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For Immediate Release

New Analyses Demonstrate Versatility and Continued Efficacy of TALVEY™ in the Treatment of Patients with Relapsed or Refractory Multiple Myeloma

Analysis from MonumenTAL-1 study showed patients with relapsed or refractory multiple myeloma treated with TALVEY™ were subsequently treated effectively with several classes of therapy, including CAR-T

Additional presentations at the 2023 ASH Annual Meeting showed potential improvement in adverse events among patients who received reduced intensity dosing and first-ever results from TALVEY™ combination study

SAN DIEGO, December 11, 2023 – Johnson & Johnson announced today an analysis from the Phase 1/2 MonumenTAL-1 study of TALVEY™ (talquetamab-tgvs) in patients with relapsed or refractory multiple myeloma (RRMM) showed that patients treated with TALVEY™ were subsequently treated effectively with several classes of therapy, including anti-B-cell maturation antigen (BCMA) chimeric antigen receptor T-cell (CAR-T) therapy as well as BCMA and anti-Fc receptor-like protein 5 (FcRH5) bispecific antibodies, after TALVEY™ treatment.[1] These data, featured in a poster presentation at the 2023 American Society of Hematology (ASH) Annual Meeting (Abstract #2007), highlight the versatility of TALVEY™ when used before or after BCMA-directed CAR-T and bispecifics in triple-class exposed patients with RRMM.[1] Additional results from the MonumenTAL-1 study, also featured in a poster presentation, support the overall versatility of TALVEY™ by showing continued strong efficacy among patients with prior exposure to T-cell redirection therapy (TCR) (Abstract #3377).[2]

In MonumenTAL-1, 297 patients with no prior exposure to TCR received TALVEY™ at the recommended Phase 2 dose (RP2D) of 0.8 mg/kg biweekly (Q2W) [n=154] or 0.4 mg/kg weekly (QW) [n=143].[1] Patients in the study received a median of five prior lines of therapy; 75 percent of patients were triple-class refractory; 29 percent were penta-drug refractory; and 12 percent had prior belantamab mafodotin exposure.[1] Overall, 162 patients received at least one subsequent antimyeloma therapy (SAT) after TALVEY™ discontinuation, including chemotherapy-based regimens63 (n=48); a proteasome inhibitor- (PI), an immunomodulatory drug- (IMiD), or other anti-neoplastic–containing regimen (n=44); anti-CD38 mAb-containing regimens (n=27); bispecific antibodies (n=23; n=19 anti–BCMA; n=4 anti–FcRH5); CAR-T therapy (n=17; including n=9 anti–BCMA-targeting CAR-T); or anti-BCMA antibody-drug conjugates (n=9).[1]

Results show that patients who discontinued TALVEY™ were able to achieve a response with SATs, including 65 percent (11/17) of patients who received subsequent CAR-T cell therapy, of whom 35 percent achieved a complete response (CR) or better.[1] Patients treated with anti-BCMA bispecific antibodies as the first SAT achieved an overall response rate (ORR) of 58 percent (11/19), and 75 percent (3/4) responded to anti-FcRH5 bispecific antibody therapy as the first SAT.[1]

A separate updated analysis of the MonumenTAL-1 study, focused on safety and efficacy of TALVEY™ in patients with RRMM after prior TCRs (n=70), showed continued strong efficacy of TALVEY™ across populations exposed to TCR (predominantly anti-BCMA), with an ORR of 73 percent and median duration of response (mDOR) of more than 1 year in the post–CAR-T cell therapy setting.[2] More than 56 percent of patients exposed to prior bispecific antibody responded.[2]

"Results from the MonumenTAL-1 analyses support the versatility of talquetamab either before or after BCMA-directed CAR-T and bispecifics in patients with triple-class exposed relapsed or refractory multiple myeloma," said Ajai Chari, M.D., Director of Multiple Myeloma Program, Professor of Clinical Medicine at the University of California, San Francisco.‡ "Talquetamab presents a new treatment option for patients and physicians who want to save BCMA-directed for later lines of therapy."

