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For Immediate Release

TECVAYLI® (teclistamab-cqyv) shows sustained deep and durable responses in patients with relapsed or refractory multiple myeloma

New MajesTEC-1 data show a median duration of response of 24 months, with responses deepening, including in patients who switched to biweekly dosing[1]

Separate analyses from the MajesTEC-1 and OPTec studies are the first to underscore the opportunity for outpatient administration of TECVAYLI®

CHICAGO (June 3, 2024) – Johnson & Johnson today announced longer-term data from the pivotal Phase 1/2 MajesTEC-1 study of TECVAYLI® (teclistamab-cqyv) showing deep and durable responses in patients with relapsed or refractory multiple myeloma (RRMM) who are triple-class exposed (TCE)[a] and who previously received three or more prior lines of therapy, including in patients who switched to less frequent dosing (Abstract #7540).[1] These data were featured at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting in a poster presentation.[1]

Additional presentations highlight the potential for outpatient step-up administration with prophylactic tocilizumab from the MajesTEC-1 study (Abstract #7517) and the first-in-class Phase 2 OPTec study (Abstract #7528), as well as first results from the subgroup analysis of patients with high-risk (HR) features that will be presented at the 2024 European Hematology Association (EHA) Congress (Abstract #923).[2,3,4] The safety run-in MajesTEC-7 study in frontline TECVAYLI® administration (Abstract #7506) will also be presented at ASCO.[4]

“With the longest follow-up of any bispecific antibody, teclistamab demonstrates continued deep and durable responses observed in patients with relapsed or refractory multiple myeloma who have limited treatment options,” said Niels van de Donk, M.D., Professor of Hematology at Amsterdam University Medical Centers, and principal study investigator.* “The results of the MajesTEC-1 study indicate the potential of teclistamab to transform the treatment paradigm, and clinical studies are investigating whether teclistamab may be a pivotal advancement for improved care and management in the broader patient population.”

Results from the MajesTEC-1 study show that, at a median follow-up of 30.4 months, patients treated with TECVAYLI® at the recommended Phase 2 dose (RP2D)[b] (n=165) demonstrated an overall response rate (ORR) of 63 percent, with responses continuing to deepen and 46 percent of patients achieving a complete response (CR) or better.[1] For patients with a CR or better, mDOR, mPFS, and mOS were not yet reached, and estimated 30-month DOR, PFS, and OS rates were 61, 61 and 74 percent, respectively.[1] Patients who achieved a partial response or better after a minimum of four cycles of therapy (Phase 1), or maintained a CR or better for a minimum of six months (Phase 2) per protocol, had the option to switch to biweekly dosing (every two weeks) (Q2W).[1] Additionally, 37 out of 38 patients who switched to Q2W dosing maintained responses.[1]

The safety profile remained consistent, with a notable decrease in new onset of severe infections over time.[1] Adverse events (AEs) included neutropenia (any grade, 72 percent; grade 3/4, 66 percent), anemia (any grade, 55 percent; grade 3/4, 38 percent), thrombocytopenia (any grade, 42 percent; grade 3/4, 23 percent), lymphopenia (any grade, 36 percent; grade 3/4, 35 percent), and infections (any grade, 79 percent; grade 3/4, 55 percent).[1] Of 22 grade 5 infections, 18 were due to COVID-19.[1] The decrease in new-onset grade 3 or greater infections may be due to switching to Q2W dosing or other factors such as implementing the use of intravenous immunoglobulin.[1]

[a] Triple-class exposed (TCE): patients who have previously received an immunomodulatory agent (IMiD), a proteasome inhibitor (PI), and an anti-CD38 monoclonal antibody (mAb).
[b] Recommended Phase 2 dose (RP2D): dose of a drug that was identified in a Phase 1 study (dose finding study).

"Over the past two years, TECVAYLI has helped over 10,000 patients with relapsed or refractory multiple myeloma," said Rachel Kobos, M.D., Vice President, Oncology Research & Development, Johnson & Johnson Innovative Medicine. "Through robust clinical data and real-world evidence, and by leveraging our team's expertise, we're working relentlessly to address unmet needs for patients with myeloma and drive the development of new treatment options for use across the treatment paradigm, including in the frontline setting."

TECVAYLI® studies investigate outpatient administration in patients with RRMM, examining a more convenient approach to treatment, including in a community setting

Extended follow-up of patients from a MajesTEC-1 cohort, investigating the prophylactic use of tocilizumab for the reduction of cytokine release syndrome (CRS) in patients treated with TECVAYLI®, were also presented at ASCO in an oral presentation (Abstract #7517).[2] Results show a single dose of tocilizumab before TECVAYLI® in patients with RRMM (n=24) reduced the incidence of CRS with a 65 percent relative reduction versus the overall MajesTEC-1 population.[2] This approach is continuing to be evaluated in the first-in-class Phase 2, multicenter, prospective OPTec study of TECVAYLI® in the community setting, presented as a poster presentation (Abstract #7528) at ASCO.[3] Data showed preliminary evidence that prophylactic tocilizumab potentially reduces the incidence of CRS, with no new safety concerns to date and underscores the opportunity for outpatient administration.[3]

Evaluation of patients with high-risk multiple myeloma from MajesTEC-1 study shows clinical benefit from treatment with TECVAYLI®

Subgroup analysis from the MajesTEC-1 study of TECVAYLI® investigating patients with HR RRMM will be presented at EHA (Abstract #923).[4] Results show at a median follow-up of 30 months, patients who were aged 75 years or older, patients who had HR cytogenetics and patients who were penta-drug refractory demonstrated similar efficacy as the overall RP2D population with an ORR of 54 percent, 61 percent and 60 percent and a CR or better rate of 42 percent, 42 percent and 48 percent, respectively.[4] The data demonstrate the clinical benefit of TECVAYLI® as an additional treatment option for some patients with HR features who typically face poor outcomes.[4] The safety profile across subgroups was consistent with the RP2D population, including overall incidence and severity of TEAEs.[4]

