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News Release

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Janssen Presents First Results from Dual Bispecific Combination Study Showing 96 Percent Overall Response Rate in Patients with Relapsed or Refractory Multiple Myeloma

BEERSE, Belgium, 03 June 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today the first results from the Phase 1b RedirecTT-1 study of TECVAYLI®▼ (teclistamab), a BCMAxCD3 bispecific antibody, and talquetamab, a GPRC5DxCD3 bispecific antibody, showing a high overall response rate (ORR) among patients with relapsed or refractory multiple myeloma (RRMM).[1] These results underscore the potential combinability of these two novel bispecific therapies which target distinct antigens on myeloma cells.[1] The investigational combination immunotherapy regimen demonstrated an ORR of 86.6 percent (71/82) across all dose levels, and an ORR of 96.3 percent (26/27) among patients receiving the recommended Phase 2 regimen (RP2R).[1] These data were presented during an oral presentation (Abstract #8002) at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place in Chicago, from 2-6 June.[1]

"By combining teclistamab and talquetamab, two bispecific antibodies that have demonstrated high efficacy responses in targeting distinct antigens, we evaluated the potential of this unique combination regimen for patients who were resistant or refractory to multiple lines of therapy," said Yael Cohen, M.D., Head of Myeloma Unit, Hematology Institute Tel-Aviv Sourasky Medical Center, Israel, and principal study investigator.[†] "The high overall response rates characterised in this study are

encouraging and support the continued evaluation of this regimen as a combination therapy."

The RedirecTT-1 study included patients who received a median of four prior lines of therapy (range, 1-11 for patients in all dose levels, n=93; range, 2-10 for patients in the RP2R dosing cohort, n=34).[1] At the RP2R, 76.5 percent of patients were triple-class refractory to an immunomodulatory drug (IMiD), proteasome inhibitor (PI) and anti-CD38 antibody; 58.8 percent of patients were penta-drug exposed to two IMiDs, two PIs and an anti-CD38 antibody; and 32.4 percent of patients had extramedullary disease (EMD), all soft tissue plasmacytomas.[1]

Results from the study showed that responses were high across all dose levels.[1] Eighty-two patients across all study cohorts and 27 patients treated at the RP2R were evaluable for response.[1] The ORR across all patients was 86.6 percent (71/82).[1] Patients who received the RP2R achieved an ORR of 96.3 percent (26/27).[1] The median duration of response was not reached in the overall study population or RP2R cohort.[1] Patients with EMD who received the RP2R achieved an 85.7 percent (6/7) ORR, and median duration of response was not reached at a median follow-up of 7.2 months (range, 0.7-14.2).[1] The median follow-up for all patients was 13.4 months (range, 0.3-25.6) with a median progression free survival (PFS) of 20.9 months (95 percent Confidence Interval [CI]: 13.0-Not Estimable [NE]).[1] The median follow-up for patients receiving the RP2R was 8.1 months (range, 0.7-15.0), and median PFS was NE for patients in the RP2R cohort (95 percent CI: 9.9-NE).[1] At data cutoff, 61 percent (57/93) of all patients remained on either teclistamab or talquetamab treatment.[1]

"Multiple myeloma remains incurable with patients often experiencing resistance to available treatment options. This means that novel therapeutic approaches offering different modes of action and cellular targeting are needed," said Edmond Chan, MBChB M.D. (Res), Senior Director EMEA Therapeutic Area Lead Haematology, Janssen-Cilag Limited. "These first results from the RedirecTT-1 study demonstrate the potential impact of combining teclistamab and talquetamab to overcome resistance mechanisms and in patients with EMD, and we look forward to evaluating this combination regimen further."

The safety profile of the combination was consistent with that observed with each drug as a monotherapy.[1] The most common haematologic adverse events (AEs) observed in 20 percent of patients or more were neutropenia (all dose levels: 65.6 percent, 61.3

percent Grade 3/4; RP2R dosing cohort: 55.9 percent, 44.1 percent Grade 3/4), anaemia (all dose levels: 50.5 percent, 34.4 percent Grade 3/4; RP2R dosing cohort: 32.4 percent, 23.5 percent Grade 3/4) and thrombocytopenia (all dose levels: 43.0 percent, 29.0 percent Grade 3/4; RP2R dosing cohort: 32.4 percent, 23.5 percent Grade 3/4).[1]

In the study, 94.1 percent (32/34) of patients at the RP2R and 96.8 percent (90/93) of the overall study population had one or more treatment-emergent adverse events (TEAEs).[1] Rates of Grade 3/4 non-haematologic AEs were low in both the full study population and the RP2R cohort, except for cytokine release syndrome (CRS) of any Grade which occurred in 76.3 percent and 73.5 percent of patients, respectively.[1] All CRS events were resolved at data cutoff.[1] The incidence and severity of CRS were consistent with teclistamab and talquetamab monotherapy treatment.[1]

"Multiple myeloma becomes progressively more difficult to treat as patients relapse or become refractory to treatment. The RedirecTT-1 data suggest the use of bispecific antibodies with high activity in myeloma, teclistamab and talquetamab may have potential to yield high efficacy responses in this patient population," said Arnob Banerjee, M.D., Ph.D., Global Medical Head, Early Development Oncology, Janssen Research & Development, LLC. "The promising preliminary results observed with the combination, even in patients with extramedullary disease, are highly supportive of continued investigation and reinforce our commitment to evaluate and develop combination regimens built on our deep disease understanding and portfolio of therapeutics."

#ENDS#

About the RedirecTT-1 Study

The RedirecTT-1 (NCT04586426) study is an ongoing Phase 1b dose escalation study of the combination of the bispecific T-cell redirection antibodies talquetamab and teclistamab in patients with RRMM.[2]

The primary objective is to identify the RP2R(s) and schedule for the study treatment and to characterise the safety of the RP2R(s) for the study treatment.[2] The RP2R(s) will describe the doses and schedules of the treatment combination to be pursued in Phase 2.[2]

About Teclistamab

Teclistamab is an off-the-shelf (or ready to use) bispecific antibody.[3] Teclistamab, a subcutaneous (SC) injection, redirects T-cells through two cellular targets (BCMA and CD3) to activate the body's immune system to fight the cancer.[3] Teclistamab is currently being evaluated in several monotherapy and combination studies.[2,4,5,6,7]

Teclistamab received European Commission (EC) approval in August 2022. The application for conditional marketing authorisation was reviewed by the Committee for Medicinal Products for Human Use (CHMP) under an accelerated timetable to enable faster patient access to this medicine.[8] This was also supported through the European Medicines Agency's (EMA) PRIority MEdicines (PRIME) scheme, which provides early and enhanced scientific and regulatory support to medicines that have a particular potential to address patients' unmet medical needs.[9]

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

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.[10]

Talquetamab, which is administered by SC injection, is an investigational therapy currently being evaluated in several monotherapy and combination studies.[11,12,13,14]

In addition to the EMA granting PRIority Medicines (PRIME) designation in January 2021, talquetamab received accelerated assessment from the EMA in November 2022.[9] 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 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.[15,16] In multiple myeloma, these malignant plasma cells change and grow out of control.[15] In Europe, more than 50,900

people were diagnosed with multiple myeloma in 2020, and more than 32,400 patients died.[17] 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.[18]

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 and Janssen Research & Development, LLC are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

[†]Yael Cohen, M.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 impacts of teclistamab and 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 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 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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