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

- *Phase 3 data from MMY3004 (CASTOR) trial shows Darzalex with 61% risk reduction of progression or death and doubling CR/sCR rates when added to Bortezomib-Dexamethasone (Vd)*
- *Trial data to be featured in the Plenary Session at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting (Abstract #LBA4) and at ASCO press programme*
- *Data to be featured as encore oral presentation at 21st Annual Congress of European Hematology Association (EHA)*

BEERSE, BELGIUM, Sunday 5 June, 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).[1]

According to results Janssen-Cilag International NV 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.[1]

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 Programme. In addition, these results will also be featured in an encore, oral presentation at the 21st Annual Congress of the European Hematology Association (EHA) on Sunday 12 June at 12:00 – 12:15 p.m. CEST (Abstract #LB2236).

"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 Haematology, 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.[1]

"At Janssen we are committed to redefining the impact cancer has on patients, through delivering innovative research and solutions. We're therefore extremely encouraged by the remarkable interim results of this study. The findings provide an important insight into the effect daratumumab can have in combination with established regimens, and illustrate the promise of this immunotherapy in earlier lines of treatment," said Jane Griffiths, Company Group Chairman, Janssen Europe, Middle East and Africa. "We're dedicated to exploring the full treatment value of daratumumab for multiple myeloma patients and look forward to the difference we can make with data like these."

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 anaemia (26 percent/31 percent). Most common grade 3 or 4 AEs (>10

percent) were thrombocytopenia (45 percent/33 percent), anaemia (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.[1]

About the MMY3004 (CASTOR) Trial

The Phase 3, multinational, open-label, randomised, multicentre, active-controlled MMY3004 study has included 498 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. Patients were randomised 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.[1]

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.[2]

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.[3] The POLLUX data have been selected for inclusion in the Presidential Symposium at EHA on Friday 10 June 2016 at 4:47 p.m. CEST (Abstract #LB2238).

About Daratumumab

Daratumumab is a first-in-class biologic targeting CD38, a surface protein that is highly expressed across multiple myeloma cells, regardless of disease stage.[4-6] Daratumumab induces rapid tumour cell death through apoptosis (programmed cell death)[7,8] and multiple immune-mediated mechanisms of action, including complement-dependent cytotoxicity (CDC), antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP).[7,9,10] Daratumumab has also demonstrated immunomodulatory effects that contribute to tumour cell death via a decrease in immune suppressive cells including T-regs, B-regs and myeloid-derived suppressor cells.[7,11] 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. For more information, please see www.clinicaltrials.gov.

In May 2016, daratumumab was approved by the European Commission (EC) 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. 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.[12]

In August 2012, Janssen Biotech, Inc. and Genmab A/S entered a worldwide agreement, which granted Janssen an exclusive license to develop, manufacture and commercialise daratumumab.

About Multiple Myeloma

Multiple myeloma is an incurable blood cancer that occurs when malignant plasma cells grow uncontrollably in the bone marrow.[13,14] 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.[15,16] Relapsed cancer means the disease has returned after a period of initial, partial or complete remission.[17] Accounting for approximately one percent of all cancers and 15 percent to 20 percent of haematologic malignancies worldwide,[18] multiple myeloma is designated as an orphan disease in both Europe and the US. Globally, it is estimated that 124,225 people were diagnosed, and 87,084 died from the disease in 2015.[19,20] 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.[21]

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/janssenEMEA.

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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 materialise, 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 behaviour 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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June 2016
PHEM/DAR/0516/0022