Data from a single-arm run-in cohort of the Phase 3 MajesTEC-7 study shows early clinical profile of TECVAYLI®-based regimen in patients with transplant ineligible/not intended newly diagnosed multiple myeloma

The results, presented in an oral presentation (Abstract #7506) at ASCO, of the first safety run-in (SRI) from a single-arm cohort of the Phase 3 MajesTEC-7 study provide preliminary data for a TECVAYLI®-based regimen in transplant-ineligible/not intended newly diagnosed multiple myeloma.[5] Patients (n=26) received TECVAYLI® in combination with daratumumab and lenalidomide (DR).[5] At a median follow-up of 13.8 months, the ORR was 92 percent, with 23 patients remaining on treatment.[5] Treatment-emergent adverse events (TEAEs) occurred in 100 percent of patients, where 61.5 percent of patients experienced grade 1/2 CRS in cycle one - all of which resolved.[5]

About the MajesTEC-1 Study

MajesTEC-1 (NCT03145181, NCT04557098) is a Phase 1/2 single-arm, open-label, multicohort, multicenter dose-escalation study evaluating the safety and efficacy of teclistamab in adults with RRMM who received three or more prior lines of therapy.[6,7]

Phase 1 of the study (NCT03145181) was conducted in two parts: dose escalation (Part 1) and dose expansion (Part 2).[6] It evaluated safety, tolerability, pharmacokinetics, and preliminary efficacy of teclistamab in adult participants with RRMM.[6] Phase 2 of the study (NCT04557098) evaluated the efficacy of teclistamab at the RP2D, established at subcutaneous 1.5 mg/kg weekly, as measured by ORR.

About the OPTec Study

OPTec (NCT05972135) is a Phase 2, single-arm, non-randomized, multicenter, prospective study evaluating the use of prophylactic tocilizumab in patients with RRMM to reduce the incidence and severity of CRS associated with administration of the step-up dosing regimen of teclistamab in the outpatient setting.

About the MajesTEC-7 Study

MajesTEC-7 (NCT05552222), is a Phase 3 randomized study, comparing teclistamab in combination with daratumumab SC and lenalidomide (Tec-DR) and talquetamab in combination with daratumumab SC and lenalidomide (Tal-DR) versus daratumumab SC, lenalidomide, and dexamethasone (DRd) in participants with newly diagnosed multiple myeloma who are either ineligible or not intended for autologous stem cell transplant as initial therapy.[8]

About TECVAYLI®

TECVAYLI® (teclistamab-cqyv) received approval from the U.S. FDA in October 2022 as an off-the-shelf (or ready-to-use) antibody that is administered as a subcutaneous treatment for adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 antibody.[2] The European Commission (EC) granted TECVAYLI® conditional marketing authorization (CMA) in August 2022 as monotherapy for the treatment of adult patients with RRMM who have received at least three prior therapies, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 antibody, and have

demonstrated disease progression since the last therapy. In August 2023, the EC granted the approval of a Type II variation application for TECVAYLI®, providing the option for a reduced dosing frequency of 1.5 mg/kg every two weeks in patients who have achieved a complete response (CR) or better for a minimum of six months. TECVAYLI® is a first-in-class, bispecific T-cell engager antibody therapy that 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. In February 2024, the U.S. FDA approved the supplemental Biologics License Application (sBLA) for TECVAYLI® for a reduced dosing frequency of 1.5 mg/kg every two weeks (Q2W) in patients with relapsed or refractory multiple myeloma who have achieved and maintained a CR or better for a minimum of six months.

For more information, visit www.TECVAYLI.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.[9] In multiple myeloma, these plasma cells proliferate and spread rapidly and replace normal cells in the bone marrow with tumors.[10] Multiple myeloma is the third most common blood cancer worldwide and remains an incurable disease.[11] In 2024, it was estimated that more than 35,000 people will be diagnosed with multiple myeloma in the U.S. and more than 12,000 people would die from the disease.[12] People living with multiple myeloma have a 5-year survival rate of 59.8 percent.[13] 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 and kidney problems or infections.[14,15]

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® and TALVEY™ Risk Evaluation and Mitigation Strategy (REMS).

INDICATION AND USAGE

TECVAYLI® (teclistamab-cqyv) is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of 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.

This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

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® and TALVEY™ REMS - TECVAYLI® is available only through a restricted program under a REMS called the TECVAYLI® and TALVEY™ REMS because of the risks of CRS and neurologic toxicity, including ICANS.

Hepatotoxicity - TECVAYLI® can cause hepatotoxicity, 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 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. Learn more at https://www.jnj.com/ or at www.janssen.com/johnson-johnson-innovative-medicine. Follow us at @JanssenUS and @JNJInnovMed. Janssen Research & Development, LLC and Janssen Biotech, Inc. are both Johnson & Johnson companies.

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 TECVAYLI® (teclistamab-cqyv). 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 Janssen Research & Development, LLC, Janssen Biotech, Inc., 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 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 www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of Janssen Research & Development, LLC, Janssen Biotech, Inc., nor Johnson & Johnson undertake to update any forward-looking statement as a result of new information or future events or developments.

˙Niels van de Donk, M.D., Professor of Hematology at Amsterdam University Medical Centers, and principal study investigator has provided consulting, advisory, and speaking services to Johnson & Johnson; he has not been paid for any media work.

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