Data from the Pivotal Phase 1/2 MonumenTAL-1 Study Highlight Reported Continued Efficacy of TALVEY™ with Reduced Intensity Dosing

An oral presentation at ASH 2023 highlighted results from 50 patients in the Phase 1/2 MonumenTAL-1 study who were switched to reduced intensity dosing based on meeting specific response criteria or to mitigate treatment-emergent adverse events (TEAEs) such as oral-, nail- and/or skin-related TEAEs, which may be related to expression of GPRC5D (Abstract #1010).[3] Patients whose dose was reduced maintained durable responses to TALVEY™ treatment.[3] Two additional cohorts, which were conducted to examine the impact of prospective reduction in dosing intensity after response was achieved, included 24 patients with a median follow-up of 13.2 months.[3] In total, 79 percent (19/24) of patients achieved a partial response (PR) or better and switched from 0.8 mg/kg Q2W to either 0.4 mg/kg Q2W or 0.8 mg/kg Q4W.[3] Following the change in dosing, at six months, mDOR was not reached.[3]

Patients who prospectively switched to reduced dosing intensity trended towards improved resolution of GPRC5D-related TEAEs, except for weight loss (prospective: 12.5 percent resolved and without dose reduction: 18.9 percent resolved).[3] Resolution of TEAEs occurred for oral-toxicities (33.3 percent and 26.9 percent); nail-toxicities (11.1 percent and 12.0 percent) and non-rash skin-toxicities (50.0 percent and 15.3 percent), in the prospective and without dose reduction cohorts, respectivly.[3] Thus, improvement or resolution of oral-, nail-, and skin-related TEAEs was observed over time in some patients in the prospective reduced and less frequent dosing cohorts.[3]

These results show the potential of modifying the TALVEY™ dose, after a response is achieved, as a strategy to manage oral-, nail-, and skin-related TEAEs and improve patient experience without compromising efficacy.[3]

First-ever Results from Study of TALVEY™ and IMiD Combination Show Promising Overall Response Rate in Patients with RRMM

Results from the Phase 1b MonumenTAL-2 study of TALVEY™ and pomalidomide for the treatment of patients with RRMM highlight the potential to combine TALVEY™ with other anti-myeloma therapies.[4] These data, from the first-ever study of a regimen combining a GPRC5D-targeted therapy and an immunomodulatory agent, were featured as an oral presentation at the 2023 ASH Annual Meeting (Abstract #1014).[4]

Patients in the Phase 1b MonumenTAL-2 study (n=35) were treated with subcutaneous (SC) TALVEY™ at the RP2D of 0.8 mg/kg Q2W (n=19) or 0.4 mg/kg QW (n=16) with step-up doses, plus two milligrams of oral pomalidomide daily.[4] With a median follow-up of 15 months in the QW cohort (n=16), the overall response rate was 94 percent among response-evaluable patients, 63 percent achieved a CR or better, and 88 percent of responders achieved a very good partial response (VGPR) or better.[4] With a median follow-up of 11.1 months in the Q2W cohort (n=19), the ORR was 84 percent in response-evaluable patients, with 37 percent achieving a CR or better and 68 percent achieving a VGPR or better.[4] Overall response rates were consistent across patient subgroups, including patients treated with prior pomalidomide or CAR-T cell therapy.[4]

Responses in both patient cohorts were rapid, with a median time to first response of 1.7 months (range, 0.9–3.3) in the QW cohort and 1.2 months (range, 0–4.8) in the Q2W cohort.[4] At nine months, 100 percent of responders maintained their response in the QW cohort and 84 percent maintained response in the Q2W cohort.[4] mDOR and progression-free survival (PFS) were not reached, and 9-month PFS rates observed in the QW and Q2W cohorts were 94 percent and 76 percent, respectively.[4]

“Findings from the MonumenTAL-2 and MonumenTAL-1 studies demonstrate the versatility of TALVEY across patient subgroups, showing the efficacy, manageable safety profile and effect of TALVEY on B-cell preservation,” said Christoph Heuck, M.D., Vice President, Hematology Clinical Development, Johnson & Johnson Innovative Medicine. “The promising early results observed with the combination of TALVEY and pomalidomide, even in patients who had previously received pomalidomide or CAR-T cell therapy, reinforce our scientific strategy in focusing on improving upon and deepening responses through combination regimens.”

