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**Phase 3 COLUMBA Study Investigating a Subcutaneous Formulation of DARZALEX®
(daratumumab) Showed Non-Inferiority to Intravenous Administration in Patients with
Relapsed/Refractory Multiple Myeloma**

New formulation also showed shorter administration time and lower rate of infusion-related reactions

CHICAGO, June 2, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today results from the Phase 3 COLUMBA ([MMY3012](#)) study, investigating a subcutaneously (SC) administered formulation of DARZALEX® (daratumumab), co-formulated with recombinant human hyaluronidase PH20 (rHuPH20) [Halozyme’s ENHANZE® drug delivery technology], in patients with relapsed/refractory multiple myeloma. The results showed non-inferior efficacy and pharmacokinetics for the SC administered formulation of DARZALEX compared to intravenous (IV) administration, the only currently approved formulation of DARZALEX ([abstract #8005](#)).¹ The data presentation – the first for this Phase 3 study with SC formulation – is being featured in an oral session at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, and was selected for the [Best of ASCO 2019 Meetings](#), which highlight cutting-edge science and reflect leading research in oncology.

“This study showed that the subcutaneous formulation of daratumumab resulted in non-inferior pharmacokinetics and efficacy compared to the current intravenous formulation, and also importantly offers the potential for a fixed-dose administration, shorter infusion times and a lower rate of infusion-related reactions,” said Maria-Victoria Mateos, M.D., Ph.D., COLUMBA primary investigator and Director of the Myeloma Unit at University Hospital of Salamanca-IBSAL, Salamanca, Spain. “Daratumumab IV has proven to be an important medication in the treatment of multiple myeloma, and a new subcutaneous formulation may offer patients a different experience, including a shorter administration time.”

At a median follow-up of 7.5 months, the overall response rate (ORR) was 41 percent for the SC administered formulation of DARZALEX compared to 37 percent for DARZALEX IV (95 percent confidence interval [CI], 1.11 (0.89-1.37); $P < 0.0001$).¹ The ORR was similar across all clinically relevant subgroups, including body weight.¹ The ratio of geometric means of C_{trough} for the SC administered formulation of DARZALEX over DARZALEX IV was 108 percent (90 percent CI, 96 percent -122 percent).¹ The progression-free survival was comparable between the SC administered formulation of DARZALEX and the current IV formulation of DARZALEX (Hazard Ratio [HR] = 0.99; 95 percent CI, 0.78-1.26; $P < 0.9258$).¹ The median duration for each SC injection was 5 minutes, compared to more than 3 hours with IV infusions.¹

The most common (>5%) Grade 3/4 treatment-emergent adverse events (TEAEs) for the SC administered formulation of DARZALEX compared to DARZALEX IV were thrombocytopenia (14 percent vs. 14 percent), anemia (13 percent vs. 14 percent) and neutropenia (13 percent vs. 8 percent), respectively.¹ A lower rate of infusion-related reactions was observed in the arm that received the SC administered formulation of DARZALEX compared to DARZALEX IV (13 percent vs. 35 percent, respectively) (Odds Ratio = 0.28; 95 percent CI, 0.18-0.44; $P < 0.0001$).¹ The primary reasons for treatment discontinuation included progressive disease (43 percent in the SC arm vs. 44 percent in the IV arm) and adverse events (7 percent in the SC arm vs. 8 percent in the IV arm).¹

“We are always exploring new ways to help patients, and these compelling findings reinforce the potential for a new route of administration for DARZALEX,” said Mark Wildgust, Ph.D., Vice President, Global Medical Affairs, Oncology, Janssen Research & Development, LLC. “We look forward to pursuing regulatory submissions for this formulation and hopefully expanding the reach of DARZALEX for patients who may be candidates for this novel formulation.”

About the COLUMBA Trial¹Error! Bookmark not defined.

The randomized, open-label, multicenter Phase 3 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 administered 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 intravenous 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 administered formulation, DARZALEX was given as 15 mL over 3-5 minutes at alternating left/right abdominal sites. Patients in both treatment arms continued until disease progression or unacceptable toxicity.

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.² CD38 is a surface protein that is present in high numbers on multiple myeloma cells, regardless of the stage of disease.³ DARZALEX binds to CD38 and inhibits tumor cell growth causing myeloma cell death.² DARZALEX may also have an effect on normal cells.² 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.^{4,5,6,7,8,9,10,11} 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.^{12,13}

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 (PI) and an immunomodulatory agent, or who are double refractory to a PI and an immunomodulatory agent.¹⁴ 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.¹⁵ 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.¹⁶ 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 ASCT, making it the first monoclonal antibody approved for newly diagnosed patients with this disease.¹⁷ 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.¹⁸ 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.^{19,20} When damaged, these plasma cells rapidly spread and replace normal cells with tumors in the bone marrow.^{20,21} 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.²¹ 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.²²

IMPORTANT SAFETY INFORMATION²

CONTRAINDICATIONS

DARZALEX[®] is contraindicated in patients with a history of severe hypersensitivity (e.g., 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 an infusion. 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 – DARZALEX[®] 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. DARZALEX[®] dose delay may be required to allow recovery of neutrophils. No dose reduction of DARZALEX[®] is recommended. Consider supportive care with growth factors.

Thrombocytopenia – DARZALEX[®] may increase thrombocytopenia induced by background

therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. DARZALEX® dose delay may be required to allow recovery of platelets. No dose reduction of DARZALEX® is recommended. Consider supportive care with transfusions.

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 $\geq 20\%$) in clinical trials were: infusion reactions, neutropenia, thrombocytopenia, fatigue, nausea, diarrhea, constipation, vomiting, muscle spasms, arthralgia, back pain, pyrexia, chills, dizziness, insomnia, cough, dyspnea, peripheral edema, peripheral sensory neuropathy and upper respiratory tract infection.

In patients who received DARZALEX® in combination with bortezomib, melphalan, and prednisone (DVMP), the most frequently reported adverse reactions (incidence $\geq 20\%$) 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%).

In patients who received DARZALEX® in combination with lenalidomide and dexamethasone, the most frequently reported adverse reactions (incidence $\geq 20\%$) were: upper respiratory tract infection (65%), infusion reactions (48%), diarrhea (43%), fatigue (35%), cough (30%), muscle spasms (26%), nausea (24%), dyspnea (21%) and pyrexia (20%). The overall incidence of serious adverse reactions was 49%. Serious adverse reactions ($\geq 2\%$ compared to Rd) were pneumonia (12%), upper respiratory tract infection (7%), influenza (3%), and pyrexia (3%). Treatment-emergent Grade 3-4 hematology laboratory abnormalities $\geq 20\%$ were neutropenia (53%) and lymphopenia (52%).

In patients who received DARZALEX® in combination with bortezomib and dexamethasone, the

most frequently reported adverse reactions (incidence $\geq 20\%$) 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%).

In patients who received DARZALEX[®] in combination with pomalidomide and dexamethasone, 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 $\geq 5\%$ patients included pneumonia (7%). Treatment-emergent hematology Grade 3-4 laboratory abnormalities $\geq 20\%$ were anemia (30%), neutropenia (82%), and lymphopenia (71%).

In patients who received DARZALEX[®] as monotherapy, the most frequently reported adverse reactions (incidence $\geq 20\%$) 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%).

DRUG INTERACTIONS

Effect of Other Drugs on Daratumumab: The coadministration of lenalidomide, pomalidomide or bortezomib with DARZALEX[®] did not affect the pharmacokinetics of daratumumab.

Effect of Daratumumab on Other Drugs: The coadministration of DARZALEX[®] with bortezomib or pomalidomide did not affect the pharmacokinetics of bortezomib or pomalidomide.

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 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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² DARZALEX Prescribing Information, June 2018.

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