

CY2024 CBER Breakthrough Therapy Approvals

Data as of March 31, 2024

Application Number	Submission Type and Number	Proprietary Name	Established Name	Applicant	Approval Date	Use
BLA 125746	SUPPLEMENT-74	CARVYKTI	ciltacabtagene autoleucel	Janssen Biotech, Inc	05-APR-2024	Treatment of adult patients with relapsed or refractory multiple myeloma, who previously received a proteasome inhibitor (PI), an immunomodulatory agent (IMiD) and an anti-CD38 antibody

* Breakthrough Therapy designation was enacted in the Food and Drug Administration Safety and Innovation Act on July 9, 2012.