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Janssen Announces DARZALEX® (daratumumab) U.S. FDA Approval for Newly Diagnosed Patients with Multiple Myeloma who are Transplant Ineligible

DARZALEX® is the first monoclonal antibody approved for newly diagnosed patients

Today's FDA approval of DARZALEX® in combination with bortezomib, melphalan and prednisone marks its fifth indication in multiple myeloma

HORSHAM, PA, May 7, 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that the U.S. Food and Drug Administration (FDA) has approved DARZALEX® (daratumumab) in combination with VELCADE® (bortezomib)*, a proteasome inhibitor (PI); melphalan, an alkylating agent; and prednisone – VMP -- for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant (ASCT). DARZALEX® is the first monoclonal antibody approved for newly diagnosed patients with this disease. Clinical trial results showed DARZALEX® in combination with VMP reduced the risk of disease progression or death by 50 percent compared to treatment with VMP alone.[1]

"This approval is significant as we now have the first antibody-based regimen for treating newly diagnosed multiple myeloma patients who are not eligible for a stem cell transplant," said Andrzej Jakubowiak, M.D., Ph.D., Director of the Multiple Myeloma Program at University of Chicago Medical Center, Chicago, Illinois and a DARZALEX® clinical study investigator. "In clinical studies, patients who received treatment with daratumumab experienced a lower risk of disease progression and higher rates of response."

The FDA approval of DARZALEX® in combination with VMP is supported by data from the randomized, open-label, multicenter Phase 3 ALCYONE (MMY3007) study, recently published in the *New England Journal of Medicine*. The combination of DARZALEX® with 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).[1] The median progression-free survival (PFS) for DARZALEX®-VMP had not yet been reached, compared to a median PFS of 18.1 months for patients who received VMP alone.[1]

"A patient's best chance at lasting remission often begins with a durable response to frontline therapy, because multiple myeloma can become more difficult to treat after relapse," said Maria-Victoria Mateos, M.D., Ph.D., Director of the Myeloma Unit at University Hospital of Salamanca-IBSAL, Salamanca, Spain and ALCYONE primary investigator. "Combination therapy with daratumumab resulted in deep and durable responses in newly diagnosed patients with multiple myeloma who are transplant ineligible, supporting this regimen as an important new treatment option for these patients."

Treatment with DARZALEX® in combination with VMP significantly improved overall response rates (91 vs. 74 percent) compared to VMP alone.[1] Additionally, measures of stringent complete response (18 vs. 7 percent), complete response or better (43 vs. 24 percent) and very good partial response or better (71 vs. 50 percent) all showed marked improvement.[1] Patients receiving DARZALEX® in combination with VMP achieved a more than three-fold increase in the minimal residual disease (MRD) negativity rate (22 vs. 6 percent) compared to those who received VMP alone.[1]

In the ALYCONE study, the most frequent adverse reactions (≥20 percent) with at least 5 percent greater frequency in the DARZALEX®-VMP arm were upper respiratory tract infection (48 vs. 28 percent), infusion reactions (28 vs. 0 percent) and peripheral edema (21 vs. 14 percent).[1] Serious adverse reactions with at least a 2 percent greater incidence in the DARZALEX®-VMP arm vs. VMP were pneumonia (11 vs. 4 percent), upper respiratory tract infection (5 vs.1 percent) and pulmonary edema (2 vs. 0 percent).[1] The most common Grade 3/4 treatment-emergent hematology laboratory abnormalities for DARZALEX®-VMP vs. VMP were lymphopenia (58 vs. 53 percent), neutropenia (44 vs. 43 percent) and thrombocytopenia (38 vs. 42 percent).[1] The warnings and precautions for DARZALEX® include infusion reactions, interference with cross-matching and red blood cell antibody screening, neutropenia and thrombocytopenia (see Important Safety Information).[1]

"Slowing the progression of myeloma translates to more time in remission for those battling the disease. This latest approval for DARZALEX® in combination with VMP is an exciting step forward for newly diagnosed patients and the healthcare teams who treat them," said Paul Giusti, President and CEO of the Multiple Myeloma Research Foundation (MMRF). "The MMRF congratulates Janssen, our long-time collaborator in myeloma research, the

dedicated healthcare providers in the myeloma community as well as the patients who donate their time and data on clinical trials, for making this critical new combination therapy possible."

