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## **New Drug Application Submitted to U.S. FDA for Ibrutinib in the Treatment of Two B-Cell Malignancies**

### **If approved, ibrutinib will address a high unmet need in relapsed/refractory chronic lymphocytic leukemia and relapsed/refractory mantle cell lymphoma**

RARITAN, NJ, July 10, 2013 - Janssen Research & Development, LLC announced the submission of a New Drug Application for ibrutinib to the U.S. Food and Drug Administration (FDA) for its use in the treatment of previously treated patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), and for its use in the treatment of previously treated patients with mantle cell lymphoma (MCL). The regulatory submission for ibrutinib is supported by data from two pivotal Phase 2 studies, one in relapsed/refractory CLL/SLL (PCYC-1102) and one in relapsed/refractory MCL (PCYC-1104), both of which were published in *The New England Journal of Medicine* online on June 19, 2013. Ibrutinib is a novel Bruton's tyrosine kinase (BTK) inhibitor being jointly developed by Janssen and Pharmacylics, Inc. for the treatment of B-cell malignancies.

If approved, ibrutinib would be the first in a class of oral BTK inhibitors and is one of the first medicines to file for FDA approval via the new Breakthrough Therapy Designation pathway. Ibrutinib will be co-commercialized in the U.S. by Janssen Biotech, Inc. and Pharmacylics.

"The FDA submission is another important milestone for ibrutinib since we formed our strategic partnership with Pharmacylics just 18 months ago," said Peter F. Lebowitz, M.D., Ph.D., Global Oncology Head, Janssen. "Both companies recognize that there is great unmet need among these patient populations, and together in close collaboration with the FDA, as part of its Breakthrough Therapy Designation pathway, we have been able to accelerate the ibrutinib development program for the benefit of patients."

Breakthrough Therapy Designation is intended to expedite the development and review time for a potential new medicine. To date, ibrutinib has been granted three Breakthrough Therapy Designations by the FDA as a monotherapy for the treatment of: patients with CLL/SLL with deletion of the short arm of chromosome 17 (del 17p), patients with relapsed/refractory MCL who have received prior therapy, and patients with Waldenström's macroglobulinemia (WM).

CLL/SLL and MCL are hematologic malignancies belonging to a type of cancers that originate from B-cells (a type of white blood cell, or lymphocyte). (CLL and SLL are considered to be different manifestations of the same underlying disease as they share similarities in signs and symptoms, genetic features, disease progression and treatment.) Data suggest ibrutinib covalently bonds to BTK in malignant B-cells, shutting down their major growth and survival pathway.

#### **About Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma**

Chronic Lymphocytic Leukemia (CLL) is a slow-growing blood cancer that most commonly originates from B-cells, a type of white blood cell (lymphocyte). B-cells are part of the immune system and play an important role in fighting infection in the body. CLL is the most common adult leukemia in the Western World. Approximately 15,680 patients in the U.S. are diagnosed each year with CLL. The prevalence of CLL is approximately 113,000 in the U.S. CLL is a chronic disease of the elderly with a five-year survival rate of approximately 82 percent.<sup>1</sup> Patients commonly receive multiple lines of treatment over the course of their disease.

In CLL, the genetic mutation del 17p occurs when part of chromosome 17 has been lost. CLL patients with del 17p have poor treatment outcomes. Del 17p is reported in seven percent of treatment-naïve CLL cases, with approximately 20 to 40 percent of relapsed/refractory patients harboring the mutation. When cancer cells are located mostly in the lymph nodes, the disease is called SLL.

#### **About Mantle Cell Lymphoma**

MCL is a B-cell malignancy, an aggressive type of B-cell non-Hodgkin lymphoma (NHL) that usually occurs in older adults.<sup>2</sup> The disease typically begins in the lymph nodes, but can spread to other tissues, such as bone marrow, liver, and spleen.<sup>3</sup> Patients typically survive an average of five years.<sup>4</sup> Ibrutinib targets the B-cell receptor pathway via inhibiting BTK, a critical mediator in malignant B-cell growth and proliferation. In the U.S., there are approximately 5,000 new cases of MCL each year.<sup>3</sup>

#### **About Ibrutinib**

Ibrutinib is an investigational, oral Bruton's tyrosine kinase (BTK) inhibitor. The effectiveness and safety of ibrutinib alone or in combination with other treatments is being studied in several B-cell malignancies. Janssen Biotech, Inc. and Pharmacylics entered a collaboration and license agreement in December 2011 to co-develop and co-commercialize ibrutinib. Details about

the complete ibrutinib clinical program are posted on [clinicaltrials.gov](http://clinicaltrials.gov).

**About Janssen Research & Development and Janssen Biotech, Inc.**

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 with serious diseases throughout the world. Beyond its innovative medicines, Janssen 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.

Janssen Research & Development and Janssen Biotech are two of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit <http://www.janssenrnd.com> or [www.janssenbiotech.com](http://www.janssenbiotech.com) for more information or call 1-800-526-7736 for U.S. medical inquiries. Follow us on Twitter at [www.twitter.com/JanssenUS](http://www.twitter.com/JanssenUS).

*(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> Cancer.net. "Leukemia - Chronic Lymphocytic - CLL". <http://www.cancer.net/cancer-types/leukemia-chronic-lymphocytic-cll/statistics>. Accessed June 2013.

<sup>2</sup> Cancer.net. "Lymphoma - Non-Hodgkin". <http://www.cancer.net/cancer-types/lymphoma-non-hodgkin/subtypes>. Accessed April 2013.

<sup>3</sup> Know Cancer. "Mantle Cell Lymphoma". Available at: <http://www.knowcancer.com/oncology/mantle-cell-lymphoma/>. Accessed April 2013.

<sup>4</sup> Geisler, C. (2010) "Front-line treatment of mantle cell lymphoma." *Haematologica*, 95:8:1241-1243. Available at: <http://www.haematologica.org/content/95/8/1241.full>

**Media Inquiries:**

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

Lisa Vaga  
Phone: 1-908-218-7316  
Mobile: 1-908-670-0363

**Investor Relations:**

Stan Panasewicz  
Phone: 1-732-524-2524

Louise Mehrotra  
Phone: 1-732-524-6491