

News Release

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Janssen Presents First Data from MajesTEC-2 Trial of TECVAYLI™ (teclistamab-cqyv) in Combination with DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) and Lenalidomide in Relapsed or Refractory Multiple Myeloma

Initial Phase 1b study results show clinical activity with immune-based triplet therapy regimen

NEW ORLEANS, December 10, 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today new results from a cohort of the Phase 1b MajesTEC-2 study of TECVAYLI™ (teclistamab-cqyv), a first-in-class, BCMAxCD3 bispecific T-cell engager antibody, in combination with DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) and lenalidomide. According to the results, the immune-based triplet therapy regimen had a manageable safety profile with no unexpected safety signals observed. A very good partial response (VGPR) or better was achieved by 90.3 percent of patients with relapsed or refractory multiple myeloma who had received one to three prior lines of therapy, including a proteasome inhibitor and immunomodulatory drug, with responses deepening over time.¹ These data were presented during the 2022 American Society of Hematology (ASH) Annual Meeting ([Abstract #160](#)).

“These results show the potential of the combination of the bispecific BCMA-directed antibody teclistamab with the anti-CD38 antibody daratumumab and lenalidomide in the treatment of patients with relapsed or refractory multiple myeloma,” said Emma Searle, M.D., Ph.D., Consultant Hematologist and Honorary Senior Lecturer, The Christie Hospital and University of Manchester, England, and study investigator.[†] “This is the first presentation of data from a teclistamab-based

triplet regimen and we are eager to better understand how this combination may benefit patients through ongoing clinical studies.”

At a median follow-up of 8.4 months (range, 1.1 to 12.9), the overall response rate (ORR) was 93.5 percent.¹ Among all patients in the trial, VGPRs or better were achieved by 90.3 percent of patients, and 54.8 percent of patients achieved a complete response (CR) or better.¹ Median time to response was one month, and responses deepened.¹ The median time to CR or better was three months (range, 1 to 10.4).¹ At data cut-off, 80.6 percent of patients remained progression-free and on treatment.¹ Responses deepened over time, and median duration of response had not been reached.¹

“Following the recent regulatory approvals of TECVAYLI in the U.S. and EU, as well as its inclusion in the NCCN Clinical Practice Guidelines in Oncology as a recommended treatment option for certain patients with multiple myeloma, we are encouraged by its potential to improve outcomes in combination regimens and for earlier lines of treatment,” said Sen Zhuang, M.D., Ph.D., Vice President, Clinical Research and Development, Janssen Research & Development, LLC. “We remain committed to addressing the unmet needs of patients with multiple myeloma through off-the-shelf immunotherapies like TECVAYLI and where we can bring together novel therapeutic approaches in the treatment of complex blood cancers.”

The primary objective of this cohort of the MajesTEC-2 study ([NCT04722146](#)) was to understand if the immunomodulatory effects of daratumumab and lenalidomide could enhance the function of TECVAYLI™, resulting in enhanced antimyeloma activity in a broader population of patients.¹ The MajesTEC-7 study ([NCT05552222](#)) will examine the potential of this combination in patients newly diagnosed with multiple myeloma.

The most frequent hematological adverse events (AEs) observed in the study included neutropenia (84.4 percent any grade, 78.1 percent grade 3/4) and thrombocytopenia (25 percent any grade, 15.6 percent grade 3/4).¹ The most frequent non-hematological AE was cytokine release syndrome (CRS) (81.3 percent, all grade 1/2); 97 percent of CRS events occurred during cycle 1.¹

Other common non-hematological AEs included fatigue (46.9 percent any grade, 6.3 percent grade 3/4); diarrhea (46.9 percent any grade, none grade 3/4); cough (40.6 percent any grade, 3.1 percent grade 3/4); COVID-19 (37.5 percent any grade, 12.5 percent grade 3/4); insomnia (37.5 percent any grade, 3.1 percent grade 3/4); hypophosphatemia (31.3 percent any grade, 6.3 percent grade 3/4); pyrexia (31.3 percent any grade, 3.1 percent grade 3/4); upper respiratory tract infection (31.3 percent any grade, none grade 3/4); increased alanine aminotransferase (ALT) (28.1 percent

any grade, 9.4 percent grade 3/4) and pneumonia (25 percent any grade, 15.6 percent grade 3/4).¹ Two patients discontinued therapy due to an AE (COVID-19), considered to be unrelated to the study by investigator assessment.¹ Infections were common among patients in the study and the majority were low grade (90.6 percent any grade, 37.5 percent grade 3/4).¹

