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News Release

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Janssen Receives Positive CHMP Opinion for Novel Bispecific Antibody TECVAYLI® (teclistamab) for the Treatment of Patients with Relapsed and Refractory Multiple Myeloma (RRMM)

Teclistamab is the first T-cell redirecting bispecific antibody to receive a positive CHMP opinion for adults with RRMM and highlights Janssen's commitment to innovation in multiple myeloma

The opinion is based on the MajesTEC-1 study where teclistamab induced durable responses that deepened over time in patients with heavily pretreated RRMM[1]

BEERSE, Belgium, 22 July 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended conditional marketing authorisation (CMA) for TECVAYLI® (teclistamab) as monotherapy for 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. Teclistamab is an off-the-shelf, T-cell redirecting bispecific antibody. It targets both B-cell maturation antigen (BCMA), a marker found on multiple myeloma cells, and CD3, on T-cells.[1]

CMA is the approval of a medicine that addresses unmet medical needs of patients based on less comprehensive data than normally required, where the benefit of immediate availability of the medicine outweighs the risk, and the applicant is able to provide comprehensive clinical data in the future.[2] While newer treatment options have nearly doubled survival outcomes for patients living with multiple myeloma over the past few

decades, it remains an incurable disease.[3] Nearly all patients will relapse and require subsequent therapy.[4] Generally, efficacy outcomes decrease with each line of therapy, and patients face poor prognoses.[5]

In December 2021, the EMA granted accelerated assessment for teclistamab. Accelerated assessment reduces the timeframe for the CHMP to review a marketing authorisation application (MAA) and is granted when a medicinal product is of major interest for public health and therapeutic innovation.[6]

"We endeavour to deliver our robust multiple myeloma pipeline of diverse mechanisms and targets with the aim of improving outcomes for patients," said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. "Teclistamab is testament to this approach. If adopted by the European Commission, the approval could be the first worldwide for teclistamab, as the first T-cell redirecting bispecific antibody for the treatment of patients with relapsed and refractory multiple myeloma."

This CHMP recommendation is based on positive results from the multicohort, open-label, Phase 1/2 MajesTEC-1 study (NCT03145181 and NCT04557098), evaluating the safety and efficacy of teclistamab in adults with RRMM.[7,8]

The latest findings from the study were recently presented at the American Society of Clinical Oncology (ASCO) 2022 Annual Meeting and published in *The New England Journal of Medicine*.[1] Teclistamab resulted in deep and durable responses in patients with triple-class exposed multiple myeloma (n=165). With a median follow-up of approximately 14 months (14.1), the overall response rate was 63 percent (95 percent confidence interval [CI]: 55.2–70.4), with 39.4 percent having a complete response (CR) or better.[1] Almost half (46 percent) of patients who achieved a CR or better were minimal residual disease (MRD) negative (10^{-5}).[1]

Adverse events (AEs) were consistent with this patient population and toxicities consistent with T-cell redirection were mostly Grade 1/2.[1] The most common AEs were cytokine release syndrome (72.1 percent; 0.6 percent Grade 3, no Grade 4) and neutropenia (70.9 percent; 64.2 percent Grade 3 or 4).[1] Infections were frequent (76.4 percent; 44.8 percent Grade 3 or 4).[1] The overall incidence of neurotoxic events was low (24 patients; 14.5 percent) and five patients (three percent) had immune effector cell-

associated neurotoxicity syndrome.[1] There were five treatment-related deaths, and dose reductions and discontinuations due to AEs were infrequent.[1]

"Our ambition to eliminate multiple myeloma is stronger today than ever before. We aim to reach this goal by investing in cutting-edge innovations that address individual patient needs and offer healthcare professionals options they have not had before," said Edmond Chan MBChB M.D. (Res), Senior Director EMEA Therapeutic Area Lead Haematology, Janssen-Cilag Limited. "Today's recommendation from the CHMP marks exciting progress in this journey, and we look forward to working with health authorities to make teclistamab available to patients across the region, as soon as possible."

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About Teclistamab

Teclistamab is an investigational, fully humanised, T-cell redirecting, IgG4 bispecific antibody targeting both BCMA and CD3, on T-cells.[1] BCMA is expressed at high levels on multiple myeloma cells.[9,10,11] Teclistamab redirects CD3-positive T-cells to BCMA-expressing myeloma cells to induce killing of tumour cells.[12]

Teclistamab is currently being evaluated in several monotherapy and combination studies.[13,14,15,16,17] In January 2021 and June 2021, teclistamab received a PRIority MEdicines (PRIME) designation by the EMA and Breakthrough Therapy Designation (BTD) by the U.S. 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.[18] The 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 based on preliminary clinical evidence that demonstrates the drug may have substantial improvement in at least one clinically significant endpoint over available therapy.[19]

In December 2021, Janssen Research & Development, LLC submitted a Biologics License Application (BLA) to the FDA seeking approval of teclistamab for the treatment of patients with RRMM; the MAA was submitted to the EMA for teclistamab approval in January 2022.

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.[20] In multiple myeloma, cancerous plasma cells change and grow out of control.[20] In Europe, more than 50,900 people were diagnosed with multiple myeloma in 2020, and more than 32,500 patients died.[21] 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.[22]

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 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 materialise, actual results could vary materially from the expectations and projections of Janssen Pharmaceutica NV, Janssen-Cilag Limited, 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 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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