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News Release

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Janssen Receives Positive CHMP Opinion Recommending CARVYKTI® (Ciltacabtagene Autoleucel) for the Treatment of Patients with Relapsed and Refractory Multiple Myeloma

Ciltacabtagene autoleucel (cilta-cel), Janssen's first cell therapy, is a structurally differentiated CAR-T with two BCMA-targeting single domain antibodies

BEERSE, BELGIUM, 25 March 2022 – 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) has recommended marketing authorisation of ciltacabtagene autoleucel (cilta-cel) 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. In December 2017, Janssen Biotech, Inc. (Janssen) entered into an exclusive worldwide license and collaboration agreement with Legend Biotech USA, Inc. to develop and commercialise cilta-cel.[1]

Cilta-cel is a chimeric antigen receptor T-cell (CAR-T) therapy featuring two B-cell maturation antigen (BCMA)-targeting single domain antibodies.[2] CAR-T therapy is a highly personalised technology where a patient's own T-cells are re-programmed to target and kill cancer cells – and is administered as a single infusion.[3]

Multiple myeloma is an incurable blood cancer, with around 50 percent of newly diagnosed patients not reaching five-year survival.[4,5] Despite the development of additional treatment options in recent years, most people living with multiple myeloma face poor prognoses after being exposed to all three major drug classes, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody.[6]

"Although significant advances have been made in the treatment of multiple myeloma, it remains a heterogenous disease that is challenging to treat," said Edmond Chan MBChB M.D. (Res), EMEA Therapeutic Area Lead Haematology, Janssen-Cilag Limited. "Therapeutic innovations with novel mechanisms of action are urgently needed. Our focus is on bringing transformative treatments to the medical community, like cilta-cel, for patients with multiple myeloma in need of new options."

The positive CHMP Opinion is supported by data from the pivotal CARTITUDE-1 study. Results from the study were presented at the American Society of Hematology (ASH) 2021 Annual Meeting (Abstract #549).[2]

"At Janssen, we are resolute in our commitment to advance science and improve outcomes for patients diagnosed with multiple myeloma," said Sen Zhuang, M.D., Ph.D., Vice President, Oncology Clinical Research, Janssen Research & Development, LLC. "Today's CHMP positive opinion marks important progress in the ongoing clinical development and registration of cilta-cel, globally."

This CHMP Opinion follows the recent approval of cilta-cel by the United States (U.S.) Food and Drug Administration (FDA) in February 2022.

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About Ciltacabtagene Autoleucel (cilta-cel)

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.[2,3] 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. [1] Upon binding to BCMA-expressing cells, the CAR promotes T-cell activation, expansion, and elimination of target cells.[9]

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In April 2021, Janssen announced its submission of a Marketing Authorisation Application to the European Medicines Agency seeking approval of cilta-cel for the treatment of patients with relapsed and/or refractory multiple myeloma. In addition to United States (U.S.) Breakthrough Therapy Designation granted in December 2019, cilta-cel received a PRIority MEdicines (PRiME) designation from the European Commission (EC) in April 2019, and a Breakthrough Therapy Designation in China in August 2020. Janssen also received Orphan Drug Designation for cilta-cel from the EC in February 2020 and from the Pharmaceuticals and Medicinal Devices Agency (PMDA) in Japan in June 2020.

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.[4,10] When damaged, these plasma cells change and grow out of control.[10] In Europe, more than 50,900 people were diagnosed with multiple myeloma in 2020, and more than 32,500 patients died.[11] While some patients with multiple myeloma initially have no symptoms, most patients are diagnosed due to symptoms, which can include bone fracture or pain, low red blood cell counts, tiredness, high calcium levels or kidney failure.[12]

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-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 2, 2022, 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

[1] JnJ.com Janssen Enters Worldwide Collaboration and License Agreement with Chinese Company Legend Biotech to Develop Investigational CAR-T Anti-Cancer Therapy. Available at: https://www.jnj.com/media-center/press-releases/janssen-enters-worldwide-collaboration-and-license-agreement-with-chinese-company-legend-biotech-to-develop-investigational-car-t-anti-cancer-therapy. Last accessed: March 2022.

[2] Martin, T. Updated Results From CARTITUDE-1: Phase 1b/2 Study of Ciltacabtagene Autoleucel, a B-cell Maturation Antigen–Directed Chimeric Antigen Receptor T Cell Therapy, in Patients With Relapsed/Refractory Multiple Myeloma. Abstract #549 [Oral]. Presented at the 2021 American Society of Hematology (ASH) Annual Meeting & Exposition Annual Meeting.

[3] NHS. CAR-T Therapy. Available at: https://www.england.nhs.uk/cancer/cdf/car-t-therapy/. Last accessed: March 2022.

[4] Abdi J, Chen G, Chang H, et al. Drug resistance in multiple myeloma: latest findings and new concepts on molecular mechanisms Oncotarget. 2013;4:2186–2207.

[5] American Society of Clinical Oncology. Multiple Myeloma: Statistics. Available at: https://www.cancer.net/cancer-types/multiple-myeloma/statistics Last accessed: March 2022.

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[6] Dhanasiri S, et al. Treatment Patterns and Outcomes in Triple-Class Exposed Patients With Relapsed and Refractory Multiple Myeloma: Findings From the Multinational ITEMISE Study. Clin Ther. 2021 Nov;43(11):1983-1996.e3.
[7] Frerichs KA, et al. Preclinical Activity of JNJ-7957, a Novel BCMA×CD3 Bispecific Antibody for the Treatment of Multiple Myeloma, Is Potentiated by Daratumumab. Clin Cancer Res. 2020 May 1;26(9):2203-2215.
[8] Cho SF, et al. Targeting B Cell Maturation Antigen (BCMA) in Multiple Myeloma: Potential Uses of BCMA-Based Immunotherapy. Front Immunol. 2018 Aug 10;9:1821.
[9] Tai YT, Anderson KC. Targeting B-cell maturation antigen in multiple myeloma. Immunotherapy. 2015;7(11):1187-1199.
[10] American Society of Clinical Oncology. Multiple myeloma: introduction. Available at: https://www.cancer.net/cancer-types/multiple-myeloma/introduction. Last accessed: March 2022.
[11] GLOBOCAN 2020. Cancer Today Population Factsheets: Europe Region. Available at: https://gco.iarc.fr/today/data/factsheets/populations/908-europe-fact-sheets.pdf. Last accessed: March 2022.
[12] American Cancer Society. Multiple myeloma: early detection, diagnosis and staging. Available at: https://www.cancer.org/content/dam/CRC/PDF/Public/8740.00.pdf. Last accessed: March 2022.