New Data from the Phase 1/2 MajesTEC-1 Study Evaluating TECVAYLI™ in Relapsed or Refractory Multiple Myeloma Patients

New correlative analyses were also presented from the MajesTEC-1 study ([NCT04557098](#)). Data from these analyses may be used to help better understand baseline immune and tumor correlatives associated with outcomes in patients treated with TECVAYLI™.² The data were presented during an oral abstract session ([Abstract #97](#)). Additional pharmacokinetic data evaluating potential drug interactions with TECVAYLI™ were presented during a separate poster session ([Abstract #3228](#)), as well as analyses of serum teclistamab-cqyv concentrations after intravenous and subcutaneous administration ([Abstract #1911](#)), to improve understanding of the clinical pharmacological profile of TECVAYLI™.^{3,4}

About the MajesTEC-2 Study

MajesTEC-2 ([NCT04722146](#)); is Phase 1b multicohort study evaluating the safety and efficacy of TECVAYLI™ in combination with other anticancer therapies in patients with relapsed or refractory multiple myeloma who received at least one prior line of therapy.¹ Patients were eligible for treatment if they had received 1-3 prior lines of therapy, including a proteasome inhibitor and immunomodulatory drug.¹

In the presented study cohort, 32 patients received weekly doses of TECVAYLI™ (0.72 mg/kg or 1.5 mg/kg, with step-up dosing) plus the approved schedules of DARZALEX FASPRO® 1800 mg and lenalidomide 25 mg.¹ Responses were investigator assessed using International Myeloma Working Group criteria, and AEs were assessed by Common Terminology Criteria for Adverse Events (CTCAE) v5.0, except for CRS and immune effector cell-associated neurotoxicity syndrome (ICANS), which were graded per American Society for Transplantation and Cellular Therapy (ASTCT) guidelines.¹

About TECVAYLI™

TECVAYLI™ (teclistamab-cqyv) [received](#) approval from the U.S. Food and Drug Administration in October 2022 as an off-the-shelf (or ready to use) bispecific antibody that is administered as a subcutaneous treatment for adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.⁵ In August 2022, TECVAYLI™ received approval from the European Commission as an off-the-shelf bispecific antibody administered as a subcutaneous

treatment for adult patients with relapsed or refractory multiple myeloma who have received at least three prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody.⁶ Teclistamab-cqyv (TECVAYLI™) was recently recommended by the National Comprehensive Cancer Network® (NCCN®) as a treatment option for these patients. TECVAYLI™ is a first-in-class, bispecific T-cell engager antibody therapy which uses innovative science to activate the immune system by binding to the CD3 receptor expressed on the surface of T cells and to the B-cell maturation antigen (BCMA) expressed on the surface of multiple myeloma cells and some healthy B-lineage cells.⁷

About DARZALEX FASPRO®

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) [received](#) U.S. FDA approval in May 2020 and is approved for eight indications in multiple myeloma (MM), three of which are for frontline treatment in newly diagnosed patients who are transplant eligible or ineligible.⁸ It is the only subcutaneous CD38-directed antibody approved to treat patients with MM. DARZALEX FASPRO® is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology.

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.⁹ In multiple myeloma, these plasma cells change, spread rapidly and replace normal cells in the bone marrow with tumors.¹⁰ 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.¹¹ 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.¹²

TECVAYLI™ IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGIC TOXICITY including IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME

- Cytokine release syndrome (CRS), including life-threatening or fatal reactions, can occur in patients receiving TECVAYLI™. Initiate treatment with TECVAYLI™ step-up dosing schedule to reduce risk of CRS.
- Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and serious and life-threatening reactions, can occur in patients receiving TECVAYLI™. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment and treat promptly.

- TECVAYLI™ is available only through a restricted program called the TECVAYLI™ Risk Evaluation and Mitigation Strategy (REMS).

WARNINGS AND PRECAUTIONS

Cytokine Release Syndrome: TECVAYLI™ can cause cytokine release syndrome (CRS), including life-threatening or fatal reactions. In the clinical trial, CRS occurred in 72% of patients who received TECVAYLI™ at the recommended dose, with Grade 1 CRS occurring in 50% of patients, Grade 2 in 21%, and Grade 3 in 0.6%. Recurrent CRS occurred in 33% of patients. Most patients experienced CRS following step-up dose 1 (42%), step-up dose 2 (35%), or the initial treatment dose (24%). Less than 3% of patients developed first occurrence of CRS following subsequent doses of TECVAYLI™. The median time to onset of CRS was 2 (range: 1 to 6) days after the most recent dose with a median duration of 2 (range: 1 to 9) days. Clinical signs and symptoms of CRS included, but were not limited to, fever, hypoxia, chills, hypotension, sinus tachycardia, headache, and elevated liver enzymes (aspartate aminotransferase and alanine aminotransferase elevation).

