News Release

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U.S. Food and Drug Administration Approves DARZALEX *FASPRO*™ (daratumumab and hyaluronidase-fihj), a New Subcutaneous Formulation of Daratumumab in the Treatment of Patients with Multiple Myeloma

- *Innovative, fixed-dose formulation significantly reduces treatment time from hours to minutes and demonstrates consistent efficacy with a reduction in administration-related reactions compared to DARZALEX® (daratumumab) for approved indications*
- *DARZALEX FASPRO™ is the only subcutaneous CD38-directed antibody approved in the treatment of multiple myeloma*

HORSHAM, Pa., May 1, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today the U.S. Food and Drug Administration (FDA) approved

DARZALEX *FASPRO*™ (daratumumab and hyaluronidase-fihj), a new subcutaneous formulation of daratumumab. DARZALEX *FASPRO*™ is approved in four regimens across five indications in multiple myeloma patients, including newly diagnosed, transplant-ineligible patients as well as relapsed or refractory patients. As a fixed-dose formulation, DARZALEX *FASPRO*™ can be administered over approximately three to five minutes, significantly less time than DARZALEX®, which is given intravenously over hours. In the Phase 3 COLUMBA study supporting the approval, DARZALEX *FASPRO*™ demonstrated a consistent overall response rate (ORR) and pharmacokinetics and a similar safety profile compared with intravenous DARZALEX® in patients with relapsed or refractory multiple myeloma. In addition, there was a nearly two-thirds reduction in systemic administration-related reactions (ARRs) for DARZALEX *FASPRO*™ compared to intravenous DARZALEX® (13 percent vs. 34 percent, respectively).

"This approval exemplifies Janssen's mission and commitment to bringing together passion, science and ingenuity to advance novel solutions for patients," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, LLC. "We are excited about the potential of this meaningful innovation in transforming the treatment experience for patients with multiple myeloma where DARZALEX *FASPRO* can be administered in approximately three to five minutes, significantly less time than intravenous DARZALEX, which is given over hours. Based on its favorable profile, we are accelerating the development of DARZALEX *FASPRO* and evaluating its potential in multiple ongoing studies."

The approval is based on data from the Phase 3 COLUMBA (MMY3012) and Phase 2 PLEIADES (MMY2040) studies.[1,2] In the COLUMBA study, the ORR was non-inferior for patients taking DARZALEX *FASPRO*™ as monotherapy compared to those taking intravenous DARZALEX® as monotherapy (41 percent vs. 37 percent, respectively). In addition, there were fewer systemic ARRs with DARZALEX *FASPRO*™ versus intravenous DARZALEX® (13 percent vs. 34 percent, respectively). In a pooled safety population of 490 patients who received DARZALEX *FASPRO*™ as monotherapy or in combination, the ARR rate was 11 percent. The safety profiles of intravenous DARZALEX® and DARZALEX *FASPRO*™ were otherwise similar.[1] Additionally, in the Phase 2 PLEIADES study evaluating

the efficacy and safety of DARZALEX *FASPRO*™ in combination therapies, objective responses were demonstrated in combination with bortezomib, melphalan and prednisone (D-VMP) in newly diagnosed transplant ineligible patients. In addition, objective responses were demonstrated in combination with lenalidomide and dexamethasone (D-Rd) in relapsed or refractory patients who received one prior line of therapy.[2]

"The Multiple Myeloma Research Foundation shares a common goal with Janssen in advancing treatments for multiple myeloma and addressing the unmet needs of this patient community," said Paul Giusti, President and CEO of the Multiple Myeloma Research Foundation (MMRF). "The approval of DARZALEX *FASPRO* marks an important milestone which will help make a positive difference in the lives of patients who depend on this effective therapy."

"Since the approval of daratumumab, a robust body of evidence has established its use as a treatment for multiple myeloma in both the frontline and relapsed and refractory settings," said Saad Z. Usmani, M.D., Division Chief of Plasma Cell Disorders, Levine Cancer Institute. "With DARZALEX *FASPRO* there may be fewer administration-related reactions compared to intravenous DARZALEX, providing an additional treatment option that may help patients, oncologists and nursing staff."

DARZALEX *FASPRO*™ is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20) [Halozyme's *ENHANZE*® drug delivery technology]. DARZALEX *FASPRO*™ will be available to patients and physicians as soon as the week of May 11, 2020. The intravenous DARZALEX® formulation will also remain available as an option for patients and their physicians.

DARZALEX *FASPRO*™ is approved in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant, in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy, in combination with bortezomib and dexamethasone in patients who have received at least

one prior therapy, as monotherapy, in patients who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.

The U.S. FDA approval of DARZALEX *FASPRO*™ marks the first approval for this innovative subcutaneous formulation globally, and Janssen continues to work with health authorities around the world in an effort to bring this new treatment option to patients living with multiple myeloma.

