Media Inquiries:
Kellie McLaughlin
Phone: 1-908-927-7477
Mobile: 1-609-468-8356

Satu Kaarina Glawe
Mobile: +49 172 294 6264

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

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

U.S. Medical Inquiries:
1-800-526-7736

Daratumumab Combination Therapy Improved Clinical Outcomes Regardless of Cytogenetic Risk for Previously-Treated Patients with Multiple Myeloma

Updated analyses of the pivotal Phase 3 POLLUX and CASTOR studies featured as an oral presentation at the American Society of Clinical Oncology (ASCO) 2017 Annual Meeting (Abstract 8006)

Additionally, Phase 1b findings from the MMY1001 clinical trial assessing daratumumab combination therapy for newly diagnosed patients featured as an oral presentation (Abstract 8000)

CHICAGO and RARITAN, NJ, June 4, 2017 – Janssen Research & Development, LLC today announced new data from updated analyses of the pivotal Phase 3 CASTOR and POLLUX clinical studies, demonstrating that DARZALEX® (daratumumab) in combination with bortezomib and dexamethasone, or lenalidomide and dexamethasone, improved progression-free survival (PFS) and the overall response rate (ORR) for previously-treated patients with multiple myeloma, regardless of cytogenetic risk.[1] These data will be featured as an oral presentation at the American Society of Clinical Oncology (ASCO) 2017 Annual Meeting on Sunday, June 4 at 11:45 a.m. CDT.[1]

Additionally, data from the Phase 1b MMY1001 study will show the potential of daratumumab in combination with carfilzomib, lenalidomide and dexamethasone (KRd) for newly diagnosed patients with multiple myeloma. These data represent the first assessment of daratumumab in combination with a next generation proteasome inhibitor (PI) and an immunomodulatory agent earlier in the treatment paradigm for multiple myeloma. The data

will be presented as an oral presentation from on Sunday, June 4 at 9:45 a.m. CDT. These data will also be featured in the Best of ASCO program, which aims to highlight the most cutting-edge science and education from the ASCO Annual Meeting.[2,3]

“These compelling findings from the Phase 3 CASTOR and POLLUX trials show daratumumab delivered deep and durable responses for previously-treated patients, regardless of cytogenetic risk,” said Dr. Katja Weisel, Associate Professor, Department of Hematology and Oncology, University Hospital of Tuebingen, Tuebingen, Germany. “Daratumumab appeared to improve poor outcomes associated with high risk cytogenetics, and these data support its consistent clinical benefit in combination with two of the most widely used treatment classes.”

Updated data from two Phase 3 clinical trials support the addition of daratumumab to standard of care regimens for previously-treated patients, regardless of cytogenetic risk:

- According to follow-up data from the CASTOR study, daratumumab (D), in combination with bortezomib (a PI) and dexamethasone (Vd), significantly reduced the risk of disease progression or death by 55 percent (Hazard Ratio [HR]=0.45; 95 percent CI [0.25-0.80]; p=0.0053) in patients with high risk cytogenetics (n=44) compared to Vd alone.[1] Additionally, the daratumumab combination regimen resulted in an ORR of 82 percent vs. 62 percent (p=0.2028), with very good partial response (VGPR) or better achieved in 64 percent vs. 35 percent of patients, and CR or better achieved in 34 percent vs. 9 percent of patients.[1]
    - In patients with standard cytogenetic risk (n=123), the addition of daratumumab reduced the risk of disease progression or death by 74 percent (HR=0.26; 95 percent CI [0.18-0.37]; p<0.0001).[1] Additionally, the daratumumab combination regimen resulted in an ORR of 85 percent vs. 64 percent (p=0.0001), with VGPR or better achieved in 64 percent vs. 26 percent of patients, and CR or better achieved in 28 percent vs. 8 percent of patients treated with DVd vs. Vd, respectively. The median duration of follow-up was 19.4 months.[1]

- According to follow-up data from the POLLUX study, daratumumab (D), in combination with lenalidomide (an immunomodulatory agent) and dexamethasone (Rd), reduced the risk of disease progression or death by 47 percent (HR=0.53; 95 percent CI [0.25-1.13]; p=0.0921) in patients with high risk cytogenetics (n=28) compared to Rd alone.[1] Additionally, the daratumumab combination regimen resulted in an ORR of 85 percent vs. 67 percent (p=0.0435), with VGPR or better achieved in 64 percent vs. 31 percent of patients, and CR or better achieved in 38 percent vs. 6 percent of patients.[1]
    - In patients with standard cytogenetic risk (n=133), the addition of daratumumab reduced the risk of disease progression or death by 70 percent (HR=0.30; 95 percent CI [0.20-0.47]; p<0.0001).[1] Additionally, the daratumumab combination regimen resulted in an ORR of 95 percent vs. 82 percent (p=0.0004), with VGPR or better achieved in 85 percent vs. 55 percent of patients, and

CR or better achieved in 58 percent vs. 27 percent of patients treated with DRd vs. Rd, respectively.[1] The median duration of follow-up was 25.4 months.[1]

