News Release

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Janssen Submits Applications in U.S. and EU Seeking Approval of DARZALEX *FASPRO*™ (daratumumab and hyaluronidase-fihj)/ DARZALEX® (daratumumab) Subcutaneous (SC) Formulation in Combination With Pomalidomide and Dexamethasone for Patients With Relapsed or Refractory Multiple Myeloma

Applications supported by positive results from the Phase 3 APOLLO study, which demonstrated longer progression-free survival in patients receiving the subcutaneous formulation of daratumumab[1]

November 12, 2020 (RARITAN, N.J.) – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today the submission of regulatory applications to the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) seeking approval of the daratumumab subcutaneous (SC) formulation, known as DARZALEX *FASPRO*™ (daratumumab and hyaluronidase-fihj) in the U.S. and as DARZALEX® SC in the European Union (EU). The applications seek approval of the combination of DARZALEX *FASPRO*™/DARZALEX® SC in combination with pomalidomide and dexamethasone (D-Pd) for the treatment of patients with relapsed or refractory multiple myeloma who have received at least one prior line of therapy. As a fixed-dose formulation, DARZALEX

FASPRO™/DARZALEX® SC can be administered over approximately three to five minutes, significantly less time than the intravenous (IV) formulation of DARZALEX®, which is given over several hours.

The supplemental Biologics License Application (sBLA) to the U.S. FDA and Type II variation application to the EMA are supported by positive findings from the Phase 3 APOLLO study (MMY3013), which met its primary endpoint of significantly longer progression-free survival (PFS) in patients with relapsed or refractory multiple myeloma who received D-Pd compared with Pd alone.[2]

Full results from the Phase 3 APOLLO study, a collaboration between Janssen Research & Development, LLC and the European Myeloma Network (EMN), will be presented in an oral session at the upcoming American Society of Hematology (ASH) Annual Meeting on Sunday, December 6, 2020 at 3:00 p.m. ET (Abstract #412).

The D-Pd regimen received approval from the U.S. FDA for the IV formulation of DARZALEX® in 2017 for patients who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor.[3] This regimen for the IV formulation is not approved for use in Europe by the EMA.

"The IV formulation of DARZALEX, which is approved in combination with pomalidomide and dexamethasone, is an important option for patients with multiple myeloma. We are excited to pursue the subcutaneous formulation of DARZALEX for this indication as we look to reduce administration time from hours to minutes compared with the IV formulation," said Craig Tendler, M.D., Vice President, Late Development and Global Medical Affairs, Oncology, Janssen Research & Development, LLC. "Today's regulatory milestones represent our continued commitment to advance innovative treatments for people living with multiple myeloma."

DARZALEX® was first approved as a monotherapy for the treatment of multiple myeloma in 2015 in the U.S. and in 2016 in the EU, making it the first anti-CD38 monoclonal antibody approved anywhere in the world for multiple myeloma.[3,4] In 2020, DARZALEX *FASPRO*™/DARZALEX® SC was approved by the U.S. FDA and the European Commission (EC) as the only CD38-directed antibody approved to be given subcutaneously to treat patients with multiple myeloma.[5,6] DARZALEX *FASPRO*™/DARZALEX® SC is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology. As of 2020, daratumumab has been

approved by global regulatory authorities across six combination regimens and as a monotherapy for the treatment of newly diagnosed patients, across relapsed and refractory multiple myeloma.[10,11,12,13,14,15]

"Despite strong progress in multiple myeloma over the last decade, it remains a disease with significant unmet need," said Catherine Taylor, M.D., Vice President, Medical Affairs Therapeutic Area Strategy, Europe, Middle East and Africa (EMEA), Johnson & Johnson Middle East FZ-LLC. "We are pleased to pursue this important DARZALEX-based combination regimen, which was in the first study showing a significant increase in progression-free survival of a subcutaneous anti-CD38 in combination with pomalidomide and dexamethasone in patients with previously treated multiple myeloma."

About the APOLLO Study[1]

APOLLO (NCT01960348) is an ongoing multicenter, Phase 3, randomized, open-label study comparing DARZALEX *FASPRO*™/DARZALEX® SC in combination with pomalidomide and low-dose dexamethasone with pomalidomide and low-dose dexamethasone alone in patients with relapsed or refractory multiple myeloma who have received at least one prior treatment regimen, have received both lenalidomide and a proteasome inhibitor, and have demonstrated disease progression. The study enrolled 304 participants. The primary endpoint is PFS between treatment arms. Secondary endpoints include rates of overall response (ORR), very good partial response (VGPR) or better, complete response (CR) or better, and duration of response.

About DARZALEX *FASPRO*™/DARZALEX® SC

In August 2012, Janssen Biotech, Inc. and Genmab A/S entered a worldwide agreement, which granted Janssen an exclusive license to develop, manufacture and commercialize daratumumab. Since launch, it is estimated that more than 154,000 patients have been treated with daratumumab worldwide.[7] DARZALEX *FASPRO*™/DARZALEX® SC is the only CD38-directed antibody approved to be given subcutaneously to treat patients with multiple myeloma.

CD38 is a surface protein that is present in high numbers on multiple myeloma cells, regardless of the stage of disease.[9] Daratumumab binds to CD38 and inhibits tumor cell growth, causing myeloma cell death.[8] Daratumumab may also have an effect on normal cells.[9] Data across seven Phase 3 clinical trials, in both the frontline and relapsed settings, have shown that daratumumab-based regimens resulted in significant improvement in progression-free survival and/or overall survival.[10,11,12,13,14,15,16,17] Additional studies are underway to assess the efficacy and safety of

DARZALEX *FASPRO*™/DARZALEX® SC in the treatment of other malignant and pre-malignant hematologic diseases in which CD38 is expressed, including smoldering myeloma and light chain (AL) amyloidosis.[18,19]

For the full U.S. Prescribing Information, please visit www.DARZALEX.com. For the full EU Summary of Product Characteristics, please click here.

DARZALEX *FASPRO*™ IMPORTANT SAFETY INFORMATION (US)

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 tract infection. The most common adverse reactions with combination therapy (≥20% for any combination) include fatigue, nausea, diarrhea, dyspnea, insomnia, pyrexia, cough, muscle spasms, back pain, vomiting, upper respiratory tract infection, peripheral sensory neuropathy, constipation, and pneumonia.

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.

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, www.twitter.com/JanssenUS, and www.twitter.com/janssenEMEA. Janssen Biotech, Inc., Janssen Research & Development, LLC and Janssen-Cilag 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., Janssen-Cilag and any of the other Janssen Pharmaceutical Companies 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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