Johnson&Johnson

NEWS RELEASE

TECVAYLI® + TALVEY® reduced the risk of disease progression or death by 89% and the risk of death by 62% in earlier-line relapsed/refractory multiple myeloma

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- Investigational MonumenTAL-6 trial is the first and only Phase 3 study of a dual antigen, BCMA and GPRC5D targeting regimen in relapsed/refractory multiple myeloma

- Fifth positive Phase 3 study evaluating Johnson & Johnson's multiple myeloma T-cell therapy portfolio in second line, further strengthening the company's leadership and commitment to advancing immunotherapy-based regimens earlier in the treatment journey

RARITAN, N.J., July 23, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ), a worldwide leader in multiple myeloma therapies, today announced positive topline results from the three-arm investigational Phase 3 MonumenTAL-6 study evaluating TECVAYLI® (teclistamab-cqyv) + TALVEY® (talquetamab-tgvs), a BCMA and GPRC5D dual antigen targeting regimen, and TALVEY® + pomalidomide in adult patients with relapsed or refractory multiple myeloma (RRMM) who received 1 to 4 prior lines of therapy, including an anti-CD38 antibody and lenalidomide.[1] The study demonstrated statistically significant and clinically meaningful improvements in progression-free survival and overall survival for both investigational arms compared with investigator's choice standard of care. TECVAYLI® + TALVEY® delivered the greatest benefit, reducing the risk of disease progression or death by 89% (HR, 0.11) and the risk of death by 62% (HR, 0.38).[1] This represents the lowest hazard ratio seen across any Phase 3 study evaluating bispecific therapies in relapsed/refractory multiple myeloma.[1]

Expert and company perspectives reinforce the potential of TECVAYLI® + TALVEY®

"These findings add to a growing body of Phase 3 evidence evaluating the survival outcomes associated with the early use of immunotherapy doublets in the treatment journey," said Ajay K. Nooka, M.D., M.P.H., F.A.C.P., Director, Myeloma Program, Department of Hematology and Medical Oncology, Emory University School of Medicine.* "TECVAYLI and TALVEY together generated deep and durable responses, demonstrating what's possible by targeting BCMA and GPRC5D at the same time, and further reinforcing the potential of this off-the-shelf regimen to improve outcomes for patients across practice settings."

"At Johnson & Johnson, we have intentionally built a multiple myeloma portfolio that spans biological targets, mechanisms, modalities and lines of therapy, giving physicians the flexibility to use our therapies across a diverse patient population and throughout the patient journey," said Yusri Elsayed, M.D., M.H.Sc., Ph.D., Global Therapeutic Area Head, Oncology, Johnson & Johnson. "These findings further reinforce immunotherapy as a cornerstone of multiple myeloma care and strengthen the growing body of evidence supporting our leadership in this space. By continuing to expand treatment options across the disease continuum, we are moving closer to our ambition of one day curing this disease."

Topline results from the Phase 3 MonumenTAL-6 study

The MonumenTAL-6 study evaluated TECVAYLI® in combination with TALVEY® (Tec-Tal) or TALVEY® with pomalidomide (Tal-P) compared to the investigator's choice of either elotuzumab, pomalidomide, and dexamethasone (EPd) or pomalidomide, bortezomib, and dexamethasone (PVd) in participants with RRMM who have received at least one line of therapy, including an anti-CD38 antibody and lenalidomide.[1] Both the Tec-Tal and Tal-P regimens met the study's primary endpoint of PFS, demonstrating statistically significant and clinically meaningful improvements versus standard of care.[1] Risk of progression or death was reduced in the Tec-Tal arm by 89% (hazard ratio [HR], 0.11; 95% confidence interval [CI], 0.08-0.16; p<0.0001) and 73% (HR, 0.27; 95% CI, 0.2-0.35) in the Tal-P arm.[1] The overall safety profiles for the Tec-Tal and Tal-P treatment arms were consistent with the known safety profiles of each monotherapy.

Based on the strength of the data, the Independent Data Monitoring Committee (IDMC) recommended unblinding the study at the first interim analysis. The full results of the Phase 3 MonumenTAL-6 study will be presented at a future major medical meeting and shared with global health authorities.

