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**Janssen Announces U.S. FDA Approval of DARZALEX® (daratumumab) in Combination with Lenalidomide and Dexamethasone for Newly Diagnosed Patients with Multiple Myeloma Who Are Transplant Ineligible**

- *Combination regimen reduced the risk of disease progression or death by 44 percent in newly diagnosed patients who are transplant ineligible*
- *Marks the sixth DARZALEX FDA-approved use in multiple myeloma and second for newly diagnosed patients*

HORSHAM, Pa., June 27, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today the U.S. Food and Drug Administration (FDA) approval of DARZALEX® (daratumumab) in combination with lenalidomide and dexamethasone (Rd) for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant (ASCT). The approval is based on results from the [Phase 3 MAIA \(MMY3008\)](#) clinical study, which showed that DARZALEX-Rd significantly reduced the risk of disease progression or death by 44 percent compared to treatment with Rd alone.<sup>1</sup> The application received approval through the U.S. FDA’s Real-Time Oncology Review (RTOR) pilot program.

"Multiple myeloma can become more difficult to treat after relapse, so it is important that patients receive an efficacious upfront therapy with a goal of extending their first remission period," said Saad Usmani, M.D., FACP, Department of Hematologic Oncology and Blood Disorders, Levine Cancer Institute/Carolinas HealthCare System, and a lead investigator of the MAIA study. "This regimen offers an important frontline treatment option for this patient population, and it has been submitted to the NCCN Multiple Myeloma Panel for review and consideration for potential inclusion in the NCCN Clinical Practice Guidelines."

Data from the Phase 3 MAIA study were recently [published](#) in *The New England Journal of Medicine* and previously [presented](#) at the 2018 American Society of Hematology (ASH) Annual Meeting. At a median follow-up of 28 months, results showed DARZALEX in combination with Rd significantly reduced the risk of disease progression or death by 44 percent in patients with newly diagnosed multiple myeloma who are transplant ineligible, compared to treatment with Rd alone (Hazard Ratio [HR] = 0.56; 95 percent confidence interval [CI]: 0.43-0.73;  $p < 0.0001$ ). **Error! Bookmark not defined.** The median progression-free survival (PFS) for DARZALEX-Rd has not yet been reached, compared to 31.9 months for patients who received Rd alone. **Error! Bookmark not defined.** The addition of DARZALEX resulted in deeper responses compared to Rd alone, including increased rates of complete response (CR) or better (48 percent vs. 25 percent), very good partial response (VGPR) or better (79 percent vs. 53 percent) and overall response (93 percent vs. 81 percent). **Error! Bookmark not defined.** DARZALEX-Rd induced a >3-fold higher rate of minimal residual disease (MRD) negativity compared to Rd alone (24 percent vs. 7 percent). **Error! Bookmark not defined.**

"For patients with multiple myeloma, optimizing response to frontline treatment is critical," said Paul Giusti, President and CEO of the Multiple Myeloma Research Foundation. "This latest indication for DARZALEX is a promising development for the myeloma community, and we are grateful to Janssen, our long-standing partner in myeloma research, as well as the patients with myeloma and healthcare providers involved in this study."

"Today's approval of DARZALEX underscores the significant clinical benefit of this CD38 monoclonal antibody and our efforts to advance treatment paradigms to change the course of the disease," said Craig Tandler, M.D., Vice President, Clinical Development and Global Medical Affairs, Oncology, Janssen Research & Development, LLC. "Importantly, this milestone also highlights the efficiency of the FDA's Real-Time Oncology Review process, ensuring that proven treatment regimens, such as DARZALEX plus lenalidomide and dexamethasone, are made available to patients as soon as possible."

The most frequent ( $\geq 20$  percent) adverse reactions were infusion reactions, diarrhea, constipation, nausea, peripheral edema, fatigue, back pain, asthenia, pyrexia, upper respiratory tract infection, bronchitis, pneumonia, decreased appetite, muscle spasms, peripheral sensory neuropathy, dyspnea and cough. **Error! Bookmark not defined.** Serious adverse reactions with a 2 percent greater incidence in the DARALEX-Rd arm compared to the Rd arm were pneumonia (15 percent vs. 8 percent), bronchitis (4 percent vs. 2 percent) and dehydration (2 percent vs.  $< 1$  percent), respectively.<sup>1</sup> Treatment-emergent Grade 3/4 hematology laboratory abnormalities ( $\geq 20$  percent) were neutropenia (56 percent), lymphopenia (52 percent) and leukopenia (35 percent).<sup>1</sup> The safety profile of DARZALEX was consistent with that of previous studies. **Error! Bookmark not defined.**

