



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

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

June 5, 2022 (CHICAGO) – The Janssen Pharmaceutical Companies of Johnson & Johnson announced updated efficacy and safety results from the teclistamab Phase 1/2 MajesTEC-1 study. 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) who have received three or more prior lines of therapy.¹ The data were featured as part of an oral session during the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting. Additional poster presentations featured data on teclistamab as a

monotherapy, as well as in combination with DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj). Applications seeking approval of teclistamab are currently under health authority review in the 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. 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 and 0.3 mg/kg across both Phase 1 ([NCT03145181](#)) and Phase 2 ([NCT04557098](#)) of the study.

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 (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 MajesTEC-1 study update suggests patients with relapsed or refractory multiple myeloma receiving teclistamab achieved a deep response that was also durable,” said Ajay K. Nooka, M.D., MPH, FACP, Associate Professor of Hematology and Medical Oncology at Emory School of Medicine and principal study investigator.[‡] “These longer-term data, notably the overall response rate and progression-free survival, are encouraging in this heavily pretreated patient population.”

No new safety signals were observed with longer follow-up.¹ In 14.1 month follow-up data presented at ASCO 2022, the most common grade 3/4 hematologic AEs were neutropenia (64.2 percent); anemia (37 percent); lymphopenia (32.7 percent) and thrombocytopenia (21.2 percent). Infections occurred in 76.4 percent of patients (44.8 percent grade 3/4).¹ The most common nonhematologic AE was cytokine release syndrome (CRS), all of which were grade 1/2 except for 1 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.³ 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.³ 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.³ At a median follow-up of 12.5 months (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.³ Responses to

teclistamab occurred early and deepened over time, with comparable response rates in patients previously treated with an ADC and/or CAR-T.³

A tolerable side-effect profile was observed in patients previously treated with anti-BCMA treatment, with no dose reductions or discontinuations due to AEs.³ The safety profile for Cohort C was comparable with that observed in BCMA treatment-naive patients, with no new safety signals.³ In 12.5 month follow-up data, 26 patients (65 percent; 30 percent grade 3/4) had infections.³ 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.³ Cytopenias (grade 3/4) were noted as follows; neutropenia (62.5 percent); thrombocytopenia (30 percent); anemia (35 percent); and lymphopenia (42.5 percent).³

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.⁴ The study analyzed 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, 2021.⁴ The metrics analyzed include function (physical, role, emotional, cognitive, social); symptoms (fatigue, nausea/vomiting, pain, appetite loss, constipation, diarrhea); and generic health (mobility, self-care, usual activities, pain/discomfort, anxiety/depression).⁴ 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.⁴ Reduction in pain scores occurred as early as cycle two.⁴ At the moment, no meaningful improvement was observed in the scales for physical functioning and fatigue.⁴ 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.⁴

As of September 7, 2021, median duration of treatment was 5.7 months and median follow-up was 7.8 months.⁴ 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.⁴ PRO assessments included European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 item (EORTC QLQ-C30).⁴ PROs were assessed on day one of each treatment cycle (28 days per cycle).⁴ Additional follow-up is needed to assess the full benefit of meaningful improvement in functional outcomes.⁴

Two Studies Investigate the Safety and Efficacy of Teclistamab and DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) in Combination for the Treatment of Patients with RRMM

Updated results from the Phase 1 TRIMM-2 study ([NCT04108195](#)) were featured during a poster session ([Abstract #8032](#)) at ASCO 2022, evaluating teclistamab in combination with DARZALEX FASPRO®, a CD38-directed monoclonal antibody approved to be given subcutaneously for the treatment of patients with multiple myeloma.⁵ In the study, patients received a median of five prior lines of therapy; 75.4 percent had prior exposure to anti-CD38 therapies, and 63.1 percent were refractory to anti-CD38 treatment.⁵ Evaluable patients achieved an ORR of 76.5 percent at a median follow-up of 8.6 months (0.3–19.6).⁵

A poster presentation for the ongoing multicenter, open-label, randomized Phase 3 MajesTEC-3 ([NCT05083169](#)) study comparing the efficacy of teclistamab in combination with daratumumab versus investigator's choice of daratumumab in combination with pomalidomide and dexamethasone (DPd) or bortezomib and dexamethasone (DVd) ([Poster TPS8072](#)) in patients with RRMM was also presented at ASCO.⁶

Additional data from both the teclistamab ([Abstract #S188](#)) and talquetamab ([Abstract #S183](#)) cohorts of the TRIMM-2 study will be featured as oral presentations at the European Hematology Association (EHA) 2022 Congress taking place in Vienna, Austria, June 9-12.^{7,8}

“The updated data presented at ASCO support the ongoing evaluation of teclistamab as a monotherapy and in combination with standard of care treatments,” 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.”

