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News Release

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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® (daratumumab) subcutaneous (SC) formulation combination biweekly regimen showed an overall response rate of more than 80 percent[1,2,3]

BEERSE, Belgium, 03 June 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) who were triple-class exposed.[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, taking place in Chicago, from 2-6 June.[1,2] Additional data from the Phase 2 TRiMM-2 study, evaluating talquetamab in combination with DARZALEX® (daratumumab) subcutaneous (SC) formulation, were presented (Abstract #8003) at the meeting.[3]

Patients in the Phase 1/2 MonumenTAL-1 study (n=339) were treated with 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]

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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 (sCR).[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 sCR.[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]

"Despite recent advances, multiple myeloma remains an incurable disease and for those who have relapsed or become refractory to all available treatments, outcomes are often poor," said Edmond Chan, MBChB M.D. (Res), Senior Director EMEA Therapeutic Area Lead Haematology, Janssen-Cilag Limited. "Today's results add to the growing body of evidence for GPRC5D as a novel therapeutic target for multiple myeloma and we look forward to progressing our clinical development programme for talquetamab, as a core component of our ambition to overcome this complex 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).[1,5] 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.[1,4] There were no talquetamab-related deaths.[5]

Analysis of Infections and Parameters of Humoral Immunity in Patients with RRMM 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] [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 Daratumumab SC Formulation

Results from the Phase 2 TRiMM-2 study showed patients with heavily pretreated multiple myeloma who received the investigational combination of talquetamab and daratumumab SC formulation 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 daratumumab SC formulation.[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 sCR.[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 sCR.[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 median PFS 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 support the benefit talquetamab may have in the treatment of relapsed or refractory multiple myeloma, not only as a monotherapy but also in combination with other established therapies such as daratumumab SC," said Maria-Victoria Mateos, M.D., Ph.D., Consultant Physician in Haematology, University Hospital of Salamanca, Spain.[†] "The combination of talquetamab with daratumumab SC showed deep and durable responses in heavily pretreated patients, demonstrating the potential of this regimen for those who have exhausted all other options, including patients with prior exposure to anti-CD38, BCMA and T-cell redirecting therapy."

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-haematologic AEs at the 0.8 mg/kg Q2W dose and 0.4 mg/kg QW dose cohorts were CRS (80.4 percent and 71.4 percent, respectively; all Grade 1/2), skin-related AEs (84.3 percent and 71.4 percent, respectively; Grade 3/4: 7.8 percent and 14.3 percent, respectively) and nail-related

AEs (68.6 percent and 57.1 percent, respectively; Grade 3/4: two percent and zero percent, respectively).[3]

"The updated findings from MonumenTAL-1 and data from the TRiMM-2 study 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 recognise 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 potential new hope to patients in need of additional treatment options."

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About the MonumenTAL-1 Study

MonumenTAL-1 (Phase 1: NCT03399799, Phase 2: NCT04634552), is a Phase 1/2 single-arm, open-label, multicohort, multicentre dose-escalation study to evaluate the safety and efficacy of talquetamab in adults with RRMM who received three or more prior lines of therapy, including a proteasome inhibitor (PI), an immunomodulatory agent, and an anti-CD38 monoclonal antibody.[6,7]

Phase 1 of the study (NCT03399799) was conducted in two parts: dose escalation and dose expansion.[1,6] It evaluated safety, tolerability, pharmacokinetics and preliminary antitumour activity of talquetamab administered to adult participants with RRMM.[1,6] Study criteria excluded patients who had an allogenic stem cell transplant within six months, Eastern Cooperative Oncology Group (ECOG) performance score of two 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.[1,6]

Phase 2 of the study (NCT04634552) evaluated the efficacy of talquetamab in participants with RRMM at the RP2Ds, established at SC 0.8 mg/kg Q2W and 0.4 mg/kg QW, respectively, as measured by ORR.[1,7]

The study also included 51 patients who were exposed to prior T-cell redirection therapy and had received at least three prior therapies.[1] Prior T-cell redirection therapy was CAR-T cell therapy for 70.6 percent of patients and bispecific antibody treatment for 35.3 percent.[1] With a median duration of follow-up of 14.8 months, ORR per IRC assessment was 64.7 percent.[1]