#### **About the MAIA Trial** **Error! Bookmark not defined.**

The randomized, open-label, multicenter Phase 3 study included 737 newly diagnosed patients with multiple myeloma ineligible for high-dose chemotherapy and ASCT aged 45-90 years old (median age of 73). Patients were randomized to receive either DARZALEX-Rd or Rd alone in 28-day cycles. In the DARZALEX-Rd treatment arm, patients received DARZALEX 16 milligrams per kilogram (mg/kg) IV weekly for cycles 1 – 2, every two weeks for cycles 3 – 6 and every 4 weeks for cycle 7 and thereafter. Patients in the DARZALEX-Rd and Rd treatment arms received 25 mg of lenalidomide on days 1 – 21 of each 28-day cycle, and dexamethasone at 40 mg once a week for each cycle. 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.<sup>1</sup> CD38 is a surface protein that is present in high numbers on multiple myeloma cells, regardless of the stage of disease.<sup>2</sup> DARZALEX binds to CD38 and inhibits tumor cell growth causing myeloma cell death. **Error! Bookmark not defined.** DARZALEX may also have an effect on normal cells.<sup>1</sup> 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.<sup>3,4,5,6,7,8,9,10</sup> 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.<sup>11,12</sup>

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.<sup>13</sup> 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.<sup>14</sup> 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.<sup>15</sup> 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.<sup>16</sup>

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.<sup>17</sup> For the full U.S. Prescribing Information, please visit [www.DARZALEX.com](http://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.<sup>18,19</sup> When damaged, these plasma cells rapidly spread and replace normal cells with tumors in the bone marrow.<sup>18,19</sup> 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.<sup>20</sup> 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.<sup>21</sup>

### **IMPORTANT SAFETY INFORMATION<sup>1</sup>**

#### **CONTRAINDICATIONS**

DARZALEX<sup>®</sup> (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<sup>®</sup> 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<sup>®</sup>. 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<sup>®</sup> 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<sup>®</sup>. Type and screen patients prior to starting DARZALEX<sup>®</sup>.

**Neutropenia and Thrombocytopenia** – DARZALEX<sup>®</sup> 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<sup>®</sup> dose delay may be required to allow recovery of neutrophils and/or platelets. No dose reduction of DARZALEX<sup>®</sup> 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  $\geq 20\%$ ) 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.

DARZALEX<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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](http://www.janssen.com). Follow us at [www.twitter.com/JanssenGlobal](https://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, 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](http://www.sec.gov), [www.jnj.com](http://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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<sup>1</sup> DARZALEX Prescribing Information, June 2019.

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- <sup>5</sup> Janssen Research & Development, LLC. A Study to Evaluate Daratumumab in Transplant Eligible Participants With Previously Untreated Multiple Myeloma (Cassiopeia). In: *ClinicalTrials.gov* [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2018 July 24]. Available at: <https://clinicaltrials.gov/ct2/show/NCT02541383?term=mmy3006&rank=2> Identifier: NCT02541383.
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- <sup>9</sup> European Myeloma Network. Compare Progression Free Survival Btw Daratumumab/Pomalidomide/Dexamethasone vs Pomalidomide/Dexamethasone (EMN14). In: *ClinicalTrials.gov* [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2018 July 24] Available at: <https://clinicaltrials.gov/ct2/show/NCT03180736?term=MMY3013&rank=2> Identifier: NCT03180736
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- <sup>13</sup> Janssen Biotech, Inc. "DARZALEX<sup>®</sup> (daratumumab) Approved by U.S. FDA: First Human Anti-CD38 Monoclonal Antibody Available for the Treatment of Multiple Myeloma." Issued November 16, 2015.
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<sup>16</sup> Janssen Pharmaceutical Companies of Johnson & Johnson. "Janssen Announces DARZALEX® (daratumumab) U.S. FDA Approval for Newly Diagnosed Patients with Multiple Myeloma who are Transplant Ineligible." Issued May 7, 2018.

<sup>17</sup> Janssen Biotech, Inc. "Janssen Biotech Announces Global License and Development Agreement for Investigational Anti-Cancer Agent Daratumumab." Issued August 30, 2012.

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