

News Release

Media Inquiries:

Satu Glawe
+49 172-294-6264

Christie Corbett
+1 857-636-0211

Investor Relations:

Raychel Kruper
+1 732-524-6164

U.S. Medical Inquiries:

+1 800-526-7736

Janssen Presents Longer-Term Talquetamab Follow-Up Data Showing Overall Response Rates of More Than 70 Percent in Heavily Pretreated Patients with Multiple Myeloma

Additional long-term data from the TRiMM-2 study in patients receiving talquetamab and DARZALEX FASPRO® combination biweekly regimen showed an overall response rate of more than 80 percent

CHICAGO, June 3, 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today updated results from the pivotal Phase 1/2 MonumenTAL-1 study of the investigational bispecific antibody talquetamab in the treatment of patients with relapsed or refractory multiple myeloma (RRMM).¹ Data from the MonumenTAL-1 study highlight safety and efficacy results ([Abstract #8036](#)) and an analysis of infections and parameters of humoral immunity in patients with RRMM treated with talquetamab ([Abstract #8020](#)).^{1,2} These data will be presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting.^{1,2} Additional data from the Phase 2 TRiMM-2 study, evaluating talquetamab in combination with DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj), were presented ([Abstract #8003](#)) at the meeting.³

Patients in the Phase 1/2 MonumenTAL-1 study (n=339) were treated with subcutaneous (SC) talquetamab at the recommended Phase 2 dose (RP2D) of 0.8 mg/kg biweekly (Q2W) or 0.4 mg/kg weekly (QW) with step-up doses.¹ The overall response rate (ORR) to talquetamab was similar across

both doses.¹ With a median follow-up of 12.7 months, 71.7 percent (104/145) of response-evaluable patients treated with the 0.8 mg/kg Q2W dose achieved a response, 60.7 percent achieved a very good partial response (VGPR) or better, nine percent achieved a complete response (CR), and 29.7 percent achieved a stringent complete response.¹ With a median follow-up of 18.8 months, 74.1 percent (106/143) of response-evaluable patients treated with the 0.4 mg/kg QW dose achieved a response, 59.4 percent achieved a VGPR or better, 9.8 percent achieved a CR, and 23.8 percent achieved a stringent CR.¹ In a separate cohort of patients treated with prior T-cell redirection therapy, 64.7 percent (33/51) achieved a response, and 54.9 percent achieved a VGPR or better, with a median follow-up of 14.8 months.¹

"The updated results from the MonumentAL-1 study continue to show the encouraging potential of talquetamab for heavily pretreated patients with multiple myeloma, including those who may have been exposed to prior T-cell redirection therapy," said Carolina Schinke, M.D., Associate Professor of Medicine at the Myeloma Center at the University of Arkansas for Medical Sciences and principal investigator.[†] "With a high overall response rate among relapsed or refractory patients, the results underscore the efficacy of talquetamab as a novel option for later-line patients who otherwise face a poor prognosis, including patients with high-risk disease."

Responses were durable; median duration of response (DOR) was not reached for patients on the Q2W dose and was 9.5 months (range, 6.7-13.3) for patients who received QW dosing.¹ The 12-month overall survival (OS) rates were 77.4 percent, 76.4 percent and 62.9 percent in the 0.8 mg/kg Q2W dose, 0.4 mg/kg QW dose, and prior T-cell redirection cohorts, respectively.¹ The 12-month progression free survival (PFS) rates were 54.4 percent, 34.9 percent and 38.1 percent in the 0.8 mg/kg Q2W dose, 0.4 mg/kg QW dose, and prior T-cell redirection cohorts, respectively.¹

