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Data from the APOLLO Study Show Clinically Meaningful Response with DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) Regimen After First or Subsequent Relapse in Multiple Myeloma

Results featured at ASH 2020 represent the first and only subcutaneous anti-CD38 in combination with pomalidomide and dexamethasone

December 4, 2020 (RARITAN, N.J.) – The Janssen Pharmaceutical Companies of Johnson & Johnson announced results of the Phase 3 APOLLO study showing that the addition of DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) to pomalidomide and dexamethasone (D-Pd) significantly reduced the risk of progression or death by 37 percent, compared to Pd alone in patients with multiple myeloma after the first or subsequent relapse of disease.[1] The APOLLO results, which will be presented on Sunday, December 6 at 3:00 p.m. EST during the American Society of Hematology (ASH) 2020 Annual Meeting and featured in the ASH press briefing today (Abstract #412), add to the body of evidence supporting treatment with DARZALEX *FASPRO*® -based regimens for patients with relapsed multiple myeloma.

These data were the basis for recent regulatory submissions in the U.S. and Europe seeking approval for DARZALEX *FASPRO*® in the U.S., known as DARZALEX® SC in the European Union, in

combination with Pd for the treatment of patients with relapsed or refractory multiple myeloma.[2] The APOLLO study represents the ninth positive Phase 3 study for daratumumab.

"For patients with multiple myeloma who relapse, it is important that efficacious treatments significantly reduce the risk of progression. The data presented at ASH makes D-Pd a compelling treatment option for early relapsed or refractory patients," said Meletios A. Dimopoulos, M.D., Professor and Chairman of the Department of Clinical Therapeutics at the National and Kapodistrian University of Athens School of Medicine, Athens, Greece, and principal investigator. "The APOLLO study also highlights the potential benefits of the subcutaneous formulation of daratumumab, which offers patients and physicians a three- to five-minute administration experience and the potential to reduce systemic administration-related reactions compared to intravenous administration of daratumumab."

Key Findings from the APOLLO Oral Presentation (Abstract #412):

- The study met its primary endpoint of improved progression-free survival (PFS). [1] When added to Pd, DARZALEX *FASPRO*® significantly reduced the risk of progression or death by 37 percent, compared to Pd alone (hazard ratio, 0.63; 95 percent confidence interval, 0.47-0.85; *P*=0.0018). [1] The median PFS for the D-Pd arm vs Pd arm was 12.4 vs. 6.9 months, respectively. [1]
- Response rates were significantly higher with D-Pd compared to Pd alone, including rates of overall response (69 percent vs. 46 percent), rates of very good partial response (VGPR) or better (51 percent vs. 20 percent), over six times the rate of complete response (CR) (25 percent vs. 4 percent) and over four times the rate of minimal residual disease-negativity (9 percent vs. 2 percent). [1]
- The rate of infusion-related reactions with DARZALEX *FASPRO*® was 5 percent (all Grade 1/2), and 2 percent of patients had local injection-site reactions (all Grade 1). Median duration of injection was five minutes. [1] Both of these parameters are in line with what is expected for DARZALEX *FASPRO*®.
- The rates of study treatment discontinuation due to treatment emergent adverse events were similar for D-Pd vs. Pd (2 percent vs. 3 percent). [1] The safety profile of D-Pd is consistent with known profiles of DARZALEX *FASPRO*® and Pd.

"We are encouraged by the efficacy of this combination with DARZALEX *FASPRO*, which has improved outcomes over pomalidomide-dexamethasone, a widely used regimen for patients with relapsed or refractory myeloma who have received prior treatment with lenalidomide," said Craig

Tendler, M.D., Vice President, Late Development and Global Medical Affairs, Janssen Research & Development, LLC. "Together with the reduced administration time for patients receiving DARZALEX *FASPRO* as compared to the intravenous formulation, the APOLLO study results further solidify this differentiated anti-CD38 monoclonal antibody as a backbone treatment in multiple myeloma for patients who are in need of additional treatment options."

About the APOLLO Study[3]

APOLLO (NCT01960348) is an ongoing multicenter, Phase 3, randomized, open-label study comparing daratumumab and hyaluronidase-fihj, 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 with both lenalidomide and a proteasome inhibitor and have demonstrated disease progression. The study, which was conducted in collaboration with the European Myeloma Network, enrolled 304 participants.

The primary endpoint is PFS between treatment arms. Secondary endpoints include rates of overall response rate (ORR), VGPR or better, CR or better and duration of response, among others. The study reinforces findings from the Phase 1b EQUULEUS (MMY1001) trial, which formed the grounds for Food and Drug Administration (FDA) approval of intravenous DARZALEX® in combination with pomalidomide and dexamethasone in 2017 for the treatment of relapsed and refractory multiple myeloma. In November 2020, Janssen submitted regulatory applications to the FDA and European Medicines Agency (EMA) seeking 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.

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 150,000 patients have been treated with daratumumab worldwide.[4] DARZALEX *FASPRO*® 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. Daratumumab binds to CD38 and inhibits tumor cell growth, causing myeloma cell death.[5] Daratumumab may also have an effect on normal cells.[6] Data across nine Phase 3 clinical trials in multiple myeloma and AL amyloidosis, 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.[7,8,9,10,11,12,13,14] 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 light chain (AL) amyloidosis.[15,16]

For the full U.S. Prescribing Information, please visit 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.[17,18] When damaged, these plasma cells rapidly spread and replace normal cells with tumors in the bone marrow. In 2020, it is estimated that more than 32,000 people will be diagnosed and close to 13,000 will die from the disease in the U.S.[19] 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.[19]

DARZALEX *FASPRO*™ is a prescription medicine used to treat adult patients with multiple myeloma:

- in combination with the medicines bortezomib, melphalan, and prednisone in people with newly diagnosed multiple myeloma who cannot receive a type of stem cell transplant that uses their own stem cells (autologous stem cell transplant)
- in combination with the medicines lenalidomide and dexamethasone in people with newly diagnosed multiple myeloma who cannot receive a type of stem cell transplant that uses their own stem cells (autologous stem cell transplant) and in people whose multiple myeloma has come back or did not respond to treatment, who have received at least one prior medicine to treat multiple myeloma
- in combination with the medicines bortezomib and dexamethasone in people who have received at least one prior medicine to treat multiple myeloma
- alone in people who have received at least three prior medicines, including a proteasome inhibitor and an immunomodulatory agent, or did not respond to a proteasome inhibitor and an immunomodulatory agent

It is not known if DARZALEX *FASPRO*™ is safe and effective in children

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 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 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™ *DARZALEX® SC. 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 Research & Development, LLC , or 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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