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News Release

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Janssen Submits Marketing Authorisation Application to the European Medicines Agency Seeking Approval of Talquetamab for the Treatment of Patients with Relapsed or Refractory Multiple Myeloma

BEERSE, BELGIUM, 3 January 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced the submission of a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) seeking approval of talquetamab for the treatment of patients with relapsed or refractory multiple myeloma (RRMM). Talquetamab is an investigational, off-the-shelf (ready to use), bispecific T-cell engager antibody targeting both GPRC5D, a novel drug target that is on some normal cells but overexpressed on myeloma cells, and CD3 on T-cells.[1]

"Despite advances, there remains a high unmet need for those with heavily pretreated multiple myeloma as only 30 percent of triple-class exposed patients respond to currently available treatment options," said Edmond Chan, MBChB M.D. (Res), Senior Director EMEA Therapeutic Area Lead Haematology, Janssen-Cilag Limited. "Innovative treatment approaches such as talquetamab, that engage novel cellular targets, are critical for improving outcomes for patients, and we look forward to working with the EMA to bring talquetamab to those in need of new options, as soon as possible."

In November 2022, the EMA granted accelerated assessment for talquetamab. Accelerated assessment reduces the timeframe for an MAA to be reviewed and is granted when a medicinal product is of major interest for public health and therapeutic innovation.[2]

This MAA is supported by data from the Phase 1/2, first-in-human MonumenTAL-1 study of talquetamab (Phase 1: NCT03399799; Phase 2: NCT04634552) in patients with RRMM who have received more than three prior lines of therapy.[3,4,5] The first Phase 2 results from the study were presented at the 2022 American Society of Hematology (ASH) Annual Meeting in an oral scientific session (Abstract #157).[5] These data were featured as part of the ASH Press Briefing and were selected to participate in the *Best of ASH* session, which highlights key scientific and clinical themes presented during the meeting. Results from the Phase 1 portion of the MonumenTAL-1 study were recently published in *The New England Journal of Medicine*.[6]

"As we deepen our scientific understanding of multiple myeloma, we are focused on advancing our portfolio of innovative therapies to address this complex disease and the needs of patients," said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. "Today's submission in Europe marks another important milestone in our progress and ambition to transform the treatment of multiple myeloma."

The application to the EMA follows a Biologics License Application (BLA) submitted to the U.S. Food and Drug Administration (FDA) in December 2022 seeking approval of talquetamab for the treatment of RRMM.

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About Talquetamab

Talquetamab is an off-the-shelf (ready to use), investigational bispecific T-cell engager antibody targeting both GPRC5D, a novel multiple myeloma target, and CD3 on T-cells.[1,5] GPRC5D is highly expressed on multiple myeloma cells and CD3 is involved in activating T-cells.[1,7]

Talquetamab, which is administered by subcutaneous injection, is currently being evaluated in several monotherapy and combination studies.[3,4,8,9,10,11,12]

In addition to the EMA granting accelerated assessment in November 2022, talquetamab received PRIority MEdicines (PRIME) designation from the EMA in January 2021 and

Breakthrough Therapy Designation from the U.S. FDA in June 2022. Janssen also received Orphan Drug Designation for talquetamab from the EMA in August 2021 and the FDA in May 2021.

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.[13,14] In multiple myeloma, these malignant plasma cells change and grow out of control.[13] In Europe, more than 50,900 people were diagnosed with multiple myeloma in 2020, and more than 32,400 patients died.[15] 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.[16]

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.twitter.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. 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,

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.

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