Study results showed a low discontinuation rate due to adverse events (AEs) (0.8 mg/kg Q2W dose, eight percent; 0.4 mg/kg QW dose, five percent).^{1,4} The most common AEs at the 0.8 mg/kg Q2W dose and 0.4 mg/kg QW dose were cytokine release syndrome (CRS; 74.5 percent, 0.7 percent Grade 3/4; 79 percent, 2.1 percent Grade 3/4, respectively); dysgeusia (71 percent and 72 percent, respectively; all Grade 1/2); and skin-related AEs (73.1 percent Grade 1/2, 0.7 percent Grade 3/4; 55.9 percent all Grade 1/2, respectively).¹ The safety profile was clinically manageable with low rates of Grade 3 or higher infections (0.8 mg/kg Q2W dose, 14.5 percent; 0.4 mg/kg QW dose, 19.6 percent) and low rates of talquetamab discontinuation due to infection (0.8 mg/kg Q2W dose, zero percent; 0.4 mg/kg QW dose, 1.4 percent).¹ Safety in the T-cell redirection subgroup was consistent with what was observed in the weekly and biweekly cohorts.¹ New onset infections were primarily

limited to the first 100 days.^{1,2} No new safety signals were observed with longer term follow-up.^{1,5} There were no talquetamab-related deaths.⁴

Analysis of Infections and Parameters of Humoral Immunity in Patients with Relapsed/Refractory Multiple Myeloma Treated with Talquetamab Monotherapy in MonumentAL-1

Patients treated with talquetamab, which targets GPRC5D, an antigen uniquely expressed on plasma cells, showed effective myeloma control with concurrent preservation of humoral immune function (i.e., antibody response by B-cells) and recovery of low blood cell counts, distinguishing talquetamab as an important emerging therapy for RRMM.² The study results suggest the incidence of infection was less frequent with talquetamab compared with data from studies of B-cell maturation antigen (BCMA)-targeted T-cell-based therapies.² No decreases in B-cells or polyclonal low serum immunoglobulin G (IgG) were observed, supporting talquetamab as a B-cell-preserving treatment and allowing maintenance of key elements of humoral immunity.² Of 339 patients, infections occurred in 65.8 percent (20.5 percent Grade 3/4) after median follow-up of 12.7, 18.8, and 14.8 months in the 0.8 mg/kg Q2W, 0.4 mg/kg QW, and prior T-cell redirection cohorts, respectively.² There were few opportunistic infections, and 1.2 percent of infections led to death.²

Updated data from the Phase 2 TRiMM-2 Study Evaluating Talquetamab in Combination with DARZALEX FASPRO®

Results from the Phase 2 TRiMM-2 study showed patients with heavily pretreated multiple myeloma who received the investigational SC combination of talquetamab and DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) achieved deep and durable responses.³ The study included some patients who were previously exposed to anti-CD38, BCMA-targeted, and T-cell redirecting therapies.³

Patients in the TRiMM-2 study were treated with talquetamab at a SC RP2D of 0.8 mg/kg Q2W or 0.4 mg/kg QW (with step-up doses) in addition to DARZALEX FASPRO®.³ With a median follow-up of 15 months, 84 percent (42/50) of patients in the 0.8 mg/kg Q2W arm achieved a response, including 74 percent who achieved a VGPR or better, 16 percent who achieved a CR, and 36 percent who achieved a stringent CR.³ The ORR among patients with prior exposure to an anti-CD38 antibody was 82.2 percent (37/45), and 78.9 percent (15/19) of patients with prior treatment with T-cell redirection therapy in the 0.8 mg/kg Q2W cohort responded.³ With a median follow-up of 16.8

months, 71.4 percent (10/14) of patients in the 0.4 mg/kg QW arm achieved a response; 57.1 percent achieved a VGPR or better, 14.3 percent achieved a CR, and 28.6 percent achieved a stringent CR.³ The ORR observed among patients with prior exposure to an anti-CD38 antibody was 63.6 percent (7/11), and the ORR was 66.7 percent (4/6) among patients with prior treatment with T-cell redirection therapy in the 0.4 mg/kg QW cohort.³

At data cutoff, 65.4 percent of responders remained on therapy (63.6 percent and 61.5 percent who were anti-CD38 exposed or refractory, respectively).³ Median DOR was 20.3 months in the 0.8 mg/kg Q2W arm and was not reached in the 0.4 mg/kg QW arm.³ Median PFS was 19.4 months in the 0.8 mg/kg Q2W arm and was not reached in the 0.4 mg/kg QW arm; 12-month mPFS rate was 67.4 percent and 77.4 percent respectively.³ Median OS was not reached in either arm; 12-month OS was 91.5 percent and 92.3 percent in the 0.8 mg/kg Q2W and 0.4 mg/kg QW arms, respectively.³

