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News Release

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Janssen Receives Positive CHMP Opinions for Novel Bispecific Antibodies TALVEY®▼ (talquetamab) and TECVAYLI®▼ (teclistamab) for the Treatment of Patients with Relapsed and Refractory Multiple Myeloma

Talquetamab is the first therapy targeting GPRC5D to receive a positive CHMP Opinion

Teclistamab, the first BCMA-targeting bispecific antibody to be approved in Europe, receives positive CHMP Opinion for reduced, biweekly dosing schedule

BEERSE, Belgium, 21 July 2023 – 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 conditional marketing authorisation (CMA) for TALVEY® (talquetamab) as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma (RRMM) 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. Talquetamab is a subcutaneous bispecific antibody that binds G protein-coupled receptor class C group 5 member D (GPRC5D), a novel target on multiple myeloma cells, and CD3, on T-cells.[1]

The CHMP also recommended the approval of a Type II variation for teclistamab, providing a reduced, biweekly dosing schedule of 1.5mg/kg every other week in patients who have achieved a complete response or better for six months or longer. Teclistamab is the first bispecific antibody targeting B-cell maturation antigen (BCMA) on myeloma cells, and CD3 on T-cells to be licensed in

Europe for the treatment of adult patients with RRMM who have had 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.[2]

Despite recent advances, multiple myeloma remains a highly heterogenous and incurable disease that is unique to every patient.[3] As the disease progresses and with each successive line of treatment, responses tend to decrease and patient outcomes become progressively worse.[4] An unmet need remains for more therapeutic options with different modes of action, including for patients treated with prior bispecific or CAR-T cell therapies, to better address the unique characteristics of every patient's individual needs through different cellular targets.[3]

"With talquetamab, a novel bispecific antibody targeting GPRC5D, we look to build on our legacy of innovation and bring forward a vital new treatment option for patients with relapsed and refractory multiple myeloma, who have a poor prognosis," said Edmond Chan, MBChB M.D. (Res), Senior Director EMEA Therapeutic Area Lead Haematology, Janssen-Cilag Limited. "Today's recommendation from the CHMP marks an exciting step for patients who continue to face the challenges of this difficult-to-treat blood cancer. We look forward to working with health authorities to bring talquetamab to patients in need across the region as soon as possible, while we continue our focus on enhancing a robust multiple myeloma portfolio of therapeutics and regimens."

The CHMP recommendation for talquetamab is based on data from the Phase 1/2 MonumenTAL-1 study (Phase 1: NCT03399799; Phase 2: NCT04634552), evaluating the safety profile and efficacy of talquetamab in patients with RRMM. The latest data from the study were recently presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting (2-6 June, Chicago) and the 2023 European Hematology Association (EHA) Hybrid Congress (8-11 June, Frankfurt).

The CHMP recommendation for teclistamab is based on data from the Phase 1/2 MajesTEC-1 study (Phase 1: NCT03145181; Phase 2: NCT04557098), evaluating the safety profile and efficacy of teclistamab in patients with RRMM. Data from the study were recently presented at the 2023 ASCO Annual Meeting.

"Pending approval, this variation for teclistamab will be an important step forward for this first BCMA bispecific therapy, offering flexible, less frequent dosing depending on a patient's response," said Sen Zhuang, M.D., Ph.D., Vice President, Clinical Research and Development, Janssen Research & Development, LLC. "Today's positive recommendations for talquetamab and

teclistamab, two novel bispecific antibodies discovered and developed at Janssen, reinforce our commitment to delivering innovative treatment options for patients with multiple myeloma."

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About Talquetamab

Talquetamab is a bispecific T-cell engaging antibody that binds to CD3, on T-cells, and GPRC5D, a novel multiple myeloma target which is highly expressed on myeloma cells and hard keratinised tissues, with minimal to no expression detected on B-cells or B-cell precursors.[1,5]

Talquetamab, which is administered by subcutaneous injection, is currently being evaluated in several monotherapy and combination studies.[6,7,8,9,10,11,12]

CMA is the approval of a medicine that addresses unmet medical needs of patients based on less comprehensive data than normally required, where the available data suggest that the benefits of the medicine outweigh the risks, and the applicant can provide comprehensive clinical data in the future.[13] Prior to the CHMP recommending this CMA, the EMA granted talquetamab PRIority Medicines (PRIME) designation in January 2021 and accelerated assessment in November 2022. The U.S. Food and Drug Administration (FDA) granted talquetamab Breakthrough Therapy Designation in June 2022. Janssen also received Orphan Drug Designation for talquetamab from the EMA in August 2021 and the FDA in May 2021.

About Teclistamab

Teclistamab is an off-the-shelf (or ready to use) bispecific antibody.[2] Teclistamab, a subcutaneous injection, redirects T-cells through two cellular targets (BCMA and CD3) to activate the body's immune system to fight the cancer. Teclistamab is currently being evaluated in several monotherapy and combination studies.[14,15,16,17,18,19]

Teclistamab received European Commission (EC) approval in August 2022. The application for CMA was reviewed by the CHMP under an accelerated timetable to enable faster patient access to this medicine.[20] This was also supported through the EMA's PRIME scheme, which provides early and enhanced scientific and regulatory support to medicines that have a particular potential to address patients' unmet medical needs.[21]

For a full list of adverse events and information on dosage and administration, contraindications and other precautions when using teclistamab please refer to the Summary of Product Characteristics. In line with EMA regulations for new medicines and those given conditional approval, teclistamab is subject to additional monitoring.

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.[3,22] In multiple myeloma, these malignant plasma cells change and grow out of control.[22] In Europe, more than 50,900 people were diagnosed with multiple myeloma in 2020, and more than 32,400 patients died.[23] While some patients with multiple myeloma initially have no symptoms, others can have common symptoms of the disease which can include bone fracture or pain, low red blood cell counts, tiredness, high calcium levels or kidney failure.[24]

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.linkedin.com/janssenEMEA for our latest news. Janssen Pharmaceutica NV, Janssen-Cilag Limited and Janssen Research & Development, LLC 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 talquetamab and teclistamab. 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 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.

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