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DARZALEX® (daratumumab) Combination Regimen Significantly Improved Outcomes for Newly Diagnosed Multiple Myeloma Patients who are Transplant Ineligible

Phase 3 ALCYONE data showed DARZALEX in combination with bortezomib, melphalan and prednisone meaningfully improved progression-free survival and response rates

Data featured as late-breaker at ASH 2017 (Abstract #LBA-4) and published in the New England Journal of Medicine

ATLANTA and RARITAN, N.J., December 12, 2017 – Janssen Research & Development, LLC today announced data from the Phase 3 ALCYONE study, showing that DARZALEX® (daratumumab) in combination with bortezomib, melphalan and prednisone (VMP) significantly improved clinical outcomes, including reducing the risk of disease progression or death by 50 percent, in patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplantation (ASCT).[1] These data were presented as a late-breaking abstract today at the 59th American Society of Hematology (ASH) Annual Meeting in Atlanta (Abstract #LBA-4). Study findings were simultaneously published in the *New England Journal of Medicine*.

“These Phase 3 results for DARZALEX demonstrated clinically meaningful improvements with a manageable safety profile,” said Dr. Maria-Victoria Mateos, Ph.D., lead ALCYONE study investigator and Director of the Myeloma Unit at University Hospital of Salamanca-IBSAL, Salamanca, Spain. “Selecting

the right treatment regimen is critical for patients who are newly diagnosed, especially if they are transplant ineligible, as these patients tend to be older and more frail. These findings strongly support this DARZALEX frontline regimen as a new standard of care for these patients."

At a median follow-up of 16.5 months, DARZALEX-VMP reduced the risk of disease progression or death by 50 percent, compared to treatment with VMP alone (Hazard Ratio [HR] = 0.50; 95 percent CI [0.38-0.65], p<0.0001). The median progression-free survival (PFS) for DARZALEX-VMP had not yet been reached, compared to an estimated median PFS of 18.1 months for patients who received VMP alone.[1]

In addition to reducing the risk of disease progression or death, DARZALEX significantly improved overall response rates (ORR) (91 percent vs. 74 percent) compared to VMP alone, including more than doubling rates of stringent complete response (sCR) (18 percent vs. 7 percent) and significantly improving rates of very good partial response (VGPR) or better (71 percent vs. 50 percent) and complete response (CR) or better (43 percent vs. 24 percent).[1] Patients receiving DARZALEX also reported a more than three-fold increase in the minimal residual disease (MRD) negativity rate (22 percent vs. 6 percent) compared to those who received VMP alone.[1]

The most common (≥10 percent) Grade 3/4 treatment-emergent adverse events (TEAEs) for DARZALEX-VMP vs. VMP were neutropenia (40 percent vs. 39 percent), thrombocytopenia (34 percent vs. 38 percent), anemia (16 percent vs. 20 percent) and pneumonia (11 percent vs. 4 percent).[1] One patient in each arm discontinued treatment due to pneumonia, and 0.9 percent of patients discontinued DARZALEX due to an infection.[1] Twenty-eight percent of patients experienced infusion reactions (IRs) due to DARZALEX.[1] In the DARZALEX-VMP arm, 42 percent of patients experienced a serious adverse event (SAE), compared to 33 percent in the VMP arm.[1] The most common (≥2 percent) SAEs were pneumonia (10 percent vs. 3 percent), anemia (2 percent vs. 3 percent), bronchitis (2 percent vs. 1 percent), lower respiratory tract infection (2 percent vs. 1 percent), upper respiratory tract infection (2 percent vs. 1 percent), febrile neutropenia (1 percent vs. 2 percent) and cardiac failure (<1 percent vs. 2 percent) for DARZALEX-VMP vs. VMP, respectivey.[1]

"DARZALEX offers compelling and consistent clinical benefit across all lines of therapy in multiple myeloma," said Sen Zhuang, M.D., Ph.D., Vice President, Oncology Clinical Research, Janssen Research & Development. "These latest results convey the promise of DARZALEX in newly diagnosed patients for whom the initial therapy is most critical for long-term survival."

On November 21, 2017, Janssen submitted a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) for DARZALEX in combination with VMP for this patient population. Janssen requested Priority Review of this sBLA, which would shorten FDA review to six

months, compared to 10 months for Standard Review. If approved, this would be the fifth indication for DARZALEX in the U.S. and its first in the frontline setting. On November 21, 2017, Janssen also submitted an application for this patient population to the European Medicines Agency.

