



May 1, 2013

## **Daratumumab Receives Breakthrough Therapy Designation in Double Refractory Multiple Myeloma from U.S. Food and Drug Administration**

### **Second Janssen oncology compound to receive Breakthrough Therapy Designation**

**RARITAN, NJ - May 1, 2013** - Janssen Research & Development, LLC (Janssen) announced the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation for daratumumab 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 IMiD. Daratumumab is an investigational human CD38 monoclonal antibody and was discovered by the Danish company Genmab A/S. In [August 2012](#), Janssen Biotech, Inc. and Genmab entered an agreement which granted Janssen an exclusive worldwide license to develop and commercialize daratumumab.

"We are honored that the FDA has granted Breakthrough Therapy Designation to another compound in our pipeline, said Peter F. Lebowitz, M.D., Ph.D., Global Oncology Therapeutic Area Head, Janssen. "Our team is looking forward to the opportunity to work closely with the FDA on the development program of this compound, which has the potential to make a difference in the lives of patients."

This FDA designation marks the second oncology compound within the Janssen pipeline to receive Breakthrough Therapy Designation in the last three months. In [April 2013](#) and [February 2013](#), the company announced that the FDA granted Breakthrough Therapy Designations for the investigational oral Bruton's tyrosine kinase (BTK) inhibitor ibrutinib as a monotherapy for three B-cell malignancies: in patients with chronic lymphocytic leukemia or small lymphocytic lymphoma with deletion of the short arm of chromosome 17 (del17p), in patients with relapsed or refractory Mantle Cell Lymphoma (MCL) who have received prior therapy, and in patients with Waldenström's macroglobulinemia (WM). Janssen and Pharmacyclics, Inc. are co-developing and will co-commercialize ibrutinib.

Enacted as part of the 2012 FDA Safety and Innovation Act (FDASIA), Breakthrough Therapy Designation is intended to expedite the development and review time for a potential new medicine "to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development."<sup>1</sup>

The implications of Breakthrough Therapy Designation cannot be determined at this time. Janssen is working with the FDA to determine any potential implications of the Breakthrough Therapy Designation to the ongoing and planned development activities.

#### **About Multiple Myeloma**

Multiple myeloma is a cancer of plasma cells and according to the American Cancer Society 2013 estimates, approximately 22,350 new cases of multiple myeloma will be diagnosed and approximately 10,710 deaths will occur in the U.S. in 2013.<sup>2</sup> At present, no cure is available. The 5-year relative survival rate for multiple myeloma is around 40%.<sup>3</sup> New treatment modalities might improve the survival.

#### **About Daratumumab**

Daratumumab is an investigational human monoclonal antibody (mAb) with broad spectrum cytotoxic activity. It targets the CD38 molecule, which is highly expressed on the surface of multiple myeloma cells and may also have potential in other cancers on which CD38 is expressed.

It is currently in Phase I/II trials for multiple myeloma and has potential applicability against other malignancies on which CD38 is expressed.

#### **About Janssen Research & Development**

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. Janssen Research & Development and Janssen Biotech are part of the Janssen Pharmaceutical Companies. Please visit <http://www.janssenrnd.com> for more information.

*This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. 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 unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, Janssen Biotech, Inc., any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to governmental laws and regulations and domestic and foreign health care reforms; trends toward health care cost containment; and increased scrutiny of the health care industry by government agencies. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 30, 2012. Copies of this Form 10-K, as well as subsequent filings, are available online at [www.sec.gov](http://www.sec.gov), [www.jnj.com](http://www.jnj.com) or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments.

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<sup>1</sup>PUBLIC LAW 112-144-JULY 9, 2012. U.S. Government Printing Office. Available at: <http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf>.

<sup>2</sup> How many people get multiple myeloma? The American Cancer Society. <http://www.cancer.org/cancer/multiplemyeloma/overviewguide/multiple-myeloma-overview-key-statistics>. Accessed March 2013.

<sup>3</sup> SEER Stat Fact Sheets: Myeloma. Surveillance Epidemiology and End Results, National Cancer Institute. <http://seer.cancer.gov/statfacts/html/mulmy.html>. Accessed March 2013.