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Updated Data Demonstrate Significant Improvement in Hematologic Complete Response with DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) in Patients with Newly Diagnosed Light Chain (AL) Amyloidosis

Further analysis from the Phase 3 ANDROMEDA study presented at the 2021 ASCO Annual Meeting also show doubling rates of organ response with no new safety signals for the first FDA-approved treatment in a rare blood cell disorder

RARITAN, N.J., May 26, 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced updated results from the Phase 3 ANDROMEDA study, which evaluated DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) for the treatment of patients with newly diagnosed light chain (AL) amyloidosis, a rare blood cell disorder associated with the deterioration of vital organs, most notably the heart, kidneys and liver.[1] Longer-term results from a median follow-up of 20.3 months showed rates of hematologic complete response (hemCR) remained significantly higher in patients treated with DARZALEX *FASPRO*® in combination with bortezomib (VELCADE®), cyclophosphamide and dexamethasone (D-VCd) compared to VCd alone (Abstract #8003).[2] These data will be featured in an oral presentation at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting on Tuesday, June 8.

"Patients with AL amyloidosis, including those with advanced organ dysfunction, often face poor outcomes, and as many as 30 percent die within the first year of diagnosis," said Efstathios Kastritis, M.D.*, Professor of Clinical Therapeutics at the National and Kapodistrian University of Athens School of Medicine, Athens, Greece and study investigator. "The longer-term results from the ANDROMEDA study show sustained overall deep hematologic responses and further establish the subcutaneous formulation of daratumumab as part of a new standard of care regimen in

patients with AL amyloidosis, and I'm also encouraged to see additional investigational data showing cardiac and renal responses in these patients."

Earlier findings from the Phase 3 study supported the U.S. Food and Drug Administration's (FDA) accelerated approval of DARZALEX *FASPRO*® in combination with VCd, representing the first-ever FDA-approved therapy for the treatment of AL amyloidosis. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). DARZALEX *FASPRO*® is not indicated and is not recommended for the treatment of patients with AL amyloidosis who have NYHA Class IIIB or Class IV cardiac disease or Mayo Stage IIIB outside of controlled clinical trials.

"These updated efficacy and safety results show the potential impact DARZALEX *FASPRO* can have in treating AL amyloidosis," said Jessica Vermeulen, M.D., Ph.D., Vice President, Clinical Development, Janssen Research & Development, LLC. "Following the FDA approval earlier this year, these latest data are a result of our commitment to further exploring the potential of DARZALEX in hematologic and rare diseases for patients in need of new options."

Key Findings from the ANDROMEDA Oral Presentation (Abstract #8003):

- In the study comparing D-VCd (n=193) to VCd (n=188), the primary endpoint, hemCR, remained significantly higher with D-VCd compared to VCd, increasing from 53 percent vs. 18 percent (at median follow-up of 11.4 months) to 59 percent vs. 19 percent (at 20.3 months).[2] At 20.3 months median follow-up, more patients achieved a very good partial response or better (≥VGPR) with D-VCd than VCd (79 percent vs. 50 percent).[2]
    - Median time from randomization to ≥VGPR was shorter in patients receiving D-VCd compared to VCd.[2]
- Among cardiac responders treated with D-VCd (n=118) compared to VCd (n=117), response rates increased from 42 percent to 57 percent at 12 months for those treated with D-VCd compared to an increase of 22 percent to 28 percent at 12 months for VCd.[2]
- Among patients who had renal responses treated with D-VCd (n=117) compared to VCd(n=113), rates remained stable increasing from 54 percent to 57 percent at 12 months for those treated with D-VCd and remaining at 27 percent at 12 months for VCd.