“The latest results from the TRiMM-2 study further reinforce the potential of talquetamab in combination with subcutaneous daratumumab as an important treatment option for patients, including those previously treated with an anti-CD38 regimen or prior T-cell redirection therapy,” said Bhagirathbhai Dholaria, M.D., M.B.B.S., Assistant Professor of Medicine in the Division of Hematology-Oncology at Vanderbilt University Medical Center in Nashville, and principal investigator.[†] “With an overall response rate of nearly 80 percent, this durable combination provides the potential for significant disease control and survival in heavily pretreated patients with relapsed or refractory multiple myeloma.”

The safety profile was clinically manageable with low rates of Grade 3/4 infections (0.8 mg/kg Q2W dose, 25.5 percent; 0.4 mg/kg QW dose, 21.4 percent) and talquetamab discontinuations (1.5 percent).³ Almost all patients (95.4 percent) received antibacterial, antifungal or antiviral prophylaxis. No new safety signals were observed with longer term follow-up.³ The most common non-hematologic AEs at the 0.8 mg/kg Q2W dose and 0.4 mg/kg QW dose cohorts were CRS (80 percent and 71 percent, respectively; all Grade 1/2), skin-related AEs (84 percent and 71 percent, respectively; Grade 3/4: eight percent and 14 percent, respectively) and nail-related AEs (69 percent and 57 percent, respectively; Grade 3/4: two percent and zero percent, respectively).³

“The updated findings from MonumenTAL-1 and data from the TRiMM-2 studies are exciting, as they demonstrate the continued promise of T-cell redirecting therapies as single agents or in combination with standard-setting treatments in multiple myeloma,” said Chris Heuck, M.D., Global Medical Head, Oncology, Janssen Research & Development, LLC. “At Janssen, we recognize that the future of

multiple myeloma treatment lies in harnessing the power of combination therapies to target this complex disease, and the talquetamab results seen to date offer new hope to patients in need of additional treatment options.”

About the MonumentAL-1 Study

MonumentAL-1 ([Phase 1: NCT03399799](#), [Phase 2: NCT04634552](#)), is a Phase 1/2 single-arm, open-label, multicohort, multicenter dose-escalation study to evaluate the safety and efficacy of talquetamab in adults with relapsed or refractory multiple myeloma who received three or more prior lines of therapy, including a PI, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

Phase 1 of the study ([NCT03399799](#)) was conducted in 2 parts: dose escalation and dose expansion. It evaluated safety, tolerability, pharmacokinetics and preliminary antitumor activity of talquetamab administered to adult participants with relapsed or refractory multiple myeloma. Study criteria excluded patients who had an allogeneic stem cell transplant within six months, Eastern Cooperative Oncology Group (ECOG) performance score of 2 or higher, known active central nervous system (CNS) involvement or clinical signs of meningeal involvement of multiple myeloma, or toxicities from previous anticancer therapies at Grade 2 or higher with the exception of alopecia or peripheral neuropathy.

Phase 2 of the study ([NCT04634552](#)) evaluated the efficacy of talquetamab in participants with relapsed or refractory multiple myeloma at the recommended Phase 2 dose(s), established at subcutaneous 0.8 mg/kg every two weeks and 0.4 mg/kg weekly, respectively, as measured by ORR.

The study also included 51 patients who were exposed to prior T-cell redirection therapy and had received at least three prior therapies. Prior T-cell redirection therapy was CAR-T cell therapy for 70.6 percent of patients and bispecific antibody treatment for 35.3 percent. With a median duration of follow-up of 14.8 months, ORR per IRC assessment was 64.7 percent.

