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Ibrutinib Data Published in The New England Journal of Medicine Show

A second study in relapsed/refractory chronic lymphocytic leukemia (CLL) also published in the online edition

RARITAN, NJ - June 19, 2013 - Janssen Research & Development, LLC (Janssen) today announced that a study published online in *The New England Journal of Medicine (NEJM)* demonstrates treatment with ibrutinib, an investigational oral Bruton's tyrosine kinase (BTK) inhibitor, resulted in an overall response rate of 68%, with 47% of patients achieving a partial response and 21% achieving a complete response, or the disappearance of all signs of cancer, in patients with relapsed/refractory mantle cell lymphoma (MCL). The response to ibrutinib did not vary based on prior exposure to bortezomib.

A separate study was published in the same online edition, examining the safety and efficacy of ibrutinib for the treatment of relapsed/refractory chronic lymphocytic leukemia (CLL). Ibrutinib is being jointly developed by Janssen and Pharmacyclics, Inc. who also sponsored the studies.

"The safety and efficacy of ibrutinib as observed in mantle cell lymphoma study have not been seen before with a single agent," said lead author Michael Wang, M.D., Department of Lymphoma/Myeloma, The University of Texas MD Anderson Cancer Center. "I am excited to see data demonstrating an increasing response to ibrutinib without an associated increase in adverse events over time."

The primary endpoint of the study was overall response rate. Secondary endpoints included: duration of response, progression free survival, overall survival and frequency and severity of adverse events.

Progression-free survival for patients in the study was 13.9 months and while the median overall survival for this study has not been reached, it is estimated to be 58% at 18 months. The estimated median duration of response for those patients who responded (n=75) was 17.5 months. The overall-survival analysis was performed at the time of the primary analysis of progression-free survival, when 70 (63.1%) of patients were alive; the median overall survival had not yet been reached.

The most common non-hematologic events regardless of causal relationship (occurring in >30% of patients) being reported were diarrhea (50%), fatigue (41%) and nausea (31%). Adverse hematologic events were relatively infrequent. Eight patients experienced an AE leading to treatment discontinuation. The most common non-hematologic Grade 3 or greater AE was pneumonia (6%). Grade 3 or greater hematological toxicities were neutropenia (16%), thrombocytopenia (11%) and anemia (10%) as the leading AEs.

This Phase 2 multicenter, open-label, study included 111 patients with relapsed/refactory MCL treated with ibrutinib at 18 sites internationally and was designed to determine the safety and efficacy of ibrutinib in patients with relapsed/refractory MCL. Patients were enrolled into two cohorts based on prior bortezomib exposure - either no prior bortezomib (n=63) or prior bortezomib (n=48) - with both groups receiving 560 mg of ibrutinib orally, once a day, and had received a median of three prior therapies. The data were presented in part at the annual meeting of the American Society of Hematology in December 2012, the European Hematology Association annual meeting in June 2013 and are being presented at the 12th International Conference on Malignant Lymphoma in Lugano, Switzerland this week.

	Bortezomib-naïve (n=63)	Bortezomib-exposed (n=48)	*All evaluated patients (n=111)*
***Complete response**, n (%)*	*12 (19)*	*11 (23)*	*23 (21)*
***Partial response**, n (%)*	*31 (49)*	*21 (44)*	*52 (47)*
***Overal response**, n (%)*	*43 (68)*	*32 (67)*	*75 (68)*

"The results of this study add to the growing body of evidence supporting the safety and efficacy of ibrutinib in patients with MCL," said Peter Lebowitz, M.D., Ph.D., Global Oncology Therapeutic Area Head, Janssen. "It's positive news to have a compound like ibrutinib in development, especially as it continues to show promise as a much needed option for patients with relapsed/refractory MCL."

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.[1] The disease typically begins in the lymph nodes, but can spread to other tissues, such as bone marrow and the liver.[2] Ibrutinib targets the B-cell receptor pathway via inhibiting BTK, a critical mediator in malignant B-cell growth and proliferation. In the United States, there are approximately 5,000 new cases of MCL each year.[2]

About Ibrutinib
Ibrutinib is an investigational, oral 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 Pharmacyclics entered a collaboration and license agreement in December 2011 to co-develop and co-commercialize ibrutinib. The regulatory filing for ibrutinib in MCL is expected to be made prior to the end of the third quarter of 2013. Details about the complete ibrutinib clinical program is posted on clinicaltrials.gov.

To date, ibrutinib has been granted three Breakthrough Therapy Designations by the U.S. Food & Drug Administration (FDA) as a monotherapy for the treatment of patients with CLL or small lymphocytic lymphoma (SLL) with deletion of the short arm of chromosome 17 (del17p); patients with relapsed/refractory MCL who have received prior therapy, and in patients with Waldenström's macroglobulinemia (WM). The implications of Breakthrough Therapy Designation cannot be determined at this time.

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. 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 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.)

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[1] Cancer.net. "Lymphoma - Non-Hodgkin". http://www.cancer.net/cancer-types/lymphoma-non-hodgkin/subtypes. Accessed April 2013.

[2] Know Cancer. Mantle Cell Lymphoma. Available at: http://www.knowcancer.com/oncology/mantle-cell-lymphoma/. Accessed April 2013.