About the ALCYONE Trial[1]

The randomized, open-label, multicenter Phase 3 ALCYONE (MMY3007) study enrolled 706 newly diagnosed patients with multiple myeloma who were ineligible for high-dose chemotherapy with ASCT. In the DARZALEX-VMP arm, the median age was 71 years (range: 40-93), 30 percent were ≥75 years and 46 percent were male. Patients were randomized to receive nine cycles of either DARZALEX combined with VMP, or VMP alone. In the DARZALEX-VMP arm, patients received 16 mg/kg of DARZALEX once weekly for six weeks (Cycle 1; 1 Cycle = 42 days), followed by once every three weeks (Cycles 2-9). Following the nine cycles, patients in the DARZALEX-VMP arm continued to receive 16 mg/kg of DARZALEX once every four weeks until disease progression.

About DARZALEX® (daratumumab) Injection, for Intravenous Infusion

DARZALEX® (daratumumab) injection for intravenous use is the first CD38-directed antibody approved anywhere in the world.[2] CD38 is a surface protein that is highly expressed across multiple myeloma cells.[3] 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.[2] A subset of myeloid derived suppressor cells (MDSCs), CD38+ regulatory T cells (Tregs) and CD38+ B cells (Bregs) were decreased by DARZALEX.[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] Additional studies are ongoing or planned to assess its potential for a solid tumor indication and in other malignant and pre-malignant diseases in which CD38 is expressed, such as smoldering myeloma.[9,10,11] DARZALEX was the first CD38-directed antibody to receive regulatory approval to treat relapsed or refractory multiple myeloma.[2]

In August 2012, Janssen Biotech, Inc. and Genmab A/S entered a worldwide agreement, which granted Janssen an exclusive license to develop, manufacture and commercialize DARZALEX.[12] DARZALEX is commercialized in the U.S. by Janssen Biotech, Inc.[12] For more information, visit 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.[13,14] Refractory cancer occurs when a patient's disease is resistant to treatment or in the case of multiple myeloma, patients progress within 60 days of their last therapy.[15,16]

Relapsed cancer means the disease has returned after a period of initial, partial or complete remission.[17] It is estimated that 30,280 people will be diagnosed and 12,590 will die from the disease in the United States in 2017.[18] While some patients with multiple myeloma have no symptoms at all, most patients are diagnosed due to symptoms, which can include bone fracture or pain, low red blood counts, fatigue, calcium elevation, kidney problems or infections.[19]

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS - None

WARNINGS AND PRECAUTIONS

Infusion Reactions – DARZALEX can cause severe infusion reactions. Approximately half of all patients experienced a reaction, most during the first infusion. 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 for life-threatening (Grade 4) reactions. 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 – In patients who received DARZALEX in combination with lenalidomide and dexamethasone, the most frequently reported adverse reactions (incidence ≥20%) were: neutropenia (92%), thrombocytopenia (73%), 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 were pneumonia (12%), upper respiratory tract infection (7%), influenza (3%) and pyrexia (3%).

In patients who received DARZALEX in combination with bortezomib and dexamethasone, the most frequently reported adverse reactions (incidence ≥20%) were: thrombocytopenia (90%), neutropenia (58%), 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 were upper respiratory tract infection (5%), diarrhea (2%) and atrial fibrillation (2%).

In patients who received DARZALEX as monotherapy, the most frequently reported adverse reactions (incidence ≥20%) were: neutropenia (60%), thrombocytopenia (48%), infusion reactions (48%), fatigue (39%), nausea (27%), back pain (23%), pyrexia (21%), cough (21%), and upper respiratory tract infection (20%). Serious adverse reactions were reported in 51 (33%) patients. The most frequent serious adverse reactions were pneumonia (6%), general physical health deterioration (3%), and pyrexia (3%).

In patients who received DARZALEX in combination with pomalidomide and dexamethasone, the most frequent adverse reactions (>20%) were infusion reactions (50%), diarrhea (38%), constipation (33%),

nausea (30%), vomiting (21%), fatigue (50%), pyrexia (25%), upper respiratory tract infection (50%), muscle spasms (26%), back pain (25%), arthralgia (22%), dizziness (21%), insomnia (23%), cough (43%) and dyspnea (33%). The overall incidence of serious adverse reactions was 49%. Serious adverse reactions reported in ≥5% patients included pneumonia (7%).

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 did not affect the pharmacokinetics of bortezomib.

About the Janssen Pharmaceutical Companies

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. Follow us at www.twitter.com/JanssenUS and www.twitter.com/JanssenGlobal.

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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 continued development of DARZALEX® (daratumumab), including implications of results from the Phase 3 ALCYONE study and potential approval of an additional indication. 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 inherent in product research and development, including uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success for or new indications; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; changes in behavior and spending patterns of purchasers of health care products and services; product efficacy or safety concerns resulting in product recalls or regulatory action; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and description 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 January 1, 2017, including under "Item 1A. Risk Factors," its most recently filed Quarterly Report on Form 10-Q, including in the section captioned "Cautionary Note Regarding Forward-Looking Statements," 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 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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