About TRIMM-2 Study

The TRIMM-2 ([NCT04108195](#)) study is an ongoing Phase 2 study of DARZALEX *FASPRO*[®] regimens in combination with talquetamab for the treatment of patients with multiple myeloma. The primary objectives of the TRiMM-2 study were to identify the Phase 2 dose (RP2D) for each component of the treatment combination (Part One); characterize the safety of the treatment combination at the RP2D (Part 2); and assess antitumor activity, pharmacokinetics and pharmacodynamics for the combination treatment (Part 3). Patients in the study (n=65) all had multiple myeloma and had

received a minimum three prior lines of therapy or were double refractory to a proteasome inhibitor (PI) and an immunomodulatory agent; patients who had been exposed or refractory to an anti-CD38 therapy more than ninety days prior to the start of the trial were also included, as well as those refractory to anti-CD38 therapy.

About Talquetamab

Talquetamab is a bispecific T-cell engaging antibody that binds to the CD3 receptor expressed on the surface of T cells and G protein-coupled receptor class C group 5 member D (GPCR5D), a novel multiple myeloma target that does not shed and is highly expressed on the surface of multiple myeloma cells and non-malignant plasma cells, as well as some healthy tissues such as epithelial cells of the skin and tongue.⁶ CD3 is involved in activating T-cells, and GPCR5D is highly expressed on multiple myeloma cells.^{7,8}

In May 2021, and August 2021, talquetamab was granted Orphan Drug Designation for the treatment of multiple myeloma by the U.S. FDA and the European Commission, respectively. Talquetamab was also granted Breakthrough Therapy Designation from the U.S. FDA in June 2022 for the treatment of adult patients with relapsed or refractory multiple myeloma, who have previously received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody. In December 2022, Janssen submitted a Biologics License Application (BLA) to the FDA seeking approval of talquetamab for the treatment of patients with relapsed or refractory multiple myeloma.

A Phase 1/2 clinical study of talquetamab for the treatment of relapsed or refractory multiple myeloma ([NCT03399799](#)) is currently underway. Talquetamab is also being explored in combination studies ([NCT04586426](#), [NCT04108195](#), [NCT05050097](#), [NCT05338775](#)) and in a randomized Phase 3 study ([NCT05455320](#)). In January 2021, talquetamab was granted PRIME designation by the European Commission.

About DARZALEX FASPRO® and DARZALEX®

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.⁹ 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.

DARZALEX® (daratumumab) received U.S. FDA approval in November 2015 and is approved in eight indications, three of which are in the frontline setting, including newly diagnosed patients who are transplant eligible and ineligible.¹⁰

DARZALEX® is the first CD38-directed antibody approved to treat multiple myeloma.¹¹ DARZALEX®-based regimens have been used in the treatment of more than 360,000 patients worldwide and more than 68,000 patients in the U.S. alone.

In [August 2012](#), Janssen Biotech, Inc. and Genmab A/S entered a worldwide agreement, which granted Janssen an exclusive license to develop, manufacture and commercialize daratumumab.

Since 2020, the National Comprehensive Cancer Network® (NCCN®) has recommended daratumumab based combination regimens for the treatment of newly diagnosed multiple myeloma and relapsed and refractory multiple myeloma.[‡] For newly diagnosed multiple myeloma, the NCCN® guidelines recommend daratumumab in combination with lenalidomide and dexamethasone as a Category 1 preferred regimen in non-transplant candidates; daratumumab in combination with bortezomib, melphalan, and prednisone as another recommended Category 1 regimen for non-transplant candidates; and daratumumab in combination with bortezomib, thalidomide and dexamethasone as a Category 2A regimen useful in certain circumstances for transplant candidates. In relapsed/refractory myeloma, four daratumumab regimens are listed as Category 1 preferred regimens for early relapses (1-3 prior therapies): daratumumab in combination with lenalidomide and dexamethasone; daratumumab in combination with bortezomib and dexamethasone; daratumumab in combination with carfilzomib and dexamethasone; and daratumumab in combination with pomalidomide and dexamethasone [after one prior therapy including lenalidomide and a proteasome inhibitor (PI)]. The NCCN® also recommends daratumumab in combination with cyclophosphamide, bortezomib and dexamethasone as another Category 2A regimen for early relapses (1-3 prior therapies) and as monotherapy as a Category 2A regimen useful in certain circumstances for early relapse patients after at least three prior therapies, including a PI and an immunomodulatory agent, or for patients who are double refractory to a PI and an immunomodulatory agent.

