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Daratumumab Significantly Extended Progression-Free Survival in Combination with Lenalidomide and Dexamethasone in Patients with Multiple Myeloma

- *Data from Phase 3 MMY3003 (POLLUX) trial to be featured in the Presidential Symposium at the European Hematology Association (EHA) Annual Congress (Abstract LB2238)*
- *Phase 3 MMY3004 (CASTOR) trial data will also be highlighted at EHA*
- *Together, these results show the potential of daratumumab in combination with either a proteasome inhibitor or immunomodulatory agent*

COPENHAGEN and RARITAN, NJ, JUNE 10, 2016 – Janssen Research & Development, LLC announced today data from the Phase 3 MMY3003 (POLLUX) trial, which show the immunotherapy daratumumab (DARZALEX®) in combination with a standard-of-care treatment regimen, lenalidomide (an immunomodulatory agent) and dexamethasone (a corticosteroid), achieved a 63 percent reduction in the risk of disease progression or death (progression-free survival, or PFS) compared to lenalidomide and dexamethasone alone in patients with multiple myeloma who had received at least one prior line of therapy (Hazard Ratio [HR] = 0.37; 95 percent CI, 0.27-0.52; p<0.0001). The median PFS in the daratumumab arm has not been reached, compared with a median of 18.4 months for patients who received lenalidomide and dexamethasone alone, with a median follow-up of 13.5 months. Additionally, daratumumab significantly increased the overall response rate (ORR) [93 percent vs. 76 percent, p<0.0001].

These data were highlighted during the official Press Briefing at the 21st Annual Congress of the European Hematology Association (EHA) at 8:30 a.m. CET and have been selected for inclusion in the Presidential Symposium from 4:47 – 5:00 p.m. CET on Friday, June 10th (Abstract LB2238).

“Daratumumab induced deep responses when combined with standard of care, more than doubling rates of complete response in these previously treated patients,” said Meletios A. Dimopoulos, M.D., Department of Clinical Therapeutics, National and Kapodistrian University of Athens School of Medicine, Alexandra General Hospital, Athens, Greece. “These striking results underscore the potential clinical benefit of daratumumab as a backbone treatment option for patients who had received one or more prior lines of therapy.”

In addition to meeting the primary endpoint of improved PFS and significantly increasing ORR compared to lenalidomide and dexamethasone alone, daratumumab doubled the rate of complete responses (CR) or better [43 percent vs. 19 percent, p<0.0001], as well as the rate of very good partial responses (VGPR) or better [76 percent vs. 44 percent, p<0.0001].

“From the outset, the Janssen team has focused on delivering a comprehensive development plan for daratumumab that accelerates our understanding of this promising compound in a variety of clinical settings,” said Peter F. Lebowitz, M.D., Ph.D., Global Oncology Head, Janssen. “Together with findings from the MMY3004 CASTOR trial presented at the American Society of Clinical Oncology Annual Meeting last week, these twin studies help pave the way for the future of daratumumab as a foundational therapy in combination with either of the two most widely used classes of therapy.”

Overall, the safety of the daratumumab combination therapy was consistent with the known safety profile of daratumumab monotherapy (D) and lenalidomide plus dexamethasone (Rd), respectively. The most common (≥25 percent) treatment-emergent adverse events (TEAEs) [DRd/Rd] were neutropenia (59 percent/43 percent), diarrhea (43 percent/25 percent), fatigue (35 percent/28 percent), upper respiratory tract infection (32 percent/21 percent), anemia (31 percent/35 percent), constipation (29 percent/25 percent), cough (29 percent/13 percent), thrombocytopenia (27 percent/27 percent) and muscle spasms (26 percent/19 percent). Most common Grade 3/4 TEAEs (>10 percent) were neutropenia (52 percent/37 percent), thrombocytopenia (13 percent/14 percent) and anemia (12 percent/20 percent). The rate of Grade 3/4 infections was 28 percent versus 23 percent, and the most common Grade 3/4 infections (≥5 percent) was pneumonia (8 percent/8 percent). Similar rates of treatment discontinuation due to TEAEs were observed (7 percent/8 percent). Daratumumab-associated infusion-related reactions (48 percent of patients) were mostly Grade 1/2 (Grade 3/4: 5 percent/0 percent), and most (92 percent) occurred during the first infusion.

About the MMY3003 (POLLUX) Trial

The MMY3003 (POLLUX) trial is a Phase 3, multinational, open-label, randomized, multicenter, active-controlled study in 569 patients with multiple myeloma who had received a median of one prior line of therapy. Patients were randomized to receive either daratumumab combined with lenalidomide and dexamethasone, or lenalidomide and dexamethasone alone. Participants were treated until disease progression, unacceptable toxicity or if they had other reasons to discontinue the study. Nineteen percent of patients received three or more prior lines of therapy. Eighty-six percent of patients received prior treatment with proteasome inhibitor (PI); 55 percent received prior treatment with an immunomodulatory agent (including 18 percent with lenalidomide); 44 percent received prior treatment with a PI and immunomodulatory agent. Twenty-seven percent of patients were refractory to their last line of prior therapy, 18 percent were refractory to a PI and none were refractory to lenalidomide.

On May 20th, 2016, the MMY3003 trial was unblinded after meeting its primary endpoint of improved PFS in a pre-planned interim analysis. Based on the recommendation of an Independent Data Monitoring Committee (IDMC), patients in the standard-of-care treatment arm were offered the option to receive daratumumab following confirmed disease progression.

Additional Daratumumab Data at EHA

Another daratumumab Phase 3 trial, MMY3004 (CASTOR), assessing the safety and efficacy of daratumumab in combination with bortezomib and dexamethasone compared with bortezomib and dexamethasone alone, will be featured as an oral presentation at EHA on Sunday, June 12th from 12:00 - 12:15 p.m. CET (Abstract LB2236). The MMY3004 results were previously presented during the Plenary Session at the American Society of Clinical Oncology (ASCO) Annual Meeting (Abstract LBA4) on June 5, 2016.

About DARZALEX® (daratumumab)

In November 2015, daratumumab (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 a confirmatory trial.[1] In May 2016, Janssen-Cilag International NV announced that the European Commission (EC) has 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. In Europe, daratumumab was approved under an accelerated assessment, a process reserved for medicinal products expected to be of major public health interest, particularly from the point of view of therapeutic innovation. [2]

DARZALEX injection for intravenous use is the first CD38-directed monoclonal antibody (mAb) approved anywhere in the world.[1] CD38 is a transmembrane protein expressed on the cell surface that is highly expressed across all multiple myeloma cells, regardless of disease stage.[3] Daratumumab is believed to induce tumor cell death through apoptosis, in which a series of molecular steps in a cell lead to its death as well as through multiple immune-mediated mechanisms of action, including complement-dependent cytotoxicity (CDC), antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP).[1,4] 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.[5]

About Multiple Myeloma

Multiple myeloma is an incurable blood cancer that occurs when malignant plasma cells grow uncontrollably in the bone marrow. [6,7] 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.[8,9] Relapsed cancer means the disease has returned after a period of initial, partial or complete remission.[7] 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.[10] Globally, it is estimated that 124,225 people were diagnosed and 87,084 died from the disease in 2015.[11,12] 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.[13] Patients who relapse after treatment with standard therapies (including PIs or immunomodulatory agents) typically have poor prognoses and few remaining options. [8]

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_1 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 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 including a potential new indication. 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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