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**New DARZALEX® (daratumumab) Phase 3 Study Shows Efficacy and Safety Data of Anti-CD38 Monoclonal Antibody in Patients with Newly Diagnosed Multiple Myeloma**

- *Phase 3 MAIA study results show DARZALEX in combination with lenalidomide and dexamethasone reduced the risk of disease progression or death in newly diagnosed patients who are transplant ineligible*
- *Data featured as a Late-Breaking Abstract at ASH 2018 (Abstract #LBA-2)*

SAN DIEGO, December 4, 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced results from the Phase 3 MAIA study demonstrating that the addition of DARZALEX® (daratumumab) to lenalidomide and dexamethasone (Rd) significantly reduced the risk of disease progression or death in patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant (ASCT) ([Abstract #LBA-2](#)).<sup>1</sup> These data were featured during the late-breaking abstract (LBA) oral session at the 60<sup>th</sup> American Society of Hematology (ASH) Annual Meeting in San Diego, CA.

“The Phase 3 MAIA study reinforces the clinical profile of daratumumab in combination with a standard of care treatment regimen for newly diagnosed patients with multiple myeloma who are transplant ineligible,” said Thierry Facon, M.D., Service des Maladies du Sang, Hôpital Claude Huriez, Lille, France, and principal investigator. “The positive data show the potential role of daratumumab in combination with lenalidomide and dexamethasone as an important new therapeutic approach for this patient population.”

At a median follow-up of 28 months, data from the Phase 3 MAIA study 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;  $p < 0.0001$ ).<sup>1</sup> 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.<sup>1</sup> 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) and improved rates of very good partial response (VGPR) or better (79 percent vs. 53 percent).<sup>1</sup> DARZALEX-Rd induced a >3-fold higher rate of minimal residual disease (MRD) negativity compared to those who received Rd alone (24 percent vs. 7 percent).<sup>1</sup>

“These data underscore the consistent clinical profile observed among newly diagnosed patients with multiple myeloma receiving DARZALEX therapy, including for those who are transplant ineligible,” said Yusri Elsayed, M.D., M.H.Sc., Ph.D., Vice President, Hematologic Malignancies Disease Area Leader, Janssen Research & Development, LLC. “This is the third study in newly diagnosed patients that has met its primary endpoint, showing DARZALEX continues to provide strong evidence of clinical benefit in combination with standard of care regimens in the treatment of multiple myeloma.”

The most common Grade 3/4 treatment-emergent adverse events (TEAEs) for DARZALEX-Rd ( $\geq 10$  percent) included neutropenia (50 percent), lymphopenia (15 percent), pneumonia (14 percent) and anemia (12 percent).<sup>1</sup> Infusion-related reactions (IRRs) occurred in 41 percent of patients, only 3 percent of which were Grade 3/4.<sup>1</sup> Incidence of invasive second primary malignancy was 3 percent in the DARZALEX-Rd arm compared to 4 percent with Rd alone.<sup>1</sup> TEAEs with an outcome of death were 7 percent in the DARZALEX-Rd arm compared to 6 percent in the Rd arm.<sup>1</sup> The safety profile of DARZALEX was consistent with that of previous studies.<sup>1</sup>

These data will support a future supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) for DARZALEX in combination with Rd for this patient population.

### **About the MAIA Trial<sup>1</sup>**

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 arm 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<sup>®</sup> (daratumumab) Injection, for Intravenous Infusion**

DARZALEX<sup>®</sup> (daratumumab) injection for intravenous use is the first CD38-directed antibody approved anywhere in the world.<sup>2</sup> CD38 is a surface protein that is highly expressed across multiple myeloma cells, regardless of disease stage.<sup>3</sup> DARZALEX is believed to induce tumor cell death through multiple immune-mediated mechanisms of action, including complement-dependent cytotoxicity (CDC), antibody-dependent cell-mediated cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP), as well as through apoptosis, in which a series of molecular steps in a cell lead to its death.<sup>2</sup> Subsets of myeloid derived suppressor cells (MDSCs), CD38+ regulatory T cells (Tregs) and CD38+ B cells (Bregs) were decreased by DARZALEX.<sup>2</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>4,5,6,7,8,9,10,11</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>12,13</sup> DARZALEX is the first and only CD38-directed antibody to receive regulatory approval to treat multiple myeloma.<sup>2</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>14</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>15</sup> In

[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>16</sup> Most recently, 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>17</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>18</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 occurs when malignant plasma cells grow uncontrollably in the bone marrow.<sup>19,20</sup> Refractory cancer occurs when a patient's disease is resistant to treatment or in the case of multiple myeloma, when patients progress within 60 days of their last therapy.<sup>21,22</sup> Relapsed cancer means the disease has returned after a period of initial, partial or complete remission.<sup>23</sup> In 2018, it is estimated that 30,700 people will be diagnosed, and 12,770 will die from the disease, in the United States.<sup>24</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, fatigue, high calcium levels, kidney problems or infections.<sup>25</sup>

### **IMPORTANT SAFETY INFORMATION<sup>2</sup>**

#### **CONTRAINDICATIONS**

DARZALEX<sup>®</sup> 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<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 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<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** – DARZALEX<sup>®</sup> 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<sup>®</sup> dose delay may be required to allow recovery of neutrophils. No dose reduction of DARZALEX<sup>®</sup> 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 the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science.

We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at [www.janssen.com](http://www.janssen.com). Follow us at [@JanssenGlobal](https://twitter.com/JanssenGlobal) and [@JanssenUS](https://twitter.com/JanssenUS). 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 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 31, 2017, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," in the company's most recently filed Quarterly Reports on Form 10-Q and in 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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