IMBRUVICA® (ibrutinib) Supplemental New Drug Application Submitted to the U.S. FDA for Waldenström's macroglobulinemia

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RARITAN, NJ, October 20, 2014 - Janssen Research & Development, LLC ("Janssen") today announced the submission of a supplemental New Drug Application (sNDA) for IMBRUVICA® (ibrutinib) to the U.S. Food and Drug Administration (FDA) by its strategic partner Pharmacyclics, Inc. If approved, this latest regulatory submission will become the fourth indication for IMBRUVICA, adding the treatment of patients with Waldenström's macroglobulinemia (WM). WM is a rare type of B-cell lymphoma for which there are no treatment options specifically approved in the U.S. IMBRUVICA received FDA Breakthrough Therapy Designation in February 2013 for patients with WM and is being jointly developed and commercialized by Janssen Biotech Inc. and Pharmacyclics.

"We are committed to bringing our medicines to new patient populations, large and small, who may benefit from them," said Peter F. Lebowitz, M.D., Ph.D., Global Oncology Head, Janssen. "By understanding the mechanism of disease and how WM was similar to other B-cell malignancies, our collaboration partner Pharmacyclics was able to pursue this submission for WM, which has the potential to make a very meaningful difference to a group of patients who do not have a sufficient number of treatment options available to them today."

"Waldenström's macroglobulinemia is considered an orphan disease. Currently, there are no approved treatment options specifically for WM," said Carl Harrington, President of the International Waldenström's Macroglobulinemia Foundation. "The potential approval of a WM-specific treatment will make an immense difference in our patients' lives, offering an FDA-approved option where we previously had none."

WM (also known as lymphoplasmacytic lymphoma) is a slow-growing, incurable, rare type of B-cell lymphoma[1] for which no established standard of care - or approved therapeutic - exists.[2,3] In the U.S., there are approximately 1,000 to 1,500 new cases each year and the median age at diagnosis is 60-70 years of age.[1,4] WM begins with a malignant change to the B cell, a type of white blood cell (lymphocyte), during its maturation so that it continues to reproduce more malignant B cells. WM cells make large amounts of a certain type of antibody (immunoglobulin M, or IgM). Antibodies such as IgM normally help the body to fight infection. Excess IgM causes the blood to thicken and causes many of the symptoms of WM, including excess bleeding, problems with vision and nervous system problems.[5]

The currently approved indications for IMBRUVICA are: 1) for the treatment of patients with chronic lymphocytic leukemia (CLL) who have received at least one prior therapy, 2) for the treatment of CLL patients with del 17p, a genetic mutation that occurs when part of chromosome 17 has been lost, and 3) for the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.[6] Accelerated approval was granted for the MCL indication based on overall response rate (ORR). Improvements in survival or disease-related symptoms have not been established. Continued approval for the MCL indication may be contingent upon verification of clinical benefit in confirmatory trials.[6] IMBRUVICA was granted Breakthrough Therapy Designation by the FDA for the MCL, WM and CLL with del 17p indications.

Janssen and Pharmacyclics are continuing an extensive clinical development program for IMBRUVICA, including Phase 3 study commitments in multiple patient populations.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hemorrhage - Grade 3 or higher bleeding events (subdural hematoma, gastrointestinal bleeding, hematuria, and post-procedural hemorrhage) have occurred in up to 6% of patients. Bleeding events of any grade, including bruising and petechiae, occurred in approximately half of patients treated with IMBRUVICA®.

The mechanism for the bleeding events is not well understood. IMBRUVICA® may increase the risk of hemorrhage in patients receiving anti-platelet or anti-coagulant therapies. Consider the benefit-risk of withholding IMBRUVICA® for at least 3 to 7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding.

Infections - Fatal and non-fatal infections have occurred with IMBRUVICA® therapy. Twenty-five percent of patients with MCL and 26% of patients with CLL had Grade 3 or greater NCI Common Terminology Criteria for Adverse Events (CTCAE). Monitor patients for fever and infections and evaluate promptly.

Cytopenias - Treatment-emergent Grade 3 or 4 cytopenias including neutropenia (range, 23 to 29%), thrombocytopenia (range, 5 to 17%), and anemia (range, 0 to 9%) occurred in patients treated with IMBRUVICA®. Monitor complete blood counts monthly.

Atrial Fibrillation - Atrial fibrillation and atrial flutter (range, 6 to 9%) have occurred in patients treated with IMBRUVICA®, particularly in patients with cardiac risk factors, acute infections, and a previous history of atrial fibrillation. Periodically monitor patients clinically for atrial fibrillation. Patients who develop arrhythmic symptoms (eg, palpitations, lightheadedness) or new-onset dyspnea should have an ECG performed. If atrial fibrillation persists, consider the risks and benefits of IMBRUVICA® treatment and dose modification.

Second Primary Malignancies - Other malignancies (range, 5 to 10%) including carcinomas (range, 1 to 3%) have occurred in patients treated with IMBRUVICA®. The most frequent second primary malignancy was non-melanoma skin cancer (range, 4 to 8%).

Embryo-Fetal Toxicity - Based on findings in animals, IMBRUVICA® can cause fetal harm when administered to a pregnant woman. Advise women to avoid becoming pregnant while taking IMBRUVICA®. If this drug is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.

