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: Ciltacabtagene autoleucel (cilta-cel; CARVYKTI) is a B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR)-T cell therapy approved in the United States for the treatment of adult patients with relapsed/refractory multiple myeloma (RRMM) who have received at least 1 prior line of therapy, including a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD), and are refractory to lenalidomide.

In the European Union, CARVYKTI has marketing authorization for the treatment of adult patients with RRMM, who have received at least 1 prior therapy, including a PI and an IMiD, have demonstrated disease progression on the last therapy, and are refractory to lenalidomide.

In Brazil, CARVYKTI is approved for the treatment of adult patients with multiple myeloma (MM), who previously received a PI and are refractory to lenalidomide, as well as adult patients with RRMM, who previously received a PI, an IMiD, and anti-CD38 antibody.

In Switzerland, CARVYKTI is indicated for the treatment of adult patients with RRMM who have received at least 3 prior therapies, with at least a PI, an IMiD, and an anti-CD38 antibody, and have demonstrated disease progression on last therapy.