News Release

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Subcutaneous Daratumumab Combination Resulted in Deep and Rapid Hematologic Responses and Improved Clinical Outcomes in the Treatment of Patients with Newly Diagnosed Light Chain (AL) Amyloidosis

Phase 3 ANDROMEDA study investigated the first and only subcutaneous anti-CD38 monoclonal antibody in treatment of rare multi-system disease with a high unmet medical need and for which there are currently no approved therapies

Data selected as late-breaking abstract and featured in press briefing at European Hematology Association (EHA) Annual Congress

RARITAN, NJ, June 13, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today results from the first randomized Phase 3 study investigating subcutaneous daratumumab[i] in the treatment of patients with newly diagnosed light chain (AL) amyloidosis, a

[i] U.S. tradename DARZALEX *FASPRO*™

rare and potentially fatal disease.[1,2] The data demonstrated subcutaneous daratumumab in combination with cyclophosphamide, bortezomib, and dexamethasone (D-CyBorD) resulted in a higher hematologic complete response rate (CR), (53 percent vs. 18 percent [*P*<0.0001]), compared to CyBorD. Additionally, treatment with D-CyBorD delayed the time to major organ deterioration progression-free survival (MOD-PFS), and enhanced event-free survival (MOD-EFS) based on MOD-PFS criteria with the time to initiation of next therapy. The combination showed a safety profile consistent with subcutaneous daratumumab or CyBorD alone.[3]

The positive results are being highlighted during a press briefing at the 25th EHA Annual Congress today and will be presented during a late-breaking oral session on Sunday, June 14 at 8:30 a.m. ET (Abstract LB2604).

AL amyloidosis is a rare and potentially fatal multi-system disorder that occurs when bone marrow produces abnormal pieces of antibodies called light chains, which clump together to form an amyloid. This amyloid is deposited in tissues and vital organs and interferes with normal organ function.[1,2] As the disease progresses, many patients experience gradual deterioration of multiple organs, including the heart, kidneys, digestive tract, liver and nervous system.[4] Diagnosis of AL amyloidosis is often delayed and prognosis is poor due to advanced, multiorgan (particularly cardiac) involvement.[5,6] Patients with AL amyloidosis have an estimated median survival ranging from six months to three years depending on the patient population and data used.[5] There are currently no approved therapy options to treat this devastating disease.

"Patients with AL amyloidosis often experience poor outcomes because their symptoms are confused with more common conditions, causing delays in diagnosis," said Raymond L. Comenzo, M.D., Director, John C. Davis Myeloma and Amyloid Program, Tufts Medical Center and study investigator. "The newly diagnosed patient population in AL amyloidosis is the most challenging to treat, and many do not reach second-line therapy. The higher rate of hematologic complete response, as well as the notable sustainment of major organ function in those receiving subcutaneous daratumumab in the ANDROMEDA study, suggest that subcutaneous daratumumab may be a promising treatment for newly diagnosed patients with AL amyloidosis who have been, for some time, in urgent need of new therapeutic options."

Results from the ANDROMEDA study showed that the primary endpoint, hematologic CR rate, was 53 percent for D-CyBorD and 18 percent for CyBorD (Odds Ratio=5.1; 95 percent confidence interval [CI], 3.2-8.2; *P*<0.0001). In addition, patients receiving D-CyBorD achieved higher rates

of overall hematologic response (92 percent vs. 77 percent) and very good partial response or better (≥VGPR; 79 percent vs. 49 percent) than patients receiving CyBorD. Among the 195 patients who achieved at least a VGPR to treatment within the D-CyBorD arm, median time to ≥VGPR/CR was 17/60 days, compared to the 193 patients in the CyBorD arm whose median time to ≥VGPR/CR was 25/85 days.

The six-month organ response rate was nearly doubled for patients treated with D-CyBorD versus CyBorD, for both cardiac (42 percent vs. 22 percent; *P*=0.0029) and renal (54 percent vs. 27 percent; *P*<0.0001) responses. Additionally, MOD-PFS (Hazard Ratio [HR]=0.58; 95 percent CI, 0.36-0.93, *P*=0.0224) and MOD-EFS (HR=0.40; 95 percent CI, 0.28-0.57, *P*<0.0001) favored the D-CyBorD arm, demonstrating substantially delayed major organ deterioration, hematologic progression or death, as well as improved event-free survival. In addition, the D-CyBorD arm, which is delivered subcutaneously, helped to limit intravenous fluid overload, an important treatment factor in the setting of cardiac compromised patients.

