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Ibrutinib Receives Two Oncology Breakthrough Therapy Designations from U.S. Food and Drug Administration

Investigational oncology agent for B-cell malignancies jointly being developed by Janssen and Pharmacyclics

RARITAN, N.J., Feb. 12, 2013 /PRNewswire/ -- Janssen Research & Development, LLC (Janssen), today announced the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designations for the investigational oral agent ibrutinib as a monotherapy for two B-cell malignancies: in patients with relapsed or refractory mantle cell lymphoma (MCL) who have received prior therapy, and in patients with Waldenstrom's macroglobulinemia (WM).

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."[1]

"We are pleased that the FDA has granted two Breakthrough Therapy Designations for ibrutinib as the designation represents a major leap forward in accelerating drug development timelines," said Paul Stoffels, M.D., Chief Scientific Officer and Worldwide Chairman, Pharmaceuticals, Johnson & Johnson. "We are committed to realizing the full potential of ibrutinib for patients with mantle cell lymphoma, Waldenstrom's macroglobulinemia, as well as other B-cell malignancies, and will work with Pharmacyclics and the FDA to ensure the clinical development program for ibrutinib continues to move forward as quickly as possible."

Janssen Biotech, Inc. and Pharmacyclics entered a collaboration and license agreement in December 2011 to co-develop and co-commercialize ibrutinib. The filing for ibrutinib in MCL is expected to be made prior to the end of 2013 and discussions with the FDA about filing in WM continue. The implications of Breakthrough Therapy Designation cannot be determined at this time. Janssen and Pharmacyclics are working with the FDA to determine any potential implications of the Breakthrough Therapy Designations to the ongoing and planned development activities.

"As an oncology product, ibrutinib receiving the Breakthrough Therapy Designation is an example of progress and hope for patients fighting a range of cancers. This designation shows that the FDA is dedicated to using an 'all hands on deck approach' to work on products that show promise in treating serious and life-threatening diseases," said Dr. Ellen Sigal, Chair and Founder of Friends of Cancer Research, a think tank and advocacy organization based in Washington DC. "The breakthrough pathway that our organization worked to create is intended to speed up the development and review of treatments that may demonstrate substantial improvement over existing therapies, and ibrutinib is a great example of using this new designation to potentially accelerate patient access to promising treatments."

About Mantle Cell Lymphoma
MCL is an aggressive type of B-cell non-Hodgkin lymphoma (NHL) that usually occurs in older adults. The disease typically begins in the lymph nodes, but can spread to other tissues, such as bone marrow and the liver. Ibrutinib targets the B-cell receptor pathway, an important pathway in malignant B-cell growth and proliferation. In the United States, there are approximately 5,000 new cases of MCL each year.

About Waldenstrom's Macroglobulinemia

Waldenstrom's macroglobulinemia is rare type of lymphoma. The disease begins with a malignant change to the B-cell during its maturation so that it continues to reproduce more malignant B-cells resulting in an overproduction of monoclonal immunoglobulin M antibody (IgM). WM is a hematologic malignancy for which no established standard of care - or approved therapeutic - exists. In the United States, there are approximately 1,500 new cases each year.[2]

About Ibrutinib
Ibrutinib was designed to specifically target and selectively inhibit an enzyme called Bruton's tyrosine kinase (BTK). BTK is a key mediator of at least three critical B-cell pro-survival mechanisms occurring in parallel — regulating apoptosis, adhesion, and cell migration and homing. Through these multiple actions, BTK helps to direct malignant B-cells to lymphoid tissues, thus allowing access to a microenvironment necessary for survival.

The effectiveness and safety of ibrutinib alone or in combination with other treatments is being studied in several B-cell

malignancies, including chronic lymphocytic leukemia/small lymphocytic lymphoma, mantle cell lymphoma, diffuse large B-cell lymphoma, follicular lymphoma, Waldenstrom's macroglobulinemia and multiple myeloma. To date, five Phase III trials have been initiated with ibrutinib and a total of 27 trials are currently registered on clinicaltrials.gov.

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 of Johnson & Johnson. 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, 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 healthcare 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 healthcare 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 January 1, 2012. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, 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).

[1] 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.

[2] Waldenstrom Macroglobulinemia. American Cancer Society. Available at: http://www.cancer.org/cancer/waldenstrommacroglobulinemia/index.

Media Inquiries:
Kellie McLaughlin
Phone: 1-908-927-7477
Mobile: 1-609-468-8356

Investor Relations:
Stan Panasewicz
Phone: 1-732-524-2524
Louise Mehrotra
Phone: 1-732-524-6491

U.S. Medical Inquiries:
1-800-JANSSEN (800-526-7736)

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