NEWS RELEASE

Janssen Submits Marketing Authorisation Application for daratumumab for European Patients With Heavily Pre-treated Multiple Myeloma

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BEERSE, BELGIUM, September 9, 2015 - Janssen-Cilag International NV announced today it has submitted a new Marketing Authorisation Application to the European Medicines Agency (EMA) for daratumumab, an investigational, human anti-CD38 monoclonal antibody, for the treatment of patients with relapsed and refractory multiple myeloma.

Multiple myeloma is an incurable blood cancer that starts in the bone marrow and is characterised by excess growth and survival of malignant plasma cells.[1] Patients who are refractory to both proteasome inhibitors (PIs) or immunomodulatory agents (IMiDs) have a poor prognosis, with an estimated median overall survival of nine months.[2]

Daratumumab works by binding to CD38, a signalling molecule found on the surface of multiple myeloma cells.[3,4,5,6] 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.[7]

The regulatory submission for daratumumab is now pending validation by the EMA and is based on data from the Phase 2 MMY2002 (SIRIUS) monotherapy study, which was presented at the 51st Annual Meeting of the American Society of Clinical Oncology (ASCO),[8] data from the Phase 1/2 GEN501 monotherapy study, which was recently **published** in The New England Journal of Medicine,[9] and data from three supportive studies.

For MMY2002, the primary efficacy endpoint was overall response rate (ORR). Ninety-five percent of patients in the study were double refractory to a PI and IMiD. Patients received three or more lines of prior therapy (median of five), including a PI and an IMiD. Daratumumab achieved an ORR of 29 percent in the group of patients who received 16 mg/kg (n=106) as a single-agent therapy, with a well tolerated safety profile.[8]

The ORR outcomes of MMY2002 are similar to the ORR data in the Phase 1/2 GEN501 study, in which safety was the primary endpoint. Patients enrolled in GEN501 received two or more lines of prior therapy (median four), including a PI and an IMiD, and 64 percent were refractory to both PIs and IMiDs. In this study, daratumumab demonstrated a tolerable safety profile and achieved an ORR of 36 percent (11 partial responses, two very good partial responses and two complete responses) in the group of patients who received 16 mg/kg, with responses improving over time. Median progression-free survival was 5.6 months (95% CI: 4.2, 8.1) and 65 percent (95% CI: 28, 68) of responders remained in remission at 12 months. The OS rate at 12 months was 77 percent (95% CI: 58, 88).[9]

"For more than a decade Janssen has focused on addressing unmet needs in multiple myeloma which, despite important advances, still remains an incurable cancer," said Jane Griffiths, Company Group Chairman, Janssen Europe, Middle East and Africa. "Through our continued commitment to research into new therapies and innovative mechanisms, we are encouraged to see the depth of therapeutic response with daratumumab. This is particularly promising for relapsed and refractory patients who have a poor prognosis and may already have exhausted all existing treatment options. We look forward to working with the EMA to make daratumumab available for people with multiple myeloma."

In **July 2013** daratumumab was granted Orphan Drug Status by the EMA for the treatment of plasma cell myeloma.[10] Furthermore, this new EMA submission 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. Janssen is currently the sponsor of all but one study globally.

#ENDS#

About MMY2002 study

MMY2002 enrolled a population of patients with heavily pre-treated (three or more lines of prior therapy; median of five, including a PI and an IMiD) or double refractory multiple myeloma who had exhausted effective treatments. In patients who received 16 mg/kg (n=106) as a single-agent therapy with a tolerable safety profile, stringent complete

responses (sCR) were achieved in three patients, very good partial responses in 10 patients, and 18 partial responses (PR) were reported. No patients discontinued treatment due to infusion-related reactions (IRRs) and 4.7 percent of patients discontinued treatment due to adverse events (AEs), none of which were considered drug-related.[8]

About GEN501 study

Safety was the primary endpoint in the GEN501 study, which enrolled a population of patients with heavily pre-treated (two or more lines of prior therapy; median of four, including a PI and an IMiD) or double refractory multiple myeloma who have exhausted effective treatments. In the 16 mg/kg cohort, serious AEs occurred in 33 percent of patients. IRRs occurred in 71 percent of patients in the 8 mg/kg and 16 mg/kg cohorts, and all were Grades 1 and 2, with the occurrence of one patient with Grade 3 reactions. The majority of IRRs occurred during the first infusion, with notably fewer during subsequent infusions. No patient discontinued treatment due to an IRR. The most common AEs in either treatment group were fatigue, allergic rhinitis, and pyrexia (fever). The most frequent hematologic AE was neutropenia (abnormally low levels of neutrophils, a type of white blood cell), which occurred in 12 percent of patients (n=5) in the 16 mg/kg cohort. Grade 3 or 4 AEs were reported in 26 percent of patients in the 16 mg/kg cohort, with pneumonia (n=5) and thrombocytopenia (abnormally low levels of platelets in the blood; n=4) as the most common in both the 8 mg/kg and 16 mg/kg cohorts.[9]

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.[1] MM is the second most common form of blood cancer, with around 39,000 new cases in Europe in 2012.[11] MM most commonly affects people over the age of 65 and is more common in men than in women.[12] Across Europe, five-year survival rates are 23 percent to 47 percent of people diagnosed.[13] Almost 29 percent of patients with MM will die within one year of diagnosis.[14] 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.[12] Patients who relapse after treatment with standard therapies, including PIs and IMiDs have poor prognoses and few treatment options available.[2]

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.[7] 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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