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

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

Medical Information:
Pharmacyclics Medical Information:
1-877-877-3536

Supplemental New Drug Application for IMBRUVICA™ (ibrutinib) Submitted to the U.S. FDA

New submission based on positive Phase 3 data from the RESONATE™ trial

RARITAN, NJ, April 8, 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 collaboration partner Pharmacyclics, Inc. This regulatory submission is based on data from the Phase 3 RESONATE™ study in relapsed or refractory chronic lymphocytic leukemia (CLL). IMBRUVICA is being jointly developed and commercialized by Janssen and Pharmacyclics.

In February 2014, IMBRUVICA received FDA approval to treat patients with CLL who have received at least one prior therapy. This indication is based on an overall response rate (ORR) from Phase 2 data and an improvement in survival or disease-related symptoms has not been established. The current approval was granted under the FDA's Accelerated Approval regulations and required the completion of an additional, larger Phase 3 trial to verify clinical benefit.

The Phase 3 PCYC-1112 (RESONATE) study is a randomized, multi-center, open-label study, which compares once-daily oral IMBRUVICA versus intravenous ofatumumab in 391 patients with CLL or small lymphocytic lymphoma (SLL), who had received at least one prior therapy. The RESONATE trial

was halted early in January 2014 based on the recommendation of an Independent Data Monitoring Committee (IDMC) at the formal pre-planned interim analysis, which found IMBRUVICA was associated with a significant improvement in progression-free survival (the primary endpoint of the study) versus ofatumumab, and in overall survival (a key secondary endpoint of the trial). Data from this study were accepted and will be presented at the upcoming 50th annual meeting of the American Society of Clinical Oncology.

"This sNDA is the first Phase 3 submission for IMBRUVICA in the U.S. and represents a growing and more mature body of clinical evidence to support the use of IMBRUVICA in patients with chronic lymphocytic leukemia who have received prior therapy," said Peter F. Lebowitz, M.D., Ph.D., Global Oncology Head, Janssen. "We and our collaboration partner Pharmacyclics are focused on ways to bring this medicine to patients as quickly as possible and this is one more important milestone in the development of this product."

CLL is a slow-growing blood cancer of white blood cells called lymphocytes, most commonly B cells.[1] CLL is the most common adult leukemia in the Western world and predominantly a disease of the elderly with a median age of diagnosis of 72.[2] This orphan disease often eventually progresses; patients are faced with fewer treatment options and are often prescribed multiple lines of therapy as they relapse or become resistant to treatments.[3]

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hemorrhage – Five percent of patients with mantle cell lymphoma (MCL) and 6% of patients with CLL had Grade 3 or higher bleeding events (subdural hematoma, ecchymoses, gastrointestinal bleeding, and hematuria). Overall, bleeding events including bruising of any grade occurred in 48% of patients with MCL treated with 560 mg daily and 63% of patients with CLL treated at 420 mg daily.

The mechanism for the bleeding events is not well understood. IMBRUVICA™ may increase the risk of hemorrhage in patients receiving antiplatelet or anticoagulant 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. At least 25% of patients with MCL and 35% of patients with CLL had infections Grade 3 or greater NCI Common Terminology Criteria for Adverse Events (CTCAE). Monitor patients for fever and infections and evaluate promptly.

Myelosuppression – Treatment-emergent Grade 3 or 4 cytopenias were reported in 41% of patients with MCL and 35% of patients with CLL. These included neutropenia (29%), thrombocytopenia (17%) and anemia (9%) in patients with MCL and neutropenia (27%) and thrombocytopenia (10%) in patients with CLL. Monitor complete blood counts monthly.

Renal Toxicity – Fatal and serious cases of renal failure have occurred with IMBRUVICA™ therapy. Treatment-emergent increases in creatinine levels up to 1.5 times the upper limit of normal occurred in 67% of patients with MCL and 23% of patients with CLL. Increases in creatinine 1.5 to 3 times the upper limit of normal occurred in 9% of patients with MCL and 4% of patients with CLL. Periodically monitor creatinine levels. Maintain hydration.