"There is an urgent need to bring forth promising treatments for people who have been diagnosed with this difficult-to-treat, rare disease where there are no approved treatment options," said Jessica Vermeulen, M.D., Ph.D., Global Medical Head/Clinical Leader, Hematology & Oncology, Janssen Research & Development, LLC. "With the ANDROMEDA study, our goal is to provide patients with AL amyloidosis new hope in their treatment journey. We are encouraged by the results generated with daratumumab, an established anti-CD38 monoclonal antibody in the treatment of multiple myeloma, and we look forward to pursuing regulatory submissions with health authorities based on the results in this disease of the plasma cells."

The most common Grade 3/4 treatment emergent adverse events occurring in more than five percent of patients for the D-CyBorD arm compared to the CyBorD arm, included lymphopenia (13 percent vs. 10 percent), pneumonia (8 percent vs. 4 percent), diarrhea (6 percent vs. 4 percent), cardiac failure (6 percent vs. 5 percent), neutropenia (5 percent vs. 3 percent), syncope (5 percent vs. 6 percent) and peripheral edema (3 percent vs. 6 percent). The study showed subcutaneous daratumumab had a low rate of administration-related reactions (ARRs).[3] Systemic ARRs in the D-CyBorD arm occurred in 14 patients (7 percent), all were Grade 1-2, and most occurred during the initial administration. A total of 56 deaths occurred (D-CyBorD, n=27; CyBorD, n=29).[3]

About the ANDROMEDA Study[3]

ANDROMEDA (NCT03201965) is an ongoing Phase 3, randomized, open-label study investigating the safety and efficacy of subcutaneous daratumumab in combination with cyclophosphamide, bortezomib and dexamethasone (CyBorD), compared to CyBorD alone, in the treatment of patients with newly diagnosed light chain (AL) amyloidosis. The study included 388 patients with newly diagnosed AL amyloidosis with measurable hematologic disease and one or more organs affected. The primary endpoint was overall complete hematologic response rate (intent-to-treat / ITT). Secondary endpoints included major organ deterioration progression-free survival, event free survival, organ response rate, overall survival, and time to hematologic response, among others.

About AL Amyloidosis

Light chain (AL) amyloidosis is a rare and potentially fatal hematologic disorder that can affect the function of multiple organs. The disease occurs when bone marrow produces abnormal pieces of antibodies called light chains, which clump together to form a substance called amyloid. These clumps of amyloid are deposited in tissues and vital organs and interfere with normal organ function, eventually causing organ deterioration.[1,2] It is the most common type of amyloidosis. AL amyloidosis frequently affects the heart, kidneys, digestive tract, liver and nervous system, and is potentially fatal if left untreated.[4] Diagnosis is often delayed and prognosis is poor due to advanced, multi-organ, particularly cardiac, involvement.[7,8] Each year, an estimated 4,500 people develop AL amyloidosis in the U.S. alone.[9]

About DARZALEX® and DARZALEX *FASPRO*™

Janssen is committed to exploring the potential of DARZALEX® (daratumumab) for patients with multiple myeloma (MM) across the spectrum of the disease. DARZALEX® has been approved in seven indications, three of which are in the frontline setting, including newly diagnosed MM patients who are transplant eligible and ineligible.

In August 2012, Janssen entered into an exclusive global license and development agreement with Genmab A/S to develop, manufacture, and commercialize DARZALEX®.[10] DARZALEX® has become a backbone therapy in the treatment of multiple myeloma, having been used in the treatment of more than 130,000 patients worldwide and more than 58,000 patients in the U.S. alone since its U.S. FDA approval in 2015. DARZALEX® is the first CD38-directed antibody approved globally to treat multiple myeloma and in 2020, DARZALEX *FASPRO*™ (daratumumab and hyaluronidase human-fihj) follows as the only subcutaneous CD38-directed antibody approved to treat patients

with multiple myeloma.[11] DARZALEX *FASPRO*™ is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology.

CD38 is a surface protein that is present in high numbers on multiple myeloma cells, regardless of the stage of disease.[4] DARZALEX® binds to CD38 and inhibits tumor cell growth causing myeloma cell death.[5] DARZALEX® may also have an effect on normal cells.[12] Data across seven Phase 3 clinical trials, in both the frontline and relapsed settings, have shown that DARZALEX®-based regimens resulted in significant improvement in progression-free survival and/or overall survival.[13,14,15,16,17,18,19,20] Additional studies are underway to assess the efficacy and safety of DARZALEX *FASPRO*™ in the treatment of other malignant and pre-malignant hematologic diseases in which CD38 is expressed, including smoldering myeloma and in AL amyloidosis.[21,22]

Please see full Prescribing Information at www.DARZALEX.com.