At longer-term follow-up, no new safety signals were observed for DARZALEX *FASPRO*®.[2] The most common adverse reactions (≥25 percent) were diarrhea, peripheral edema, constipation,

peripheral sensory neuropathy, fatigue, nausea, upper respiratory tract infection and insomnia. Grade 3 or 4 treatment emergent adverse events (TEAE) occurred in ≥5% of patients and included diarrhea, peripheral edema, lymphopenia, neutropenia, pneumonia, syncope and cardiac failure. From cycle 7 onward, no Grade 3 or 4 TEAEs occurred in ≥5% of patients.[2]

About the ANDROMEDA Study[2]

ANDROMEDA (NCT03201965) is an ongoing Phase 3, randomized, open-label study investigating the safety and efficacy of DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) in combination with bortezomib, cyclophosphamide and dexamethasone (D-VCd), compared to VCd alone, for the treatment of adult 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). Patients received DARZALEX *FASPRO*® 1,800 mg/ 30,000 units administered subcutaneously once weekly from weeks one to eight, once every two weeks from weeks nine to 24 and once every four weeks starting with week 25 until disease progression or unacceptable toxicity or a maximum of two years. Among patients who received D-VCd, 74 percent were exposed for 6 months or longer and 32 percent were exposed for greater than one year.

About DARZALEX *FASPRO*®

In August 2012, Janssen Biotech, Inc. and Genmab A/S entered into a worldwide agreement, which granted Janssen an exclusive license to develop, manufacture and commercialize daratumumab. DARZALEX *FASPRO*® is the only CD38-directed antibody approved to be given subcutaneously to treat patients with multiple myeloma and now AL amyloidosis. DARZALEX *FASPRO*® is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology.

DARZALEX *FASPRO*® is indicated for the treatment of adult patients with multiple myeloma:

- 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, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant

- 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

DARZALEX FASPRO® in combination with bortezomib, cyclophosphamide, and dexamethasone is indicated for the treatment of adult patients with newly diagnosed light chain (AL) amyloidosis. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Limitations of Use

DARZALEX FASPRO® is not indicated and is not recommended for the treatment of patients with light chain (AL) amyloidosis who have NYHA Class IIIB or Class IV cardiac disease or Mayo Stage IIIB outside of controlled clinical trials.

Full prescribing information will be available at www.DARZALEX.com.

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.[3,4] 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.[5] Diagnosis is often delayed and prognosis is poor due to advanced, multi-organ, particularly cardiac, involvement.[6,7] Each year, an estimated 4,500 people develop AL amyloidosis in the U.S. alone.[8]

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[2]

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 683 patients with multiple myeloma (N=490) or light chain (AL) amyloidosis (N=193) who received DARZALEX *FASPRO*™ as monotherapy or in combination, 10% of patients experienced a systemic administration-related reaction (Grade 2: 3.5%, Grade 3: 1%). Systemic administration-related reactions occurred in 9% of patients with the first injection, 0.4% with the second injection, and cumulatively 1% with subsequent injections. The median time to onset was 3.2 hours (range: 9 minutes to 3.5 days). Of the 117 systemic administration-related reactions that occurred in 66 patients, 100 (85%) occurred on the day of DARZALEX *FASPRO*™ administration. Delayed systemic administration-related reactions have occurred in 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 9% of patients, including Grade 2 reactions in 0.7%. The most frequent (>1%) injection-site reaction was injection site erythema. These local reactions occurred a median of 5 minutes (range: 0 minutes to 4.7 days) after starting administration of DARZALEX *FASPRO*™. Monitor for local reactions and consider symptomatic management.

Cardiac Toxicity in Patients with Light Chain (AL) Amyloidosis[2]

Serious or fatal cardiac adverse reactions occurred in patients with light chain (AL) amyloidosis who received DARZALEX *FASPRO*™ in combination with bortezomib, cyclophosphamide and dexamethasone. Serious cardiac disorders occurred in 16% and fatal cardiac disorders occurred in 10% of patients. Patients with NYHA Class IIIA or Mayo Stage IIIA disease may be at greater risk. Patients with NYHA Class IIIB or IV disease were not studied. Monitor patients with cardiac involvement of light chain (AL) amyloidosis more frequently for cardiac adverse reactions and administer supportive care as appropriate.

Neutropenia[2]

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[2]

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[2]

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[2]

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[2]

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[2]

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 adverse reactions (≥20%) in patients with light chain (AL) amyloidosis who received DARZALEX *FASPRO*™ are upper respiratory tract infection, diarrhea, peripheral edema, constipation, fatigue, peripheral sensory neuropathy, nausea, insomnia, dyspnea, and cough.

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 Biotech, Inc., Janssen Research & Development, LLC and Janssen Biologics B.V. are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

*Dr. Kastritis has served as a consultant to Janssen; he has not been paid for any media work.

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 Biologics B.V., 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 January 3, 2021, 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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