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**Janssen Submits Application to U.S. FDA Seeking Approval of New DARZALEX®
(daratumumab) Subcutaneous Formulation**

Submission inclusive of data from Phase 3 COLUMBA study presented at ASCO

RARITAN, NJ, July 12, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) seeking approval of a new subcutaneous (SC) formulation of DARZALEX® (daratumumab), an intravenous (IV) treatment approved for certain patients with multiple myeloma.

The submission is supported by data from the Phase 3 COLUMBA ([MMY3012](#)) study first [presented](#) at the American Society of Clinical Oncology (ASCO) Annual Meeting that included a non-inferiority comparison to DARZALEX IV administration for co-primary endpoints of overall response rate and maximum C_{trough} concentration. Data from the Phase 2 PLEIADES ([MMY2040](#)) study are also included in the BLA. The subcutaneous formulation of DARZALEX is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20) [Halozyme's ENHANZE® drug delivery technology].

“This submission represents our commitment to develop innovative treatment options for people living with multiple myeloma,” said Craig Tendler, M.D., Vice President, Clinical Development and Global Medical Affairs, Oncology, Janssen Research & Development, LLC. “The DARZALEX subcutaneous formulation showed non-inferiority to the existing IV formulation, both as a monotherapy and in combination with common background therapies, while administered with a considerably shorter infusion time. We look forward to working closely with the FDA in their review of the data supporting this regulatory application.”

Today’s submission follows two recent milestones for the DARZALEX intravenous formulation, including an [approval](#) of DARZALEX in combination with lenalidomide and dexamethasone for the treatment of newly diagnosed, transplant ineligible patients with multiple myeloma supported by the Phase 3 MAIA study, and Priority Review designation following submission of a supplemental BLA based on the [Phase 3 CASSIOPEIA](#) study, which is seeking approval of DARZALEX in combination with bortezomib, thalidomide and dexamethasone for newly diagnosed patients with multiple myeloma who are transplant eligible.

About the COLUMBA Study (MMY3012)¹

The randomized, open-label, multicenter Phase 3 COLUMBA study included 522 patients 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 (median age of 67). In the arm that received the SC formulation of DARZALEX (n=263), patients received a fixed dose of DARZALEX 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 DARZALEX IV arm (n=259), patients received DARZALEX for IV 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 the SC formulation, DARZALEX was given as a fixed volume over 3 – 5 minutes. In the arm that received the IV administration, the median durations of the first, second and subsequent DARZALEX IV infusions were 7.0, 4.3 and 3.4 hours, respectively. Patients in both treatment arms continued until disease progression or unacceptable toxicity.

About the PLEIADES Study (MMY2040)²

The non-randomized, open-label, parallel assignment Phase 2 PLEIADES study included 240 adults either newly diagnosed or with relapsed or refractory multiple myeloma. Patients with newly diagnosed multiple myeloma were treated with 1,800 mg of the SC formulation in combination with either bortezomib, lenalidomide and dexamethasone (D-VRd) or bortezomib, melphalan, and prednisone (D-VMP). Patients with relapsed or refractory disease were treated with 1,800 mg of the SC formulation plus lenalidomide and dexamethasone (D-Rd). The primary endpoint for the D-VMP and D-Rd cohorts was overall response rate. The primary endpoint for the D-VRd cohort was very good partial response or better rate. An additional cohort of patients with relapsed and refractory multiple myeloma treated with daratumumab plus carfilzomib and dexamethasone was subsequently added to the study.

About DARZALEX[®] (daratumumab)

DARZALEX[®] (daratumumab), the first CD38-directed antibody approved anywhere in the world, is the only CD38-directed antibody approved to treat multiple myeloma.³ 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.³ DARZALEX may also have an effect on normal cells.³ DARZALEX is being evaluated in a comprehensive clinical development program across a range of treatment settings in multiple myeloma, such as in frontline and relapsed settings.^{5,6,7,8,9,10,11,12} Additional studies are ongoing or planned to assess its potential in other malignant and pre-malignant hematologic diseases in which CD38 is expressed, such as smoldering myeloma.^{13,14}

In the United States, DARZALEX received initial FDA approval in [November 2015](#) as a monotherapy for patients with multiple myeloma who have received at least three prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent, or who are double refractory to a PI and an immunomodulatory agent.¹⁵ DARZALEX received additional approvals in [November 2016](#) 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 autologous stem cell transplant (ASCT), making it the first monoclonal antibody approved for newly diagnosed patients with this disease.¹⁸ Most recently, in [June 2019](#), DARZALEX was approved in combination with lenalidomide and dexamethasone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for ASCT.¹⁹ More than 80,000 patients have been treated with DARZALEX worldwide.

In [August 2012](#), Janssen Biotech, Inc. entered into a global license and development agreement with Genmab A/S, which granted Janssen an exclusive license to develop, manufacture and commercialize DARZALEX.²⁰ 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.^{21,22} When damaged, these plasma cells rapidly spread and replace normal cells with tumors in the bone marrow.^{22,23} In 2019, it is estimated that more than 32,000 people will be diagnosed, and nearly 13,000 will die from the disease in the United States.²³ 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 counts, tiredness, high calcium levels, kidney problems or infections.²⁴

IMPORTANT SAFETY INFORMATION³

CONTRAINDICATIONS

DARZALEX[®] (daratumumab) is contraindicated in patients with a history of severe hypersensitivity (eg, 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 $\geq 20\%$) 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 ($\geq 20\%$) 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%), decreased appetite (22%), and peripheral sensory neuropathy (24%) were also reported. In newly diagnosed patients, serious adverse reactions ($\geq 2\%$ compared to Rd) were dehydration (2%), bronchitis (4%), and pneumonia (15%), and treatment-emergent Grade 3-4 hematology laboratory abnormalities ($\geq 20\%$) were leukopenia (35%), neutropenia (56%), and lymphopenia (52%). In relapsed/refractory patients, serious adverse reactions ($\geq 2\%$ 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 ($\geq 20\%$) were neutropenia (53%) and lymphopenia (52%).

DARZALEX® in combination with bortezomib, melphalan, and prednisone (DVMP): The most frequently reported adverse reactions ($\geq 20\%$) were upper respiratory tract infection (48%), infusion reactions (28%), and peripheral edema (21%). Serious adverse reactions ($\geq 2\%$ 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 ($\geq 20\%$) were lymphopenia (58%), neutropenia (44%), and thrombocytopenia (38%).

DARZALEX[®] in combination with bortezomib and dexamethasone (DVd): The most frequently reported adverse reactions ($\geq 20\%$) 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 ($\geq 2\%$ compared to Vd) were upper respiratory tract infection (5%), diarrhea (2%), and atrial fibrillation (2%). Treatment-emergent Grade 3-4 hematology laboratory abnormalities ($\geq 20\%$) were lymphopenia (48%) and thrombocytopenia (47%).

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 $\geq 5\%$ of patients included pneumonia (7%). Treatment-emergent Grade 3-4 hematology laboratory abnormalities ($\geq 20\%$) were anemia (30%), neutropenia (82%), and lymphopenia (71%).

DARZALEX[®] as monotherapy: The most frequently reported adverse reactions ($\geq 20\%$) 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 ($\geq 20\%$) were lymphopenia (40%) and neutropenia (20%).

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 members 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 the benefits of DARZALEX® (daratumumab) for the treatment of patients with multiple myeloma. 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, 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 30, 2018, 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. Neither the Janssen Pharmaceutical Companies of Johnson & Johnson 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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³ DARZALEX Prescribing Information, June 27, 2019.

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