About Teclistamab

Teclistamab is an investigational, fully humanized IgG4, T-cell redirecting, bispecific antibody targeting both BCMA (B-cell maturation antigen) and CD3, the T-cell receptor. BCMA is expressed at high levels on multiple myeloma cells.^{9,10,11,12,13} Teclistamab redirects CD3-positive T-cells to BCMA-expressing myeloma cells to induce killing of tumor cells.⁸

Teclistamab is currently being evaluated in several monotherapy and combination studies. In 2020, the European Commission 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 U.S. FDA, respectively. PRIME offers enhanced interaction and early dialogue to optimize drug development plans and speed up evaluation of cutting-edge, scientific advances that target a high unmet medical need.¹⁴ 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.¹⁵ In December 2021, Janssen submitted a Biologics License Application (BLA) to the FDA seeking approval of teclistamab for the treatment of patients with relapsed or refractory multiple myeloma; a marketing authorization application (MAA) was submitted to the EMA for teclistamab approval in January 2022.

About DARZALEX FASPRO®

In [August 2012](#), Janssen Biotech, Inc. and Genmab A/S entered into a worldwide agreement, which granted Janssen an exclusive license to develop, manufacture and commercialize daratumumab. DARZALEX FASPRO® is the only CD38-directed antibody approved to be given subcutaneously to treat patients with multiple myeloma and now light chain (AL) amyloidosis. DARZALEX FASPRO® is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology.

DARZALEX FASPRO® is indicated for the treatment of adult patients with multiple myeloma:

- in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant
- in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy
- in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant
- in combination with pomalidomide and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor
- in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy

- in combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy
- as monotherapy in patients who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent

DARZALEX *FASPRO*[®] in combination with bortezomib, cyclophosphamide, and dexamethasone is indicated for the treatment of adult patients with newly diagnosed AL amyloidosis. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Limitations of Use

DARZALEX *FASPRO*[®] is not indicated and is not recommended for the treatment of patients with AL amyloidosis who have NYHA Class IIIB or Class IV cardiac disease or Mayo Stage IIIB outside of controlled clinical trials.

Full prescribing information for DARZALEX *FASPRO*[®] is available [here](#).

DARZALEX *FASPRO*[®] IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

DARZALEX *FASPRO*[®] is contraindicated in patients with a history of severe hypersensitivity to daratumumab, hyaluronidase or any of the components of the formulation.

WARNINGS AND PRECAUTIONS

Hypersensitivity and Other Administration Reactions

Both systemic administration-related reactions, including severe or life-threatening reactions, and local injection-site reactions can occur with DARZALEX *FASPRO*[®].

Fatal reactions have been reported with daratumumab-containing products, including DARZALEX FASPRO®.

Systemic Reactions

In a pooled safety population of 898 patients with multiple myeloma (N=705) or light chain (AL) amyloidosis (N=193) who received DARZALEX FASPRO® as monotherapy or in combination, 9% of patients experienced a systemic administration-related reaction (Grade 2: 3.2%, Grade 3: 1%). Systemic administration-related reactions occurred in 8% of patients with the first injection, 0.3% with the second injection, and cumulatively 1% with subsequent injections. The median time to onset was 3.2 hours (range: 4 minutes to 3.5 days). Of the 140 systemic administration-related reactions that occurred in 77 patients, 121 (86%) occurred on the day of DARZALEX FASPRO® administration. Delayed systemic administration-related reactions have occurred in 1% of the patients.

Severe reactions included hypoxia, dyspnea, hypertension and tachycardia. Other signs and symptoms of systemic administration-related reactions may include respiratory symptoms, such as bronchospasm, nasal congestion, cough, throat irritation, allergic rhinitis, and wheezing, as well as anaphylactic reaction, pyrexia, chest pain, pruritis, chills, vomiting, nausea, and hypotension.

Pre-medicate patients with histamine-1 receptor antagonist, acetaminophen and corticosteroids. Monitor patients for systemic administration-related reactions, especially following the first and second injections. For anaphylactic reaction or life-threatening (Grade 4) administration-related reactions, immediately and permanently discontinue DARZALEX FASPRO®. Consider administering corticosteroids and other medications after the administration of DARZALEX FASPRO® depending on dosing regimen and medical history to minimize the risk of delayed (defined as occurring the day after administration) systemic administration-related reactions.

Local Reactions

In this pooled safety population, injection-site reactions occurred in 8% of patients, including Grade 2 reactions in 0.7%. The most frequent (>1%) injection-site reaction was injection site erythema. These local reactions occurred a median of 5 minutes (range: 0 minutes to 6.5 days) after starting administration of DARZALEX *FASPRO*[®]. Monitor for local reactions and consider symptomatic management.