A cohort in the Phase 1b MMY1001 EQUULEUS study showed that the overall safety profile of daratumumab (D) in combination with carfilzomib, lenalidomide and dexamethasone (KRd) in patients with newly diagnosed multiple myeloma was consistent with the known safety profiles of D and KRd, respectively.[2] Serious treatment-emergent adverse events (TEAEs), such as pyrexia, influenza and pulmonary embolism, occurred in 46 percent of patients, 14 percent of which were potentially daratumumab-related.[2] The most common Grade 3/4 hematologic TEAEs (≥30 percent) were lymphopenia (64 percent) and neutropenia (14 percent).[2] Treatment with this daratumumab combination regimen yielded promising results with an ORR (≥partial response) of 100 percent, with 91 percent achieving VGPR or better and 43 percent achieving CR or better, after a short-term follow-up.[2]

“Together, these data for daratumumab demonstrate its potential as a backbone therapy in combination with a range of standard of care regimens for patients with multiple myeloma across various stages of disease,” said Peter F. Lebowitz, M.D., Ph.D., Oncology Therapeutic Area Head, Janssen Research & Development. “We are especially excited by early data for daratumumab showing its potential in the frontline setting and look forward to fully understanding its potential clinical benefit for patients with cancer.”

DARZALEX is the first CD38-directed antibody approved anywhere in the world.[4] 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 immunomodulatory agent.[5] It received additional approvals in November 2016 by the FDA 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.[6]

About DARZALEX® (daratumumab) Injection, for Intravenous Infusion

DARZALEX® (daratumumab) injection for intravenous use is the first CD38-directed antibody approved anywhere in the world.[4] CD38 is a surface protein that is highly expressed across multiple myeloma cells, regardless of disease stage.[7] Daratumumab 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.[4] A subset of myeloid derived suppressor cells (MDSCs), CD38+ regulatory T cells (Tregs) and CD38+ B cells (Bregs) were decreased by daratumumab.[4] 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 the 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 antibody to receive regulatory approval to treat relapsed or refractory multiple myeloma.[5]

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.[16] DARZALEX is commercialized in the U.S. by Janssen Biotech, Inc.[17] 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.[17,18] 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.[19,20] Relapsed cancer means the disease has returned after a period of initial partial or complete remission.[21] Globally, it is estimated that 124,225 people were diagnosed and 87,084 died from the disease in 2015.[22,23] 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

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%).

DRUG INTERACTIONS

Effect of Other Drugs on daratumumab: The coadministration of lenalidomide 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.

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 potential of daratumumab and expectations for its further development. 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, Janssen Biotech, Inc. 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 January 1, 2017, including under "Item 1A. Risk Factors," its most recently filed Quarterly Report on Form 10-Q, including under the caption "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] Weisel K et al. Efficacy Of Daratumumab In Combination With Lenalidomide Plus Dexamethasone (Drd) Or Bortezomib Plus Dexamethasone (Dvd) In Relapsed Or Refractory Multiple Myeloma (RRMM) Based On Cytogenetic Risk Status. *2017 American Society of Clinical Oncology Annual Meeting.* June 2017.
[2] Jakubowiak A et al. Daratumumab (DARA) In Combination with Carfilzomib, Lenalidomide, And Dexamethasone (Krd) In Patients (Pts) With Newly Diagnosed Multiple Myeloma (MMY1001): An Open-Label, Phase 1b Study. *2017 American Society of Clinical Oncology Annual Meeting.* June 2017.
[3] Best of ASCO 2017 Annual Meeting. New Orleans, LA Program. American Society of Clinical Oncology. June 28-29, 2017. Available at: http://central-boa.asco.org/program.
[4] DARZALEX Prescribing Information, November 2016.
[5] 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.
[6] 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.
[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 MyelomaIn: 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] Janssen Biotech, Inc. "Janssen Biotech Announces Global License and Development Agreement for Investigational Anti-Cancer Agent Daratumumab" Issued August 30, 2012.
[17] Kumar, SK et al. Leukemia. 2012 Jan; 26(1):149-57.
[18]American Cancer Society. "Multiple Myeloma Overview." Available at: http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-what-is-multiple-myeloma. Accessed November 2015.
[19] National Cancer Institute. "NCI Dictionary of Cancer Terms: Refractory." Available at: http://www.cancer.gov/publications/dictionaries/cancer-terms?expand=R. Accessed November 2015.
[20] Richardson, et al. "The Treatment of Relapsed and Refractory Multiple Myeloma." ASH Education Book January 1, 2007 vol. 2007 no. 1 317-323.
[21] National Cancer Institute. "NCI Dictionary of Cancer Terms: Relapsed." Available at: http://www.cancer.gov/publications/dictionaries/cancer-terms?expand=R. Accessed November 2015.
[22] 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 August 2016.
[23] 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 November 2015.
[24] American Cancer Society. "How is Multiple Myeloma Diagnosed?" Available at: http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-diagnosis. Accessed November 2015.