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For Immediate Release

TALVEY®▼ (talquetamab) demonstrated highly durable, longer-term responses in patients with relapsed or refractory multiple myeloma

24-month overall survival rate of 67 percent achieved with talquetamab 0.8mg/kg biweekly dosing in the Phase 1/2 MonumenTAL-1 study[1]

BEERSE, BELGIUM (14 June 2024) – Janssen-Cilag International NV, a Johnson & Johnson company announced today that long-term data from the Phase 1/2 MonumenTAL-1 study showed that with 20 to 30 months of median follow-up, triple class exposed patients with relapsed or refractory multiple myeloma (RRMM) who were treated with TALVEY®▼ (talquetamab) maintained high overall response rates (ORR) and durable responses, irrespective of whether they had received prior T-cell redirection therapy.[1] These data, featured in a poster presentation at the 2024 European Hematology Association (EHA) Congress, taking place in Madrid from 13-16 June (Abstract #P915), demonstrate the efficacy and durability of talquetamab when used before or after chimeric antigen receptor T-cell (CAR-T) therapy or bispecific antibody therapies in triple class exposed patients with RRMM.[1]

"Results from the MonumenTAL-1 study continue to show deeper response levels and a longer duration of response in patients treated with either of the approved dose options of talquetamab, while the median overall survival has yet to be reached at two years," said Dr. Leo Rasche, attending physician on the myeloma service, University Hospital of Würzburg.‡ "It is encouraging to see no notable increases in treatment-related discontinuations with this longer follow-up across cohorts."

In MonumenTAL-1, 297 patients with no prior exposure to T-cell redirection therapy received talquetamab at the recommended Phase 2 dose (RP2D) of 0.8 mg/kg biweekly (Q2W) (n=154) or 0.4 mg/kg weekly (QW) (n=143).[1] At a median follow-up of 23.4 months, patients in the Q2W cohort demonstrated a median duration of response (DOR) of 17.5 months, with median DOR not reached in patients with complete response (CR) or better.[1] For patients in the QW arm, a median follow-up of 29.8 months showed a median DOR of 9.5 months, with a median DOR of 28.6 months in patients with a CR or better.[1] At 24 months, 67.1 percent and 60.6 percent of patients were alive from the two dosing cohorts, respectively.[1]

At a median follow-up of 20.5 months, talquetamab continued to show strong efficacy in patients with prior T-cell redirection therapy exposure (n=78), with 55.1 percent of patients achieving very good partial response (VGPR) or better and 57.3 percent alive at 24.2 months.[1]

Infection rates remained lower than in studies of B-cell maturation antigen (BCMA)-targeted bispecific antibodies, consistent with previous reports.[1] No increase in grade 3/4 infections was observed with longer follow-up.[1] GPRC5D associated adverse events (AEs) led to few dose reductions and discontinuations.[1] One additional patient discontinued treatment due to AEs since the previous report.[1] Weight loss, as assessed by vital signs, was evident early but stabilised and improved over time, including in patients with oral toxicities.[1]

"There remains a high unmet need for patients with heavily pretreated multiple myeloma as with each new line of therapy, patients tend to experience decreased responses, resulting in more frequent relapses," said Edmond Chan, MBChB, M.D. (Res), EMEA Therapeutic Area Lead Haematology, Johnson & Johnson Innovative Medicine. "By targeting the novel receptor GPRC5D, and offering a biweekly dosing option, talquetamab plays an important role in the multiple myeloma treatment pathway. We remain focused on harnessing the potential of this pioneering therapy as we build on our ambition to transform outcomes for patients and eliminate cancer."

Data from MonumenTAL-2 supports continued durable responses at one year, with investigational combination of talquetamab and pomalidomide, in patients with RRMM who had two or more prior lines of therapy

Longer follow-up from the Phase 1b MonumenTAL-2 study of the investigational use of talquetamab and pomalidomide showed deep responses and a manageable safety profile in patients with RRMM and support the potential to combine talquetamab with an immunomodulatory agent (IMiD).[2] These updated data, from the first study of a regimen combining a GPRC5D-targeted therapy and an immunomodulatory agent, were featured as a poster presentation at the 2024 EHA Congress (Abstract #P911).[2]

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Patients in the Phase 1b MonumenTAL-2 study (n=35) were treated with subcutaneous (SC) talquetamab at the RP2D of 0.8 mg/kg Q2W (n=19) or 0.4 mg/kg QW (n=16) with step-up doses, plus 2.0 mg of oral pomalidomide daily.[2,3] At a median follow-up of 16.8 months (range, 1.2-25.1), response-evaluable patients demonstrated an ORR of 88.6 percent (VGPR or better, 80 percent).[2]