Cardiac Toxicity in Patients with Light Chain (AL) Amyloidosis

Serious or fatal cardiac adverse reactions occurred in patients with light chain (AL) amyloidosis who received DARZALEX *FASPRO*[®] in combination with bortezomib, cyclophosphamide and dexamethasone. Serious cardiac disorders occurred in 16% and fatal cardiac disorders occurred in 10% of patients. Patients with NYHA Class IIIA or Mayo Stage IIIA disease may be at greater risk. Patients with NYHA Class IIIB or IV disease were not studied. Monitor patients with cardiac involvement of light chain (AL) amyloidosis more frequently for cardiac adverse reactions and administer supportive care as appropriate.

Neutropenia

Daratumumab may increase neutropenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. Monitor patients with neutropenia for signs of infection. Consider withholding DARZALEX *FASPRO*[®] until recovery of neutrophils. In lower body weight patients receiving DARZALEX *FASPRO*[®], higher rates of Grade 3-4 neutropenia were observed.

Thrombocytopenia

Daratumumab may increase thrombocytopenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. Consider withholding DARZALEX *FASPRO*[®] until recovery of platelets.

Embryo-Fetal Toxicity

Based on the mechanism of action, DARZALEX *FASPRO*[®] can cause fetal harm when administered to a pregnant woman. DARZALEX *FASPRO*[®] may cause depletion of fetal immune cells and decreased bone density. Advise pregnant women of the potential risk to a fetus. Advise females with reproductive potential to use effective contraception during treatment with DARZALEX *FASPRO*[®] and for 3 months after the last dose.

The combination of DARZALEX *FASPRO*[®] with lenalidomide is contraindicated in pregnant women, because lenalidomide may cause birth defects and death of the unborn child. Refer to the lenalidomide prescribing information on use during pregnancy.

Interference with Serological Testing

Daratumumab binds to CD38 on red blood cells (RBCs) and results in a positive Indirect Antiglobulin Test (Indirect Coombs test). Daratumumab-mediated positive indirect antiglobulin test may persist for up to 6 months after the last daratumumab administration. Daratumumab bound to RBCs masks detection of antibodies to minor antigens in the patient's serum. The determination of a patient's ABO and Rh blood type are not impacted.

Notify blood transfusion centers of this interference with serological testing and inform blood banks that a patient has received DARZALEX *FASPRO*[®]. Type and screen patients prior to starting DARZALEX *FASPRO*[®].

Interference with Determination of Complete Response

Daratumumab is a human IgG kappa monoclonal antibody that can be detected on both the serum protein electrophoresis (SPE) and immunofixation (IFE) assays used for the clinical monitoring of endogenous M-protein. This interference can impact the determination of complete response and of disease progression in some DARZALEX *FASPRO*[®]-treated patients with IgG kappa myeloma protein.

ADVERSE REACTIONS

The most common adverse reaction ($\geq 20\%$) with DARZALEX *FASPRO*[®] monotherapy is upper respiratory tract infection. The most common adverse reactions with combination therapy ($\geq 20\%$ for any combination) include fatigue, nausea, diarrhea, dyspnea, insomnia, pyrexia, cough, muscle spasms, back pain, vomiting, upper respiratory tract infection, peripheral sensory neuropathy, constipation, pneumonia, and peripheral edema.

The most common adverse reactions ($\geq 20\%$) in patients with light chain (AL) amyloidosis who received DARZALEX *FASPRO*[®] are upper respiratory tract infection, diarrhea, peripheral edema, constipation, fatigue, peripheral sensory neuropathy, nausea, insomnia, dyspnea, and cough.

The most common hematology laboratory abnormalities ($\geq 40\%$) with DARZALEX *FASPRO*[®] are decreased leukocytes, decreased lymphocytes, decreased neutrophils, decreased platelets, and decreased hemoglobin.

Please see full [Prescribing Information](#) for DARZALEX *FASPRO*[®].

About Multiple Myeloma

Multiple myeloma is an incurable blood cancer that affects some white blood cells called plasma cells, which are found in the bone marrow.¹⁶ When damaged, these plasma cells rapidly spread and replace normal cells in the bone marrow with tumors. In 2020, worldwide an estimated 176,000 people were diagnosed with multiple myeloma.¹⁷ In 2022, it is estimated that more than 34,000 people will be diagnosed with multiple myeloma, and more than 12,000 people will die from the disease in the U.S.¹⁸ While some people diagnosed with multiple myeloma initially have no symptoms, most patients are diagnosed due to symptoms that can include bone fracture or pain, low red blood cell counts, tiredness, high calcium levels, kidney problems or infections.¹⁹

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. Follow us at www.twitter.com/JanssenGlobal. Janssen Research & Development, LLC is one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

†Dr. Nooka has served as a paid consultant to Janssen; he has not been paid for any media work.

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 and DARZALEX FASPRO®. 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 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 behavior 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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