FOR EU MEDICAL AND TRADE MEDIA ONLY

News Release

Media Inquiries:
Jenni Mildon
Phone: +44 7920 418 552
Email: jmildon@its.jnj.com

Investor Relations:
Raychel Kruper
Phone: +1 732-524-6164
Email: rkruper@its.jnj.com

Janssen Marks First Approval Worldwide for TECVAYLI®▼(teclistamab) with EC Authorisation of First-in-Class Bispecific Antibody for the Treatment of Patients with Multiple Myeloma

Teclistamab, an off-the-shelf (ready to use) subcutaneously administered therapy, induced deep and rapid responses in triple-class exposed patients with relapsed and refractory multiple myeloma[1]

BEERSE, BELGIUM, 24 August 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that the European Commission (EC) has granted conditional marketing authorisation (CMA) of TECVAYLI®▼ (teclistamab) as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma (RRMM). Patients must 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.[1] Today's milestone marks the first approval worldwide for teclistamab, a first-in-class bispecific antibody that redirects CD3-positive T-cells to B-cell maturation antigen (BCMA)-expressing myeloma cells to induce the killing of tumour cells.[1]

Multiple myeloma remains an incurable blood cancer, with nearly all patients relapsing and requiring subsequent therapy.[2,3] As the disease progresses, relapses for patients become more aggressive with each new line of therapy, and remissions become progressively shorter.[4]

"Despite important scientific progress, patients who develop relapsed and refractory disease after having been exposed to the three major drug classes have limited therapeutic options and

generally face poor outcomes," said Maria-Victoria Mateos, M.D., Ph.D., Consultant Physician in Haematology, University Hospital of Salamanca.* "Teclistamab has the potential to provide substantial clinical benefit and new hope to these patients, with high rates of deep and durable responses, and the added convenience of being off-the-shelf."

"The approval of teclistamab followed an accelerated approval pathway, supported via the EMA's PRIME scheme," said Edmond Chan, MBChB M.D. (Res), Senior Director EMEA Therapeutic Area Lead Haematology, Janssen-Cilag Limited. "We would like to thank the medical community for recognising the promise of teclistamab. Multiple myeloma is a complex disease that requires a complex set of solutions. Only by working together can we ensure that patients are able to benefit from innovation, such as teclistamab, as early as possible."

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.[5]

The CMA was supported by 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 (n =165).[1,6,7] Patients received a weekly subcutaneous injection of teclistamab at a dose of 1.5 mg/kg, after receiving step-up doses of 0.06 mg/kg and 0.3 mg/kg.[1] In the study, 104 out of 165 patients achieved an overall response rate (ORR) of 63 percent (95 percent Confidence Interval [CI]; range, 55.2–70.4) after a median of five prior lines of therapy.[1] Notably, 58.8 percent of patients receiving teclistamab achieved a very good partial response (VGPR) or better and 39.4 percent achieved a complete response (CR) or better.[1] The median time to the first confirmed response was 1.2 months (range, 0.2–5.5 months) and the median duration of response was 18.4 months (95 percent CI; range, 14.9–not estimable).[1]

Results from the MajesTEC-1 study were also published in *The New England Journal of Medicine* and showed that treatment with teclistamab resulted in deep and durable responses.[8] The median duration of progression-free survival was 11.3 months (95 percent CI; range, 8.8–17.1) and the median duration of overall survival was 18.3 months (95 percent CI; range, 15.1–not estimable).[8]

Adverse events (AEs) were consistent with this patient population. The most common AEs were cytokine release syndrome (72 percent; 0.6 percent Grade 3, no Grade 4), neutropenia (71

percent; 64 percent Grade 3 or 4) and anaemia (55 percent; 37 percent Grade 3 or 4).[1] Infections were frequent with the most common being upper respiratory tract infections (37 percent; 2.4 percent Grade 3 or 4) and pneumonia (28 percent; 19 percent Grade 3 or 4).[1] Hypogammaglobinaemia occurred in 123 patients (75 percent) and 39 percent of patients received intravenous or subcutaneous immunoglobulin therapy.[1] Neurotoxic events were low grade (15 percent; 14 percent Grade 1 or 2) and five patients (three percent) had immune effector cell-associated neurotoxicity syndrome.[1]

"With nearly 20 years of dedicated leadership in this area, our ambition to advance the best science to deliver novel therapies and regimens for the treatment of multiple myeloma is as strong today as it has ever been. We now look forward to collaborating with Health Authorities worldwide to make this treatment available to patients," said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC.

"This first approval for teclistamab worldwide marks significant progress for patients with relapsed and refractory multiple myeloma," said William N. Hait, M.D., Ph.D., Executive Vice President, Chief External Innovation, Medical Safety and Global Public Health Officer, Johnson & Johnson. "Teclistamab is an important addition to our multiple myeloma portfolio. We are continuing to invest in clinical development to expand its potential and offer novel options for patients and physicians."

