

1 Category/Product

Category of application: Best biotechnology product

Drug name: CARVYKTI® (ciltacabtagene autoleucel)

Technical name: Ciltacabtagene autoleucel

Trade name: CARVYKTI®

Date of US approval: February 28, 2022

Date of EU approval: May 26, 2022

Therapeutic categories: Oncology: multiple myeloma (MM)

Indications: CARVYKTI® is a B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR)-T cell therapy approved in the United States of America for the treatment of adult patients with relapsed or refractory MM after 4 or more prior lines of therapy including a proteasome inhibitor (PI), an immunomodulatory agent (IMiD), and an anti-CD38 monoclonal antibody.

In the European Union, CARVYKTI® has conditional marketing authorization for the treatment of adult patients with relapsed or refractory MM after 3 or more prior therapies including a PI, an IMiD, and an anti-CD38 antibody, and have demonstrated disease progression on the last therapy.

CARVYKTI® is indicated in Korea for the treatment of adult patients with relapsed or refractory MM who previously received at least 4 prior therapies including a PI, an IMiD, and an anti-CD38 antibody.

In Japan, CARVYKTI® is approved for the treatment of patients with MM who have received 3 or more lines of therapy including an IMiD, a PI, and an anti-CD38 monoclonal antibody, and in whom MM has not responded to or has relapsed following the most recent therapy.