About MonumenTAL-6

MonumenTAL-6 (NCT06208150) is a global, randomized, Phase 3 study evaluating TECVAYLI® plus TALVEY® and TALVEY® plus pomalidomide versus investigator's choice of elotuzumab, pomalidomide and dexamethasone (EPd) or pomalidomide, bortezomib and dexamethasone (PVd) in patients with relapsed or refractory multiple myeloma who have received one to four prior lines of therapy, including an anti-CD38 monoclonal antibody and lenalidomide. The primary endpoint is progression-free survival (PFS) as assessed by independent review

committee. Key secondary endpoints include overall response rate (ORR), complete response or better (≥CR), MRD-negative complete response and overall survival (OS).

About Multiple Myeloma

Multiple myeloma is a complex blood cancer that affects a type of white blood cell called plasma cells, which are found in the bone marrow.[2] In multiple myeloma, these plasma cells proliferate and spread rapidly and replace normal cells in the bone marrow with tumors.[3] Multiple myeloma is the second most common blood cancer worldwide.[4] More than 180,000 new cases of multiple myeloma are diagnosed globally each year.[5] People living with multiple myeloma have a 5-year survival rate of 59.8%.[6] 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.[7,8] In recent years, overall survival has improved from years to decades, with effective treatment options now available across every stage and line of therapy.[9]

About Johnson & Johnson's Multiple Myeloma Portfolio

Johnson & Johnson is a global leader in multiple myeloma therapies, with a broad and differentiated portfolio designed to address the complexity and heterogeneity of the disease. Our portfolio spans multiple mechanisms of action, targets and treatment modalities, including CD38-directed therapies, BCMA- and GPRC5D-targeting bispecific antibodies, and cellular therapies.

Over the past decade, Johnson & Johnson therapies have helped extend survival for patients with multiple myeloma from just a few years to a decade or more. With the right medicines, used as early as possible, combined and sequenced for the best results, Johnson & Johnson is expanding treatment options to match the right therapy to the right patient at the right stage of disease and drive deeper and more durable responses.

Through ongoing research and a robust clinical program, Johnson & Johnson is committed to transforming multiple myeloma into a more manageable condition that is no longer treated to progression but has the potential to, ultimately, be cured.

About TECVAYLI®

TECVAYLI® (teclistamab-cqyv) 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. TECVAYLI® received accelerated **approval** from the U.S. Food and Drug Administration (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 received at least four prior lines of

therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody.[10]

In March 2026, the U.S. FDA **approved** TECVAYLI® in combination with DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent. The supplemental Biologics License Application was proactively selected for the Commissioner's National Priority Voucher Pilot Program and also granted the application Breakthrough Therapy Designation and Real-Time Oncology Review. This approval expanded the use of TECVAYLI® into earlier lines of therapy and is the first bispecific antibody-based combination regimen in this setting.

To date, more than 30,700 patients have been treated worldwide with TECVAYLI®.

The European Commission (EC) granted TECVAYLI® **conditional marketing authorization** 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 **approved** a Type II variation application for TECVAYLI®, providing the option for a reduced dosing frequency of 1.5 mg/kg every two weeks (Q2W) in patients who have achieved a complete response or better for a minimum of six months.

In June 2026, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommended the approval of an indication extension of TECVAYLI ® in combination with daratumumab for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least one prior therapy.

For more information, visit **www.TECVAYLI.com**.

About TALVEY®

TALVEY® 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 which is highly expressed on the surface of multiple myeloma cells and nonmalignant plasma cells, as well as some healthy tissues such as epithelial cells of the skin and tongue.

TALVEY® (talquetamab-tgvs) received accelerated approval from the U.S. FDA in August 2023 as a first-in-class GPRC5D-targeting bispecific antibody 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 antibody.[11] The European Commission (EC) granted conditional marketing authorization (CMA) of TALVEY® (talquetamab-tgvs) in August 2023 as monotherapy for the treatment of

adult patients with relapsed and refractory multiple myeloma (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.[12] Since FDA approval, more than 11,000 patients have been treated with TALVEY®.

