Media Inquiries:
Megan Farina
Phone: 1-215-325-6861
Mobile: 1-610-724-1079

Linda Davis
Phone: 1-215-325-3562
Mobile: 1-215-272-8787

Investor Relations:
Lesley Fishman
Phone: 1-732-524-3922

Joseph J. Wolk
Phone: 1-732 524-1142

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

DARZALEX combination therapy offers new option for patients previously treated with two commonly used treatments (lenalidomide and a proteasome inhibitor)

HORSHAM, PA, June 16, 2017 – Janssen Biotech, Inc. announced today that the U.S. Food and Drug Administration (FDA) has approved the immunotherapy DARZALEX® (daratumumab) in combination with pomalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least two prior therapies including lenalidomide (an immunomodulatory agent) and a proteasome inhibitor (PI).[1] Clinical trial results showed an overall response rate (ORR) of 59.2 percent with DARZALEX in combination with pomalidomide and dexamethasone in these patients.[1]

DARZALEX is the first CD38-directed antibody approved anywhere in the world.[2] It was first approved by the FDA in November 2015 as a monotherapy treatment 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.[3] It 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.[4] To date, approximately 16,000 patients have been treated with DARZALEX.[5]

“Despite tremendous progress, most patients with multiple myeloma continually relapse or become resistant to available therapies, such as PIs and immunomodulatory agents. Therefore, these patients continue to need new options,” said Ajai Chari M.D., Associate Professor of Medicine, Multiple Myeloma Program and Associate Director of Clinical Research, Mount Sinai Hospital. “With today’s approval of DARZALEX, we now have a promising new combination therapy that in clinical trials demonstrated pronounced clinical benefit for patients who have relapsed on two of the most widely used treatments.”

This new indication for DARZALEX is supported by data from the Phase 1b EQUULEUS study, which showed that the combination of DARZALEX with pomalidomide and dexamethasone resulted in an ORR of 59.2 percent (95 percent CI: 49.1, 68.8), with very good partial response (VGPR) achieved in 28.2 percent of patients. Complete response (CR) was achieved in 5.8 percent of patients, stringent CR (sCR) was achieved in 7.8 percent of patients, and partial response (PR) was achieved in 17.5 percent of patients.[1] The median time to response was one month (range: 0.9 to 2.8 months), and the median duration of response was 13.6 months (range: 0.9+ to 14.6+ months).[1]

“The recent approval of DARZALEX is significant for patients and clinicians who urgently need new options and regimens. This milestone underscores the versatility of DARZALEX with a range of treatment regimens,” said Peter F. Lebowitz, M.D., Ph.D., Global Oncology Head, Janssen Research & Development, LLC. “We look forward to continued study of daratumumab in earlier stages of multiple myeloma and other cancers.”

Overall, the safety of the DARZALEX combination therapy was consistent with the known safety profiles of DARZALEX monotherapy and pomalidomide plus dexamethasone, respectively. Warnings and precautions in the Prescribing Information include: infusion reactions, interference with cross-matching and red blood cell antibody screening, neutropenia and thrombocytopenia.[1] In the EQUULEUS trial, the most frequent (>20 percent) adverse reactions (ARs) were infusion reactions (50 percent), diarrhea (38 percent), constipation (33 percent), nausea (30 percent), vomiting (21 percent), fatigue (50 percent), pyrexia (25 percent), upper respiratory tract infection (50 percent), muscle spasms (26 percent), back pain (25 percent), arthralgia (22 percent), dizziness (21 percent), insomnia (23 percent), cough (43 percent) and dyspnea (33 percent).[1] The overall incidence of serious ARs was 49 percent.[1] Serious ARs (Grade 3/4) reported in ≥5 percent of patients included pneumonia (7 percent).[1] Thirteen percent of patients discontinued therapy due to an AR.[1] The most common treatment-emergent hematology laboratory abnormalities were neutropenia (95 percent), lymphopenia (94 percent), thrombocytopenia (75 percent) and anemia (57 percent).[1] The most common Grade 3 treatment-emergent hematology laboratory abnormalities were lymphopenia (45 percent), neutropenia (36 percent), anemia (30 percent) and thrombocytopenia (10 percent).[1] The most common Grade 4 treatment-emergent hematology

laboratory abnormalities were neutropenia (46 percent), lymphopenia (26 percent) and thrombocytopenia (10 percent).[1]

The Phase 1b EQUULEUS study included 103 patients with multiple myeloma who had received a prior PI and an immunomodulatory agent.[1] Patients received 16 mg/kg of DARZALEX in combination with pomalidomide and low-dose dexamethasone until disease progression.[1] The median patient age was 64 years, with 8 percent of patients aged 75 or older.[1] Patients in the study had received a median of four prior lines of therapy, and 74 percent of patients had received prior autologous stem cell transplant (ASCT).[1] Ninety-eight percent of patients received prior bortezomib treatment and 33 percent of patients received prior carfilzomib treatment. All patients received prior lenalidomide treatment, with 98 percent of patients previously treated with the combination of bortezomib and lenalidomide.[1] Eighty nine percent of patients were refractory to lenalidomide, 71 percent were refractory to bortezomib, and 64 percent of patients were refractory to bortezomib and lenalidomide.[1]