Access to DARZALEX *FASPRO*™ (daratumumab and hyaluronidase-fihj)

Janssen offers comprehensive access and support information, resources and services to assist U.S. patients in gaining access to DARZALEX *FASPRO*™ through the Janssen CarePath Program. Through the program, eligible commercial patients pay no more than $5 per injection, regardless of individual income level. Information on the enrollment process is available online at www.CarePathSavingsProgram.com/DARZALEX.

For more information, healthcare providers or patients can contact: 1-844-55DARZA (1-844-553-2792). Information will also be available at www.DARZALEX.com. Dedicated case coordinators are available to work with both healthcare providers and patients.

About the COLUMBA Study [1]

The randomized, open-label, multicenter Phase 3 COLUMBA study (MMY3012) included 522 patients (median age of 67 years) with multiple myeloma who had received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory drug (IMiD), or whose disease was refractory to both a PI and an IMiD. In the arm that received DARZALEX *FASPRO*™ (n=263), patients received a fixed dose of DARZALEX *FASPRO*™ 1,800 milligrams (mg), co-formulated with recombinant human hyaluronidase PH20 (rHuPH20) 2,000 Units per milliliter (U/mL), subcutaneously weekly for Cycles 1 – 2, every two weeks for Cycles 3 – 6 and every four weeks for Cycle 7 and thereafter. In the intravenous DARZALEX® arm (n=259), patients received DARZALEX® for intravenous infusion 16 milligrams per kilogram (mg/kg) weekly for Cycles 1 – 2, every two weeks for Cycles 3 – 6 and every four weeks for Cycle 7 and thereafter. Each cycle was 28 days. In

the arm that received DARZALEX *FASPRO*™, it was given in a fixed volume of 15 mL over three to five minutes; the median injection time was five minutes. In the arm that received the intravenous administration, the median durations of the first, second and subsequent intravenous DARZALEX® infusions were 7.0, 4.3 and 3.4 hours, respectively. Patients in both arms continued treatment until disease progression or unacceptable toxicity.

About the PLEIADES Study [2]

The non-randomized, open-label, parallel assignment Phase 2 PLEIADES study (MMY2040) included more than 240 adults with multiple myeloma, including 67 patients with newly diagnosed multiple myeloma who were treated with 1,800 mg of DARZALEX *FASPRO*™ in combination with bortezomib, melphalan, and prednisone (D-VMP) and 65 patients with relapsed or refractory disease who were treated with 1,800 mg of DARZALEX *FASPRO*™ plus lenalidomide and dexamethasone (D-Rd). The primary endpoint for the D-VMP and D-Rd cohorts was overall response rate.

About DARZALEX® and DARZALEX *FASPRO*™

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

DARZALEX® has become a backbone therapy in the treatment of multiple myeloma, having been used in the treatment of 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.[2]

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.[3] 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. [4,5,6,7,8,9,10,11] 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 amyloidosis.[12,13]

Key DARZALEX® Milestones:

- In August 2012, Janssen entered into an exclusive global license and development agreement with Genmab A/S to develop, manufacture, and commercialize DARZALEX®.[14]
- In November 2015 DARZALEX® received initial U.S. FDA approval as a monotherapy for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy, including a proteasome inhibitor (PI) and an immunomodulatory agent, or who are double refractory to a PI and an immunomodulatory agent.[15]
- In November 2016 DARZALEX® received an additional approval in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy.[16]
- In June 2017, DARZALEX® received approval in combination with pomalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least two prior therapies, including lenalidomide and a PI.[17]
- In May 2018, DARZALEX® received approval in combination with bortezomib, melphalan, and prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for ASCT, making it the first monoclonal antibody approved for newly diagnosed patients with this disease.[18]
- In June 2019, DARZALEX® received approval in combination with lenalidomide and dexamethasone for the treatment of patients with newly diagnosed multiple myeloma who are transplant ineligible.[19]
- In September 2019, DARZALEX® received approval in combination with bortezomib, thalidomide, and dexamethasone for the treatment of newly diagnosed patients who are eligible for autologous stem cell transplant.[20]

- In April 2020, DARZALEX *FASPRO*™, a subcutaneous formulation of DARZALEX®, received approval for the treatment of certain patients with newly diagnosed or relapsed/refractory multiple myeloma, including in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant, in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy, in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy, as monotherapy, in patients who have received at least three prior lines of therapy including a PI and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.

Please see full Prescribing Information at www.DARZALEX.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.[21,22] When damaged, these plasma cells rapidly spread and replace normal cells with tumors in the bone marrow. In 2020, it is estimated that 32,270 people will be diagnosed and 12,830 will die from the disease in the U.S.[24] While some patients with multiple myeloma have no symptoms, most patients are diagnosed due to symptoms, which can include bone fracture or pain, low red blood cell counts, tiredness, high calcium levels, kidney problems or infections.[23]

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. 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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