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

Ciltacabtagene autoleucel

January 10, 2024

Non-proprietary name

Ciltacabtagene autoleucel

Brand name (marketing authorization holder)

Carvykti Suspension for Intravenous Infusion

Japanese market launch

Before market launch

Indications

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 relapsed after the last therapy

Summary of revisions

Precautions concerning lymphoid neoplasm of CAR-positive T-cell origin should be added to the Important Precautions section.

Investigation results and background of the revision

A case involving lymphoid neoplasm of CAR-positive T-cell origin was evaluated. As a result of consultation with expert advisors regarding the causality assessment of the case

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and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary based on the fact that a case in which lymphoid neoplasm of CAR-positive T-cell origin occurred after administration of ciltacabtagene autoleucel was confirmed while a causal relationship to ciltacabtagene autoleucel is unclear.

Reference: Number of cases* and patient mortalities involving lymphoid neoplasm of CAR-positive T-cell origin reported overseas

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

No patient mortalities have been reported to date.

*: Cases collected in the PMDA's database for defects or adverse events, etc. reports

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).