TECVAYLI® INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS 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:

• in combination with daratumumab and hyaluronidase-fihj in patients who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent.

• as monotherapy, in patients who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

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, life-threatening, or fatal 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).

WARNINGS AND PRECAUTIONS

Cytokine Release Syndrome -

TECVAYLI can cause cytokine release syndrome (CRS), including life-threatening or fatal reactions.

In the clinical trials (monotherapy and combination therapy; N=448), CRS occurred in 64% of patients who received TECVAYLI at the recommended dosage, with Grade 1 CRS occurring in 46% of patients, Grade 2 in 18%, and Grade 3 in 0.2%. Recurrent CRS occurred in 27% of patients. Most patients experienced CRS during the initial step-up dosing schedule (step-up dose 1 [37%], step-up dose 2 [32%], or the initial treatment dose [20%]). CRS first occurred following subsequent doses of TECVAYLI in 2.5% of patients. The median time to onset of CRS was 2 (range: 1 to 9) days after the most recent dose and the median duration of CRS was 2 (range: 1 to 22) 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 the patient for hospitalization. Administer supportive care based on severity and consider further management per current practice guidelines. Withhold until CRS resolves or permanently discontinue TECVAYLI based on severity.

TECVAYLI is available only through a restricted program under a REMS.

Neurologic Toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome -

TECVAYLI can cause serious, life-threatening, or fatal neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS).

In the clinical trials (monotherapy and combination therapy trials; N=448), neurologic toxicity occurred in 60% of patients who received TECVAYLI at the recommended dosage, with Grade 3 or 4 neurologic toxicity in 6%. Neurologic toxicities reported in ≥5% of patients included headache (27%), sensory neuropathy (16%), motor dysfunction (15%), insomnia (12%), encephalopathy (11%), and dizziness (8%). Fatal neurologic toxicity occurred in 0.4% of patients, including Guillain-Barré syndrome and status epilepticus (one patient each).

In MajesTEC-1, ICANS was reported in 6% of patients who received TECVAYLI as monotherapy at the recommended dosage. 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 TECVAYLI doses. 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.

In MajesTEC-3, ICANS was reported in 1.1% of patients who received the recommended TECVAYLI dosage in combination with daratumumab and hyaluronidase-fihj, including Grade 4 ICANS in 1 patient. All events of ICANS occurred during the step-up dosing schedule. The median time to onset of ICANS was 2 (range: 1 to 3) days after the most recent dose and the median duration of ICANS was 2 (range: 1 to 2) days. The clinical manifestations of ICANS reported were amnesia, encephalopathy and delirium.

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, including ICANS during TECVAYLI treatment. At the first sign of neurologic toxicity, including ICANS, immediately evaluate patient and provide supportive therapy based on severity. Withhold until neurologic toxicity resolves 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 receiving TECVAYLI 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. There was one fatal case of hepatic failure in MajesTEC-1. In patients who received TECVAYLI at the recommended dosage in the clinical trials (monotherapy and combination therapy trials; N=448) elevated aspartate aminotransferase (AST) occurred in 47% of patients, with Grade 3 or 4 elevations in 2.9%. Elevated alanine aminotransferase (ALT) occurred in 48% of patients, with Grade 3 or 4 elevations in 3.8%. Elevated total bilirubin occurred in 10% of patients with Grade 3 or 4 elevations in 0.7%. 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 MajesTEC-1 (N=165), in patients who received the recommended TECVAYLI dosage, serious infections, including opportunistic infections, occurred in 30% of patients, Grade 3 or 4 infections in 35% of patients, and fatal infections in 4.2% of patients.

In MajesTEC-3 (N=283), in patients who received TECVAYLI in combination with daratumumab and hyaluronidase-fihj at the recommended dosage, serious infections, including opportunistic infections, occurred in 54% of patients, Grade 3 or Grade 4 infections in 54% of patients, and fatal infections in 4.6% of patients.

Monitor patients for signs and symptoms of infection prior to and during treatment with TECVAYLI and treat appropriately. Administer prophylactic antimicrobials according to current practice guidelines.

