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News Release

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Updated Data for Janssen's Bispecific Teclistamab Suggest Continued Deep and Durable Responses in the Treatment of Patients with Relapsed or Refractory Multiple Myeloma

New teclistamab data presented at the 2022 ASCO Annual Meeting report longer follow-up from Phase 1/2 MajesTEC-1 study evaluating the BCMAxCD3 bispecific antibody, including progression-free survival and subgroup analyses[1]

Data from MajesTEC-1 study published in The New England Journal of Medicine[2]

BEERSE, Belgium, 5 June 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced updated efficacy and safety results from the teclistamab Phase 1/2 MajesTEC-1 study.[1] Teclistamab is an investigational, off-the-shelf, T-cell redirecting bispecific antibody targeting B-cell maturation antigen (BCMA), which is being studied in patients with relapsed or refractory multiple myeloma (RRMM).[1] The data were featured as part of an oral session during the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting. Applications seeking approval of teclistamab are currently under health authority review in the United States (U.S.) and Europe.

The multicohort, open-label, Phase 1/2 MajesTEC-1 study is investigating the safety and efficacy of teclistamab in patients with RRMM who received at least three prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody.[3] As of March 2022, 165 patients were treated with teclistamab at the recommended subcutaneous (SC) Phase 2 dose (RP2D) of 1.5 mg/kg preceded by step-up

doses of 0.06 mg/kg and 0.3 mg/kg across both Phase 1 (NCT03145181) and Phase 2 (NCT04557098) of the study.[1]

Longer Follow-up from MajesTEC-1 Study in Patients with Triple Class Exposed Multiple Myeloma (Abstract #8007)

At a median follow-up of 14.1 months (range, 0.26-24.4), an overall response rate (ORR) of 63 percent (95 percent Confidence Interval [CI], range, 55.2-70.4) was observed in patients with triple class exposed multiple myeloma, with a complete response (CR) or better achieved in 39.4 percent of patients.[1] Study participants had three or more prior lines of therapy, with a median of five prior lines, including a prior proteasome inhibitor, immunomodulatory drug and anti-CD38 antibody.[1] The majority of patients were triple-class refractory and/or refractory to their last line of treatment.[1] Although response duration data are not mature, the median duration of response at this time is 18.4 months and has not been reached in patients who achieved a CR or better (95 percent CI, 14.9 not estimable).[1] This suggests responses to teclistamab were durable and deepened over time.[1] The medium progression-free survival (PFS) was 11.3 months (95 percent CI, 8.8–17.1).[1] Adverse events (AEs) were low-grade for the most part and manageable with no new safety signals seen.[1]

These results from the MajesTEC-1 study were also simultaneously published online in *The New England Journal of Medicine*.[2]

"The longer term results from the MajesTEC-1 study suggest that patients are able to achieve deep and durable responses when treated with teclistamab," said Maria-Victoria Mateos, M.D., Ph.D., Consultant Physician in Haematology, University Hospital of Salamanca.* "These encouraging data reinforce the potential of teclistamab as a monotherapy for eligible patients with heavily pretreated multiple myeloma, in need of new treatment options."

No new safety signals were observed with longer follow-up.[1] In 14.1 month follow-up data presented, the most common grade 3/4 haematologic AEs were neutropenia (64.2 percent); anaemia (37 percent); lymphopenia (32.7 percent) and thrombocytopenia (21.2 percent).[1] Infections occurred in 76.4 percent of patients (44.8 percent grade 3/4).[1] The most common nonhaematologic AE was cytokine release syndrome (CRS), all of which were grade

1/2 except for one transient grade 3 CRS (72.1 percent all grade).[1] The median time to CRS onset was two days (range, 1-6) and median duration was two days (range, 1-9).[1] There were five treatment-related deaths, and dose reductions and discontinuations due to AEs were infrequent.[1]

First Results from Cohort C of the MajesTEC-1 Study of Teclistamab in Patients with RRMM with Prior Exposure to BCMA Targeted Treatment (Abstract #8013)

