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

RARITAN, N.J., December 29, 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) seeking approval of teclistamab for the treatment of patients with relapsed or refractory (R/R) multiple myeloma. Teclistamab is an investigational, off-the-shelf, T-cell redirecting, bispecific antibody targeting both B-cell maturation antigen (BCMA) and CD3.

"Despite all the gains that have been made in treating multiple myeloma, the unmet need still remains very high. Our relentless pursuit of treatments for this disease continues with the same sense of urgency that we have always had," said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. "We look forward to working with the FDA in their review of our teclistamab submission."

The BLA submission for teclistamab is supported by data from MajesTEC-1 (NCT04557098, NCT03145181), an open-label, multicenter clinical trial evaluating

the safety and efficacy of teclistamab in adults with R/R multiple myeloma. In the study, investigators assessed efficacy outcomes, including overall response rate, very good partial response and complete response using International Myeloma Working Group (IMWG) criteria, as well as the safety profile of teclistamab. Updated MajesTEC-1 data were recently presented at the American Society of Hematology annual meeting.[1]

"The deep expertise, creativity and persistence of the entire Janssen R&D organization enabled the expeditious advancement of teclistamab for multiple myeloma," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, Johnson & Johnson. "Today's submission is another important step in our commitment to bring to patients truly transformational medicines that profoundly impact their health."

Multiple myeloma is an incurable blood cancer that affects white blood cells called plasma cells, which are found in the bone marrow and normally make antibodies which fight infection.[2,3] When these plasma cells become malignant and develop into multiple myeloma, these myeloma cells proliferate and replace normal cells in the bone marrow. In 2021, it is estimated that nearly 35,000 people will be diagnosed and more than 12,000 will die from this disease in the U.S.[4] While some patients with multiple myeloma initially have no symptoms, many 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.[5]

About Teclistamab

Teclistamab is an investigational, off-the-shelf, T-cell redirecting, bispecific antibody targeting both BCMA (B-cell maturation antigen) and CD3, the T-cell receptor. BCMA is expressed at high levels on multiple myeloma cells.[6,7,8,9,10] Teclistamab redirects CD3-positive T-cells to BCMA-expressing myeloma cells to induce killing of tumor cells.[8]

Teclistamab is currently being evaluated in several monotherapy and combination studies. In 2020, the European Commission and the U.S. FDA each granted teclistamab Orphan Drug Designation for the treatment of multiple myeloma. In January 2021 and June 2021, teclistamab received a PRIority MEdicines (PRIME) designation by the European Medicines Agency (EMA) and Breakthrough Therapy Designation (BTD) by the U.S. FDA, respectively. PRIME offers enhanced interaction and early dialogue to optimize drug development plans and speed up evaluation of cutting-edge, scientific advances that target a high unmet medical need.[11] The U.S. FDA grants BTD to expedite the development and regulatory review of an investigational medicine that is intended to treat a serious or life-threatening condition and is based on preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy.[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. Follow us at www.twitter.com/JanssenUS and www.twitter.com/JanssenGlobal. Janssen Research & Development, LLC is one 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 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 materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC 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 3, 2021, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent 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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