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Janssen Enters Immunotherapy Clinical Collaboration with Bristol-Myers Squibb to Evaluate daratumumab (DARZALEX®) in Combination with nivolumab (OPDIVO®)

Phase 1b/Phase 2 studies planned in multiple myeloma and solid tumors

HORSHAM, PA, January 5, 2017 – Janssen Biotech, Inc. today announced that the company has entered a clinical trial collaboration with Bristol-Myers Squibb Company (BMS) to evaluate the combination of the first CD38-directed cytolytic antibody daratumumab (DARZALEX®) and checkpoint inhibitor nivolumab (OPDIVO®) in Phase 1b/Phase 2 clinical studies in multiple myeloma and several solid tumor types. Nivolumab is developed and commercialized by BMS. Janssen licensed daratumumab from Genmab A/S and is responsible for all global development, marketing and manufacturing.

The multiple myeloma study will evaluate the safety and tolerability of daratumumab in combination with nivolumab with or without pomalidomide and dexamethasone in relapsed/refractory multiple myeloma. The solid tumor studies will evaluate the safety, tolerability and clinical benefit of daratumumab combined with nivolumab in patients with advanced or metastatic tumors, including non-small cell lung, head and neck, pancreatic, colorectal and triple negative breast cancers. Additional tumor types may also be evaluated. Studies are expected to start this year.

“Immunotherapy has vastly changed the way cancer is treated. We are excited to study this novel combination of two potentially synergistic immunotherapies,” said Peter F. Lebowitz, M.D., Ph.D., Global Oncology Head, Janssen. “This agreement allows us to extend our footprint in immuno-oncology and will be a significant addition to the growing body of clinical data for daratumumab in combination with other novel agents, in a variety of tumor types.”

DARZALEX is the first CD38-directed cytolytic antibody approved anywhere in the world. It was first approved by the U.S. Food and Drug Administration (FDA) in November 2015 as a monotherapy for 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 immunomodulatory agent.[1] It is also approved in Europe, Canada and several other countries for a similar patient population.

DARZALEX was more recently approved by the FDA in November 2016 for use in combination with lenalidomide (an immunomodulatory agent) and dexamethasone, or bortezomib (a PI) and dexamethasone, in patients with multiple myeloma who have received at least one prior therapy.[2] DARZALEX received Breakthrough Therapy Designation from the FDA for this indication in July 2016.[3]

About DARZALEX® (daratumumab) Injection, for Intravenous Infusion

DARZALEX® (daratumumab) injection for intravenous use is the first CD38-directed cytolytic antibody approved anywhere in the world.[1] CD38 is a surface protein that is highly expressed across multiple myeloma cells, regardless of disease stage.[4] Daratumumab is believed to induce tumor cell death through multiple immune-mediated mechanisms of action, including complement-dependent cytotoxicity (CDC), antibody-dependent cellular 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.[5] A subset of myeloid derived suppressor cells (MDSCs), CD38+ regulatory T cells (Tregs) and CD38+ B cells (Bregs) were decreased by daratumumab.[5] 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.[6,7,8,9,10] 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 and non-Hodgkin's lymphoma.[11,12,13] DARZALEX was the first cytolytic antibody 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.[14] DARZALEX is commercialized in the U.S. by Janssen Biotech, Inc. 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.[15,16] 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.[17,18] Relapsed cancer means the disease has returned after a period of initial partial or complete remission.[19]

Globally, it is estimated that 124,225 people were diagnosed, and 87,084 died from the disease in 2015.[20,21] 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.[22] Patients who relapse after treatment with standard therapies (including PIs or immunomodulatory agents) typically have poor prognoses and few remaining options.[16]

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.

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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 planned clinical trials and expected expansion of clinical data on 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. 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; 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, 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.

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