NEWS RELEASE

Janssen Initiates Rolling Submission of Biologic License Application (BLA) for daratumumab with U.S. FDA for the Treatment of Multiple Myeloma

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RARITAN, N.J., June 5, 2015 - Janssen Research & Development, LLC (Janssen) has initiated the rolling submission of its Biologic License Application (BLA) for daratumumab to the U.S. Food and Drug Administration (FDA) for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD), or who are double refractory to a PI and an IMiD. Daratumumab - an investigational human anti-CD38 monoclonal antibody - received Breakthrough Therapy Designation by the U.S. FDA for this set of patients in **May 2013**. A rolling submission allows the company to submit portions of the regulatory application to the FDA as they are completed.[1]

In **August 2012**, Janssen Biotech, Inc. and Genmab A/S entered into an agreement which granted Janssen a worldwide exclusive license to develop, manufacture and commercialize daratumumab. With the exception of one study sponsored globally by the French multiple myeloma cooperative group, Intergroupe Francophone du Myelome (IFM), Janssen is the global sponsor of all current and future clinical studies for daratumumab.

Multiple myeloma is an incurable blood cancer.[2] Approximately 26,850 new patients will be diagnosed with multiple myeloma and approximately 11,240 people will die from the disease in the U.S. in 2015.[3] Patients who relapse after treatment with standard therapies, including PIs or IMiDs, have poor prognoses and few treatment options.[4]

The regulatory submission for daratumumab will be primarily supported by data from the Phase 2 MMY2002 (SIRIUS) monotherapy study announced in **May 2015** at the 51st Annual Meeting of the American Society of Clinical

Oncology (ASCO), along with additional data from four other studies, including the Phase 1/2 GEN501 monotherapy study.

"Despite therapeutic advances over the last 10 years, multiple myeloma remains an incurable disease, and many people eventually relapse or grow resistant to available therapies, which has underscored the need for newer medicines with novel mechanisms of action," said Peter F. Lebowitz, M.D., Ph.D., Global Oncology Head, Janssen. "We are proud of the Breakthrough Therapy Designation daratumumab received and look forward to working in close collaboration with the FDA during its review."

Daratumumab is the second medicine in the Janssen oncology portfolio to receive Breakthrough Therapy Designation, which is intended to expedite the development and review time for a potential new medicine. If approved, daratumumab would be commercialized in the U.S. by Janssen Biotech, Inc.

About Multiple Myeloma

Multiple myeloma is an incurable blood cancer that starts in the bone marrow and is characterized by an excess proliferation of plasma cells.[5] Multiple myeloma is the third most common blood cancer in the United States (U.S.), following only leukemia and lymphoma.[6] Globally, it is estimated that 114,251 people will be diagnosed and 80,019 will die from the disease.[7] While some patients with multiple myeloma 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.[8]

About Daratumumab

Daratumumab is an investigational human monoclonal antibody (mAb) that binds with high affinity to the transmembrane ectoenzyme, CD38, on the surface of multiple myeloma cells. It induces rapid tumor cell death through diverse mechanisms of action.[9] Five Phase 3 clinical studies with daratumumab in relapsed and frontline settings are currently ongoing. Additional studies are planned or underway to assess its potential in other malignant and pre-malignant diseases on which CD38 is expressed, such as smoldering myeloma and non-Hodgkin's lymphoma.

About Janssen Research & Development, LLC

At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people throughout the world. Please visit **http://www.janssenrnd.com** for more information.

About Janssen Biotech, Inc.

Janssen Biotech, Inc. redefines the standard of care in immunology, oncology, urology and nephrology. Built upon a

rich legacy of innovative firsts, Janssen Biotech has delivered on the promise of new treatments and ways to improve the health of individuals with serious disease. Beyond its innovative medicines, Janssen Biotech is at the forefront of developing education and public policy initiatives to ensure patients and their families, caregivers, advocates and health care professionals have access to the latest treatment information, support services and quality care. For more information on Janssen Biotech, Inc. or its products, visit **www.janssenbiotech.com**. Follow us on Twitter at **www.twitter.com/JanssenUS**.

Janssen Research & Development, LLC and Janssen Biotech, Inc. 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 hematologic 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, individualized use of our therapies; as well as safe and effective identification and treatment of early changes in the tumor microenvironment. Please visit **www.oncology.janssenrnd.com**.

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product 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 Research & Development, LLC, Janssen Biotech, Inc. and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in new product development, including the uncertainty of clinical success and of obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; challenges to patents; 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 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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[1] U.S. Food and Drug Administration. "Guidance for Industry Expedited Programs for Serious Conditions - Drugs and

[1] U.S. Food and Drug Administration. "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics." Available at **http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf**. Accessed June 2015.

[2] American Cancer Society. "Multiple Myeloma Overview" **http://www.cancer.net/cancer-types/multiple-myeloma/overview**. Accessed June 2015.

[3] American Cancer Society. "What are the key statistics about multiple myeloma?" **http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-key-statistics**. Accessed June 2015.

[4] Kumar, SK et al. Leukemia. 2012 Jan;26(1):149-57.

[5] American Cancer Society. "Multiple Myeloma Overview" **http://www.cancer.net/cancer-types/multiple-myeloma/overview**. Accessed June 2015.

[6] National Cancer Institute. "A Snapshot of Myeloma." Available at **www.cancer.gov/research/progress/snapshots/myeloma**. Accessed June 2015.

[7] GLOBOCAN 2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide. Available at **http://globocan.iarc.fr/Pages/fact_sheets_population.aspx**. Accessed June 2015.

[8] American Cancer Society. "How is Multiple Myeloma Diagnosed?" **http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-diagnosis**. Accessed June 2015.

[9] Jansen JH, et al. Blood. 2012; 120.2974

Media Inquiries:

Kellie McLaughlin

Phone: 1-908-927-7477

Mobile: 1-609-468-8356

Satu Kaarina Glawe

Mobile: +49 172 294 62 64

Megan Farina

Phone: 1-215-325-6861

Investor Relations:

Lesley Fishman

Phone: 1-732-524-3922

Louise Mehrotra

Phone: 1-732-524-6491