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Janssen Announces European Commission Approval of Darzalex®▼ (daratumumab) Split Dosing Regimen

BEERSE, BELGIUM, December 20, 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that the European Commission has granted marketing authorisation to provide healthcare professionals with the option to split the first infusion of Darzalex® (daratumumab) over two consecutive days.

"We are committed to the development of new treatments, combinations, and formulations that will support people living with multiple myeloma across the full disease spectrum," said Dr Catherine Taylor, Europe, Middle East and Africa (EMEA) Haematology Therapeutic Area Lead, Janssen. "This is an important decision for healthcare professionals and patients, as it provides flexibility in administration that may help address individual patient needs."

The decision was based on data from the Phase 1b EQUULEUS (MMY1001) clinical trial, which demonstrated daratumumab pharmacokinetics concentrations were comparable regardless of

whether the first dose was administered as a split infusion or single first infusion in patients with multiple myeloma.[1] The safety profile of daratumumab was comparable when administered initially as a split or single dose.[1]

The approval follows the Positive Opinion from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) on 19 November 2018.[2]

#ENDS#

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.[3] 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.[4] A subset of myeloid derived suppressor cells (CD38+ MDSCs), CD38+ regulatory T cells (Tregs) and CD38+ B cells (Bregs) were decreased by daratumumab.[4] Daratumumab is being evaluated in a comprehensive clinical development programme across a range of treatment settings in multiple myeloma, such as in frontline and relapsed settings.[5,6,7,8,9,10,11,12] Additional studies are ongoing or planned to assess its potential in other malignant and pre-malignant haematologic diseases in which CD38 is expressed, such as smouldering myeloma.[13,14] For more information, please see www.clinicaltrials.gov.

In Europe, daratumumab is indicated for use 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, as monotherapy for the treatment 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, and 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.[4] For further information on daratumumab, please see the Summary of Product Characteristics at https://www.ema.europa.eu/documents/product-information/darzalex-epar-product-information_en.pdf.

In August 2012, Janssen Biotech, Inc. and Genmab A/S entered a worldwide agreement, which granted Janssen an exclusive licence to develop, manufacture and commercialise daratumumab.[15]

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.[16] More than 45,000 people were diagnosed with multiple myeloma in Europe in 2016, and more than 29,000 patients died.[17] Up to half of newly diagnosed patients do not reach five-year survival,[18] and almost 29% of patients with multiple myeloma will die within one year of diagnosis.[19]

Although treatment may result in remission, unfortunately, patients will most likely relapse as there is currently no cure.[20] Refractory multiple myeloma is when a patient's disease progresses within 60 days of their last therapy.[21,22] Relapsed cancer is when the disease has returned after a period of initial, partial or complete remission.[23] 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.[24] Patients who relapse after treatment with standard therapies, including PIs and immunomodulatory agents, have poor prognoses and few treatment options available.[25]

About the Janssen Pharmaceutical Companies of Johnson & Johnson

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.

Janssen Biotech, Inc., Janssen-Cilag International NV, and Janssen-Cilag Limited 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 a recommendation to broaden the existing marketing authorisation for daratumumab. 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-Cilag International NV, Janssen-Cilag Limited, Janssen Biotech, Inc., any of the Janssen Pharmaceutical Companies of

Johnson & Johnson 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 December 31, 2017, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," in the company's most recently filed Quarterly Report on Form 10-Q and in 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. Neither the Janssen Pharmaceutical Companies of Johnson & Johnson nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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