Withhold TECVAYLI or consider permanent discontinuation of TECVAYLI based on severity.

Monitor immunoglobulin levels prior to and during treatment with TECVAYLI and administer subcutaneous or intravenous immunoglobulin (IVIG) to maintain the serum levels >400 mg/dL.

Neutropenia - TECVAYLI can cause neutropenia and febrile neutropenia. In patients who received TECVAYLI at the recommended dosage in the clinical trials (monotherapy and combination therapy trials; N=448), decreased neutrophils occurred in 88% of patients, with Grade 3 or 4 decreased neutrophils in 70%. Febrile neutropenia occurred in 6% 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 the recommended TECVAYLI dosage in the clinical trials (monotherapy and combination therapy trials; N=448), 2.5% of patients experienced systemic-administration reactions, which included recurrent pyrexia and rash.

Local Reactions - In patients who received TECVAYLI at the recommended dosage in the clinical trials (monotherapy and combination therapy trials; N=448), injection-site reactions occurred in 37% of patients, with Grade 1 injection-site reactions in 29% and Grade 2 in 9%.

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 patient. Advise pregnant patients 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%) in patients who received TECVAYLI monotherapy were pyrexia, CRS, musculoskeletal pain, injection site reaction, fatigue, upper respiratory tract infection, nausea, headache, pneumonia, and diarrhea. The most common adverse reactions (≥20%) in patients who received TECVAYLI in combination with daratumumab and hyaluronidase-fihj were hypogammaglobulinemia, upper respiratory tract infection, CRS, cough, diarrhea, musculoskeletal pain, COVID-19, pneumonia, injection site reaction, fatigue, pyrexia, headache, nausea, gastroenteritis, and weight decreased.

The most common Grade 3 to 4 laboratory abnormalities (≥20%) with TECVAYLI (as monotherapy or in combination with daratumumab and hyaluronidase-fihj) were decreased lymphocytes, decreased neutrophils, decreased white blood cells, decreased hemoglobin, and decreased platelets.

Please read full **Prescribing Information**, including Boxed WARNING, for TECVAYLI.

TALVEY® IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE

TALVEY® (talquetamab-tgvs) is 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 and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

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 TALVEY®. Initiate TALVEY® treatment with step-up dosing to reduce the risk of CRS. Withhold TALVEY® until CRS resolves or permanently discontinue based on severity.

Neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), and serious and life-threatening or fatal reactions, can occur with TALVEY®. Monitor patients for signs and symptoms of neurologic toxicity including ICANS during treatment and treat promptly. Withhold or permanently discontinue TALVEY® based on severity.

Because of the risk of CRS and neurologic toxicity, including ICANS, TALVEY® is available only through a restricted program called the TECVAYLI® and TALVEY® Risk Evaluation and Mitigation Strategy (REMS).

CONTRAINDICATIONS: None.

WARNINGS AND PRECAUTIONS

Cytokine Release Syndrome (CRS): TALVEY® can cause cytokine release syndrome, including life-threatening or fatal reactions. In the clinical trial, CRS occurred in 76% of patients who received TALVEY® at the recommended dosages, with Grade 1 CRS occurring in 57% of patients, Grade 2 in 17%, and Grade 3 in 1.5%. Recurrent CRS occurred in 30% of patients. Most events occurred following step-up dose 1 (29%) or step-up dose 2 (44%) at the recommended dosages. CRS occurred in 33% of patients with step-up dose 3 in the biweekly dosing schedule (N=153). CRS occurred in 30% of patients with the first 0.4 mg/kg treatment dose and in 12% of patients treated with the first 0.8 mg/kg treatment dose. The CRS rate for both dosing schedules combined was less than 3% for each of the remaining doses in Cycle 1 and less than 3% cumulatively from Cycle 2 onward. The median time to onset of CRS was 27 (range: 0.1 to 167) hours from the last dose, and the median duration was 17 (range: 0 to 622) hours. Clinical signs and symptoms of CRS include but are not limited to pyrexia, hypotension, chills, hypoxia, headache, and tachycardia. Potentially life-threatening complications of CRS may include cardiac dysfunction, acute respiratory distress syndrome, neurologic toxicity, renal and/or hepatic failure, and disseminated intravascular coagulation (DIC).