The most common adverse events across both cohorts were oral related (86 percent); cytokine release syndrome (CRS; 74 percent; 3 percent Grade 3/4); neutropenia (63 percent).[4] Most common grade 3/4 hematologic AEs were neutropenia (54 percent), anemia (26 percent), and thrombocytopenia (20 percent).[4] Nail, skin, and rash toxicities occurred in 69 percent, 74 percent, and 20 percent of patients, respectively; the majority were Grade 1/2 with no discontinuations.[4] Grade 1 immune effector cell-associated neurotoxicity syndrome occurred in three patients.[4] Infections occurred in 80 percent of patients (23 percent Grade 3/4); most common were pneumonia (23 percent) and upper respiratory tract infection (23 percent).[4] Adverse events led to TALVEY™ dose reduction or schedule change in 34 percent of patients and dose reduction of pomalidomide in 46 percent of patients.[4] In total, four patients discontinued treatment. One patient died due to pulmonary embolism.[4]

About TALVEY™

TALVEY™ (talquetamab-tgvs) received 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.[5] The European Commission (EC) granted conditional marketing authorization (CMA) of TALVEY™ ▼ (talquetamab) 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.[6]

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 non-malignant plasma cells, as well as some healthy tissues such as epithelial cells of the skin and tongue.

For more information, visit www.TALVEY.com.

About MonumenTAL-1

MonumenTAL-1 (Phase 1: NCT03399799, Phase 2: NCT04634552) is a Phase 1/2 single-arm, open-label, multicohort, multicenter dose-escalation study involving more than 300 patients.[7,8] Phase 1 evaluated the safety and efficacy of TALVEY™ in adults with relapsed or refractory multiple myeloma who received three or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.[1,2] The study excluded patients who experienced T-cell redirection therapy within 3 months, prior Grade 3 or higher CRS related to any T-cell redirection therapy, an autologous stem cell transplant within the 12 weeks, an allogenic stem cell transplant within the 6 months, Eastern Cooperative Oncology Group (ECOG) performance score of 3 or higher, stroke or seizure within 6 months, CNS involvement or clinical signs of meningeal involvement of multiple myeloma, plasma cell leukemia, or active or documented history of autoimmune disease (exception of vitiligo, resolved childhood atopic dermatitis or resolved Grave's Disease that is euthyroid based on clinical and laboratory testing).[7,8]

Phase 2 of the study evaluated the efficacy of TALVEY™ in participants with relapsed or refractory multiple myeloma at the recommended Phase 2 dose(s) (RP2Ds), established as SC 0.4 mg/kg weekly and 0.8 mg/kg every two weeks, respectively. Efficacy was based on overall response rate (ORR) and duration of response (DOR) as assessed by an Independent Review Committee using the International Myeloma Working Group (IMWG) criteria.[3]

About MonumenTAL-2

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

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.[11] 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.[12] People living with multiple myeloma have a five-year relative 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]

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. Withhold or 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. 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 or life-threatening neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), including fatal reactions. In the clinical trial, neurologic toxicity 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 (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. 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 of 5% or greater, regardless of having an oral toxicity, including 28% 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. 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 permanently discontinue 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.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.

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Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development and the potential benefits and treatment impact of 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 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 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 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.

‡ *Dr. Ajai Chari has provided consulting, advisory, and speaking services to Janssen; he has not been paid for any media work.*

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