The recommended dose of DARZALEX is 16 mg/kg body weight administered as an intravenous infusion.[1] The dosing schedule for DARZALEX in combination with pomalidomide and dexamethasone begins with weekly administration (weeks 1-8) and reduces in frequency over time to every two weeks (weeks 9-24) and ultimately every four weeks (week 25 onwards until disease progression).[1]

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.[6] DARZALEX is commercialized in the U.S. by Janssen Biotech, Inc. 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.[2] CD38 is a surface protein that is highly expressed across multiple myeloma cells, regardless of disease stage.[7] 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] A subset 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 that includes five Phase 3 studies across a range of treatment settings in multiple myeloma, such as in frontline and relapsed settings.[8,9,10,11,12] 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.[13,14,15] DARZALEX was the first CD38-directed antibody to receive regulatory approval to treat relapsed or refractory multiple myeloma.[3]

About Multiple Myeloma

Multiple myeloma is an incurable blood cancer that occurs when malignant plasma cells grow uncontrollably in the bone marrow.[16,17] 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.[18,19] Relapsed cancer means the disease has returned after a period of initial, partial or complete remission.[20] Globally, it is estimated that 124,225 people were diagnosed and 87,084 died from the disease in 2015.[21,22] 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.[23]

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.

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.

# # #

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding DARZALEX's potential benefits and further development of daratumumab. 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 Biotech, Inc., Janssen Research & Development, LLC and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in product research and development, including the uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success for new products or new indications; manufacturing difficulties or delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; 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" and "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. None of the Janssen Pharmaceutical Companies or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

---

[1] DARZALEX Prescribing Information, June 2017.
[2] Janssen Biotech, Inc. "Janssen Submits Application to U.S. FDA to Expand Indication for Daratumumab (DARZALEX®)." Issued August 17, 2016.
[3] 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.
[4] 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.
[5] Data on File. Janssen Research & Development, LLC. May 2017.
[6] Janssen Biotech, Inc. "Janssen Biotech Announces Global License and Development Agreement for Investigational Anti-Cancer Agent Daratumumab." Issued August 30, 2012.
[7] 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.
[8] 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 2016 Nov 11]. Available at: https://clinicaltrials.gov/ct2/show/NCT02076009?term=mmy3003&rank=1 NLM Identifier: NCT02136134.
[9] 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 2016 Nov 11]. Available at: https://clinicaltrials.gov/ct2/show/NCT02136134?term=mmy3004&rank=1 NLM Identifier: NCT02076009.
[10] 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 2016 Nov 11]. Available at: https://clinicaltrials.gov/ct2/show/NCT02541383?term=mmy3006&rank=2 NLM Identifier: NCT02541383.
[11] 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 2016 Nov 11]. Available at: https://clinicaltrials.gov/ct2/show/NCT02195479?term=mmy3007&rank=1 Identifier: NCT02195479.
[12] 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 2016 Nov 11]. Available at: https://clinicaltrials.gov/ct2/show/NCT02252172?term=mmy3008&rank=1Identifier: NCT02252172.
[13] 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.
[14] 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 2016 Nov 11]. Available at: https://clinicaltrials.gov/ct2/show/NCT02316106?term=smm2001&rank=1 Identifier: NCT02316106.
[15] 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 2016 Nov 11]. Available at: https://clinicaltrials.gov/ct2/show/NCT02413489?term=lym2001&rank=1 Identifier: NCT02413489.
[16] Kumar, SK et al. Leukemia. 2012 Jan; 26(1):149-57.
[17] American Cancer Society. "Multiple Myeloma Overview." Available at: http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-what-is-multiple-myeloma. May 2017.
[18] National Cancer Institute. "NCI Dictionary of Cancer Terms: Refractory." Available at: https://www.cancer.gov/publications/dictionaries/cancer-terms?CdrID=350245. Accessed November 2015.
[19] Richardson, et al. "The Treatment of Relapsed and Refractory Multiple Myeloma." ASH Education Book January 1, 2007 vol. 2007 no. 1 317-323.
[20] National Cancer Institute. "NCI Dictionary of Cancer Terms: Relapsed." Available at: https://www.cancer.gov/publications/dictionaries/cancer-terms?CdrID=45866. Accessed November 2015.

[21] GLOBOCAN 2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide: Number of New Cancers in 2015. Available at: http://globocan.iarc.fr/old/burden.asp?selection_pop=224900&Text-p=World&selection_cancer=17270&Text-c=Multiple+myeloma&pYear=3&type=0&window=1&submit=%C2%A0Execute. Accessed May 2017.
[22] GLOBOCAN 2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide: Number of Cancer Deaths in 2015. Available at: http://globocan.iarc.fr/old/burden.asp?selection_pop=224900&Text-p=World&selection_cancer=17270&Text-c=Multiple+myeloma&pYear=3&type=1&window=1&submit=%C2%A0Execute. Accessed May 2017.
[23] American Cancer Society. "How is Multiple Myeloma Diagnosed?" Available at: http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-diagnosis. Accessed November 2015.