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

BEERSE, BELGIUM, 31 January 2022 – 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 teclistamab for the treatment of patients with relapsed or refractory multiple myeloma (RRMM). Teclistamab is an investigational, off-the-shelf, T-cell redirecting, bispecific antibody targeting both B-cell maturation antigen (BCMA) and CD3.¹

“Despite the significant progress that has been made in the treatment of multiple myeloma, it remains an incurable cancer, with approximately half of newly diagnosed patients not reaching five-year survival and almost a third dying within one year of diagnosis,” said Edmond Chan MBChB M.D. (Res), Senior Director, EMEA Therapeutic Area Lead Haematology, Janssen-Cilag Limited. “Today’s submission is an important step forward in our mission to improve outcomes for people living with multiple myeloma, where the need for new treatment strategies remains high.”

In December 2021, the EMA granted accelerated assessment for teclistamab. Accelerated assessment reduces the timeframe for the Committee for Medicinal Products for Human Use (CHMP) to review a MAA and is granted when a medicinal product is of major interest for public health and therapeutic innovation.²

The submission to the EMA is supported by data from MajesTEC-1 ([NCT03145181](https://clinicaltrials.gov/ct2/show/study/NCT03145181), [NCT04557098](https://clinicaltrials.gov/ct2/show/study/NCT04557098)), an open-label, multicentre clinical trial evaluating the safety and efficacy of teclistamab in adults with RRMM.¹ Efficacy outcomes assessed included overall response

rate, very good partial response and complete response, using the International Myeloma Working Group (IMWG) criteria.³ Safety outcomes evaluated included dose limiting toxicity and the number of participants with adverse events as a measure of safety and tolerability.⁴ Updated MajesTEC-1 data were recently [presented](#) at the American Society of Hematology 2021 annual meeting.¹

“We are pleased to announce the submission of teclistamab to the European Medicines Agency. Once again, this shows our commitment to continue to provide innovative, transformative therapies for patients with relapsed or refractory multiple myeloma,” said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC.

The application to the EMA follows a Biologics License Application (BLA) submitted to the U.S. Food and Drug Administration (FDA) [seeking approval](#) of teclistamab for the treatment of RRMM. Additionally, a MAA for teclistamab was recently submitted to the Swiss Agency for Therapeutic Products (Swissmedic) through a Type A Project Orbis submission. [Project Orbis](#) is an initiative of the FDA Oncology Center of Excellence, and provides a framework for concurrent submission and review of oncology products among international partners, with the aim of facilitating faster patient access to high-impact, innovative cancer therapies across multiple countries.⁵ A Type A application is submitted concurrently (within 30 days) to the FDA and the Project Orbis Partners (POPs), allowing for maximal collaboration during the review phase and the possibility of concurrent approval decisions.⁵

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About Teclistamab

Teclistamab is an investigational, off-the-shelf, T-cell redirecting bispecific antibody targeting both BCMA and CD3. 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 tumour cells.¹¹

Teclistamab is currently being evaluated in several monotherapy and combination studies.^{3,12,13,14,15} In 2020, the European Commission (EC) 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 EMA and Breakthrough Therapy Designation (BTD) by the FDA, respectively. PRIME offers enhanced interaction and early dialogue to optimise drug development plans and

speed up evaluation of cutting-edge, scientific advances that target a high unmet medical need.¹⁶ The FDA grants BTM 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.¹⁷

About Multiple Myeloma

Multiple myeloma is currently an incurable blood cancer that affects a type of white blood cell called plasma cells, which are found in the bone marrow.^{18,19} When damaged, these plasma cells change and grow out of control. Abnormal plasma cells can crowd out or suppress the growth of other healthy cells in the bone marrow.¹⁹ In Europe, more than 50,900 people were diagnosed with multiple myeloma in 2020, and more than 32,500 patients died.²⁰ While some patients with multiple myeloma initially have no symptoms, most patients are diagnosed due to symptoms, which can include bone fracture or pain, low red blood cell counts, tiredness, high calcium levels, or kidney failure.²¹

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/emea. Follow us at www.twitter.com/janssenEMEA for our latest news. Janssen Pharmaceutica NV, Janssen Research & Development, LLC and Janssen-Cilag Limited are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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Cautions Concerning Forward-Looking Statement

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding the 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 Pharmaceutica NV, Janssen Research & Development, LLC and Janssen-Cilag Limited and/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 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 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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