About the TRiMM-2 Study

The TRiMM-2 (NCT04108195) study is an ongoing Phase 2 study of subcutaneous daratumumab regimens in combination with talquetamab for the treatment of patients with multiple myeloma.[3,8] The primary objectives of the TRiMM-2 study were to identify the RP2D for each component of the treatment combination (Part One); characterise the safety of the treatment combination at the RP2D (Part 2); and assess antitumour activity, pharmacokinetics and pharmacodynamics for the combination treatment (Part 3).[3,8] 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 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.[3,8]

About Talquetamab

Talquetamab is a bispecific T-cell engaging antibody that binds to CD3, on T-cells, and G protein-coupled receptor class C group 5 member D (GPRC5D), an orphan receptor primarily expressed in plasma cells and hard keratinised tissues, with low expression in normal human tissues.[9]

Talquetamab, which is administered by subcutaneous injection, is an investigational therapy currently being evaluated in several monotherapy and combination studies.[6,7,8,10,11,12,13]

In addition to the EMA granting PRIority Medicines (PRIME) designation in January 2021, talquetamab received accelerated assessment from the EMA in November 2022. Talquetamab also received Breakthrough Therapy Designation from the U.S. FDA in June 2022. Janssen also received Orphan Drug Designation for talquetamab from the EMA in August 2021 and the FDA in May 2021.

About daratumumab and daratumumab SC

Janssen is committed to exploring the potential of daratumumab for patients with multiple myeloma across the spectrum of the disease. Daratumumab has been approved in eight indications

for multiple myeloma, three of which are in the frontline setting, including newly diagnosed patients who are transplant eligible and ineligible.[14]

In August 2012, Janssen Biotech, Inc. and Genmab A/S entered a worldwide agreement, which granted Janssen an exclusive license to develop, manufacture and commercialise daratumumab. Since launch in 2016, daratumumab has become a foundational treatment component across the multiple myeloma pathway,[14] treating more than 390,000 patients worldwide to date.[15]

Daratumumab is the only CD38-directed antibody approved to be given subcutaneously to treat patients with multiple myeloma.[16] Daratumumab SC is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology.[16] CD38 is a surface protein highly expressed on multiple myeloma cells, regardless of disease stage.[14] Daratumumab binds to CD38, triggering the patient's immune system to attack the cancer cells, resulting in rapid tumour cell death through multiple immune-mediated responses and other mechanisms.[14] Data across eight Phase 3 clinical trials, the largest body of evidence for a CD38-directed antibody in MM, in both the frontline and relapsed settings, have shown that daratumumab based regimens resulted in significant improvement in PFS and, in many cases OS.[17,18,19,20,21,22,23,24]

For a full list of adverse events and information on dosage and administration, contraindications and other precautions when using daratumumab please refer to the Summary of Product Characteristics.

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.[25,26] In multiple myeloma, these malignant plasma cells change and grow out of control.[25] In Europe, more than 50,900 people were diagnosed with multiple myeloma in 2020, and more than 32,400 patients died.[27] While some patients with multiple myeloma initially have no symptoms, others can have common symptoms of the disease which can include bone fracture or pain, low red blood cell counts, tiredness, high calcium levels or kidney failure.[28]

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 https://www.linkedin.com/company/janssen-europe-middle-east-&-africa/ for our latest news. Janssen Pharmaceutica NV, Janssen-Cilag Limited, Janssen Research & Development, LLC and Janssen Biotech, Inc. are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

†Maria-Victoria Mateos, M.D., Ph.D. has served as a paid consultant to Janssen; she has not been paid for any media work.

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Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development and the potential benefits and treatment impact of talquetamab, daratumumab SC and teclistamab. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialise, actual results could vary materially from the expectations and projections of Janssen Pharmaceutica NV, Janssen-Cilag Limited, Janssen Research & Development, LLC, Janssen Biotech Inc. 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

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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.

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