News Release

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Janssen Submits Biologics License Application to U.S. FDA for Talquetamab for the Treatment of Patients with Relapsed or Refractory Multiple Myeloma

RARITAN, N.J., December 9, 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for talquetamab for the treatment of patients with relapsed or refractory multiple myeloma. 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 separately targets CD3 on T cells.[1]

"Despite the therapies that have been developed for the treatment of multiple myeloma, there remains persistent unmet needs for patients who relapse or become refractory," said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. "Through our discovery and development of talquetamab, a novel GPRC5DxCD3 bispecific antibody, we remain relentlessly committed to the investigation of innovative therapies for patients and oncologists. We look forward to working closely with the FDA in their review of the talquetamab submission."

This BLA 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 relapsed or refractory multiple myeloma who have received more than three prior lines of therapy.[1] The first presentation of Phase 2 results from the MonumenTAL-1 study will be highlighted at the American Society of Hematology (ASH) Annual Meeting on December 10, 2022 in an oral scientific session (Abstract #157)[2] and featured as part of the ASH Press Briefing.

About Talquetamab

Talquetamab is a first-in-class, off-the-shelf (ready to use), investigational bispecific T-cell engager antibody targeting both GPRC5D, a novel multiple myeloma target, and CD3, a primary component of the T-cell receptor.[1] CD3 is involved in activating T cells, and GPRC5D is highly expressed on multiple myeloma cells.[3,4]

Talquetamab, which is given by subcutaneous injection, is currently being evaluated in the Phase 1/2 MonumenTAL-1 clinical study for the treatment of relapsed or refractory multiple myeloma (NCT03399799), and in combination studies RedirecTT-1 (NCT04586426), TRIMM-2 (NCT04108195), TRIMM-3 (NCT05338775), MonumenTAL-2 (NCT05050097) and MonumenTAL-3 (NCT05455320).

Talquetamab received Breakthrough Therapy designation from the U.S. FDA in June 2022 for the treatment of adult patients with relapsed or refractory multiple myeloma, who have previously received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody. In May 2021 and August 2021, talquetamab received an Orphan Drug designation for the treatment of multiple myeloma by the U.S. FDA and the European Commission, respectively. In January 2021, talquetamab received a PRIME designation by the European Commission.

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.[5] In multiple myeloma, these plasma cells change, spread rapidly and replace normal cells in the bone marrow with tumors.[6] In 2022, it is estimated that more than 34,000 people will be diagnosed with multiple myeloma, and more than 12,000 people will die from the disease in the U.S.[7] While some people diagnosed with multiple myeloma initially have no symptoms, most patients are diagnosed due to

symptoms that can include bone fracture or pain, low red blood cell counts, tiredness, high calcium levels, kidney problems or infections.[8]

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. Follow us at @JanssenGlobal and @JanssenUS. 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 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 materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, Janssen Biotech, Inc., 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 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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[1] Pillarisetti K et al. *Blood*. 2020;135(15):1232-1243.
[2] Chari A et al. Talquetamab, a G Protein-Coupled Receptor Family C Group 5 Member D x CD3 Bispecific Antibody, in Patients with Relapsed/Refractory Multiple Myeloma (RRMM): Phase 1/2 Results from MonumenTAL-1. American Society of Hematology 2022 Annual Meeting. December 2022.
[3] Labrijn AF et al. *Proc Natl Acad Sci USA*. 2013;110:5145.
[4] Cohen, Y., et al. *Hematology*. 2013 Nov; 18(6):348-51.
[5] Rajkumar SV. Multiple myeloma: 2020 update on diagnosis, risk-stratification and management. *Am J Hematol*.2020;95(5):548-5672020;95(5):548-567. http://www.ncbi.nlm.nih.gov/pubmed/32212178.
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[7] American Cancer Society. "Key Statistics About Multiple Myeloma." Available at: https://www.cancer.org/cancer/multiple-myeloma/about/key-statistics.html#:~:text=Multiple%20myeloma%20is%20a%20relatively,men%20and%2015%2C370%20in%20women). Accessed September 2022.
[8] American Cancer Society. "What Is Multiple Myeloma?" Available at: https://www.cancer.org/cancer/multiple-myeloma/about/what-is-multiple-myeloma.html. Accessed September 2022.