



News Release

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European Commission Approves Reduced Dosing Frequency for Janssen’s Bispecific Antibody TECVAYLI®▼ (teclistamab)

Teclistamab, the first BCMA-targeting bispecific antibody to receive approval in Europe, maintained deep and durable responses, with reduced onset of Grade 3 or higher infections, in eligible patients with relapsed and refractory multiple myeloma (RRMM) switching from weekly to reduced, biweekly dosing schedule.^{1,2}

BEERSE, Belgium, 18 August 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that the European Commission (EC) has granted the approval of a Type II variation application for TECVAYLI®▼ (teclistamab), providing the option for a reduced dosing frequency of 1.5mg/kg every two weeks in patients who have achieved a complete response (CR) or better for a minimum of six months.¹

Teclistamab was the first bispecific antibody targeting B-cell maturation antigen (BCMA) on multiple myeloma cells, and CD3 on T-cells, to receive approval in Europe for the treatment of 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.¹

“Every patient’s experience with multiple myeloma is unique and requires a different treatment approach, tailored to their specific needs,” said Niels van de Donk, M.D., Professor of Hematology at Amsterdam University Medical Centers.[†] “With a decreased incidence of new onset Grade 3 or

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higher infections, low discontinuation rates and depth of responses maintained, this biweekly dosing option for teclistamab could provide substantial benefit for people living with multiple myeloma, potentially offering reduced time spent in hospital.”

The EC approval was supported by positive results from the Phase 1/2 MajesTEC-1 study ([Phase 1: NCT03145181](#); [Phase 2: NCT04557098](#)), evaluating the safety and efficacy of teclistamab in patients with RRMM.^{3,4}

The latest data from the study were recently [presented](#) at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting (2-6 June, Chicago) and the 2023 European Hematology Association (EHA) Congress (8-11 June, Frankfurt).^{2,5} Patients in the study had received a median of five prior lines of therapy (range, 2-14) and, following an initial step-up phase, were initially treated with the recommended Phase 2 dose (RP2D) of 1.5 mg/kg teclistamab weekly (QW) administered subcutaneously.^{1,2} Patients who had achieved a confirmed partial response (PR) or better after four or more cycles of treatment (Phase 1), or a confirmed CR or better for six months or longer (Phase 2) were eligible to reduce dosing frequency to 1.5 mg/kg subcutaneously every two weeks (Q2W) until disease progression or unacceptable toxicity.^{1,2}

“Following the initial European Commission approval for teclistamab in August 2022, our research has remained focused on how we can continue to advance the use of teclistamab to better meet individual patient needs and improve patient experiences,” said Edmond Chan, MBChB M.D. (Res), Senior Director EMEA Therapeutic Area Lead Haematology, Janssen-Cilag Limited. “Today’s approval for teclistamab provides eligible patients, their caregivers and physicians an additional, more flexible weight-based option with less frequent dosing depending on a patient’s response.”

Of 104/165 responders who had received teclistamab at the RP2D, 63 patients switched to Q2W dosing.² Results from the analysis showed that at the time of switch, 85.7 percent of patients achieved a CR or better, 12.7 percent achieved a very good partial response (VGPR) and 1.6 percent achieved a PR.² The median time to switch from first QW to first Q2W dose was 11.3 months (range, 3-30).² At a median follow-up of 12.6 months (range, 1-25) since switching, the median duration of response was not yet reached and 68.7 percent (95 percent Confidence Interval [CI], 53.6-79.7) of patients who switched remained in response for two or more years from the time of first response.² The new onset of Grade 3 or higher infections after 12-18 months of follow up was lower in responders who switched to Q2W dosing on or before 12 months compared to

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those who remained on QW dosing at 12 months (15.6 percent vs. 33.3 percent).² As of data cut-off, 41 patients (65 percent) remained on treatment.

“When advancing immune-based therapies such as teclistamab, tailored approaches are essential to allow us to respond to evolving data and evidence to find the most suitable balance of efficacy and safety,” said Sen Zhuang, M.D., Ph.D., Vice President, Clinical Research and Development, Janssen Research & Development, LLC. “Today’s approval reinforces our focus on strengthening our multiple myeloma portfolio by investing in cutting-edge research that will help us continue to improve patient outcomes and importantly, their quality of life.”