Today's FDA approval marks the fifth indication for DARZALEX®, the first CD38-directed antibody approved anywhere in the world and the first antibody approved for newly diagnosed patients with multiple myeloma who are transplant ineligible.[1] DARZALEX® was first approved by the FDA in November 2015 as a monotherapy for patients with multiple myeloma who have received at least three prior lines of therapy, including a PI and an immunomodulatory agent, or who are double refractory to a PI and an immunomodulatory agent.[2] 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.[3] 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.[4]

"We are grateful to the patients and physicians who participated in the clinical program that enabled today's important approval of DARZALEX® combination therapy as a treatment option for newly diagnosed patients with multiple myeloma who are transplant ineligible," said Peter Lebowitz, M.D., Ph.D, Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. "DARZALEX® has redefined how we approach the treatment of multiple myeloma, and we continue to evaluate its potential in combination with other regimens, with the aim of arresting the disease at its earliest stages."

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®.[5] Janssen Biotech, Inc. commercializes DARZALEX® in the U.S. For full Prescribing Information, please visit www.DARZALEX.com.

About DARZALEX® (daratumumab) Injection, for Intravenous Infusion

DARZALEX® (daratumumab) injection for intravenous use is the first CD38-directed antibody approved anywhere in the world.[1] CD38 is a surface protein that is highly expressed across multiple myeloma cells, regardless of disease stage.[6] 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.[1] Subsets of myeloid derived suppressor cells (MDSCs), CD38+ regulatory T cells (Tregs) and CD38+ B cells (Bregs) were decreased by DARZALEX®.[1] 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.[7,8,9,10,11,12,13,14] 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, as well as in solid tumors.[15,16,17] DARZALEX® is the first and only CD38-directed antibody to receive regulatory approval to treat multiple myeloma.[1]

About Multiple Myeloma

Multiple myeloma is an incurable blood cancer that occurs when malignant plasma cells grow uncontrollably in the bone marrow.[18,19] 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.[20,21] Relapsed cancer means the disease has returned after a period of initial, partial or complete remission.[22] In 2018, it is estimated that 30,700 people will be diagnosed and 12,770 will die from the disease in the United States.[23] 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.[24]

IMPORTANT SAFETY INFORMATION[1]

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 bortezomib, melphalan, and prednisone, the most frequently reported adverse reactions (incidence **≥**20%) were: upper respiratory tract infection (48%), infusion reactions (28%), and peripheral edema (21%). Serious adverse reactions (**≥**2% greater 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 **≥**20% were thrombocytopenia (38%), neutropenia (44%), and lymphopenia (58%).

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 or pomalidomide did not affect the pharmacokinetics of bortezomib.

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. Follow us at @JanssenGlobal and @JanssenUS. Janssen Research & Development, LLC is part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

*VELCADE® (bortezomib) is a registered trademark of Millennium Pharmaceuticals, Inc.