Initiate therapy with step-up dosing and administer pre-treatment medications (corticosteroids, antihistamine, and antipyretics) prior to each dose of TALVEY® in the step-up dosing schedule to reduce the risk of CRS. Monitor patients following administration accordingly. In patients who experience CRS, pre-treatment medications should

be administered prior to the next TALVEY® dose.

Counsel patients to seek medical attention should signs or symptoms of CRS occur. At the first sign of CRS, immediately evaluate patient for hospitalization and institute treatment with supportive care based on severity, and consider further management per current practice guidelines. Withhold TALVEY® until CRS resolves or permanently discontinue based on severity.

Neurologic Toxicity including ICANS: TALVEY® can cause serious, life-threatening neurologic toxicity or fatal neurologic toxicity, including ICANS.

In the clinical trial, neurologic toxicity, including ICANS, occurred in 55% of patients who received the recommended dosages, with Grade 3 or 4 neurologic toxicity occurring in 6% of patients. The most frequent neurologic toxicities were headache (20%), encephalopathy (15%), sensory neuropathy (14%), and motor dysfunction, including ataxia/cerebellar ataxia (10%). ICANS was reported in 9% of 265 patients where ICANS was collected and who received the recommended dosages. Recurrent ICANS occurred in 3% of patients. Most patients experienced ICANS following step-up dose 1 (3%), step-up dose 2 (3%), step-up dose 3 of the biweekly dosing schedule (1.8%), or the initial treatment dose of the weekly dosing schedule (2.6%) (N=156) or the biweekly dosing schedule (3.7%) (N=109). The median time to onset of ICANS was 2.5 (range: 1 to 16) days after the most recent dose with a median duration of 2 (range: 1 to 22) days. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. Clinical signs and symptoms of ICANS may include but are not limited to confusional state, depressed level of consciousness, disorientation, somnolence, lethargy, and bradyphrenia.

Monitor patients for signs and symptoms of neurologic toxicity during treatment and treat promptly. At the first sign of neurologic toxicity, including ICANS, immediately evaluate the patient and provide supportive care based on severity. Withhold or permanently discontinue TALVEY® based on severity and consider further management per current practice guidelines [see Dosage and Administration (2.5)].

Due to the potential for neurologic toxicity, patients receiving TALVEY® are at risk of depressed level of consciousness. Advise patients to refrain from driving or operating heavy or potentially dangerous machinery during the step-up dosing schedule and for 48 hours after completion of the step-up dosing schedule, and in the event of new onset of any neurological symptoms, until symptoms resolve.

TECVAYLI® and TALVEY® REMS: TALVEY® 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.

Further information about the TECVAYLI® and TALVEY® REMS program is available at **www.TEC-TALREMS.com** or by telephone at 1-855-810-8064.

Oral Toxicity and Weight Loss: TALVEY® can cause oral toxicities, including dysgeusia, dry mouth, dysphagia, and stomatitis.

In the clinical trial, 80% of patients had oral toxicity, with Grade 3 occurring in 2.1% of patients who received the recommended dosages. The most frequent oral toxicities were dysgeusia (49%), dry mouth (34%), dysphagia (23%), and ageusia (18%). The median time to onset of oral toxicity was 15 (range: 1 to 634) days, and the median time to resolution to baseline was 43 (1 to 530) days. Oral toxicity did not resolve to baseline in 65% of patients.

TALVEY® can cause weight loss. In the clinical trial, 62% of patients experienced weight loss, regardless of having an oral toxicity, including 29% of patients with Grade 2 (10% or greater) weight loss and 2.7% of patients with Grade 3 (20% or greater) weight loss. The median time to onset of Grade 2 or higher weight loss was 67 (range: 6 to 407) days, and the median time to resolution was 50 (range: 1 to 403) days. Weight loss did not resolve in 57% of patients who reported weight loss.

