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**News Release**

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# Janssen Seeks European Commission Approval of a New Indication for CARVYKTI®▼ (ciltacabtagene autoleucel; cilta-cel) for the Earlier Treatment of Patients with Relapsed and Refractory Multiple Myeloma

*Application to the European Medicines Agency is supported by data from the Phase 3 CARTITUDE-4 study, which evaluated the safety profile and efficacy of cilta-cel in the treatment of patients who received one to three prior lines of therapy*[1]

*CARTITUDE-4 is the first randomised Phase 3 study investigating the efficacy of a cell therapy as early as after first relapse in multiple myeloma*[1,2]

**BEERSE, BELGIUM, 25 May 2023** – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced the submission of a Type II variation application to the European Medicines Agency (EMA) seeking approval of a new indication for CARVYKTI® (ciltacabtagene autoleucel; cilta-cel) for the treatment of adult patients with relapsed and lenalidomide-refractory multiple myeloma.

"The previous European Commission approval recognised the potential for cilta-cel to positively impact outcomes for people living with relapsed and refractory multiple myeloma," said Edmond Chan, MBChB M.D. (Res), Senior Director, EMEA Therapeutic Area Lead Haematology, Janssen-Cilag Limited. "Today's submission to the EMA is an important step towards helping patients benefit from this CAR-T therapy earlier in

their treatment journey. If approved, this will be the first and only CAR-T therapy available to treat relapsed and refractory multiple myeloma patients as early as second line."

The application is supported by data from the CARTITUDE-4 study (NCT04181827), the first randomised Phase 3 study evaluating the efficacy and safety profile of cilta-cel versus pomalidomide, bortezomib and dexamethasone (PVd) or daratumumab, pomalidomide and dexamethasone (DPd) in the treatment of patients with relapsed and lenalidomide-refractory multiple myeloma who received one to three prior lines of therapy.[1]

The CARTITUDE-4 study results will be presented in a special session at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL on Monday 5 June 2023 at 16:45 CEST.

"This submission is a testament to our relentless commitment to advance science, transform outcomes, challenge what a multiple myeloma diagnosis means for patients and ultimately, work towards our goal of one day curing this complex disease," said Sen Zhuang, M.D., Ph.D., Vice President, Clinical Research and Development, Janssen Research & Development, LLC. "We look forward to collaborating with the EMA to bring this potential new indication for cilta-cel to the multiple myeloma community as soon as possible."

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**About Ciltacabtagene Autoleucel (cilta-cel)**

Cilta-cel received conditional marketing authorisation from the European Commission in May 2022, for the treatment of adults with relapsed and refractory multiple myeloma who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody, and have demonstrated disease progression on the last therapy.[3,4] In February 2022, the FDA approved cilta-cel for the treatment of adults with relapsed or refractory multiple

myeloma after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.[5]

Cilta-cel is a B-cell maturation antigen (BCMA)-directed, genetically modified autologous T-cell immunotherapy, which involves reprogramming a patient's own T-cells with a transgene encoding a chimeric antigen receptor (CAR) that identifies and eliminates cells that express BCMA.[6] BCMA is primarily expressed on the surface of malignant multiple myeloma B-lineage cells, as well as late-stage B-cells and plasma cells.[7,8] The cilta-cel CAR protein features two BCMA-targeting single domain antibodies designed to confer high avidity against human BCMA.[6] The CAR-modified T-cells express fusion proteins of antigen receptors against tumour-associated surface antigens and T-cell activation domains, and upon binding to BCMA-expressing cells redirect the effector T-cells and enhance tumour-specific immunosurveillance.[9]

In December 2017, Janssen Biotech, Inc. (Janssen) entered into a worldwide license and collaboration agreement with Legend Biotech USA, Inc. to develop and commercialise cilta-cel.[10]

## About Multiple Myeloma

Multiple myeloma is an incurable blood cancer that affects a type of white blood cell called plasma cells, which are found in the bone marrow.[11] In multiple myeloma, these malignant plasma cells change and grow out of control.[8] In Europe, more than 50,900 people were diagnosed with multiple myeloma in 2020, and more than 32,400 patients died.[12] While some patients with multiple myeloma initially have no symptoms, others can have common signs and symptoms of the disease, which can include bone fracture or pain, low red blood cell counts, tiredness, high calcium levels, or kidney failure.[13]

## About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving

access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular, Metabolism & Retina; Immunology; Infectious Diseases & Vaccines; Neuroscience; Oncology; and Pulmonary Hypertension.

Learn more at www.janssen.com/emea. Follow us at www.twitter.com/janssenEMEA for our latest news.

Janssen Pharmaceutica NV, Janssen-Cilag Limited, Janssen Research & Development, LLC and Janssen Biotech, Inc., are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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***Cautions Concerning Forward-Looking Statements***

*This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding ciltacabtagene autoleucel (cilta-cel). The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialise, actual results could vary materially from the expectations and projections of Janssen Pharmaceutica NV, Janssen-Cilag Limited, Janssen Research & Development, LLC and Janssen Biotech, Inc., and any of the other Janssen Pharmaceutical Companies, and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behaviour and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends*

*toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 1, 2023, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.*

## References


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