DARZALEX *FASPRO*™ IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

DARZALEX *FASPRO*™ is contraindicated in patients with a history of severe hypersensitivity to daratumumab, hyaluronidase or any of the components of the formulation.

WARNINGS AND PRECAUTIONS

Hypersensitivity and Other Administration Reactions

Both systemic administration-related reactions, including severe or life-threatening reactions, and local injection-site reactions can occur with DARZALEX *FASPRO*™.

Systemic Reactions

In a pooled safety population of 490 patients who received DARZALEX *FASPRO*™ as monotherapy or in combination, 11% of patients experienced a systemic administration-related reaction (Grade 2: 3.9%, Grade 3: 1.4%). Systemic administration-related reactions occurred in 10% of patients with the first injection, 0.2% with the second injection, and cumulatively 0.8% with subsequent injections. The median time to onset was 3.7 hours (range: 9 minutes to 3.5 days). Of the 84 systemic administration-related reactions that occurred in 52 patients, 73 (87%) occurred on the day of DARZALEX *FASPRO*™ administration. Delayed systemic administration-related reactions have occurred in less than 1% of the patients.

Severe reactions included hypoxia, dyspnea, hypertension and tachycardia. Other signs and symptoms of systemic administration-related reactions may include respiratory symptoms, such as bronchospasm, nasal congestion, cough, throat irritation, allergic rhinitis, and wheezing, as well as anaphylactic reaction, pyrexia, chest pain, pruritis, chills, vomiting, nausea, and hypotension.

Pre-medicate patients with histamine-1 receptor antagonist, acetaminophen and corticosteroids. Monitor patients for systemic administration-related reactions, especially following the first and second injections. For anaphylactic reaction or life-threatening (Grade 4) administration-related reactions, immediately and permanently discontinue DARZALEX *FASPRO™.* Consider administering corticosteroids and other medications after the administration of DARZALEX *FASPRO™* depending on dosing regimen and medical history to minimize the risk of delayed (defined as occurring the day after administration) systemic administration-related reactions.

Local Reactions

In this pooled safety population, injection-site reactions occurred in 8% of patients, including Grade 2 reactions in 0.6%. The most frequent (>1%) injection-site reaction was injection site erythema. These local reactions occurred a median of 7 minutes (range: 0 minutes to 4.7 days) after starting administration of DARZALEX *FASPRO™*. Monitor for local reactions and consider symptomatic management.

Neutropenia

Daratumumab may increase neutropenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. Monitor patients with neutropenia for signs of infection. Consider withholding DARZALEX *FASPRO™* until recovery of neutrophils. In lower body weight patients receiving DARZALEX *FASPRO™*, higher rates of Grade 3-4 neutropenia were observed.

Thrombocytopenia

Daratumumab may increase thrombocytopenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. Consider withholding DARZALEX *FASPRO™* until recovery of platelets.

Embryo-Fetal Toxicity

Based on the mechanism of action, DARZALEX *FASPRO™* can cause fetal harm when administered to a pregnant woman. DARZALEX *FASPRO™* may cause depletion of fetal immune cells and decreased bone density. Advise pregnant women of the potential risk to a fetus. Advise females with

reproductive potential to use effective contraception during treatment with DARZALEX *FASPRO*™ and for 3 months after the last dose.

The combination of DARZALEX *FASPRO*™ with lenalidomide is contraindicated in pregnant women, because lenalidomide may cause birth defects and death of the unborn child. Refer to the lenalidomide prescribing information on use during pregnancy.

Interference with Serological Testing

Daratumumab binds to CD38 on red blood cells (RBCs) and results in a positive Indirect Antiglobulin Test (Indirect Coombs test). Daratumumab-mediated positive indirect antiglobulin test may persist for up to 6 months after the last daratumumab administration. Daratumumab bound to RBCs masks detection of antibodies to minor antigens in the patient's serum. The determination of a patient's ABO and Rh blood type are not impacted.

Notify blood transfusion centers of this interference with serological testing and inform blood banks that a patient has received DARZALEX *FASPRO*™*.* Type and screen patients prior to starting DARZALEX *FASPRO*™.

Interference with Determination of Complete Response

Daratumumab is a human IgG kappa monoclonal antibody that can be detected on both the serum protein electrophoresis (SPE) and immunofixation (IFE) assays used for the clinical monitoring of endogenous M-protein. This interference can impact the determination of complete response and of disease progression in some DARZALEX *FASPRO*™ -treated patients with IgG kappa myeloma protein.

