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News Release

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European Commission Approves TALVEY®▼ (talquetamab), Janssen's Novel Bispecific Therapy for the Treatment of Patients with Relapsed and Refractory Multiple Myeloma

Talquetamab, the first bispecific antibody targeting GPRC5D, showed an overall response rate of more than 70 percent with durable responses, including responses achieved by over 60 percent of patients with prior T-cell redirection therapy.[1,2]

BEERSE, Belgium, 22 August 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that the European Commission (EC) has granted conditional marketing authorisation (CMA) of 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.[1]

Talquetamab is a bispecific T-cell engaging antibody that binds to CD3, on the surface of T-cells, and G protein-coupled receptor class C group 5 member D (GPRC5D), a novel target expressed on the surface of multiple myeloma cells and hard keratinised tissues, with minimal to no expression detected on B-cells and B-cell precursors.[1] Talquetamab is approved as a weekly (QW) or biweekly (Q2W) subcutaneous (SC) injection, after an initial step-up phase.[1]

"As multiple myeloma progresses and patients cycle through treatments, the disease becomes more difficult to treat and remission periods shorten," said Maria-Victoria Mateos, M.D., Ph.D., Consultant Physician in Haematology, University Hospital of Salamanca.[†] "Targeting GPRC5D has been shown to deliver deep responses, and unlike many other targets for multiple myeloma, its

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expression is limited on immune cells providing an important new approach to targeting this heterogenous disease."

The CMA was supported by positive results from the Phase 1/2 MonumenTAL-1 study (Phase 1: NCT03399799; Phase 2: NCT04634552), evaluating the safety and efficacy of talquetamab in patients with RRMM.[3,4] 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) Congress (8-11 June, Frankfurt).

Patients in the study (0.8 mg/kg Q2W: n=145; 0.4 mg/kg QW: n=143) had received a median of five (range, 2-17) prior lines of therapy and showed meaningful overall response rates (ORR) across both doses. With a median follow-up of 12.7 months, 71.7 percent (95 percent Confidence Interval [CI], 63.7-78.9) of response-evaluable patients treated at the 0.8 mg/kg Q2W dose achieved a response, 60.8 percent achieved a very good partial response (VGPR) or better and 38.7 percent achieved a complete response (CR) or better.[1] With a median follow-up of 18.8 months, 74.1 percent (95 percent CI, 66.1-81.1) of response-evaluable patients treated with the 0.4 mg/kg QW dose achieved a response, 59.5 percent achieved a VGPR or better and 33.6 percent achieved a CR or better.[1] Responses were durable with a median duration of response not reached (95 percent CI, 13-Not Estimable [NE]) in the 0.8 mg/kg Q2W dose group and 9.5 months (95 percent CI, 6.7-13.3) in the 0.4 mg/kg QW dose group.[1] An estimated 76.3 percent and 51.5 percent of patients maintained a response for at least nine months at the 0.8 mg/kg Q2W and 0.4 mg/kg QW doses, respectively.[1]

The MonumenTAL-1 study also included 51 patients with prior T-cell redirection therapy.[2] Patients had received a median of five (3-15) prior lines of therapy, including prior exposure to a bispecific antibody (35.3 percent), CAR-T cell therapy (70.6 percent) or both (six percent).[2] With a median duration of follow-up of 14.8 months, 64.7 percent of patients achieved a response, 54.9 percent achieved a VGPR or better and 35.3 percent achieved a CR or better.[2] Median duration of response was 11.9 months (95 percent CI, 4.8-NE) and the 12-month overall survival rate was 62.9 percent.[2]

"Today's European Commission decision brings a new off-the-shelf option with a novel cellular target and the immediate option of biweekly dosing, to an area of high unmet clinical need," said Edmond Chan, MBChB M.D. (Res), Senior Director EMEA Therapeutic Area Lead Haematology, Janssen-Cilag Limited. "The high overall response rates in patients with heavily pretreated multiple

myeloma, including those with prior T-cell redirection therapy, are encouraging and we believe talquetamab has the potential to offer physicians flexibility and versatility when determining the optimal treatment regimen for their patients."