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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 the Janssen Pharmaceutical Companies of Johnson & Johnson and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: uncertainty of commercial success; challenges to patents; competition, including technological advances, new products and patents attained by competitors; manufacturing difficulties and delays; product efficacy or safety concerns resulting in product recalls or regulatory action; changes to applicable laws and regulations, including global health care reforms; changes in behavior and spending patterns of purchasers of health care products and services; 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," and in the company's subsequent Quarterly Reports on Form 10-Q and other 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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[1] DARZALEX Prescribing Information, May 7, 2018.
[2] Janssen Biotech, Inc. "DARZALEX® (daratumumab) Approved by U.S. FDA: First Human Anti-CD38 Monoclonal Antibody Available for the Treatment of Multiple Myeloma." Issued November 16, 2015.
[3] Janssen Biotech, Inc. "DARZALEX® (daratumumab) Approved by U.S. FDA in Combination with Two Standard of Care Regimens for the Treatment of Patients with Multiple Myeloma Who Have Received At Least One Prior Therapy." Issued November 21, 2016.
[4]Janssen Biotech, Inc. "DARZALEX® (daratumumab) Approved by the U.S. FDA in Combination with Pomalidomide and Dexamethasone for Patients with Multiple Myeloma Who Have Received At Least Two Prior Therapies." Issued June 16, 2017.
[5] Janssen Biotech, Inc. "Janssen Biotech Announces Global License and Development Agreement for Investigational Anti-Cancer Agent Daratumumab." Issued August 30, 2012.
[6] Fedele G et al. CD38 Ligation in Peripheral Blood Mononuclear Cells of Myeloma Patients Induces Release of Protumorigenic IL-6 and Impaired Secretion of IFNγ Cytokines and Proliferation. *Mediators Inflamm*. 2013;2013:564687.
[7] Janssen Research & Development, LLC. A Study Comparing Daratumumab, Lenalidomide, and Dexamethasone With Lenalidomide and Dexamethasone in Relapsed or Refractory Multiple Myeloma. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2018 March 19]. Available at: https://clinicaltrials.gov/ct2/show/NCT02076009?term=mmy3003&rank=1 NLM Identifier: NCT02136134.
[8] Janssen Research & Development, LLC. Addition of Daratumumab to Combination of Bortezomib and Dexamethasone in Participants With Relapsed or Refractory Multiple Myeloma. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2018 March 19]. Available at: https://clinicaltrials.gov/ct2/show/NCT02136134?term=mmy3004&rank=1 NLM Identifier: NCT02076009.
[9] 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 March 19]. Available at: https://clinicaltrials.gov/ct2/show/NCT02541383?term=mmy3006&rank=2 NLM Identifier: NCT02541383.
[10] Janssen Research & Development, LLC. A Study of Combination of Daratumumab and Velcade (Bortezomib) Melphalan-Prednisone (DVMP) Compared to Velcade Melphalan-Prednisone (VMP) in Participants With Previously Untreated Multiple Myeloma In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2018 March 19]. Available at: https://clinicaltrials.gov/ct2/show/NCT02195479?term=mmy3007&rank=1 Identifier: NCT02195479.
[11] Janssen Research & Development, LLC. Study Comparing Daratumumab, Lenalidomide, and Dexamethasone With Lenalidomide and Dexamethasone in Participants With Previously Untreated Multiple Myeloma. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2018 March 19]. Available at: https://clinicaltrials.gov/ct2/show/NCT02252172?term=mmy3008&rank=1 Identifier: NCT02252172.
[12] Janssen Research & Development, LLC. A Study of VELCADE (Bortezomib) Melphalan-Prednisone (VMP) Compared to Daratumumab in Combination With VMP (D-VMP), in Participants With Previously Untreated Multiple Myeloma Who Are Ineligible for High-Dose Therapy (Asia Pacific Region). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2018 March 19] Available at: https://clinicaltrials.gov/ct2/show/NCT03217812?term=MMY3011&rank=1 Identifier: NCT03217812.
[13] 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 28 June 2017] Available at: https://clinicaltrials.gov/ct2/show/NCT03180736?term=MMY3013&rank=2 Identifier: NCT03180736
[14] Amgen. Study of Carfilzomib, Daratumumab and Dexamethasone for Patients With Relapsed and/or Refractory Multiple Myeloma. (CANDOR). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2018 March 19] Available at: https://clinicaltrials.gov/ct2/show/NCT03158688?term=NCT03158688&rank=1 Identifier: NCT03158688.
[15] Janssen Research & Development, LLC. “Janssen Announces the Initiation of Two Studies Evaluating Daratumumab (DARZALEX®) and Atezolizumab in Multiple Myeloma and Solid Tumor.” Issued March 21, 2016.
[16] Janssen Research & Development, LLC. A Study to Evaluate 3 Dose Schedules of Daratumumab in Participants With Smoldering Multiple Myeloma In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2018 March 19]. Available at: https://clinicaltrials.gov/ct2/show/NCT02316106?term=smm2001&rank=1 Identifier: NCT02316106.
[17] Janssen Research & Development, LLC. An Efficacy and Safety Proof of Concept Study of Daratumumab in Relapsed/Refractory Mantle Cell Lymphoma, Diffuse Large B-Cell Lymphoma, and Follicular Lymphoma In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2018 March 19]. Available at: https://clinicaltrials.gov/ct2/show/NCT02413489?term=lym2001&rank=1 Identifier: NCT02413489
[18] Kumar, SK et al. Leukemia. 2012 Jan; 26(1):149-57.
[19] American Cancer Society. "What Is Multiple Myeloma?." Available at: http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-what-is-multiple-myeloma. Accessed March 2018.
[20] National Cancer Institute. “NCI Dictionary of Cancer Terms: Refractory.” Available at: https://www.cancer.gov/publications/dictionaries/cancer-terms?CdrID=350245. Accessed March 2018.
[21] Richardson, et al. “The Treatment of Relapsed and Refractory Multiple Myeloma.” ASH Education Book. January 1, 2007 vol. 2007 no. 1 317-323.
[22] National Cancer Institute. “NCI Dictionary of Cancer Terms: Relapsed.” Available at: https://www.cancer.gov/publications/dictionaries/cancer-terms?CdrID=45866. Accessed March 2018.
[23] American Cancer Society. “Key Statistics for Multiple Myeloma.” Available at: https://www.cancer.org/cancer/multiple-myeloma/about/key-statistics.html. Accessed March 2018.
[24] American Cancer Society. "Diagnosing Multiple Myeloma From Test Results." Available at: http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-diagnosis. Accessed March 2018.