Second Primary Malignancies – Other malignancies have occurred in 5% of patients with MCL and 10% of patients with CLL who have been treated with IMBRUVICA™. Four percent of patients with MCL had skin cancers, and 1% had other carcinomas. Eight percent of patients with CLL had skin cancers and 2% had other carcinomas.

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

CLL: The most commonly occurring adverse reactions (≥ 20%) in the clinical trial were thrombocytopenia*, diarrhea (63%), bruising (54%), neutropenia*, anemia*, upper respiratory tract infection (48%), fatigue (31%), musculoskeletal pain (27%), rash (27%), pyrexia (25%), constipation (23%), peripheral edema (23%), arthralgia (23%), nausea (21%), stomatitis (21%), sinusitis (21%), and dizziness (21%).

*Treatment-emergent decreases (all grades) of platelets (71%), neutrophils (54%) and hemoglobin (44%) were based on laboratory measurements per IWCLL criteria and adverse reactions.

The most common Grade 3 or 4 non-hematological adverse reactions (≥ 5%) were pneumonia (8%), hypertension (8%), atrial fibrillation (6.3%), sinusitis (6%), skin infection (6%), dehydration (6.4%), and musculoskeletal pain (6%). Treatment-emergent Grade 3 or 4 cytopenias were reported in 35% of patients.

Five patients (10%) discontinued treatment due to adverse reactions in the trial (N=48). These included 3 patients (6%) with infections and 2 patients (4%) with subdural hematomas. Adverse reactions leading to dose reduction occurred in 13% of patients.

MCL: The most commonly occurring 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 (5.4%), 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.

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.
SPECIAL POPULATIONS – **Hepatic Impairment** – Avoid use in patients with baseline hepatic impairment.

For the full prescribing information, visit http://www.IMBRUVICA.com/.

About IMBRUVICA

IMBRUVICA was one of the first therapies to receive U.S. approval via the FDA's Breakthrough Therapy Designation and was approved under the FDA's Subpart H regulation.[4] IMBRUVICA is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) who have received at least one prior therapy and the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.[5] These indications are both based on an overall response rate (ORR). An improvement in survival or disease-related symptoms has not been established.[5]

IMBRUVICA works by blocking a specific protein called Bruton's tyrosine kinase (BTK).[5] 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.[5,6] IMBRUVICA targets and blocks BTK, inhibiting cancer cell survival and spread.[5]

Janssen Biotech and Pharmacyclics are striving to make the process of obtaining IMBRUVICA and navigating insurance benefits easy for patients. The YOU&i Access™ program is designed specifically for patients who are prescribed IMBRUVICA and provides personalized attention coupled with access services designed to make obtaining medication simple and convenient for patients and those involved in their care.

This includes a YOU&i Access™ Instant Savings program, which provides co-pay support and benefits information to eligible commercially-insured patients. Patients can access the program by contacting 1-877-877-3536, option 1 or by visiting 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 is part of the Janssen Pharmaceutical Companies. 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 unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: economic factors, such as interest rate and currency exchange rate fluctuations; competition, including 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; general industry conditions including 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 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. Neither Janssen nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.)

---

[1] American Cancer Society. Detailed guide: what is chronic lymphocytic leukemia. Available from: http://www.cancer.org/acs/groups/cid/documents/webcontent/003111-pdf.pdf Accessed March 2014.
[2] Decision Resources estimate 2013.
[3] Veliz M, Pinilla-Ibarz J. Treatment of relapsed or refractory chronic lymphocytic leukemia. *Cancer Control*. 2012 Jan;19(1):37-53.
[4] The U.S. Food and Drug Administration. CFR - Code of Federal Regulations Title 21. Available from: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=314&showFR=1&subpartNode=21:5.0.1.1.4.8. Accessed March 2014.
[5] IMBRUVICA Prescribing Information, February 2014.
[6] Genetics Home Reference. Isolated growth hormone deficiency. Available from: http://ghr.nlm.nih.gov/condition/isolated-growth-hormone-deficiency. Accessed March 2014.