独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

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Summary of Investigation Results

Idecabtagene vicleucel
Ciltacabtagene autoleucel
Tisagenlecleucel

January 13, 2026

Non-proprietary name

a. Idecabtagene vicleucel

b. Ciltacabtagene autoleucel

c. Tisagenlecleucel

Brand name (marketing authorization holder)

a. Abecma for intravenous infusion (Bristol-Myers Squibb K.K.)

b. Carvykti Suspension for Intravenous Infusion (Janssen Pharmaceutical K.K.)

c. Kymriah for i.v. infusion (Novartis Pharma K.K.)

Japanese market launch

See attachment.

Indications or performance

See attachment.

Summary of revisions

Precautionary statements concerning progressive multifocal leukoencephalopathy should be added to the text of “Infections” in the Clinically Significant Adverse Reactions section.

Pharmaceuticals and Medical Devices Agency

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Investigation results and background of the revision

Cases involving progressive multifocal leukoencephalopathy (hereinafter referred to as "PML") were evaluated. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary for the following reasons.

- For ciltacabtagene autoleucel and tisagenlecleucel, cases involving PML in which a causal relationship with these products was reasonably possible have been reported.
- Although no cases involving PML in which a causal relationship with idecabtagene vicleucel was reasonably possible were identified, it is considered to be highly probable that cases involving PML in which a causal relationship with the product was reasonably possible will also be reported for idecabtagene vicleucel in consideration of the following points, and therefore, issuing common precautions for PML was deemed to be appropriate.
  - ✓ Cases of PML-related events have been reported in patients treated with idecabtagene vicleucel.
  - ✓ Literature suggesting a relationship between CAR-T cell therapy and PML has been reported (Blood 2023;141: 673-7).
  - ✓ Precautionary statements concerning PML have already been included in the package inserts of multiple CAR-T cell products in Japan.

Reference: Number of cases* and patient mortalities involving PML reported in Japan and overseas

a. No cases have been reported in Japan to date.

b. No cases have been reported in Japan to date.

c. One case has been reported in Japan to date. (A causal relationship between the regenerative medical product and the event could not be established for this case.)

One instance of patient mortality has been reported in Japan to date. (A causal relationship between the regenerative medical product and the death following the event could not be established for this case.)

a. One case has been reported overseas to date. (A causal relationship between the regenerative medical product and the event could not be established for this case.)

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No patient mortalities have been reported overseas to date.

b. A total of 5 cases have been reported overseas to date (including 2 cases in which a causal relationship between the regenerative medical product and the event was reasonably possible.)
A total of 3 patient mortalities have been reported overseas to date (including 1 case in which a causal relationship between the regenerative medical product and the death following the event was reasonably possible.)

c. A total of 2 cases have been reported overseas to date. (including 2 cases in which a causal relationship between the regenerative medical product and the event was reasonably possible.)
One instance of patient mortality has been reported overseas to date. (A causal relationship between the regenerative medical product and the death following the event could not be established for this case.)

*: Cases collected in the PMDA's safety database for regenerative medical products

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).

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Attachment

No.	Non-proprietary name	Brand name	Marketing authorization holder	Japanese market launch	Indications or performance
a.	Idecabtagene vicleucel	Abecma for intravenous infusion	Bristol-Myers Squibb K.K.	April 2022	Relapsed or refractory multiple myeloma. Abecma should be used only in patients meeting both 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 2 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
b.	Ciltacabtagene autoleucel	Carvykti Suspension for Intravenous Infusion	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 with no history of BCMA-targeted chimeric antigen receptor-expressing T cell infusion therapy ・ Patients who have received at least 3 prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody and who have failed to respond to or have

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					relapsed after the last therapy
c.	Tisagenlecleucel	Kymriah for i.v. infusion	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

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					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 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;

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					or patients who received ≥1 line of systemic therapy after relapse and achieved a response but subsequently relapsed again