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Janssen Seeks Expanded Use of DARZALEX®▼ (daratumumab) from EMA in Newly Diagnosed Multiple Myeloma

BEERSE, BELGIUM, 21 November, 2017 – Janssen-Cilag International NV today announced the submission of a Type II variation application to the European Medicines Agency (EMA), for the immunotherapy DARZALEX®▼ (daratumumab). The application seeks to broaden the existing marketing authorisation to include daratumumab in combination with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.

"This submission to health authorities takes us one step closer to our goal of redefining combination therapy in multiple myeloma, with the potential to make daratumumab available to more patients throughout the treatment continuum: from newly diagnosed, to heavily pre-treated," said Dr Catherine Taylor, Haematology Therapeutic Area Lead, Janssen Europe, Middle East and Africa (EMEA). "We look forward to working closely with the EMA throughout the review process to deliver on this ambition to optimise clinical benefits for multiple myeloma patients."

The regulatory submission is now pending validation by the EMA and is supported by data from the Phase 3 ALCYONE (MMY3007) study. Additional information about this study can be found at www.ClinicalTrials.gov (NCT02195479), and study findings will be presented at the 59th Annual Meeting of the American Society of Hematology (ASH).

Daratumumab is currently indicated for use in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy;[1] and as monotherapy for the treatment 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.[1]

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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.[2,3,4] Daratumumab is believed to induce tumour cell death through multiple immune-mediated mechanisms of action, including complement-dependent cytotoxicity (CDC), antibody-dependent cell-mediated 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] A subset of myeloid derived suppressor cells (MDSCs), CD38+ regulatory T cells (Tregs) and CD38+ B cells (Bregs) were decreased by daratumumab.[1] Daratumumab is being evaluated in a comprehensive clinical development program that includes nine Phase 3 studies across a range of treatment settings in multiple myeloma, such as in frontline and relapsed settings.[5-13] Additional studies are ongoing or planned to assess its potential for a solid tumour indication and in other malignant and pre-malignant diseases in which CD38 is expressed, such as smouldering myeloma.[14-21] For more information, please see www.clinicaltrials.gov.

For further information on daratumumab, please see the Summary of Product Characteristics at http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/004077/WC500207296.pdf.

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 (MM) is an incurable blood cancer that starts in the bone marrow and is characterised by an excessive proliferation of plasma cells.[22] MM is the second most

common form of blood cancer, with around 39,000 new cases worldwide in 2012.[23] MM most commonly affects people over the age of 65 and is more common in men than in women.[24] The most recent five-year survival data for 2000-2007 show that across Europe, up to half of newly diagnosed patients do not reach five-year survival.[25] Almost 29% of patients with MM will die within one year of diagnosis.[26]

Although treatment may result in remission, unfortunately, patients will most likely relapse as there is currently no cure.[27] While some patients with MM have no symptoms at all, most patients are diagnosed due to symptoms that can include bone problems, low blood counts, calcium elevation, kidney problems or infections.[28] Patients who relapse after treatment with standard therapies, including PIs and immunomodulatory agents, have poor prognoses and few treatment options available.[29]

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 for our latest news.

Cilag GmbH International; Janssen Biotech, Inc.; Janssen Oncology, Inc. and Janssen-Cilag International NV are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding the potential of daratumumab and expectations for its further development. 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-Cilag International NV, any of the other Janssen Pharmaceutical Companies 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; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behaviour and spending patterns 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 descriptions 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 1, 2017, including under "Item 1A. Risk Factors," its most recently filed Quarterly Report on Form 10-Q, including under the caption "Cautionary Note Regarding Forward-Looking Statements," 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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