For more information, visit www.DARZALEX.com.

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. In multiple myeloma, these plasma cells change, spread rapidly and replace normal cells in the bone marrow with tumors. Multiple myeloma is the third most common blood cancer and remains an incurable disease. In 2023, it is estimated that more than 35,000 people will be diagnosed with multiple myeloma in the U.S. and more than 12,000 people will die from the disease. People living with multiple myeloma have a 5-year relative survival rate of 53 percent. 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.

DARZALEX® IMPORTANT SAFETY INFORMATION

INDICATIONS

DARZALEX® (daratumumab) is indicated for the treatment of adult patients with multiple myeloma:

- 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, melphalan, and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant
- In combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant
- 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
- In combination with pomalidomide and dexamethasone in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor
- 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[®] is contraindicated in patients with a history of severe hypersensitivity (e.g., anaphylactic reactions) to daratumumab or any of the components of the formulation.

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

DARZALEX[®] can cause severe and/or serious infusion-related reactions including anaphylactic reactions. These reactions can be life-threatening, and fatal outcomes have been reported. In clinical trials (monotherapy and combination: N=2066), infusion-related reactions occurred in 37% of patients with the Week 1 (16 mg/kg) infusion, 2% with the Week 2 infusion, and cumulatively 6% with subsequent infusions. Less than 1% of patients had a Grade 3/4 infusion-related reaction at Week 2 or subsequent infusions. The median time to onset was 1.5 hours (range: 0 to 73 hours). Nearly all reactions occurred during infusion or within 4 hours of completing DARZALEX[®]. Severe reactions have occurred, including bronchospasm, hypoxia, dyspnea, hypertension, tachycardia, headache, laryngeal edema, pulmonary edema, and ocular adverse reactions, including choroidal effusion, acute myopia, and acute angle closure glaucoma. Signs and symptoms may include respiratory symptoms, such as nasal congestion, cough, throat irritation, as well as chills, vomiting, and nausea. Less common signs and symptoms were wheezing, allergic rhinitis, pyrexia, chest discomfort, pruritus, hypotension and blurred vision.

When DARZALEX[®] dosing was interrupted in the setting of ASCT (CASSIOPEIA) for a median of 3.75 months (range: 2.4 to 6.9 months), upon re-initiation of DARZALEX[®], the incidence of infusion-related reactions was 11% for the first infusion following ASCT. Infusion-related reactions occurring at re-initiation of DARZALEX[®] following ASCT were consistent in terms of symptoms and severity (Grade 3 or 4: <1%) with those reported in previous studies at Week 2 or subsequent infusions. In EQUULEUS, patients receiving combination treatment (n=97) were administered the first 16 mg/kg dose at Week 1 split over two days, i.e., 8 mg/kg on Day 1 and Day 2, respectively. The incidence of any grade infusion-related reactions was 42%, with 36% of patients experiencing infusion-related reactions on Day 1 of Week 1, 4% on Day 2 of Week 1, and 8% with subsequent infusions.

Pre-medicate patients with antihistamines, antipyretics, and corticosteroids. Frequently monitor patients during the entire infusion. Interrupt DARZALEX[®] infusion for reactions of any severity and institute medical management as needed. Permanently discontinue DARZALEX[®] therapy if an anaphylactic reaction or life-threatening (Grade 4) reaction occurs and institute appropriate

emergency care. For patients with Grade 1, 2, or 3 reactions, reduce the infusion rate when re-starting the infusion.

To reduce the risk of delayed infusion-related reactions, administer oral corticosteroids to all patients following DARZALEX[®] infusions. Patients with a history of chronic obstructive pulmonary disease may require additional post-infusion medications to manage respiratory complications. Consider prescribing short- and long-acting bronchodilators and inhaled corticosteroids for patients with chronic obstructive pulmonary disease.