“With multiple dosing options and the ability to be used both before or after CAR-T therapy and BCMA bispecifics, talquetamab is an important and versatile treatment option for the treatment of relapsed or refractory multiple myeloma,” said Jordan Schecter, M.D., Vice President, Disease Area Leader, Multiple Myeloma, at Johnson & Johnson Innovative Medicine. “The manageable rate of grade 3/4 infections seen in MonumenTAL-2 suggests the flexibility of talquetamab as a combination partner with an immunomodulatory agent for patients who continue to face limited treatment options with this complex haematologic disease.”

At 12 months, 80.4 percent of patients who achieved a CR or better maintained their response.[2] The progression-free survival (PFS) rate at 12 months was 72.6 percent.[2]

The most common grade 3/4 haematologic AEs were neutropenia (57.1 percent), anaemia (25.7 percent), and thrombocytopenia (20 percent).[2] Taste, nail, skin, and rash toxicities of any grade occurred in 85.7 percent, 68.6 percent, 74.3 percent, and 28.6 percent of patients, respectively; the majority were grade 1/2 with few discontinuations.[2] Cytokine release syndrome (CRS) occurred in 74.3 percent and infections occurred in 80 percent (22.9 percent grade 3/4) of patients.[2]

About MonumenTAL-1

MonumenTAL-1 (Phase 1: NCT03399799, Phase 2: NCT04634552) is a Phase 1/2 single-arm, open-label, multicohort, multicentre dose-escalation study involving more than 300 patients.[4,5] Phase 1 evaluated the safety and efficacy of talquetamab in adults with RRMM who received three or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.[4] The study excluded patients who had an allogenic stem cell transplant within the past six months, unresolved grade 2 or higher toxicities from previous anticancer therapies (excluding alopecia and peripheral neuropathy), Eastern Cooperative Oncology Group (ECOG) performance score above one, central nervous system (CNS) involvement or clinical signs of meningeal involvement of multiple myeloma.[4]

Phase 2 of the study evaluated the efficacy of talquetamab in participants with RRMM at the RP2Ds, established as SC 0.4 mg/kg weekly and 0.8 mg/kg every two weeks, respectively.[1,5] Efficacy was based on ORR and DOR, as assessed by an Independent Review Committee using the International Myeloma Working Group (IMWG) criteria.[1,5]

About MonumenTAL-2

The MonumenTAL-2 (NCT05050097) study is an ongoing Phase 1 study of SC talquetamab in combination with carfilzomib, daratumumab SC, lenalidomide or pomalidomide, for the treatment of patients with multiple myeloma.[6] The primary objective of the MonumenTAL-2 study is to identify and characterise the safety of the treatment combinations.[6] Secondary objectives of the MonumenTAL-2 study include ORR, DOR and time to response.[6]

About Talquetamab

Talquetamab received conditional marketing authorisation (CMA) from the European Commission (EC) in August 2023, as monotherapy for the treatment of adult patients with RRMM who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.[7] The U.S. FDA also granted talquetamab approval in August 2023, for the treatment of adult patients with RRMM who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody.[8]

Talquetamab is a bispecific T-cell engaging antibody that binds to CD3 on T-cells, and GPRC5D, a novel target which is highly expressed on the surface of multiple myeloma cells, with minimal to no expression detected on B-cells or B-cell precursors.[5]

For a full list of adverse events and information on dosage and administration, contraindications and other precautions when using talquetamab, please refer to the Summary of Product Characteristics. In line with the European Medicine Agency’s regulations for new medicines and those given conditional approval, talquetamab is subject to additional monitoring.

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.[9,10] In multiple myeloma, these malignant plasma cells change and grow out of control.[9] In the European Union, it is estimated that more than 35,000 people were diagnosed with multiple myeloma in 2022, and more than 22,700 patients died.[11] 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.[12]

About Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity.

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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. 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 and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behaviour and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 31, 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 http://www.sec.gov/, http://www.jnj.com/ or on request from Johnson & Johnson. None of Janssen Pharmaceutica NV, Janssen-Cilag Limited, Janssen Research & Development, LLC nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

‡Dr. Leo Rasche has provided consulting, advisory, and speaking services to Johnson & Johnson; he has not been paid for any media work.

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