drip Infusion	Axicabtagene ciloleucel	Gilead Sciences K.K.	May 2022	The following relapsed or refractory large B-cell lymphoma: ・ Diffuse large B-cell lymphoma, primary mediastinal large B-cell lymphoma, transformed follicular lymphoma, and high-grade B-cell lymphoma Yescarta should be used only in patients who have not received prior infusion of chimeric antigen receptor-expressing T-cells targeted at CD19 antigen.
b.	Abecma Intravenous Infusion	Idecabtagene vicleucel	Bristol-Myers Squibb K.K.	April 2022	Relapsed or refractory multiple myeloma Abecma should be used only in patients meeting all of the following criteria: ・ Patients with no history of BCMA-targeted chimeric antigen receptor-expressing T cell infusion therapy ・ Patients who have received at least 3 prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD 38 monoclonal antibody, and showed disease progression or relapse after the last prior therapy
c.	Carvykti Suspension for Intravenous Infusion	Ciltacabtagene autoleucel	Janssen Pharmaceutical K.K.	Before market launch	Relapsed or refractory multiple myeloma Carvykti must be used only in patients meeting both of the following criteria. ・ Patients who are naïve to BCMA-targeted chimeric antigen receptor T-cell infusion therapy ・ Patients who have received at least 3 prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

					anti-CD38 monoclonal antibody and who have failed to respond to or have relapsed after the last therapy
d.	Kymriah Suspension for Intravenous Infusion	Tisagenlecleucel	Novartis Pharma K.K.	May 2019	1. Relapsed or refractory CD19-positive B-cell acute lymphoblastic leukemia Kymriah should be used only in patients meeting any of the following criteria who are naïve to CD19-targeted chimeric antigen receptor T-cell infusion therapy: ・ Newly diagnosed patients who failed to achieve remission with ≥2 lines of standard chemotherapy ・ Patients with relapsed disease who failed to achieve remission with ≥1 line of chemotherapy ・ Patients who are ineligible for, or relapsed after, allogeneic haematopoietic stem cell transplantation 2. Relapsed or refractory diffuse large B-cell lymphoma Kymriah should be used only in patients meeting any of the following criteria who are naïve to CD19-targeted chimeric antigen receptor T cell infusion therapy and are ineligible for, or relapsed after, autologous haematopoietic stem cell transplantation: ・ Newly diagnosed patients who failed to achieve a complete response to ≥2 lines of chemotherapy; newly diagnosed patients who achieved a complete response to ≥2 lines of chemotherapy but subsequently relapsed; patients who received ≥1 line of chemotherapy after relapse but failed to achieve a complete response; or patients who received ≥1 line of chemotherapy after relapse and achieved a complete response but subsequently relapsed again ・ Patients with diffuse large B-cell lymphoma transformed

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

					from follicular lymphoma who failed to achieve a complete response to ≥2 lines of chemotherapy including ≥1 line after the transformation, or who achieved a complete response to ≥2 lines of chemotherapy including ≥1 line after the transformation but subsequently relapsed 3. Relapsed or refractory follicular lymphoma Kymriah should be used only in patients meeting any of the following criteria who are naïve to CD19-targeted chimeric antigen receptor T-cell infusion therapy: ・ Newly diagnosed patients who failed to achieve a response to ≥2 lines of systemic therapy; newly diagnosed patients who achieved a response to ≥2 lines of systemic therapy but subsequently relapsed; patients who received ≥1 line of systemic therapy after relapse but failed to achieve a response; or patients who received ≥1 line of systemic therapy after relapse and achieved a response but subsequently relapsed again
e.	Breyanzi Suspension for Intravenous Infusion	Lisocabtagene maraleucel	Bristol-Myers Squibb K.K.	May 2021	The following relapsed or refractory large B-cell lymphoma: ・ Diffuse large B-cell lymphoma, primary mediastinal large B-cell lymphoma, transformed low-grade non-Hodgkin's lymphoma, high-grade B-cell lymphoma Relapsed or refractory follicular lymphoma Breyanzi should be used only in patients who have not received prior infusion of chimeric antigen receptor-expressing T-cells targeted at CD19 antigen.

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp