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DARZALEX® (Daratumumab) Regimen Shows Significant Increase in Progression-Free Survival in Treatment of Patients with Relapsed/Refractory Multiple Myeloma

- *First Phase 3 study showing addition of the CD38-directed antibody DARZALEX® to carfilzomib in combination with dexamethasone*
- *Data selected as a Late-Breaking Abstract at ASH 2019*

ORLANDO, Fla., December 10, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today results from the Phase 3 CANDOR study showing the addition of DARZALEX® (daratumumab) to carfilzomib (Kyprolis®) and dexamethasone (DKd), compared to carfilzomib and dexamethasone (Kd) alone, significantly improved progression-free survival (PFS) in patients with relapsed/refractory multiple myeloma, resulting in a 37 percent reduction in the risk of progression or death (HR, 0.63; 95 percent

CI, 0.46–0.85; $P=0.0014$).¹ The study results were reported for the first time and presented as a Late-Breaking Abstract at the 2019 American Society of Hematology (ASH) Annual Meeting ([Abstract #LBA-6](#)).

“These data from the Phase 3 CANDOR study reinforce the growing body of evidence supporting the use of daratumumab-containing regimens in the treatment of multiple myeloma,” said Saad Z. Usmani, M.D., Division Chief of Plasma Cell Disorders, Levine Cancer Institute, and principal investigator. “The results provide important evidence for this combination regimen in the relapsed and refractory setting, where there is still significant unmet need, especially among lenalidomide refractory patients.”

Results from the CANDOR study showed that, compared to Kd alone, DKd resulted in significantly longer PFS rates and response rates. The primary endpoint of PFS was met after a median follow-up of 16.9 months and 16.3 months for the DKd and Kd arms, respectively.¹ Median PFS was not reached in the DKd arm versus 15.8 months in the Kd arm. At 12 months, patients in the DKd arm had a 10 times higher rate of minimal residual disease (MRD)-negativity compared to patients treated with Kd alone (12.5 percent vs. 1.3 percent; $P<0.0001$).¹ Overall response rate (ORR) was 84 percent in the DKd arm, compared to 75 percent in the Kd arm ($P=0.0040$).¹ The rate of complete response (CR) or better was 29 percent (DKd) and 10 percent (Kd).¹ Median treatment duration was longer in the DKd arm than in the Kd arm (17.5 vs. 10.1 months, respectively).¹

“The CANDOR data show that DARZALEX in combination with carfilzomib and dexamethasone may be a promising treatment option for patients with multiple myeloma who have relapsed after 1-3 prior regimens, especially in patients with previous lenalidomide and bortezomib treatment,” said Craig Tendler, M.D., Vice President, Clinical Development and Global Medical Affairs, Janssen Research & Development, LLC. “This Phase 3 study adds to the body of evidence related to the use of DARZALEX in combination with established regimens for the treatment of patients with relapsed multiple myeloma. We are committed to the continued study of DARZALEX as a treatment for patients with multiple myeloma.”

CANDOR is an Amgen-sponsored study and is co-funded by Janssen Research & Development.¹ The study included patients who had received 1–3 prior lines of therapy for multiple myeloma.¹ Of the patients randomized in the study, 42 percent and 90 percent had previous exposure to lenalidomide and bortezomib, respectively; 33 percent were lenalidomide-refractory and 29 percent were bortezomib-refractory.¹

Median overall survival (OS) was not reached in either arm at a median follow-up time of 17 months (HR, 0.75; 95 percent CI, 0.49–1.13; $P=0.08$).¹ In general, the safety profile of DKd was consistent with the known safety profiles of daratumumab and Kd, with the exception of treatment emergent fatal adverse events which were higher in the DKd arm compared to the Kd arm.¹ The incidence of Grade 3 and above adverse events (AEs) was 82 percent and 74 percent of patients in DKd and Kd, respectively, while serious AEs (SAEs) occurred in 56 percent and 46 percent of patients, respectively.¹ The frequency of Grade 3 and above cardiac failure was 4 percent (DKd) and 9 percent (Kd); rate of cardiac failure event leading to discontinuation of carfilzomib was similar in both arms at 4 percent (DKd) and 5 percent (Kd).¹ The rate of treatment discontinuation due to AEs was similar in both arms (DKd, 22 percent vs. Kd 25 percent).¹ Five deaths were reported as treatment-related in the DKd arm (pneumonia, sepsis, septic shock, acinetobacter infection and cardio-respiratory arrest, n=1 each).¹

