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News Release

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Janssen Receives Positive CHMP Opinion for CARVYKTI®▼ (ciltacabtagene autoleucel; cilta-cel) for Treatment in Earlier Lines of Relapsed and Refractory Multiple Myeloma

Results from the Phase 3 CARTITUDE-4 study, which supported the CHMP recommendation, showed that cilta-cel has the potential to offer significant benefit to patients in earlier lines of treatment[1]

Most patients with multiple myeloma relapse after current standard treatments and remain in need of additional therapeutic options at earlier stages of the disease[1]

BEERSE, BELGIUM, 23 February 2024 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended the approval of a Type II variation for CARVYKTI®▼ (ciltacabtagene autoleucel; cilta-cel) for the earlier treatment of relapsed and refractory multiple myeloma (RRMM). The recommended indication for cilta-cel is for the treatment of adult patients with RRMM, who have received at least one prior therapy, including an immunomodulatory agent (IMiD) and a proteasome inhibitor (PI), have demonstrated disease progression on the last therapy, and are refractory to lenalidomide.[2] Cilta-cel is the first chimeric antigen receptor T-cell (CAR-T) therapy to receive a positive CHMP opinion for the treatment of this patient population, as early as after first relapse. Cilta-cel is an innovative CAR-T therapy directed against B-cell maturation antigen (BCMA),[3,4] a protein that is highly expressed on myeloma cells.[5]

"Early resistance to standard treatments is becoming more common in patients with lenalidomide-refractory multiple myeloma, highlighting a need for new options earlier in the course of treatment," said Edmond Chan, MBChB, M.D. (Res), Senior Director, EMEA Therapeutic Area Lead Haematology, Janssen-Cilag Limited, a Johnson & Johnson Company. "Today's recommendation from the CHMP recognises the potential of cilta-cel to significantly improve outcomes for eligible patients with relapsed and refractory multiple myeloma, as early as after first relapse."

The CHMP recommendation for cilta-cel 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) for the treatment of patients with relapsed and lenalidomide-refractory multiple myeloma who received one to three prior lines of therapy.[2,6]

"We are committed to the advancement of cilta-cel and other immunotherapies, as we aim to improve outcomes for patients and redefine the multiple myeloma treatment paradigm," said Sen Zhuang, M.D., Ph.D., Vice President, Clinical Research and Development, Johnson & Johnson Innovative Medicine. "Today's milestone represents an important step forward in the treatment of this complex disease and in our ultimate goal of one day delivering a cure."

Cilta-cel is currently approved under conditional marketing authorisation (CMA) for the treatment of adults with RRMM, after three prior lines of therapy.[3] In further positive news, the CHMP have now recommended converting the CMA to a standard marketing authorisation, as the obligations of the conditional approval have now been met.[2]

#ENDS#

About Ciltacabtagene Autoleucel (cilta-cel)

Cilta-cel received a CMA from the European Commission in May 2022, for the treatment of adults with RRMM who have received at least three prior therapies, including an IMiD, a PI and an anti-CD38 antibody, and have demonstrated disease progression on the last therapy.[33,7] In February 2022, the U.S. Food and Drug Administration (FDA) approved cilta-cel for the treatment of adults with RRMM after four or more prior lines of therapy, including a PI, an IMiD, and an anti-CD38 monoclonal antibody.[8,9] For a full list of adverse events and

information on dosage and administration, contraindications and other precautions when using cilta-cel please refer to the Summary of Product Characteristics for further information.[33] In line with EMA regulations for new medicines and those given conditional approval, cilta-cel is subject to additional monitoring.[33]

Cilta-cel is a BCMA-directed, genetically modified autologous T-cell immunotherapy, which involves reprogramming a patient's own T-cells with a transgene encoding a CAR that binds and promotes elimination of cells that express BCMA.[10] BCMA is primarily expressed on the surface of malignant multiple myeloma B-lineage cells, as well as late-stage B-cells and plasma cells.[11,12] The cilta-cel CAR protein features two BCMA-targeting single domain antibodies designed to confer high avidity against human BCMA.[10] 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.[13]

In December 2017, Janssen Biotech, Inc., a Johnson & Johnson Company, entered into a worldwide licence and collaboration agreement with Legend Biotech USA, Inc. to develop and commercialise cilta-cel.[14]

About Multiple Myeloma

Multiple myeloma is currently an incurable blood cancer that affects a type of white blood cell called plasma cells, which are found in the bone marrow.[15,16] In multiple myeloma, these malignant plasma cells continue to proliferate, accumulating in the body and crowding out normal blood cells, as well as often causing bone destruction and other serious complications.[16] In the European Union, it is estimated that more than 35,000 people were diagnosed with multiple myeloma in 2022, and more than 22,700 patients died.[17] 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, fatigue, high calcium levels, infections, or kidney damage.[18]

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: Oncology, Immunology, Neuroscience, Cardiovascular, Pulmonary Hypertension, and Retina.[19]

Learn more at www.janssen.com/emea. Follow us at www.linkedin.com/janssenEMEA for our latest news. Janssen Pharmaceutica NV, Janssen-Cilag Limited, Janssen Biotech, Inc., and Janssen Research & Development, LLC are Johnson & Johnson companies.

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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 product development and the potential benefits and treatment impact of 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 Biotech, Inc., Janssen Research & Development, LLC, 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; competition, including technological advances, new products and patents attained by competitors; challenges to patents; 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 December 31, 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 http://www.sec.gov/, http://www.jnj.com/ or on request from Johnson & Johnson. None of Janssen Pharmaceutica NV, Janssen-Cilag Limited, Janssen Biotech, Inc., Janssen Research & Development, LLC, nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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