#ENDS#

About Teclistamab

Teclistamab is a first-in-class, off-the-shelf (ready to use) bispecific antibody.[1] Teclistamab, a subcutaneous injection, redirects T-cells through two cellular targets (BCMA and CD3) to activate the body's immune system to fight the cancer.[1]

The application for conditional marketing authorisation was reviewed by the Committee for Medicinal Products for Human Use (CHMP) under an accelerated timetable to enable faster patient access to this medicine.[9] This was also supported though the European Medicines Agency's (EMA) PRIority MEdicines (PRIME) scheme, which provides early and enhanced scientific and regulatory support to medicines that have a particular potential to address patients' unmet medical needs.[10]

Teclistamab is currently being evaluated in several monotherapy and combination studies.[7,11,12,13,14]

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.[15] In multiple myeloma, cancerous plasma cells change and grow out of control.[15] In Europe, more than 50,900 people were diagnosed with multiple myeloma in 2020, and more than 32,400 patients died.[16] 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.[17]

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.

# # #

**Maria-Victoria Mateos, M.D., Ph.D., has been a paid consultant to Janssen; she has not been paid for contributing to this press release.*

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.

References:

[1] European Medicines Agency. TECVAYLI Summary of Product Characteristics. August 2022.

[2] Padala SA et al. Epidemiology, Staging, and Management of Multiple Myeloma. *Med Sci* (Basel). 2021;9(1):3.

[3] Rajkumar SV, Kumar S. Multiple myeloma current treatment algorithms. *Blood Cancer J*. 2020;10(9):94.

[4] Yong K et al. Multiple myeloma: patient outcomes in real-world practice. *Br J Haematol*. 2016;175(2):252–264.

[5] Conditional marketing authorisation. The European Medicines Agency. Available at: https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/conditional-marketing-authorisation. Last accessed: August 2022.

[6] ClinicalTrials.gov. Dose Escalation Study of Teclistamab, a Humanized BCMA*CD3 Bispecific Antibody, in Participants With Relapsed or Refractory Multiple Myeloma (MajesTEC-1). Available at: https://clinicaltrials.gov/ct2/show/NCT03145181. Last accessed: August 2022.

[7] ClinicalTrials.gov. A Study of Teclistamab, in Participants With Relapsed or Refractory Multiple Myeloma (MajesTEC-1). Available at: https://clinicaltrials.gov/ct2/show/NCT04557098. Last accessed: August 2022.

[8] Moreau P et al. Teclistamab in Relapsed or Refractory Multiple Myeloma [e-pub before print]. Available at: https://www.nejm.org/doi/full/10.1056/NEJMoa2203478. Last accessed: August 2022.

[9] European Medicines Agency. Accelerated assessment. Available at: https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/accelerated-assessment. Last accessed: August 2022.

[10] European Medicines Agency. PRIME Factsheet. Available at: https://www.ema.europa.eu/en/human-regulatory/research-development/prime-priority-medicines. Last accessed: August 2022.

[11] ClinicalTrials.gov. A Study of the Combination of Talquetamab and Teclistamab in Participants With Relapsed or Refractory Multiple Myeloma. Available at: https://clinicaltrials.gov/ct2/show/NCT04586426. Last accessed: August 2022.

[12] ClinicalTrials.gov. A Study of Subcutaneous Daratumumab Regimens in Combination With Bispecific T Cell Redirection Antibodies for the Treatment of Participants With Multiple Myeloma. Available at: https://clinicaltrials.gov/ct2/show/NCT04108195. Last accessed: August 2022.

[13] ClinicalTrials.gov. A Study of Teclistamab With Other Anticancer Therapies in Participants With Multiple Myeloma. Available at: https://clinicaltrials.gov/ct2/show/NCT04722146. Last accessed: August 2022.

[14] ClinicalTrials.gov. A Study of Teclistamab in Combination With Daratumumab Subcutaneously (SC) (TecDara) Versus Daratumumab SC, Pomalidomide, and Dexamethasone (DPd) or Daratumumab SC, Bortezomib, and Dexamethasone (DVd) in Participants With Relapsed or Refractory Multiple Myeloma (MajesTEC-3). Available at: https://clinicaltrials.gov/ct2/show/NCT05083169. Last accessed: August 2022.

[15] American Society of Clinical Oncology. Multiple myeloma: introduction. Available at: https://www.cancer.net/cancer-types/multiple-myeloma/introduction Last accessed: August 2022.

[16] GLOBOCAN 2020. Cancer Today Population Factsheets: Europe Region. Available at: https://gco.iarc.fr/today/data/factsheets/populations/908-europe-fact-sheets.pdf. Last accessed: August 2022.

[17] American Cancer Society. Multiple myeloma: early detection, diagnosis and staging. Available at: https://www.cancer.org/content/dam/CRC/PDF/Public/8740.00.pdf. Last accessed: August 2022.