



NEWS RELEASE

Janssen Announces the Initiation of Two Studies Evaluating Daratumumab (DARZALEX®) and Atezolizumab in Multiple Myeloma and Solid Tumor

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Janssen Announces the Initiation of Two Studies Evaluating Daratumumab (DARZALEX®) and Atezolizumab in Multiple Myeloma and Solid Tumor RARITAN, N.J., March 21, 2016 /PRNewswire/ -- Janssen Research & Development, LLC announced today it has entered into a clinical trial collaboration agreement with Genentech, a member of the Roche Group, to initiate two studies to determine the safety and tolerability of daratumumab (DARZALEX®), the first CD38-directed monoclonal antibody (mAb), in combination with atezolizumab, an investigational mAb designed to bind with a protein called programmed cell death-ligand 1 (PD-L1). These studies will assess the potential of the combination therapy in multiple myeloma and in solid tumor. Atezolizumab is currently in development by Roche. Janssen licensed daratumumab from Genmab A/S and is responsible for development and marketing.

As part of the collaboration, Janssen will sponsor a Phase 1b, open-label, multicenter study that will investigate the potential of daratumumab in combination with atezolizumab in patients with solid tumor. Genentech is the sponsor of an ongoing Phase 1b, open-label, multicenter study that will be amended to assess atezolizumab in combination with daratumumab, with daratumumab and lenalidomide, and with daratumumab and pomalidomide in patients with relapsed or refractory multiple myeloma. These studies are anticipated to start dosing patients within a year.

"We are excited to see if the immunomodulatory properties of daratumumab may have synergistic treatment effects when used in combination with this promising anti-PDL1 antibody," said Peter F. Lebowitz, M.D., Ph.D., Global Oncology Head, Janssen Research & Development. "This is the first time we're exploring daratumumab in solid tumor, and we look forward to better understanding how combining these two immunotherapies may potentially benefit patients with multiple myeloma and solid tumor, who are urgently in need of new options."

In **November 2015**, DARZALEX was approved by the U.S. Food and Drug Administration for the treatment of 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. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.¹

About DARZALEX[®] (daratumumab)

DARZALEX[®] (daratumumab) injection for intravenous use is the first CD38-directed monoclonal antibody (mAb) approved anywhere in the world.¹ CD38 is a surface protein that is highly expressed across multiple myeloma cells, regardless of disease stage.² Daratumumab is believed to induce tumor cell death through apoptosis, in which a series of molecular steps in a cell lead to its death^{1,3} as well as immunomodulatory effects and multiple immune-mediated mechanisms of action, including complement-dependent cytotoxicity (CDC), antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP).^{1,4,5} Five Phase 3 clinical studies with daratumumab in relapsed and frontline settings are currently ongoing. Additional studies are ongoing or planned to assess its potential in other malignant and pre-malignant diseases on which CD38 is expressed, such as smoldering myeloma and non-Hodgkin's lymphoma. DARZALEX is the first mAb to receive regulatory approval to treat relapsed or refractory multiple myeloma.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. DARZALEX is commercialized in the U.S. by Janssen Biotech, Inc.⁶

DARZALEX[®] (daratumumab) Important Safety Information - Professional 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, and hypertension. Signs and symptoms may include respiratory symptoms, such as cough, wheezing, larynx and throat tightness and irritation, laryngeal edema, pulmonary edema, nasal congestion, and allergic rhinitis. Less common symptoms were hypotension, headache, rash, urticaria, pruritus, nausea, vomiting, and chills.

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 the first and second day after all infusions. Patients with a history of obstructive pulmonary disorders may require additional post-infusion medications to manage respiratory complications. Consider prescribing short- and long-acting bronchodilators and inhaled corticosteroids for patients with obstructive pulmonary disorders.

Interference with Serological Testing - Daratumumab binds to CD38 on red blood cells (RBCs) and results in a positive Indirect Antiglobulin Test (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.

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 =20%) were: fatigue, nausea, back pain, pyrexia, cough, and upper respiratory tract infection.

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 - No drug interaction studies have been performed.

About Janssen Research & Development, LLC

At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people throughout the world. Janssen Research & Development, LLC and Janssen Biotech, Inc. are part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit <http://www.janssen.com> for more information.

Janssen in Oncology

Our goal is to fundamentally alter the way cancer is understood, diagnosed and managed, reinforcing our commitment to the patients who inspire us. In looking to find innovative ways to address the cancer challenge, our primary efforts focus on several treatment and prevention solutions. These include a focus on hematologic malignancies, prostate cancer and lung cancer; cancer interception with the goal of developing products that interrupt the carcinogenic process; biomarkers that may help guide targeted, individualized use of our therapies; as well as safe and effective identification and treatment of early changes in the tumor microenvironment. Please visit <http://www.janssen.com> for more information.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product 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 and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in new product research and development, including uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success for new products; 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 3, 2016, including in Exhibit 99 thereto, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, <http://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, November 2015. Available at <https://www.darzalex.com/shared/product/darzalex/darzalex-prescribing-information.pdf>. Accessed November 2015.

² Fedele, G et al. CD38 Ligation in Peripheral Blood Mononuclear Cells of Myeloma Patients Induces Release of Protumorigenic IL-6 and Impaired Secretion of IFN γ Cytokines and Proliferation. *Mediators Inflamm.* 2013;2013:564687.

³ Jansen, JH et al. *Blood.* 2012; 120:2974.

⁴ de Weers, M et al. Daratumumab, a Novel Therapeutic Human CD38 Monoclonal Antibody, Induces Killing of

Multiple Myeloma and Other Hematological Tumors. The Journal of Immunology. February 1, 2011. Vol. 186, No. 3
1840-1848.

⁵ Overdijk, M et al. Phagocytosis Is A Mechanism of Action for Daratumumab. Available at
<https://ash.confex.com/ash/2012/webprogram/Paper51257.html>. Accessed December 2015.

⁶ Janssen Biotech, Inc. "Janssen Biotech Announces Global License and Development Agreement for Investigational
Anti-Cancer Agent Daratumumab." Issued August 30, 2012.

Media Inquiries:

Kellie McLaughlin

Phone: 1-908-927-7477

Satu Kaarina Glawe

Mobile: +49 172 294 62 64

Investor Relations:

Lesley Fishman

Phone: 1-732-524-3922

Louise Mehrotra

Phone: 1-732-524-6491

U.S. Medical Inquiries:

1-800-526-7736