Initial results were also presented from Cohort C of the MajesTEC-1 study evaluating teclistamab in the treatment of patients with RRMM who had previously been exposed to an anti-BCMA treatment.[4] These patients had received a median of six prior lines of therapy, most (85 percent) were triple-class refractory and 35 percent were penta-drug refractory.[4] The use of teclistamab following prior treatment with chimeric antigen receptor T-cell (CAR-T) therapy and/or an antibody drug conjugate (ADC) (e.g., belantamab mafodotin) targeting BCMA resulted in a promising response rate in patients with heavily pretreated RRMM.[4] At a median follow-up of 12.5 months (range, 0.7-14.4), the ORR was 52.5 percent (95 percent CI, 36.1-68.5) among 40 patients who received teclistamab in Cohort C.[4] Responses to teclistamab occurred early and deepened over time, with comparable response rates in patients previously treated with an ADC and/or CAR-T.[4]

A tolerable side-effect profile was observed in patients previously treated with anti-BCMA treatment, with no dose reductions or discontinuations due to AEs.[4] The safety profile for Cohort C was comparable with that observed in BCMA treatment-naive patients, with no new safety signals.[4] In 12.5 month follow-up data, 26 patients (65 percent; 30 percent grade 3/4) had infections.[4] The most common AEs (n=40) were CRS (65 percent any grade), with a median time to CRS onset and duration of two days (range, 2-6) and two days (range, 1-4) respectively.[4] Cytopenias (grade 3/4) were noted as follows; neutropenia (62.5 percent); thrombocytopenia (30 percent); anaemia (35 percent); and lymphopenia (42.5 percent).[4]

"Patients with relapsed or refractory multiple myeloma have limited treatment options and only 30 percent will be able to achieve a response using conventional therapies," said Edmond Chan MBChB M.D. (Res), EMEA Therapeutic Area Lead Haematology, Janssen-Cilag Limited. "While unmet needs remain, we continue to be dedicated to developing innovative

treatment approaches that improve outcomes for people living with multiple myeloma, at all stages of the disease."

Initial Patient-Reported Health-Related Quality of Life (HRQoL) Outcomes in Patients with RRMM Treated with Teclistamab (Abstract #8033)

Initial results from an analysis of patient-reported health-related quality of life (HRQoL) outcomes following treatment with teclistamab were also shared in a poster session.[5] The study analysed patient-reported assessments of quality of life metrics among patients in the MajesTEC-1 trial who had received their first treatment dose by March 18, 2021.[5] The metrics analysed include function (physical, role, emotional, cognitive, social); symptoms (fatigue, nausea/vomiting, pain, appetite loss, constipation, diarrhoea); and generic health (mobility, self-care, usual activities, pain/discomfort, anxiety/depression).[5] Over 80 percent of the 110 patients included in the patient-reported outcomes (PRO) analysis noted meaningful improvement (percentages of patients with clinically meaningful change from baseline (EORTC QLQ-C30 scales: ≥10 points)) in at least one of the symptom scales.[5] Reduction in pain scores occurred as early as cycle two.[5] At the moment, no meaningful improvement was observed in the scales for physical functioning and fatigue.[5] These initial PRO results complement recent clinical data and support teclistamab as a potential off-the-shelf, T-cell redirecting therapy for patients with RRMM.[5]

As of September 7, 2021, median duration of treatment was 5.7 months and median follow-up was 7.8 months.[5] Global health status scores significantly improved from baseline (95 percent CIs for least squares mean change did not cross 0) at cycles four, six, and eight; emotional functioning significantly improved at all time points.[5] PRO assessments included European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 item (EORTC QLQ-C30).[5] PROs were assessed on day one of each treatment cycle (28 days per cycle).[5] Additional follow-up is needed to assess the full benefit of meaningful improvement in functional outcomes.[5]

"The updated data presented at ASCO support the ongoing evaluation of teclistamab for the treatment of relapsed or refractory multiple myeloma," said Yusri Elsayed, M.D., M.HSc., Ph.D., Vice President, Disease Area Leader, Hematologic Malignancies, Janssen Research & Development, LLC. "These results underscore our ongoing commitment to address the

unmet need for new therapeutic options and our effort to bring forward novel treatments for multiple myeloma patients in the near future."

