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Daratumumab (DARZALEX®) Granted Breakthrough Therapy Designation by U.S. Food and Drug Administration (FDA) for Use in Combination with Standard of Care Regimens for Patients with Multiple Myeloma

FDA action underscores potential clinical benefit of daratumumab as a backbone therapy in combination with either a proteasome inhibitor (PI) or an immunomodulatory agent for patients who have received at least one prior therapy

Marks the second Breakthrough Therapy Designation for daratumumab

RARITAN, NJ, July 25, 2016 – The U.S. Food and Drug Administration (FDA) has granted a Breakthrough Therapy Designation to the immunotherapy daratumumab (DARZALEX®) in combination with lenalidomide (an immunomodulatory agent) and dexamethasone, or bortezomib (a proteasome inhibitor [PI]) and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy, Janssen Research & Development, LLC announced today. This marks the second time daratumumab has received a Breakthrough Therapy Designation, which is intended to expedite the development and review timelines of potential new medicines to treat serious or life-threatening diseases, where preliminary clinical evidence shows that the medicine may provide substantial improvement over existing therapies.[1] Multiple myeloma is an incurable blood cancer that occurs when malignant plasma cells grow uncontrollably in the bone marrow.[2,3]

“Despite tremendous progress in the past 15 years, multiple myeloma remains a highly complex and difficult disease to treat, with most patients relapsing or becoming resistant to therapy,” said MMY3003 (POLLUX) lead study author Meletios A. Dimopoulos, M.D., Department of Clinical Therapeutics, National and Kapodistrian

University of Athens School of Medicine, Alexandra General Hospital, Athens, Greece. “Daratumumab has already shown pronounced activity as a monotherapy in heavily pre-treated patients. This designation underscores the potential of daratumumab in combination with either a proteasome inhibitor or an immunomodulatory agent to provide much-needed benefit to patients with at least one prior therapy.”

Breakthrough Therapy Designation was granted to daratumumab based on data from two Phase 3 studies:

- The MMY3004 (CASTOR) clinical trial evaluating daratumumab in combination with bortezomib and dexamethasone, compared to bortezomib and dexamethasone alone, in patients with multiple myeloma who received at least one prior therapy. Overall, the daratumumab combination therapy demonstrated a reduction in the risk of disease progression or death.
    - These results were presented at the 52nd Annual Meeting of the American Society of Clinical Oncology (ASCO) in June 2016. More information can be found at www.ClinicalTrials.gov (NCT02136134).
- The MMY3003 (POLLUX) clinical trial evaluating daratumumab in combination with lenalidomide and dexamethasone, compared to lenalidomide and dexamethasone alone, in patients with multiple myeloma who received at least one prior therapy. Overall, the addition of daratumumab reduced the risk of disease progression or death in these patients.
    - These results were presented at the 21st Annual Congress of the European Hematology Association (EHA) in June 2016. More information can be found at www.ClinicalTrials.gov (NCT02076009).

“We are pleased that the FDA has granted a second Breakthrough Therapy Designation to daratumumab. This is an important recognition of the transformative potential of daratumumab and its possible benefit as a backbone therapy in combination with two of the most widely used regimens for multiple myeloma,” said Craig L. Tendler, M.D., Vice President, Late-Stage Development and Global Medical Affairs for Oncology, Hematology and Supportive Care, Janssen Research & Development, LLC. “We look forward to working closely with the FDA throughout the review process and remain committed to exploring the full clinical benefit of this promising compound for multiple myeloma patients who are eagerly awaiting new treatment options.”

In November 2015, daratumumab (DARZALEX®) was approved by the FDA for the treatment of 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. 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 a confirmatory trial.[4] In May 2013, daratumumab received Breakthrough Therapy Designation from the FDA for this indication.

In May 2016, the European Commission (EC) granted conditional approval to DARZALEX for monotherapy of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a PI and an immunomodulatory agent and who have demonstrated disease progression on the last therapy.

About DARZALEX® (daratumumab)

DARZALEX® (daratumumab) injection for intravenous use is the first CD38-directed monoclonal antibody (mAb) approved anywhere in the world.[4] CD38 is a surface protein that is highly expressed across multiple myeloma cells, regardless of disease stage.[5] 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.[4] Daratumumab is also believed to induce tumor cell death through immunomodulatory effects, according to a study recently presented at the 57th Annual Meeting and Exposition of the American Society of Hematology (ASH).[6] 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. Additional studies are ongoing or planned to assess its potential in other malignant and pre-malignant diseases in which CD38 is expressed, such as smoldering myeloma, non-Hodgkin's lymphoma and a solid tumor indication. DARZALEX was the first mAb to receive regulatory approval to treat relapsed or refractory multiple myeloma.[4]

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. 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.[7,8] 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.[9,10] Relapsed cancer means the disease has returned after a period of initial, partial or complete remission.[7,11] Accounting for approximately one percent of all cancers and 15 percent to 20 percent of haematologic malignancies worldwide, multiple myeloma is designated as an orphan disease in both the U.S. and Europe.[11] Globally, it is estimated that 124,225 people were diagnosed, and 87,084 died from the disease in 2015.[12,13] 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.[14] Patients who relapse after treatment with standard therapies (including PIs or immunomodulatory agents) typically have poor prognoses and few remaining options.[3]

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: 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 - No drug interaction studies have been performed

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 product development and the potential benefits 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 Research & Development, LLC 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; competition, including technological advances, new products and patents attained by competitors; challenges to patents; manufacturing difficulties and delays; changes in behavior and spending patterns or financial distress 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 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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