Johnson & Johnson

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IMBRUVICA™ (ibrutinib) Now Approved in the U.S. for Patients with Chronic Lymphocytic Leukemia Who Have Received At Least One Prior Therapy

HORSHAM, PA, February 12, 2014 - Janssen Biotech, Inc. ["Janssen"] today announced the U.S. Food and Drug Administration (FDA) has approved IMBRUVICA™ (ibrutinib) capsules for the treatment of patients with chronic lymphocytic leukemia (CLL) who have received at least one prior therapy. IMBRUVICA was first approved in November 2013 for the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.[1] Both indications are based on an overall response rate (ORR). An improvement in survival or disease-related symptoms has not been established.[1]

IMBRUVICA is the first once-daily, single-agent, oral Bruton's tyrosine kinase (BTK) inhibitor for patients with CLL who have received one prior therapy and is being jointly developed and commercialized by Janssen and Pharmacyclics, Inc. Both indications were granted priority review and were approved under the FDA's accelerated approval program; in addition, IMBRUVICA is one of the first medicines with the FDA's Breakthrough Therapy Designation to receive U.S. approval.

CLL is a slow-growing blood cancer of white blood cells called lymphocytes, most commonly B cells.[2] CLL is an orphan disease (which is defined as a disease impacting fewer than 200,000 Americans[3]) and is primarily diagnosed in those over 70 years old.[2] In the U.S., an estimated 16,000 people are diagnosed with CLL each year[4] and it is estimated that nearly 4,600 will unfortunately die due to this disease.[5] The U.S. prevalence of CLL is approximately 114,500 people.[6]

"CLL is a challenging disease and many physicians switch their patients from therapy to therapy as their disease relapses. There has been a significant need for new alternatives for these patients," said John C. Byrd, M.D., director, Division of Hematology, The Ohio State University Comprehensive Cancer Center - Arthur G. James Cancer Hospital & Richard J. Solove Research Institute and lead investigator for pivotal CLL trial PCYC-1102-CA.† "The approval of IMBRUVICA provides a new, once-daily oral therapy option for physicians."

"The speed at which we were able to bring IMBRUVICA to this point epitomizes the sense of urgency that drives oncology drug developers to bring important new medicines to patients in need," said Craig Tendler, M.D., vice president, Late-Stage Development and Global Medical Affairs for Oncology, Janssen. "We're delighted and proud of today's approval, because it represents our commitment to making a difference for patients. We appreciate the ongoing collaboration between the companies and the FDA, which made this possible."

IMBRUVICA works by blocking a specific protein called BTK.[1] Non-clinical studies have shown that blocking BTK inhibits the enzyme needed by the cancer to multiply and spread.[1]

IMBRUVICA in CLL

The safety and efficacy of IMBRUVICA in patients with relapsed or refractory CLL were evaluated in an open-label, multi-center Phase 1b/2 trial (PCYC-1102-CA) of 48 patients for a median treatment duration of 15.6 months.[1] IMBRUVICA was administered at 420 mg once daily until disease progression or until no longer tolerated by the patient. The ORR and duration of response (DOR) were evaluated according to a modified version of the International Workshop on CLL (IWCLL) criteria by an Independent Review Committee. ORR was 58.3 percent of patients (95% confidence interval (CI) (%), 43.2, 72.4), all partial responses. None of the patients had a complete response. The DOR ranged from 5.6 to 24.2+ months. The median DOR was not reached.[1]

The Warnings and Precautions for IMBRUVICA include hemorrhage, infections, myelosuppression (reduced ability for the bone marrow to produce blood cells), renal toxicity, second primary malignancies and embryo-fetal toxicity.[1] For more information about Warnings and Precautions, please see page four of this release.

The most common Grade 3 or 4 non-hematological adverse reactions (occurring in five percent or more of patients) were pneumonia (8%), hypertension (8%), atrial fibrillation (6.3%), sinusitis (6%), skin infection (6%), dehydration (6.4%) and musculoskeletal pain (6%). The most commonly occurring side effects (adverse reactions in 20 percent or more of CLL patients 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 (fever, 25%), constipation (23%), peripheral edema (23%), arthralgia (joint pain, 23%), nausea (21%), stomatitis (inflammation in the mouth, 21%), sinusitis (21%) and

dizziness (21%).[1] (Note: *Treatment-emergent decreases (all grades) of platelets (71%), neutrophils (54%) and hemoglobin (44%) were based on laboratory measurements per IWCLL criteria and adverse reactions.)

Five patients (10%) discontinued treatment due to adverse reactions in the clinical trial (N=48). These included three patients (6%) with infections and two patients (4%) with subdural hematomas. Adverse reactions leading to dose reduction occurred in 13 percent of patients.[1]

The recommended dose of IMBRUVICA for CLL is 420 mg (three 140 mg capsules) orally once daily.[1]

The IMBRUVICA PCYC-1102-CA CLL study was published online in *The New England Journal of Medicine* in June 2013.[7]

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 - Five percent of patients with 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 IMBRUVICATM 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 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.1 These indications are both based on an overall response rate (ORR). An improvement in survival or disease-related symptoms has not been established.[1] IMBRUVICA was approved under the FDA's Subpart H regulation.[8] For more information, visit http://www.imbruvica.com/.

IMBRUVICA works by blocking a specific protein called Bruton's tyrosine kinase (BTK).[1] 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.[1,9] IMBRUVICA targets and blocks BTK, inhibiting cancer cell survival and spread.[1]

Janssen Biotech is 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 Biotech, Inc.
Janssen Biotech, Inc. redefines the standard of care in immunology, oncology, urology and nephrology. Built upon a rich legacy of innovative firsts, Janssen Biotech has delivered on the promise of new treatments and ways to improve the health of individuals with serious disease. Beyond its innovative medicines, Janssen Biotech 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. For more information on Janssen Biotech, Inc. or its products, visit www.janssenbiotech.com.

Janssen Biotech is one of the Janssen Pharmaceutical Companies of Johnson & Johnson, which are dedicated to addressing and solving some of the most important unmet medical needs in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we work together to bring innovative ideas, products, services and solutions to people throughout the world. Follow us on Twitter at www.twitter.com/JanssenUS.

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, including regarding plans for further clinical development of IMBRUVICA. 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 Biotech, Inc. or Johnson & Johnson. Risks and uncertainties include, but are not limited to, technological advances, new products and patents attained by competitors; challenges and difficulties inherent in new product development, including obtaining regulatory approvals; manufacturing difficulties or delays; and trends toward health care cost containment. A further list and description of 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 and in its subsequent reports on Form 10-Q and Form 8-K. 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 statements as a result of new information or future events or developments.)

†**Disclaimer:** Dr. Byrd serves as national principal investigator of this Pharmacyclics-sponsored clinical study forming the basis for ibrutinib FDA-approval. He has served as an unpaid advisor to both Pharmacyclics and Janssen in developing the compound ibrutinib. Dr. Byrd does not have a financial interest in either company.

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

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[1] IMBRUVICA Prescribing Information, February 2014

[2] 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 January 2014.

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[6] IMS [Data on File]

[7] Byrd JC et al. Targeting BTK with Ibrutinib in Relapsed Chronic Lymphocytic Leukemia. N Engl J Med 2013;369(1):32-42.

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