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Janssen's daratumumab accepted for accelerated CHMP assessment for treatment of European patients with heavily pre-treated multiple myeloma

BEERSE, BELGIUM, September 25, 2015 – Janssen-Cilag International NV announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has accepted its request for an accelerated assessment of the daratumumab Marketing Authorisation Application (MAA). This acceptance follows the earlier regulatory submission of a MAA which seeks authorisation of daratumumab as a single agent for the treatment of patients with relapsed and refractory multiple myeloma and is currently pending validation by the EMA.

The CHMP grants accelerated assessment when a medicinal product is expected to be of major public health interest particularly from the point of view of therapeutic innovation.

Daratumumab is an investigational, human anti-CD38 monoclonal antibody that works by binding to CD38, a signalling molecule found on the surface of multiple myeloma cells.[1,2,3,4] In doing so, daratumumab triggers the patient's own immune system to attack the cancer cells, resulting in rapid tumour cell death through multiple immune-mediated and other mechanisms of action.[5]

The MAA includes data from the Phase 2 MMY2002 (SIRIUS) monotherapy study, presented at the 51st Annual Meeting of the American Society of Clinical Oncology (ASCO),[6] and data from the Phase 1/2 GEN501 monotherapy study, recently published in *The New England Journal of Medicine*,[7] and data from three additional supportive studies.

"Janssen is pleased with the CHMP's acceptance of an accelerated regulatory review timeline for daratumumab, which reflects the high unmet need for new treatment options for patients with multiple myeloma, currently an incurable disease," said Jane Griffiths, Company Group Chairman, Janssen Europe, Middle East and Africa. "We continue to work closely with European health authorities to make daratumumab available to these patients as soon as possible."

In July 2013 daratumumab was granted Orphan Drug Status by the EMA for the treatment of plasma cell myeloma.[8] Furthermore, this step forward in Europe also follows the acceptance for Priority Review of the Biologics License Application for daratumumab with the U.S. FDA on September 4, 2015.

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

#ENDS#

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.[9] MM is the second most common form of blood cancer, with around 39,000 new cases in Europe in 2012.[10] MM most commonly affects people over the age of 65 and is more common in men than in women.[11] Across Europe, five-year survival rates are 23 percent to 47 percent of people diagnosed.[12] Almost 29 percent of patients with MM will die within one year of diagnosis.[13] Although treatment may result in remission, unfortunately patients will most likely relapse as there is currently no cure. While some patients with MM have no symptoms at all, most patients are diagnosed due to symptoms which can include bone problems, low blood counts, calcium elevation, kidney problems or infections.[11] Patients who relapse after treatment with standard therapies, including proteasome inhibitors (PIs) and immunomodulatory agents (IMiDs), have poor prognoses and few treatment options available.[14]

About Daratumumab

Daratumumab is an investigational human monoclonal antibody that binds with high affinity to the CD38 molecule, which is found on the surface of multiple myeloma cells. It is believed to induce rapid tumour cell death through multiple immune-mediated mechanisms, including complement-dependent cytotoxicity, antibody-dependent cellular

phagocytosic and antibody-dependent cellular cytotoxicity, as well as via induction of apoptosis.[5] 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 in which CD38 is expressed, such as smouldering myeloma and non-Hodgkin lymphoma.

About Janssen

The Janssen Pharmaceutical Companies of Johnson & Johnson are dedicated to addressing and solving the most important unmet medical needs of our time, including oncology (e.g. multiple myeloma and prostate cancer), immunology (e.g. psoriasis), neuroscience (e.g. schizophrenia, dementia and pain), infectious disease (e.g. HIV/AIDS, hepatitis C and tuberculosis), and cardiovascular and metabolic diseases (e.g. diabetes). Driven by our commitment to patients, we develop sustainable, integrated healthcare solutions by working side-by-side with healthcare stakeholders, based on partnerships of trust and transparency. More information can be found on www.janssen-emea.com. Follow us on www.twitter.com/janssenEMEA for our latest news.

Janssen Pharmaceutical NV, Janssen Research & Development, LLC, Janssen Biotech, Inc., and Janssen-Cilag International NV are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Janssen in Oncology

In oncology, our goal is to fundamentally alter the way cancer is understood, diagnosed and managed, reinforcing our commitment to the patients who inspire us. In looking to find innovative ways to address the cancer challenge, our primary efforts focus on several treatment and prevention solutions. These include a focus on haematologic malignancies, prostate cancer and lung cancer; cancer interception with the goal of developing products that interrupt the carcinogenic process; biomarkers that may help guide targeted, individualised use of our therapies; as well as safe and effective identification and treatment of early changes in the tumour microenvironment.

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 approval of a 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 any of the Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in new product

development, including uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success; 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 or financial distress of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; manufacturing difficulties and delays; 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 December 28, 2014, 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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