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Daratumumab (DARZALEX®) Combination Therapy Significantly Extended Progression-Free Survival in Previously Treated Patients with Multiple Myeloma

- *Phase 3 data from the MMY3004 (CASTOR) trial to be featured in the Plenary Session at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting (Abstract #LBA4)*
- *Data also to be highlighted in ASCO Press Program*

CHICAGO and RARITAN, NJ, June 5, 2016 – Data from the Phase 3 MMY3004 (CASTOR) clinical trial show the immunotherapy daratumumab (DARZALEX®) in combination with a standard of care therapy, bortezomib (a proteasome inhibitor [PI]) and dexamethasone (a corticosteroid), demonstrated a 61 percent reduction in the risk of disease progression or death (progression-free survival, or PFS) compared to bortezomib and dexamethasone alone in patients with multiple myeloma who received a median of two prior lines of therapy (Hazard Ratio (HR) = 0.39; 95 percent CI (0.28-0.53), p<0.0001).

According to results Janssen Research & Development, LLC announced today, daratumumab also significantly increased the overall response rate (ORR) [83 percent vs. 63 percent, p<0.0001]. The median PFS in the daratumumab arm has not been reached, compared with a median PFS of 7.16 months for patients who received bortezomib and dexamethasone alone.

These data will be presented in full today at 3:10 – 3:25 p.m. CDT during the “Plenary Session: Including the Science of Oncology Award and Lecture” at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago. They have also been selected for inclusion in the ASCO Press Program.

“We saw clinically meaningful improvements in progression-free survival and overall response rates with daratumumab when combined with standard of care,” said Antonio Palumbo, M.D., Myeloma Unit Chief, Department of Oncology, Division of Hematology, University of Torino, Italy. “These compelling Phase 3 results demonstrate that a regimen built on daratumumab deepens clinical responses and help to underscore its potential for multiple myeloma patients who have been previously treated.”

In addition to meeting the primary endpoint of improved PFS at a median follow-up of 7.4 months and significantly increasing the ORR compared to bortezomib and dexamethasone alone, daratumumab doubled rates of complete response (CR) or better [19 percent vs. 9 percent, $p<0.0012$], including doubling rates of very good partial response (VGPR) [59 percent vs. 29 percent, $p<0.0001$]. The median PFS has not been reached, compared with a median PFS of 7.16 months for patients who received bortezomib and dexamethasone alone. The treatment benefit of the daratumumab combination regimen was maintained across clinically relevant subgroups.

"We’re excited to share these data with the oncology community at ASCO, just two months after an Independent Data Monitoring Committee recommended unblinding the study,” said Peter F. Lebowitz, M.D., Ph.D., Oncology Therapeutic Area Head, Janssen Research & Development. “This rapid progress for daratumumab mirrors last year, when Phase 3 HELIOS combination data for IMBRUVICA were unblinded just before the meeting.”

“In both cases, the studies were part of fast-moving, comprehensive development plans that have sought to broaden the clinical utility of these newly-approved medicines for patients in need,” added Lebowitz. “We look forward to presenting additional data on daratumumab at the Annual Congress of the European Hematology Association next week, which will expand our understanding of this promising compound in combination with standard therapies.”

Overall, the safety of the daratumumab combination therapy was consistent with the known safety profile of daratumumab monotherapy (D) and bortezomib plus dexamethasone (Vd), respectively. The most common (>25 percent) adverse events (AEs) [DVd/Vd] were thrombocytopenia (59 percent/44 percent), peripheral sensory neuropathy (47 percent/38 percent), diarrhea (32 percent/22 percent) and anemia (26 percent/31 percent). Most common grade 3 or 4 AEs (>10 percent) were thrombocytopenia (45 percent/33 percent), anemia (14 percent/16 percent) and neutropenia (13 percent/4 percent). The rate of Grade 3/4 infections/infestations was 21 percent in the DVd group and 19 percent in the Vd group. The most common Grade 3/4 infections/infestations treatment-emergent AEs, or TEAEs, (≥5 percent) was pneumonia (8 percent/10 percent). The number of patients with Grade 3 or 4 bleeding events (3 patients in DVd group, 2 patients in Vd group) was low in both treatment groups. Few (7 percent/9 percent) patients discontinued therapy due to a TEAE.

About the MMY3004 (CASTOR) Trial

The Phase 3, multinational, open-label, randomized, multicenter, active-controlled MMY3004 study enrolled approximately 490 patients with multiple myeloma who received a median of two prior lines of therapy. Sixty-six percent of patients received prior treatment with bortezomib; 76 percent received prior treatment with an immunomodulatory agent; and 48 percent received prior treatment with a PI and immunomodulatory agent. Thirty-three percent of patients were refractory to an immunomodulatory agent, and 32 percent were refractory to their last line of prior therapy. A total of 498 patients were randomized to receive either daratumumab combined with subcutaneous bortezomib and dexamethasone (n=251) or bortezomib and dexamethasone alone (n=247). Participants were treated with daratumumab until disease progression, unacceptable toxicity, or if they had other reasons to discontinue the study.

On March 30, 2016, the MMY3004 (CASTOR) trial was unblinded after meeting its primary endpoint of improved PFS in a pre-planned interim analysis (HR = 0.39, p<0.0001). 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. Findings from the MMY3004 trial will also be featured in an encore, oral presentation at the 21st Annual Congress of the European Hematology Association (EHA) on Sunday, June 12 at 12:00 – 12:15 CEST (Abstract #LB2236).

Janssen will initiate discussions with regulatory authorities about the potential for a regulatory submission for this indication based on the results of this study. A comprehensive clinical study report is being prepared for submission to global health authorities.

Additional Combination Data

The Phase 3 MMY3003 (POLLUX) study, comparing daratumumab in combination with lenalidomide and dexamethasone versus lenalidomide and dexamethasone alone in patients with multiple myeloma who received at least one prior line of therapy, was also unblinded in May 2016. Based on the results at the pre-planned interim analysis conducted by an IDMC, the study met its primary endpoint of improved PFS. The POLLUX data have been selected for inclusion in the Presidential Symposium at EHA on Friday, June 10 at 4:47 pm CEST and featured in an oral presentation on Sunday, June 12 at 12:30 – 12:45 pm CEST (Abstract #LB2238).

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 (MM), whose prior therapy included a proteasome inhibitor (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® (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.[3] 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.[1] 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).[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. 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.[5,6] 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.[7,8] 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.[9] Globally, it is estimated that 124,225 people were diagnosed, and 87,084 died from the disease in 2015.[10,11] 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.[12] 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.

Editor's Note: IMBRUVICA is jointly developed and commercialized by Janssen Biotech, Inc. and Pharmacyclics LLC, an AbbVie company.

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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[1] DARZALEX Prescribing Information, November 2015.

[2] Johnson & Johnson. Janssen's daratumumab accepted for accelerated CHMP assessment for treatment of European patients with heavily pre-treated multiple myeloma. Available at: http://www.jnj.com/news/all/Janssens-daratumumab-accepted-for-accelerated-CHMP-assessment-for-treatment-of-European-patients-with-heavily-pre-treated-multiple-myeloma. Last accessed May 2016.

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[4] Krejcik, J. et al. Immunomodulatory Effects and Adaptive Immune Response to Daratumumab in Multiple Myeloma. Available from: https://ash.confex.com/ash/2015/webprogram/Paper79122.html. Accessed May 2016.
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