The most common adverse events (AEs) observed in the study were cytokine release syndrome (CRS; 77 percent, 1.5 percent Grade 3 or 4), dysgeusia (72 percent, all Grade 1 or 2), hypogammaglobulinaemia (67 percent, all Grade 1 or 2) and nail disorders (56 percent, all Grade 1 or 2).[1] In addition, 40 percent of patients experienced weight loss, including 3.2 percent with Grade 3 or 4 weight loss.[1] The most common infections were upper respiratory tract infection (29 percent, 2.1 percent Grade 3 or 4) and COVID-19 (19 percent, 2.9 percent Grade 3 or 4).[1] Neurologic toxicities were reported in 29 percent of patients, including immune effector cell-associated neurotoxicity syndrome (ICANS; 10 percent, 2.3 percent Grade 3 or 4).[1] Adverse reactions leading to treatment discontinuation were mainly due to ICANS (1.1 percent) and weight loss (0.9 percent).[1]

The EC approval follows the U.S. Food and Drug Administration (FDA) approval of talquetamab for the treatment of adult patients with relapsed or refractory multiple myeloma who received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody, in August 2023.

"As our fifth innovative therapy and second bispecific antibody for multiple myeloma, talquetamab is testament to our continued ambition to discover and develop a portfolio of innovative and complementary therapies," said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. "We now look forward to bringing this new option to patients and physicians."

#ENDS#

About the MonumenTAL-1 Study

MonumenTAL-1 (Phase 1: NCT03399799, Phase 2: NCT04634552), is a Phase 1/2 single-arm, open-label, multicohort, multicentre dose-escalation study to evaluate the safety and efficacy of talquetamab in adults with RRMM who received three or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.[3,4]

Phase 1 of the study (NCT03399799) was conducted in two parts: dose escalation and dose expansion.[3] It evaluated safety, tolerability, pharmacokinetics and preliminary antitumour activity of talquetamab administered to adult participants with RRMM.[3] Phase 2 of the study (NCT04634552) evaluated the efficacy of talquetamab in participants with RRMM at the recommended phase 2 doses (RP2Ds), established at SC 0.8 mg/kg Q2W and 0.4 mg/kg QW, respectively, as measured by ORR.[4]

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 the surface of multiple myeloma cells and hard keratinised tissues, with minimal to no expression detected on B-cells or B-cell precursors.[1] Talquetamab, which is administered by subcutaneous injection, is currently being evaluated in several monotherapy and combination studies.[3,4,5,6,7,8,9]

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.[10] 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. FDA granted talquetamab Breakthrough Therapy Designation in June 2022. Janssen also received Orphan Drug Designation for talquetamab from the FDA in May 2021 and in July 2023, the Committee for Orphan Medicinal Products (COMP) of the EMA recommended by consensus that the orphan designation for talquetamab be maintained, on the basis of clinical data demonstrating improved and durable responses with talquetamab in patients with RRMM, who had been pretreated with the authorised medicinal products TECVAYLI®▼ (teclistamab), ABECMA®▼ (idecabtagene vicleucel) and CARVYKTI®▼ (ciltacabtagene autoleucel; cilta-cel).

For a full list of adverse events and information on dosage and administration, contraindications and other precautions when using talquetamab please refer to the Summary of Product Characteristics. In line with the European Medicine Agency's regulations for new medicines and those given conditional approval, talquetamab 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.[11,12] In multiple myeloma, these malignant plasma cells

change and grow out of control.[12] In Europe, more than 50,900 people were diagnosed with multiple myeloma in 2020, and more than 32,400 patients died.[13] 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.[14]

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.

†Maria-Victoria Mateos, M.D., Ph.D. has served as a paid consultant to Janssen; she has not been paid for any media work.

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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. 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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