Monitor patients for signs and symptoms of oral toxicity. Counsel patients to seek medical attention should signs or symptoms of oral toxicity occur and provide supportive care as per current clinical practice, including consultation with a nutritionist. Monitor weight regularly during therapy. Evaluate clinically significant weight loss further. Withhold TALVEY® or permanently discontinue based on severity.

Infections: TALVEY® can cause infections, including life-threatening or fatal infections.

In the clinical trial, serious infections occurred in 16% of patients, with fatal infections in 1.5% of patients. Grade 3 or 4 infections occurred in 17% of patients. The most common serious infections reported were bacterial infection (8%), which included sepsis, and COVID-19 (2.7%).

Monitor patients for signs and symptoms of infection prior to and during treatment with TALVEY® and treat appropriately. Administer prophylactic antimicrobials according to local guidelines. Withhold or consider permanent discontinuation of TALVEY® as recommended based on severity.

Cytopenias: TALVEY® can cause cytopenias, including neutropenia and thrombocytopenia.

In the clinical trial, Grade 3 or 4 decreased neutrophils occurred in 35% of patients, and Grade 3 or 4 decreased platelets occurred in 22% of patients who received TALVEY®. The median time to onset for Grade 3 or 4 neutropenia was 22 (range: 1 to 312) days, and the median time to resolution to Grade 2 or lower was 8 (range: 1 to 79) days. The median time to onset for Grade 3 or 4 thrombocytopenia was 12 (range: 2 to 183) days, and the median time to resolution to Grade 2 or lower was 10 (range: 1 to 64) days. Monitor complete blood counts during

treatment and withhold TALVEY® as recommended based on severity.

Skin Toxicity: TALVEY® can cause serious skin reactions, including rash, maculo-papular rash, erythema, and erythematous rash.

In the clinical trial, skin reactions occurred in 62% of patients, with Grade 3 skin reactions in 0.3%. The median time to onset was 25 (range: 1 to 630) days. The median time to improvement to Grade 1 or less was 33 days.

Monitor for skin toxicity, including rash progression. Consider early intervention and treatment to manage skin toxicity. Withhold TALVEY® as recommended based on severity.

Hepatotoxicity: TALVEY® can cause hepatotoxicity. Elevated ALT occurred in 33% of patients, with Grade 3 or 4 ALT elevation occurring in 2.7%; elevated AST occurred in 31% of patients, with Grade 3 or 4 AST elevation occurring in 3.3%. Grade 3 or 4 elevations of total bilirubin occurred in 0.3% of patients. Liver enzyme elevation can occur with or without concurrent CRS.

Monitor liver enzymes and bilirubin at baseline and during treatment as clinically indicated. Withhold TALVEY® or consider permanent discontinuation of TALVEY® based on severity [see Dosage and Administration (2.5)].

Embryo-Fetal Toxicity: Based on its mechanism of action, TALVEY® 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 TALVEY® and for 3 months after the last dose.

Adverse Reactions: The most common adverse reactions (≥20%) are pyrexia, CRS, dysgeusia, nail disorder, musculoskeletal pain, skin disorder, rash, fatigue, weight decreased, dry mouth, xerosis, dysphagia, upper respiratory tract infection, diarrhea, hypotension, and headache.

The most common Grade 3 or 4 laboratory abnormalities (≥30%) are lymphocyte count decreased, neutrophil count decreased, white blood cell decreased, and hemoglobin decreased.

Please read full **Prescribing Information**, including Boxed WARNING, for TALVEY®.

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.innovativemedicine.jnj.com**. Follow us at **@JNJInnovMed**.

Caution Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 related to TECVAYLI® (teclistamab-cqyv) and TALVEY® (talquetamab-tgvs). 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 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 most recent Annual Report on Form 10-K, 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**, **www.investor.jnj.com** or on request from Johnson & Johnson. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

Footnotes

*Ajay K. Nooka, M.D., M.P.H., F.A.C.P, Director, Myeloma Program, Department of Hematology and Medical Oncology**,** Emory University School of Medicine, has provided consulting, advisory, and speaking services to Johnson & Johnson; he has not been paid for any media work.

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