Adverse Reactions

The most common adverse reaction (≥20%) with DARZALEX *FASPRO*™ monotherapy is: upper respiratory tracts infection.

The most common adverse reactions (≥20%) with D-VMP are upper respiratory tract infection, constipation, nausea, fatigue, pyrexia, peripheral sensory neuropathy, diarrhea, cough, insomnia, vomiting, and back pain. The most common adverse reactions (≥20%) with D-Rd are fatigue, diarrhea, upper respiratory tract infection, muscle spasms, constipation, pyrexia, pneumonia and dyspnea.

The most common hematology laboratory abnormalities (≥40%) with DARZALEX *FASPRO*™ are decreased leukocytes, decreased lymphocytes, decreased neutrophils, decreased platelets, and decreased hemoglobin.

Please see full Prescribing Information at www.DARZALEX.com.

DARZALEX® IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

DARZALEX® (daratumumab) is contraindicated in patients with a history of severe hypersensitivity (e.g., anaphylactic reactions) to daratumumab or any of the components of the formulation.

WARNINGS AND PRECAUTIONS

Infusion Reactions – DARZALEX® can cause severe and/or serious infusion reactions, including anaphylactic reactions. In clinical trials, approximately half of all patients experienced an infusion reaction. Most infusion reactions occurred during the first infusion and were Grade 1-2. Infusion reactions can also occur with subsequent infusions. Nearly all reactions occurred during infusion or within 4 hours of completing DARZALEX®. Prior to the introduction of post-infusion medication in clinical trials, infusion reactions occurred up to 48 hours after infusion. Severe reactions have occurred, including bronchospasm, hypoxia, dyspnea, hypertension, laryngeal edema, and pulmonary edema. Signs and symptoms may include respiratory symptoms, such as nasal congestion, cough, throat irritation, as well as chills, vomiting, and nausea. Less common symptoms were wheezing, allergic rhinitis, pyrexia, chest discomfort, pruritus, and hypotension.

Pre-medicate patients with antihistamines, antipyretics, and corticosteroids. Frequently monitor patients during the entire infusion. Interrupt infusion for reactions of any severity and institute medical management as needed. Permanently discontinue therapy if an anaphylactic reaction or life-threatening (Grade 4) reaction occurs and institute appropriate emergency care. For patients with Grade 1, 2, or 3 reactions, reduce the infusion rate when re-starting the infusion.

To reduce the risk of delayed infusion reactions, administer oral corticosteroids to all patients following DARZALEX® infusions. Patients with a history of chronic obstructive pulmonary disease may require additional post-infusion medications to manage respiratory complications. Consider prescribing short- and long-acting bronchodilators and inhaled corticosteroids for patients with chronic obstructive pulmonary disease.

Interference with Serological Testing – Daratumumab binds to CD38 on red blood cells (RBCs) and results in a positive Indirect Antiglobulin Test (Indirect Coombs test). Daratumumab-mediated positive indirect antiglobulin test may persist for up to 6 months

after the last daratumumab infusion. Daratumumab bound to RBCs masks detection of antibodies to minor antigens in the patient's serum. The determination of a patient's ABO and Rh blood type are not impacted. Notify blood transfusion centers of this interference with serological testing and inform blood banks that a patient has received DARZALEX®. Type and screen patients prior to starting DARZALEX®.

Neutropenia and Thrombocytopenia – DARZALEX® may increase neutropenia and/or thrombocytopenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to the manufacturer's prescribing information for background therapies. Monitor patients with neutropenia for signs of infection. DARZALEX® dose delay may be required to allow recovery of neutrophils and/or platelets. No dose reduction of DARZALEX® is recommended. Consider supportive care with growth factors for neutropenia or transfusions for thrombocytopenia.

Interference with Determination of Complete Response – Daratumumab is a human IgG kappa monoclonal antibody that can be detected on both the serum protein electrophoresis (SPE) and immunofixation (IFE) assays used for the clinical monitoring of endogenous M-protein. This interference can impact the determination of complete response and of disease progression in some patients with IgG kappa myeloma protein.

Adverse Reactions – The most frequently reported adverse reactions (incidence ≥20%) were: infusion reactions, neutropenia, thrombocytopenia, fatigue, asthenia, nausea, diarrhea, constipation, decreased appetite, vomiting, muscle spasms, arthralgia, back pain, pyrexia, chills, dizziness, insomnia, cough, dyspnea, peripheral edema, peripheral sensory neuropathy, bronchitis, pneumonia, and upper respiratory tract infection.

