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News Release

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Janssen Announces CAR-T Therapy Ciltacabtagene Autoleucel (Cilta-cel) Accepted for Accelerated Assessment in Europe for the Treatment of Patients with Heavily Pretreated Multiple Myeloma

BEERSE, BELGIUM, 01 February 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) will perform an accelerated assessment of the Marketing Authorisation Application (MAA) for the B-cell maturation antigen (BCMA)-targeted chimeric antigen receptor T-cell (CAR-T) therapy ciltacabtagene autoleucel (cilta-cel). Accelerated assessment is granted by the CHMP when a medicinal product is expected to be of major public health interest and therapeutic innovation and can significantly reduce the review timelines to evaluate an MAA.[1]

Cilta-cel is an investigational BCMA-directed CAR-T therapy in development for the treatment of adults with relapsed and/or refractory multiple myeloma.[2] CAR-T therapy is a highly personalised technology where a patient's own T-cells are re-programmed to target and eradicate cancer.[3]

"Multiple myeloma is a rare, incurable cancer, and has long been an area of focus for Janssen," said Sen Zhuang, M.D., Ph.D., Vice President, Clinical Research Development, Janssen Research & Development, LLC. "We are deeply committed to improving outcomes for patients with multiple myeloma, with a goal of delivering innovations that have the potential to expand current remission periods and improve quality of life."

The cilta-cel MAA, which is targeted for submission in the first half of 2021, is supported by the positive results from the Phase 1b/2 CARTITUDE-1 study.[2]
The latest results from the CARTITUDE-1 study were presented at the American Society of Hematology (ASH) 2020 Annual Meeting.[2]

"We are excited that the potential clinical benefit of cilta-cel is being recognised and now look forward to working with the EMA to bring this highly innovative treatment to patients in need," said Saskia De Haes, Vice President, EMEA Regulatory Affairs, Janssen R&D BE.

This accelerated approval milestone in Europe follows the December 2020 announcement of a rolling submission of the Biologics License Application (BLA) for cilta-cel to the U.S. Food and Drug Administration (FDA).[4]

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About CARTITUDE-1

CARTITUDE-1 (NCT03548207) is an ongoing Phase 1b/2, open-label, multicentre study evaluating the safety and efficacy of cilta-cel in adults with relapsed and/or refractory multiple myeloma, 99 percent of whom were refractory to the last line of treatment; 88 percent of whom were triple-class refractory, meaning their cancer did not, or no longer responds to an immunomodulatory agent (IMiD), a proteasome inhibitor (PI) and an anti-CD38 antibody.[2,5]

The primary objective of the CARTITUDE-1 study is to characterise the safety and confirm the dose of cilta-cel, informed by the first-in-human study with LCAR-B38M CAR-T cells (LEGEND-2) and to evaluate the efficacy of cilta-cel with overall response as the primary endpoint.[2,5]

About Ciltacabtagene Autoleucel (cilta-cel)

Cilta-cel is an investigational chimeric antigen receptor T cell (CAR-T) therapy for the treatment of patients with multiple myeloma. The design comprises a structurally differentiated CAR-T with two BCMA-targeting single domain antibodies.[2] CAR-T cells are an innovative approach to eradicating cancer cells by harnessing the power of a patient's own immune system.[6] BCMA is a protein that is highly expressed on myeloma cells.[7]

In December 2017, Janssen Biotech, Inc. (Janssen) entered into an exclusive worldwide license and collaboration agreement with Legend Biotech to develop and commercialise cilta-cel.[8] In May 2018, Janssen initiated a Phase 1b/2 CARTITUDE-1 trial (NCT03548207) to evaluate the efficacy and safety of cilta-cel in adults with relapsed and/or refractory multiple myeloma, informed by the LEGEND-2 study results.[5,9]

In April 2019, cilta-cel was granted PRIME (PRIority MEdicines) designation by the European Medicines Agency (EMA).[10] PRIME offers enhanced interaction and early dialogue with developers of promising medicines, to optimise drug development plans and speed up evaluation of cutting-edge, scientific advances that target a high unmet medical need.[11] In February 2020, the European Commission granted orphan designation for cilta-cel.[12]

About Multiple Myeloma

Multiple myeloma (MM) is an incurable blood cancer that starts in the bone marrow and is characterised by an excessive proliferation of plasma cells.[13] In Europe, more than 48,200 people were diagnosed with MM in 2018, and more than 30,800 patients died.[14] Around 50 percent of newly diagnosed patients do not reach five-year survival,[15,16] and almost 29 percent of patients with multiple myeloma will die within one year of diagnosis.[17]

Although treatment may result in remission, unfortunately, patients will most likely relapse as there is currently no cure.[18] Refractory MM is when a patient's disease progresses within 60 days of their last therapy.[19] Relapsed cancer is when the disease has returned after a period of initial, partial or

complete remission.[19] While some patients with MM have no symptoms at all, others are diagnosed due to symptoms that can include bone problems, low blood counts, calcium elevation, kidney problems or infections.[20] Patients who relapse after treatment with standard therapies, including protease inhibitors and immunomodulatory agents, have poor prognoses and require new therapies for continued disease control.[21]

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, 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 Research & Development, LLC, Janssen R&D BE, 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 product development and the potential benefits and treatment impact of ciltacabtagene autoleucel. 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 and/or 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 behavior 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 29, 2019, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent 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.

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