Ocular adverse reactions, including acute myopia and narrowing of the anterior chamber angle due to ciliochoroidal effusions with potential for increased intraocular pressure or glaucoma, have occurred with DARZALEX infusion. If ocular symptoms occur, interrupt DARZALEX infusion and seek immediate ophthalmologic evaluation prior to restarting DARZALEX.

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 infusion. 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 is not impacted. Notify blood transfusion centers of this interference with serological testing and inform blood banks that a patient has received DARZALEX[®]. Type and screen patients prior to starting DARZALEX[®].

Neutropenia and Thrombocytopenia

DARZALEX[®] may increase neutropenia and thrombocytopenia 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[®] until recovery of neutrophils or for recovery of platelets.

Interference With Determination of Complete Response

Daratumumab is a human immunoglobulin G (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 patients with IgG kappa myeloma protein.

Embryo-Fetal Toxicity

Based on the mechanism of action, DARZALEX® can cause fetal harm when administered to a pregnant woman. DARZALEX® 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® and for 3 months after the last dose.

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

ADVERSE REACTIONS

The most frequently reported adverse reactions (incidence $\geq 20\%$) were: upper respiratory infection, neutropenia, infusion-related reactions, thrombocytopenia, diarrhea, constipation, anemia, peripheral sensory neuropathy, fatigue, peripheral edema, nausea, cough, pyrexia, dyspnea, and asthenia. The most common hematologic laboratory abnormalities ($\geq 40\%$) with DARZALEX® are: neutropenia, lymphopenia, thrombocytopenia, leukopenia, and anemia.

Please [click here](#) to see the full Prescribing Information.

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

†Drs. Schinke and Dholaria have served as paid consultants to Janssen; neither has been paid for any media work.

‡See the NCCN Guidelines for detailed recommendations, including other treatment options.

###

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 of talquetamab. 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 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.

-
- ¹ Schinke C et al. Pivotal Phase 2 MonumentAL-1 Results of Talquetamab, a GPRC5D×CD3 Bispecific Antibody, for Relapsed/Refractory Multiple Myeloma. Poster presentation (#8036) at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting. June 2023.
- ² Rodríguez-Otero P et al. Analysis of Infections and Parameters of Humoral Immunity in Patients With Relapsed/Refractory Multiple Myeloma Treated With Talquetamab Monotherapy in MonumentAL-1. Poster presentation (#8020) at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting. June 2023.
- ³ Dholaria B et al. Talquetamab + Daratumumab in Patients With Relapsed/Refractory Multiple Myeloma: Updated TRIMM-2 Results. Oral presentation (#8003) at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting. June 2023.
- ⁴ Schinke C et al. Pivotal Phase 2 MonumentAL-1 Results of Talquetamab, a GPRC5D×CD3 Bispecific Antibody, for Relapsed/Refractory Multiple Myeloma. Abstract (#8036) at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting. June 2023.
- ⁵ Chari A et al. Talquetamab, a G Protein-Coupled Receptor Family C Group 5 Member D x CD3 Bispecific Antibody, in Patients with Relapsed/Refractory Multiple Myeloma (RRMM): Phase 1/2 Results from MonumentAL-1. American Society of Hematology 2022 Annual Meeting. Oral Presentation (#157) at the American Society of Hematology (ASH) Annual Meeting. December 2022.
- ⁶ Pillarisetti K et al. *Blood*. 2020;135(15):1232-1243.
- ⁷ Labrijn AF et al. *Proc Natl Acad Sci USA*. 2013;110:5145.
- ⁸ Cohen, Y., et al. *Hematology*. 2013 Nov; 18(6):348-51.
- ⁹ DARZALEX FASPRO® Prescribing Information, November 2022.
- ¹⁰ DARZALEX® Prescribing Information, January 2023.
- ¹¹ ClinicalTrials.gov Identifier NCT02076009. <https://clinicaltrials.gov/ct2/show/NCT02076009>. Accessed May 2023.