Initiate therapy according to TECVAYLI™ step-up dosing schedule to reduce risk of CRS. Administer pretreatment medications to reduce risk of CRS and monitor patients following administration of TECVAYLI™ accordingly. At the first sign of CRS, immediately evaluate patient for hospitalization, manage per consensus guidelines, and administer supportive care based on severity; withhold or permanently discontinue TECVAYLI™ based on severity.

TECVAYLI™ is available only through a restricted program under a REMS.

Neurologic Toxicity including ICANS: TECVAYLI™ can cause serious or life-threatening neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)

In the clinical trial, neurologic toxicity occurred in 57% of patients who received TECVAYLI™ at the recommended dose, with Grade 3 or 4 neurologic toxicity occurring in 2.4% of patients. The most frequent neurologic toxicities were headache (25%), motor dysfunction (16%), sensory neuropathy (15%), and encephalopathy (13%). With longer follow-up, Grade 4 seizure and fatal Guillain-Barré syndrome (one patient each) occurred in patients who received TECVAYLI™.

In the clinical trial, ICANS was reported in 6% of patients who received TECVAYLI™ at the recommended dose [see *Adverse Reactions (6.1)*]. Recurrent ICANS occurred in 1.8% of patients. Most patients experienced ICANS following step-up dose 1 (1.2%), step-up dose 2 (0.6%), or the initial treatment dose (1.8%). Less than 3% of patients developed first occurrence of ICANS following subsequent doses of TECVAYLI™. The median time to onset of ICANS was 4 (range: 2 to 8) days

after the most recent dose with a median duration of 3 (range: 1 to 20) days. The most frequent clinical manifestations of ICANS reported were confusional state and dysgraphia. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS.

Monitor patients for signs and symptoms of neurologic toxicity during treatment. At the first sign of neurologic toxicity, including ICANS, immediately evaluate patient and provide supportive therapy based on severity; withhold or permanently discontinue TECVAYLI™ based on severity and follow management recommendations.

Due to the potential for neurologic toxicity, patients are at risk of depressed level of consciousness. Advise patients to refrain from driving or operating heavy or potentially dangerous machinery during and for 48 hours after completion of TECVAYLI™ step-up dosing schedule and in the event of new onset of any neurologic toxicity symptoms until neurologic toxicity resolves.

TECVAYLI™ is available only through a restricted program under a REMS.

TECVAYLI™ REMS: TECVAYLI™ is available only through a restricted program under a REMS called the TECVAYLI™ REMS because of the risks of CRS and neurologic toxicity, including ICANS.

Hepatotoxicity: TECVAYLI™ can cause hepatotoxicity, including fatalities. In patients who received TECVAYLI™ at the recommended dose in the clinical trial, there was one fatal case of hepatic failure. Elevated aspartate aminotransferase (AST) occurred in 34% of patients, with Grade 3 or 4 elevations in 1.2%. Elevated alanine aminotransferase (ALT) occurred in 28% of patients, with Grade 3 or 4 elevations in 1.8%. Elevated total bilirubin occurred in 6% of patients with Grade 3 or 4 elevations in 0.6%. Liver enzyme elevation can occur with or without concurrent CRS.

Monitor liver enzymes and bilirubin at baseline and during treatment as clinically indicated. Withhold TECVAYLI™ or consider permanent discontinuation of TECVAYLI™ based on severity.

Infections: TECVAYLI™ can cause severe, life-threatening, or fatal infections. In patients who received TECVAYLI™ at the recommended dose in the clinical trial, serious infections, including opportunistic infections, occurred in 30% of patients, with Grade 3 or 4 infections in 35%, and fatal infections in 4.2%. Monitor patients for signs and symptoms of infection prior to and during treatment with TECVAYLI™ and treat appropriately. Administer prophylactic antimicrobials according to guidelines. Withhold TECVAYLI™ or consider permanent discontinuation of TECVAYLI™ based on severity.

Monitor immunoglobulin levels during treatment with TECVAYLI™ and treat according to guidelines, including infection precautions and antibiotic or antiviral prophylaxis.

Neutropenia: TECVAYLI™ can cause neutropenia and febrile neutropenia. In patients who received TECVAYLI™ at the recommended dose in the clinical trial, decreased neutrophils occurred in 84% of patients, with Grade 3 or 4 decreased neutrophils in 56%. Febrile neutropenia occurred in 3% of patients.