DARZALEX® in combination with lenalidomide and dexamethasone (DRd): The most frequent (≥20%) adverse reactions for newly diagnosed or relapsed/refractory patients were, respectively, infusion reactions (41%, 48%), diarrhea (57%, 43%), nausea (32%, 24%), fatigue (40%, 35%), pyrexia (23%, 20%), upper respiratory tract infection (52%, 65%), muscle spasms (29%, 26%), dyspnea (32%, 21%), and cough (30%, 30%). In newly diagnosed patients, constipation (41%), peripheral edema (41%), back pain (34%), asthenia (32%), bronchitis (29%), pneumonia (26%), peripheral sensory neuropathy (24%), and decreased appetite (22%) were also reported. In newly diagnosed patients, serious adverse reactions (≥2% compared to Rd) were pneumonia (15%),

bronchitis (4%), and dehydration (2%), and treatment-emergent Grade 3-4 hematology laboratory abnormalities (≥20%) were neutropenia (56%), lymphopenia (52%), and leukopenia (35%). In relapsed/refractory patients, serious adverse reactions (≥2% compared to Rd) were pneumonia (12%), upper respiratory tract infection (7%), influenza (3%), and pyrexia (3%), and treatment-emergent Grade 3-4 hematology laboratory abnormalities (≥20%) were neutropenia (53%) and lymphopenia (52%).

DARZALEX® in combination with bortezomib, melphalan, and prednisone (DVMP): The most frequently reported adverse reactions (≥20%) were upper respiratory tract infection (48%), infusion reactions (28%), and peripheral edema (21%). Serious adverse reactions (≥2% compared to the VMP arm) were pneumonia (11%), upper respiratory tract infection (5%), and pulmonary edema (2%). Treatment-emergent Grade 3-4 hematology laboratory abnormalities (≥20%) were lymphopenia (58%), neutropenia (44%), and thrombocytopenia (38%).

DARZALEX® in combination with bortezomib and dexamethasone (DVd): The most frequently reported adverse reactions (≥20%) were peripheral sensory neuropathy (47%), infusion reactions (45%), upper respiratory tract infection (44%), diarrhea (32%), cough (27%), peripheral edema (22%), and dyspnea (21%). The overall incidence of serious adverse reactions was 42%. Serious adverse reactions (≥2% compared to Vd) were upper respiratory tract infection (5%), diarrhea (2%), and atrial fibrillation (2%). Treatment-emergent Grade 3-4 hematology laboratory abnormalities (≥20%) were lymphopenia (48%) and thrombocytopenia (47%).

DARZALEX® in combination with bortezomib, thalidomide, and dexamethasone (DVTd): The most frequent adverse reactions (≥20%) were infusion reactions (35%), nausea (30%), upper respiratory tract infection (27%), pyrexia (26%), and bronchitis (20%). Serious adverse reactions (≥2% compared to the VTd arm) were bronchitis (DVTd 2% vs. VTd <1%) and pneumonia (DVTd 6% vs. VTd 4%). Treatment-emergent Grade 3-4 hematology laboratory abnormalities (≥20%) were lymphopenia (59%), neutropenia (33%), and leukopenia (24%).

DARZALEX® in combination with pomalidomide and dexamethasone (DPd): The most frequent adverse reactions (>20%) were fatigue (50%), infusion reactions (50%), upper respiratory tract infection (50%), cough (43%), diarrhea (38%), constipation (33%), dyspnea (33%), nausea (30%), muscle spasms (26%), back pain (25%), pyrexia (25%), insomnia (23%), arthralgia (22%), dizziness (21%), and vomiting (21%). The overall incidence of serious adverse reactions

was 49%. Serious adverse reactions reported in ≥5% of patients included pneumonia (7%). Treatment-emergent Grade 3-4 hematology laboratory abnormalities (≥20%) were neutropenia (82%), lymphopenia (71%), and anemia (30%).

DARZALEX® as monotherapy: The most frequently reported adverse reactions (≥20%) were infusion reactions (48%), fatigue (39%), nausea (27%), back pain (23%), pyrexia (21%), cough (21%), and upper respiratory tract infection (20%). The overall incidence of serious adverse reactions was 33%. The most frequent serious adverse reactions were pneumonia (6%), general physical health deterioration (3%), and pyrexia (3%). Treatment-emergent Grade 3-4 hematology laboratory abnormalities (≥20%) were lymphopenia (40%) and neutropenia (20%).

Please see full Prescribing Information at www.DARZALEX.com.

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, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenGlobal and www.twitter.com/JanssenUS. Janssen Research & Development, LLC and Janssen Biotech, Inc. are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding DARZALEX FASPRO™. 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 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 29, 2019, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent 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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