About the CANDOR Study¹

CANDOR is a randomized, open-label Phase 3 study of DARZALEX[®] (daratumumab), carfilzomib and dexamethasone (DKd) compared to carfilzomib and dexamethasone (Kd) alone. The study evaluated 466 relapsed or refractory patients with multiple myeloma from 120 global sites who had received 1-3 prior therapies. Patients were treated until disease progression. The primary endpoint was PFS and the key secondary endpoints were overall response rate, minimal residual disease and overall survival. PFS was defined as time from randomization until disease progression or death from any cause.

All patients received carfilzomib as a 30-min intravenous (IV) infusion on days 1, 2, 8, 9, 15, and 16 of each 28-day cycle (20 mg/m² on days 1 and 2 during cycle 1 and 56 mg/m² thereafter) and received 40 mg dexamethasone oral or IV weekly (20 mg/m² for patients >75 years). In the treatment arm, DARZALEX[®] (8 mg/kg) was administered via IV on days 1 and 2 of cycle 1 and at 16 mg/kg once weekly for the remaining doses of the first 2 cycles, then every 2 weeks for 4 cycles (Cycles 3–6), and every 4 weeks thereafter.

For more information about this trial, please visit www.clinicaltrials.gov under trial identification number NCT03158688.

About DARZALEX[®]

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.² 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.^{3,4,5,6,7,8,9,10} 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.^{11,12}

In the U.S., 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.¹³ 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.¹⁴ 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.¹⁵ 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.¹⁶ In [June 2019](#), DARZALEX[®] received approval in combination with lenalidomide and dexamethasone for the treatment of patients with newly diagnosed multiple myeloma who are transplant ineligible.¹⁷ In [September 2019](#), DARZALEX[®] received approval in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant.¹⁸

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[®].¹⁹ 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.^{20,21} When damaged, these plasma cells rapidly spread and replace normal cells with tumors in the bone marrow. In 2019, it is estimated that 32,110 people will be diagnosed and 12,960 will die from the disease in the U.S.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

DARZALEX® IMPORTANT SAFETY INFORMATION

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%), peripheral sensory neuropathy (24%), and decreased appetite (22%) were also reported. In newly diagnosed patients, serious adverse reactions ($\geq 2\%$ compared to Rd) were pneumonia (15%), bronchitis (4%), and dehydration (2%), and treatment-emergent Grade 3-4 hematology laboratory abnormalities ($\geq 20\%$) were neutropenia (56%), lymphopenia (52%), and leukopenia (35%). 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

(≥20%) were lymphopenia (48%) and thrombocytopenia (47%).

DARZALEX® in combination with bortezomib, thalidomide, and dexamethasone (DVTd): The most frequent adverse reactions (≥20%) were infusion reactions (35%), nausea (30%), upper respiratory tract infection (27%), pyrexia (26%), and bronchitis (20%). Serious adverse reactions (≥2% compared to the VTd arm) were bronchitis (DVTd 2% vs VTd <1%) and pneumonia (DVTd 6% vs VTd 4%). Treatment-emergent Grade 3-4 hematology laboratory abnormalities (≥20%) were lymphopenia (59%), neutropenia (33%), and leukopenia (24%).

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

DARZALEX® as monotherapy: The most frequently reported adverse reactions (≥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 (≥20%) were lymphopenia (40%) and neutropenia (20%).

Please [click here](#) to see the full Prescribing Information.

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 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 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, 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 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, September 2019.
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