ADVERSE REACTIONS
MCL: The most common adverse reactions (≥20%) in the clinical trial were thrombocytopenia*, diarrhea (51%), neutropenia*, anemia*, fatigue (41%), musculoskeletal pain (37%), peripheral edema (35%), upper respiratory tract infection (34%), nausea (31%), bruising (30%), dyspnea (27%), constipation (25%), rash (25%), abdominal pain (24%), vomiting (23%), and decreased appetite (21%). *Treatment-emergent decreases (all grades) of platelets (57%), neutrophils (47%) and hemoglobin (41%) were based on laboratory measurements and adverse reactions. The most common Grade 3 or 4 non-hematological adverse reactions (≥5%) were pneumonia (7%), abdominal pain (5%), atrial fibrillation (5%), diarrhea (5%), fatigue (5%), and skin infections (5%). Treatment-emergent Grade 3 or 4 cytopenias were reported in 41% of patients. Ten patients (9%) discontinued treatment due to adverse reactions in the trial (N=111). The most frequent adverse reaction leading to treatment discontinuation was subdural hematoma (1.8%). Adverse reactions leading to dose reduction occurred in 14% of patients.
Fatal and serious cases of renal failure have occurred. Increases in creatinine 1.5 to 3 times the upper limit of normal occurred in 9% of patients.

CLL: The most common adverse reactions (?20%) in the clinical trials were thrombocytopenia (56%), neutropenia (51%), diarrhea (51%), anemia (37%), fatigue (28%), musculoskeletal pain (28%), upper respiratory tract infection (28%), rash (26%), nausea (25%), and pyrexia (24%). Approximately 5% of patients receiving IMBRUVICA® discontinued treatment due to adverse events. These included infections, subdural hematomas, and diarrhea. Adverse events leading to dose reduction occurred in approximately 6% of patients.

DRUG INTERACTIONS
CYP3A Inhibitors - Avoid concomitant administration with strong or moderate inhibitors of CYP3A. If a moderate CYP3A inhibitor must be used, reduce the IMBRUVICA® dose.
CYP3A Inducers - Avoid co-administration with strong CYP3A inducers.

SPECIFIC POPULATIONS
Hepatic Impairment - Avoid use in patients with baseline hepatic impairment.

For the full prescribing information, visit www.IMBRUVICA.com.

About IMBRUVICA
IMBRUVICA was one of the first therapies to receive U.S. approval via the FDA's Breakthrough Therapy Designation. IMBRUVICA works by blocking a specific protein called Bruton's tyrosine kinase (BTK).[6] The BTK protein transmits important signals that tell B cells to mature and produce antibodies and is needed by specific cancer cells to multiply and spread.[6,7] IMBRUVICA targets and blocks BTK, inhibiting cancer cell survival and spread.[6]

Janssen and Pharmacyclics are striving to make the process of obtaining IMBRUVICA and navigating insurance benefits easy for patients. The YOU&i ™ Support Program is a personalized program that includes information on access and affordability, nurse call support and resources for patients being treated with IMBRUVICA.

This includes the YOU&i ™ Instant Savings program, which provides co-pay support and benefits information to eligible commercially-insured patients. Not valid for patients with Medicare or Medicaid. Patients can access the program by contacting 1-877-877-3536, option 1 or by visiting http://www.imbruvica.com.

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, LLC and Janssen Biotech, Inc. are part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit www.janssenrnd.com for more information.

Janssen in Oncology
In oncology, our goal is to fundamentally alter the way cancer is understood, diagnosed, and managed, reinforcing our commitment to the patients who inspire us. In looking to find innovative ways to address the cancer challenge, our primary efforts focus on several treatment and prevention solutions. These include a focus on hematologic malignancies, prostate cancer and lung cancer; cancer interception with the goal of developing products that interrupt the carcinogenic process; biomarkers that may help guide targeted, individualized use of our therapies; as well as safe and effective identification and treatment of early changes in the tumor microenvironment.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development. 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 known 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: challenges inherent in new product development, including obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to laws and regulations, including domestic and foreign health care reforms; and general industry conditions, including trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2013, including in Exhibit 99 thereto, and our subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.)

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[1] American Cancer Society. "What are the key statistics about Waldenstrom macroglobulinemia?" Available at: http://www.cancer.org/cancer/waldenstrommacroglobulinemia/detailedguide/waldenstrom-macroglobulinemia-key-statistics-w-m. Accessed October 2014.
[2] Treon SP, Gertz MA, Dimopoulos M, et al. (2006) Update on treatment recommendations from the Third International Workshop on Waldenstrom's

macroglobulinemia. Blood 107:3442-3446.
[3] Ghobrial, I. Choice of Therapy for Patients with Waldenstrom Macroglobulinemia. Journal of Clinical Oncology. 2012. doi: 10.1200/JCO.2012.46.6177.
[4] Fonseca R, Hayman S. Waldenström macroglobulinaemia. Br J Haematol.2007;138(6):700-720.
[5] American Cancer Society. "What is Waldenstrom macroglobulinemia?" Available at: http://www.cancer.org/cancer/waldenstrommacroglobulinemia/index. Accessed October 2014.
[6] IMBRUVICA Prescribing Information, July 2014
[7] Genetics Home Reference. Isolated growth hormone deficiency. Available from: http://ghr.nlm.nih.gov/condition/isolated-growth-hormone-deficiency. Accessed October 2014.

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