News Release

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Janssen Submits Application Seeking U.S. FDA Approval of DARZALEX *FASPRO*™ (daratumumab and hyaluronidase-fihj) for the Treatment of Patients with Light Chain (AL) Amyloidosis

Application is based on positive results from the Phase 3 ANDROMEDA study evaluating the efficacy and safety of combination therapy with DARZALEX FASPRO™

RARITAN, NJ, September 10, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today the submission of a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) seeking approval of DARZALEX *FASPRO*™ (daratumumab and hyaluronidase-fihj), a subcutaneous formulation of daratumumab, for the treatment of patients with light chain (AL) amyloidosis, a rare and potentially fatal disease for which there are no currently approved therapies.[1,2] The sBLA is supported by positive results from the Phase 3 ANDROMEDA study, which were presented as a late-breaking abstract at the 25th European Hematology Association Annual Congress in June. ANDROMEDA evaluated subcutaneous daratumumab in combination with bortezomib, cyclophosphamide and dexamethasone (D-VCd)

compared to VCd alone and met its primary endpoint of overall hematologic complete response rate.

"We are excited about the potential of helping patients with AL amyloidosis who currently have no FDA-approved therapies for the treatment of their disease," said Craig Tendler, M.D., Vice President, Clinical Development and Global Medical Affairs, Oncology, Janssen Research & Development, LLC. "The results from the Phase 3 ANDROMEDA study also provide preliminary evidence of DARZALEX *FASPRO*'s potential to modify the organ damage that is a hallmark of this serious disease with high unmet needs and we look forward to collaborating with the agency in the review of the application."

The sBLA is being reviewed under the FDA Real-Time Oncology Review (RTOR) program, which allows data for certain applications to be reviewed before the applicant formally submits the complete application. The RTOR program aims to explore a more efficient review process to help ensure treatments are available as soon as possible for patients. Selection into the RTOR program does not guarantee or influence approvability of the supplemental application.

The submission is also being reviewed under Project Orbis, an initiative of the FDA Oncology Center of Excellence, which provides a framework for concurrent submission and review of oncology medicine applications among international regulatory agencies.[3]

AL amyloidosis is a life-threatening disorder that occurs when plasma cells in the bone marrow produce abnormal light chains, that form amyloid deposits, which build up in vital organs and eventually cause organ deterioration.[1,2] The disease can affect different organs in different people, but the most frequently affected organs are the heart, kidneys, liver, spleen, GI tract and nervous system.[4] Diagnosis of AL amyloidosis is often delayed because patients present with non-specific symptoms that mimic other conditions, resulting in a poor prognosis.[5] There are currently no FDA-approved therapies to treat this devastating disease. While AL amyloidosis is the most common type of amyloidosis, it remains a rare disease with an estimated 30,000 to 45,000 people living with the disease in the U.S. and Europe.[6] Each year, an estimated 4,500 people develop AL amyloidosis in the U.S. alone.[6]

About the ANDROMEDA Study[7]

ANDROMEDA (NCT03201965) is an ongoing Phase 3, randomized, open-label study investigating the safety and efficacy of daratumumab and hyaluronidase-fihj in combination with bortezomib,

cyclophosphamide and dexamethasone (D-VCd), compared to VCd alone, for the treatment of patients with newly diagnosed light chain (AL) amyloidosis. The study includes 388 patients with newly diagnosed AL amyloidosis with measurable hematologic disease and one or more organs affected. The primary endpoint is overall complete hematologic response rate by intent-to-treat (ITT). Secondary endpoints include major organ deterioration progression-free survival, event-free survival, organ response rate, overall survival, and time to hematologic response, among others.

About DARZALEX *FASPRO*™

Janssen is committed to exploring the potential of DARZALEX *FASPRO*™ (daratumumab and hyaluronidase-fihj) for patients with multiple myeloma (MM) across the spectrum of the disease.

In August 2012, Janssen entered into an exclusive global license and development agreement with Genmab A/S to develop, manufacture and commercialize DARZALEX®.[8] In 2020, DARZALEX *FASPRO*™ (daratumumab and hyaluronidase human-fihj) was approved as the only subcutaneous CD38-directed antibody approved to treat patients with MM.[9] 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] Daratumumab binds to CD38 and inhibits tumor cell growth causing myeloma cell death.[5] DARZALEX *FASPRO*™ may also have an effect on normal cells.[10] 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.[11,12,13,14,15,16,17,18] 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.[19,20]

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 tract 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.

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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