News Release

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

CHICAGO, June 3, 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today the first-ever results from the Phase 1b RedirecTT-1 study of TECVAYLI® (teclistamab-cqyv), a first-in-class BCMAxCD3 bispecific antibody, and talquetamab, a first-in-class 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 session at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting (Abstract #8002).

"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 characterized 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 TECVAYLI® or talquetamab treatment.[1]

The safety profile of the combination was consistent with that observed with each drug as a monotherapy.[1] The most common hematologic 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), anemia (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 nonhematologic 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 cut-off. The incidence and severity of CRS were consistent with TECVAYLI® 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, TECVAYLI 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."

About the RedirecTT-1 Study[2]

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 TECVAYLI® in patients with relapsed or refractory multiple myeloma.

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

About TECVAYLI®[3]

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.[3] TECVAYLI® is the only

approved BCMA×CD3 bispecific antibody with a personalized, weight-based dosing schedule for the treatment of triple-class exposed RRMM.

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.[4] TECVAYLI® was recommended by the National Comprehensive Cancer Network® (NCCN®) as a treatment option for these patients.[5]

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.[3]

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 (GPRC5D), 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 GPRC5D 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 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] 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.[11] 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.[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. Withhold TECVAYLI® until CRS resolves or permanently discontinue based on severity.
- 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. Withhold TECVAYLI® until neurologic toxicity resolves or permanently discontinue based on severity.

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. Administer supportive care based on severity and consider further management per current practice guidelines. 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. 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 per recommendations and consider further management per current practice guidelines.

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 hepatoxicity, 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.

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®.

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 is one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

[†]Dr. Cohen has served as a paid consultant to Janssen; he 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 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 materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, 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.

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