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

- *Phase 3 data from MMY3003 (POLLUX) trial shows daratumumab with 63% risk reduction of progression or death when added to Lenalidomide-Dexamethasone (Ld)*
- *Trial data to be featured in the Presidential Symposium at the European Hematology Association (EHA) Annual Congress (Abstract LB2238)*

COPENHAGEN, DENMARK AND BEERSE, BELGIUM, Friday June 10, 2016 – Janssen-Cilag International NV announced today data from the Phase 3 MMY3003 (POLLUX) trial, which show the immunotherapy daratumumab in combination with a standard of care treatment regimen, lenalidomide (an immunomodulatory agent) and dexamethasone (a corticosteroid), achieved a significant 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).[1] The median PFS in the daratumumab arm has not been reached, compared with a median PFS of 18.4 months for patients who received lenalidomide and dexamethasone alone.[1] Additionally, daratumumab significantly increased the overall response rate (ORR) [93 percent vs. 76 percent, p<0.0001].[1]

These data will be highlighted during the Press Briefing at the 21st Annual Congress of the European Hematology Association (EHA) at 8:30 a.m. CEST and have been selected for

inclusion in the Presidential Symposium from 4:47 – 5:00 p.m. CEST on Friday, June 10th (Abstract LB2238).

“Daratumumab induced deep and durable responses when combined with standard of care, more than doubling the rates of complete response or better in these previously treated patients,” said Meletios A. Dimopoulos, MD, Department of Clinical Therapeutics, National and Kapodistrian University of Athens School of Medicine, Alexandra General Hospital, Athens, Greece and lead author of the abstract. “These striking results underscore the clinical benefit of a treatment plan built on daratumumab for patients with one or more prior lines of therapy.”

In addition to meeting the primary endpoint of significantly improved PFS at a median follow-up of 13.5 months and significantly increasing ORR compared to lenalidomide and dexamethasone alone, daratumumab doubled rates of complete response (CR) or better [43 percent vs. 19 percent, p<0.0001], including rates of very good partial response (VGPR) or better [76 percent vs. 44 percent, p<0.0001].[1] The treatment effect for daratumumab was consistent across all pre-specified subgroups.

“We’re so pleased to see daratumumab delivering consistent results across the treatment continuum in multiple myeloma. MMY3003 is the second Phase 3 study with daratumumab in combination to standard therapy, to meet its primary endpoint before the final analysis,” said Jane Griffiths, Company Group Chairman, Janssen Europe, Middle East and Africa. “These data will be discussed in more detail at EHA today, and we look forward to what will be an extremely exciting medical meeting for Janssen Oncology.”

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. Similar rates of treatment discontinuation due to TEAEs were observed (7 percent/8 percent) in both the experimental arm and the control arm.[1] The most common (<25 percent) treatment-emergent adverse events (TEAEs) [DRd/Rd] were neutropenia (59 percent/43 percent), diarrhoea (43 percent/25 percent), fatigue (35 percent/28 percent), upper respiratory tract infection (32 percent/21 percent), anaemia (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).[1] Most common grade 3/4 TEAEs (>10 percent) were neutropenia (52 percent/37 percent),

thrombocytopenia (13 percent/14 percent) and anaemia (12 percent/20 percent).[1] 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).[1] 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.[1]

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About the MMY3003 (POLLUX) Trial[1]

The MMY3003 (POLLUX) trial is a Phase 3, multinational, open-label, randomised, multicentre, active-controlled study in 569 patients with multiple myeloma who received a median of one prior line of therapy. Patients were randomised 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); and 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 20, 2016, the MMY3003 trial was stopped early after meeting its primary endpoint of significantly improved PFS in a pre-planned interim analysis. Based on the recommendation of an Independent Data Monitoring Committee (IDMC), patients in the control treatment arm were offered the option to receive daratumumab following confirmed disease progression.

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.[2-4]Daratumumab induces rapid tumour cell death through apoptosis (programmed cell death)[5,6] and multiple immune-mediated mechanisms of action, including complement-dependent cytotoxicity (CDC), antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular

phagocytosis (ADCP).[5,7,8] Daratumumab has also demonstrated immunomodulatory effects that contribute to tumour cell death via a decrease in immune suppressive cells including T-regs and myeloid-derived suppressor cells.[5,9] 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 conditionally approved by the European Commission for monotherapy of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy.[5] 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.[10]

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.[11,12] 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.[13,14] Relapsed cancer means the disease has returned after a period of initial, partial or complete remission.[15] Accounting for approximately one percent of all cancers and 15 percent to 20 percent of haematologic malignancies worldwide,[16] 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.[17,18] 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.[19]

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/emea. 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 Jans Janssen-Cilag International, NV 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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