#ENDS#

About the MajesTEC-1 Study

MajesTEC-1 ([NCT03145181](#), [NCT04557098](#)), is a Phase 1/2 single-arm, open-label, multicohort, multicentre dose-escalation study to evaluate the safety and efficacy of teclistamab in adults with RRMM who received three or more prior lines of therapy (n=165).^{3,4}

Phase 1 of the study (NCT03145181) was conducted in two parts: dose escalation (Part 1) and dose expansion (Part 2).³ It evaluated safety, tolerability, pharmacokinetics, and preliminary efficacy of teclistamab in adult participants with RRMM.³ Phase 2 of the study (NCT04557098) evaluated the efficacy of teclistamab at the RP2D, established at subcutaneous 1.5 mg/kg weekly, as measured by ORR.⁴

About Teclistamab

Teclistamab is an off-the-shelf (or 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. Teclistamab is currently being evaluated in several monotherapy and combination studies.^{3,4,6,7,8,9}

Teclistamab received European Commission (EC) approval in [August 2022](#).¹ The [application](#) for conditional marketing approval was reviewed by the Committee for Medicinal Products for Human Use (CHMP) under an accelerated timetable to enable faster patient access to this medicine.¹⁰ This was also supported through 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.¹¹

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For a full list of adverse events and information on dosage and administration, contraindications and other precautions when using teclistamab please refer to the [Summary of Product Characteristics](#). In line with the European Medicine Agency's regulations for new medicines and those given conditional approval, teclistamab is subject to additional monitoring.

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.^{12,13} In multiple myeloma, these malignant plasma cells change and grow out of control.¹³ In Europe, more than 50,900 people were diagnosed with multiple myeloma in 2020, and more than 32,400 patients died.¹⁴ 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.¹⁵

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.linkedin.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.

†Niels van de Donk, M.D., has served as a paid consultant to Janssen; he has not been paid for any media work.

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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

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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 and 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 1, 2023, 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 2023.

² Usmani S et al. Durability of Responses With Biweekly Dosing of Teclistamab in Patients With Relapsed/Refractory Multiple Myeloma Achieving a Clinical Response in the MajesTEC-1 Study. Poster presentation (#8034) at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting. June 2023.

³ 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 2023.

⁴ 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 2023.

⁵ Bhutani et al. . Durability of Responses With Biweekly Dosing of Teclistamab in Patients With Relapsed/Refractory Multiple Myeloma Achieving a Clinical Response in the MajesTEC-1 Study. Poster presentation (#881) at the European Haematology Association (EHA) Annual Meeting. June 2023.

⁶ ClinicalTrials.gov. A Study of Teclistamab With Other Anticancer Therapies in Participants With Multiple Myeloma (MajesTEC-2). Available at: <https://clinicaltrials.gov/ct2/show/NCT04722146>. Last accessed: August 2023.

⁷ ClinicalTrials.gov. A Study of the Combination of Talquetamab and Teclistamab in Participants With Relapsed or Refractory Multiple Myeloma. Available at: <https://classic.clinicaltrials.gov/ct2/show/NCT04586426>. Last accessed: August 2023.

⁸ 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://classic.clinicaltrials.gov/ct2/show/NCT04108195>. Last accessed: August 2023.

⁹ 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://classic.clinicaltrials.gov/ct2/show/NCT05083169>. Last accessed: August 2023.

¹⁰ European Medicines Agency. Accelerated assessment. Available at:

<https://www.ema.europa.eu/en/humanregulatory/marketing-authorisation/accelerated-assessment>. Last accessed: August 2023.

¹¹ European Medicines Agency. PRIME Factsheet. Available at: <https://www.ema.europa.eu/en/human-regulatory/research-development/prime-priority-medicines>. Last accessed: August 2023.

¹² Abdi J et al. Drug resistance in multiple myeloma: latest findings and new concepts on molecular mechanisms Oncotarget. 2013;4(12):2186–2207.

¹³ American Society of Clinical Oncology. Multiple myeloma: introduction. Available at: <https://www.cancer.net/cancer-types/multiple-myeloma/introduction>. Last accessed: August 2023.

¹⁴ 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 2023.

¹⁵ 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 2023.