Monitor complete blood cell counts at baseline and periodically during treatment and provide supportive care per local institutional guidelines.

Monitor patients with neutropenia for signs of infection.

Withhold TECVAYLI™ based on severity [*see Dosage and Administration (2.4)*].

Hypersensitivity and Other Administration Reactions: TECVAYLI™ can cause both systemic administration-related and local injection-site reactions. Systemic Reactions - In patients who received TECVAYLI™ at the recommended dose in the clinical trial, 1.2% of patients experienced systemic-administration reactions, which included Grade 1 recurrent pyrexia and Grade 1 swollen tongue. Local Reactions - In patients who received TECVAYLI™ at the recommended dose in the clinical trial, injection-site reactions occurred in 35% of patients with Grade 1 injection-site reactions in 30% and Grade 2 in 4.8%. Withhold TECVAYLI™ or consider permanent discontinuation of TECVAYLI™ based on severity.

Embryo-Fetal Toxicity: Based on its mechanism of action, TECVAYLI™ may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with TECVAYLI™ and for 5 months after the last dose.

Adverse Reactions: The most common adverse reactions (≥20%) were pyrexia, CRS, musculoskeletal pain, injection site reaction, fatigue, upper respiratory tract infection, nausea, headache, pneumonia, and diarrhea. The most common Grade 3 to 4 laboratory abnormalities (≥20%) were decreased lymphocytes, decreased neutrophils, decreased white blood cells, decreased hemoglobin and decreased platelets.

Please read full [Prescribing Information](#) including Boxed Warning for TECVAYLI™.

DARZALEX FASPRO® IMPORTANT SAFETY INFORMATION

INDICATIONS

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) 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 carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy
- In combination with bortezomib and dexamethasone in patients who have received at least one prior 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

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 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 [@JanssenGlobal](#) and [@JanssenUS](#). Janssen Research & Development, LLC and Janssen Biotech, Inc. are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

[†]*Dr. Searle has served as a consultant to Janssen; she 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 TECVAYLI™ (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 materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, Janssen Biotech, Inc., 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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¹ Searle, et. al. Teclistamab in Combination with Subcutaneous Daratumumab and Lenalidomide in Patients with Multiple Myeloma: Results from One Cohort of MajesTEC-2, a Phase1b, Multicohort Study. American Society of Hematology Meeting 2022. December 2022.

² Cortes-Selva, et. al. Teclistamab, a B-cell Maturation Antigen (BCMA) x CD3 Bispecific Antibody, in Patients with Relapsed/Refractory Multiple Myeloma (RRMM): Correlative Analyses from MajesTEC-1. American Society of Hematology Meeting 2022. December 2022.

³ Marie-Emilie Willemin, et. al. Drug Interaction Potential As a Result of Cytokine Release Syndrome Using a Physiologically Based Pharmacokinetic Model: Case Study of Teclistamab. American Society of Hematology Meeting 2022. December 2022.

⁴ Xin Miao, et. al. Teclistamab Population Pharmacokinetics and Exposure-Response Relationship Support 1.5 Mg/Kg Dose Regimen in Relapsed/Refractory Multiple Myeloma. American Society of Hematology Meeting 2022. December 2022.

⁵ TECVAYLI™ U.S. Prescribing Information. October 2022.

⁶ Padala SA et al. Epidemiology, Staging, and Management of Multiple Myeloma. Med Sci (Basel). 2021;9(1):3.

⁷ Frerichs KA et al. Clin Cancer Res. 2020; doi: 10.1158/1078-0432.CCR-19-2299.

⁸ DARZALEX FASPRO® Prescribing Information, March 2021.

⁹ Rajkumar SV. Multiple myeloma: 2020 update on diagnosis, risk-stratification and management. Am J Hematol.2020;95(5):548-567. <http://www.ncbi.nlm.nih.gov/pubmed/32212178>.

¹⁰ National Cancer Institute. Plasma Cell Neoplasms. Accessed September 2022.

<https://www.cancer.gov/types/myeloma/patient/myeloma-treatment-pdq>.

¹¹ American Cancer Society. "Key Statistics About Multiple Myeloma." Available at: <https://www.cancer.org/cancer/multiple-myeloma/about/key-statistics.html#:~:text=Multiple%20myeloma%20is%20a%20relatively,men%20and%2015%2C370%20in%20women>). Accessed September 2022.

¹² American Cancer Society. "What Is Multiple Myeloma?" Available at: <https://www.cancer.org/cancer/multiple-myeloma/about/what-is-multiple-myeloma.html>. Accessed September 2022.