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About Teclistamab

Teclistamab is an investigational, fully humanised IgG4, T-cell redirecting, bispecific antibody targeting both BCMA and CD3, on T-cells.[1] 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.[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. Food and Drug Administration (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 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 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.[17] In December 2021, Janssen submitted a Biologics License Application (BLA) to the FDA seeking approval of teclistamab for the treatment of patients with RRMM; a marketing authorisation application (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.[18] In multiple myeloma, cancerous plasma cells change and grow out of control.[18] In Europe, more than 50,900 people were diagnosed with multiple myeloma in 2020, and more than 32,500 patients died.[19] 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.[20]

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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**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 development 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 and 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 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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[1] Nooka A et al. Teclistamab, a B-cell maturation antigen (BCMA) x CD3 bispecific antibody, in patients with relapsed/refractory multiple myeloma (RRMM): Updated efficacy and safety results from MajesTEC-1. 2022 ASCO Annual Meeting – American Society of Clinical Oncology. June 2022.
[2] Moreau P et al. Teclistamab, a BCMAxCD3 antibody, in triple class exposed multiple myeloma. *New England Journal of Medicine.* June 2022.
[3] ClinicalTrials.gov. A Study of Teclistamab, in Participants With Relapsed or Refractory Multiple Myeloma. Available at: https://clinicaltrials.gov/ct2/show/NCT04557098. Last accessed: June 2022.
[4] Touzeau C et al. Efficacy and safety of teclistamab (tec), a B-cell maturation antigen (BCMA) x CD3 bispecific antibody, in patients (pts) with relapsed/refractory multiple myeloma (RRMM) after exposure to other BCMA-targeted agents. 2022 ASCO Annual Meeting – American Society of Clinical Oncology. June 2022.
[5] Martin T et al. Health-related quality of life in patients with relapsed/refractory multiple myeloma (RRMM) treated with teclistamab, a B-cell maturation antigen (BCMA) x CD3 bispecific antibody: patient-reported outcomes in MajesTEC-1. 2022 ASCO Annual Meeting – American Society of Clinical Oncology. June 2022.
[6] Labrijn AF, et al. Efficient generation of stable bispecific IgG1 by controlled Fab-arm exchange. *Proc Natl Acad Sci U S A*. 2013 Mar 26;110(13):5145-50.
[7] Frerichs KA, et al. Preclinical Activity of JNJ-7957, a Novel BCMA×CD3 Bispecific Antibody for the Treatment of Multiple Myeloma, Is Potentiated by Daratumumab. *Clin Cancer Res*. 2020 May 1;26(9):2203-2215.
[8] Cancer Research Institute. "Adoptive Cell Therapy: TIL, TCR, CAR T, AND NK CELL THERAPIES." Available at: https://www.cancerresearch.org/immunotherapy/treatment-types/adoptive-cell-therapy. Last accessed: June 2022.
[9] Cho SF, et al. Targeting B Cell Maturation Antigen (BCMA) in Multiple Myeloma: Potential Uses of BCMA-Based Immunotherapy. *Front Immunol*. 2018 Aug 10;9:1821.
[10] Benonisson H, et al. CD3-Bispecific Antibody Therapy Turns Solid Tumors into Inflammatory Sites but Does Not Install Protective Memory. *Mol Cancer Ther*. 2019 Feb;18(2):312-322.
[11] Usmani SZ, et al. Teclistamab, a B-cell maturation antigen × CD3 bispecific antibody, in patients with relapsed or refractory multiple myeloma (MajesTEC-1): a multicentre, open-label, single-arm, phase 1 study. *Lancet*. 2021 Aug 21;398(10301):665-674.
[12] 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: June 2022.
[13] 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: June 2022.
[14] 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: June 2022.
[15] 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: June 2022.
[16] European Medicines Agency. PRIME Factsheet. Available at: https://www.ema.europa.eu/en/human-regulatory/research-development/prime-priority-medicines. Last accessed: June 2022.
[17] The U.S. Food and Drug Administration. "Expedited Programs for Serious Conditions." Available at: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358301.pdf. Last accessed: June 2022.
[18] American Society of Clinical Oncology. Multiple myeloma: introduction. Available at: https://www.cancer.net/cancer-types/multiple-myeloma/introduction Last accessed: June 2022.
[19] 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: June 2022.
[20] 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: June 2022.