Johnson & Johnson

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Ibrutinib Receives Third Oncology Breakthrough Therapy Designation from U.S. Food and Drug Administration

Designation granted in the treatment of patients with chronic lymphocytic leukemia or small lymphocytic lymphoma with a genetic mutation, del17p
Ibrutinib is an investigational oral Bruton's tyrosine kinase inhibitor being studied in several B-cell malignancies

RARITAN, N.J., April 8, 2013 /PRNewswire/ -- Janssen Research & Development, LLC (Janssen) announced today that the U.S. Food and Drug Administration (FDA) has granted a third Breakthrough Therapy Designation for the investigational oral Bruton's tyrosine kinase (BTK) inhibitor ibrutinib. Ibrutinib has been granted Breakthrough Therapy Designation as a monotherapy in the treatment of patients with chronic lymphocytic leukemia or small lymphocytic lymphoma with deletion of the short arm of chromosome 17 (del17p). Del17p is a genetic mutation that occurs in some patients with CLL/SLL; it is associated with a poor prognosis. Ibrutinib is jointly being developed by Janssen and Pharmacyclics Inc.

"Ibrutinib continues to demonstrate promise for patients living with B-cell malignancies, and we are pleased that the FDA has recognized its potential for people living with CLL and the del17p mutation," said Peter F. Lebowitz, M.D., Ph.D., Global Oncology Therapeutic Area Head, Janssen. "This third Breakthrough Therapy Designation reflects the potential importance of ibrutinib for patients diagnosed with a 17p deletion chromosomal abnormality in CLL/SLL, and we are committed to working with Pharmacyclics and the FDA to expedite development and review of ibrutinib as quickly as possible."

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 Designation to the ongoing and planned development activities.

In February 2013, FDA granted Breakthrough Therapy Designations for 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]

About Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma
Chronic Lymphocytic Leukemia (CLL) is a slow-growing cancer of the white blood cells (lymphocytes), most commonly B-cells. CLL is the most common adult leukemia.[2] The genetic mutation 17p occurs when part of chromosome 17 has been lost. CLL patients with 17p deletion have poor treatment outcomes.[3] 17p deletion is reported in seven percent of CLL cases at diagnosis,[4] with approximately 20 to 40% of relapsed or refractory patients harboring the mutation.[5] Small Lymphocytic Lymphoma (SLL) is a slow-growing lymphoma in which too many immature white blood cells cause lymph nodes to become larger than normal.[6]

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 30 trials are currently registered on clinicaltrials.gov.

Janssen Biotech, Inc. and Pharmacyclics entered a collaboration and license agreement in December 2011 to co-develop and co-commercialize ibrutinib.

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, 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, 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] How Common is CLL? Leukemia & Lymphoma Society. http://www.lls.org/#/diseaseinformation/leukemia/chroniclymphocyticleukemia/incidence/. Accessed March 2013.

[3]Non-Hodgkin's Lymphomas. Version 1.2013. NCCN Clinical Practice Guidelines in Oncology. http://www.nccn.org/professionals/physician_gls/pdf/nhl.pdf. Accessed March 2013.

[4]Non-Hodgkin's Lymphomas. Version 1.2013. NCCN Clinical Practice Guidelines in Oncology. http://www.nccn.org/professionals/physician_gls/pdf/nhl.pdf. Accessed March 2013.

[5] Stilgenbaueer S and Zenz T. Understanding and Managing Ultra High-Risk Chronic Lymphocytic Leukemia. Hematology. 2010: 481-488.

[6] Small Lymphocytic Lymphoma. National Cancer Institute. http://www.cancer.gov/dictionary?cdrid=407751. Accessed March 2013.

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