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IMBRUVICA® (ibrutinib) Receives Regular Approval by U.S. FDA in Chronic Lymphocytic Leukemia (CLL) and CLL patients with del 17p

Approval based on Phase 3 RESONATE data with statistically significant improvements in progression-free and overall survival

HORSHAM, PA, July 28, 2014 – The U.S. Food and Drug Administration (FDA) has approved the supplemental New Drug Application (sNDA) for IMBRUVICA® (ibrutinib) capsules for the treatment of patients with chronic lymphocytic leukemia (CLL) who have received at least one prior therapy.[1] The FDA also approved IMBRUVICA for CLL patients with del 17p,[1] a genetic mutation that occurs when part of chromosome 17 has been lost. CLL patients with del 17p are considered to have the poorest prognosis.[2] IMBRUVICA is jointly developed and commercialized by Janssen Biotech, Inc. and Pharmacyclics, Inc.

The update to the IMBRUVICA label is based on data from the Phase 3 RESONATE™ study, which demonstrated IMBRUVICA significantly improved progression-free survival (PFS) and overall survival (OS) versus ofatumumab in patients with previously treated CLL or small lymphocytic leukemia (SLL).[3]

IMBRUVICA was initially approved in February 2014 under Subpart H regulation, the FDA's accelerated approval process, based on data from a Phase 1b/2 study for patients with CLL who have received at least one prior therapy.[1] This indication was based on an overall response rate (ORR). An improvement in survival or disease-related symptoms was not established. In accord with the accelerated approval process, confirmation of clinical benefit in a subsequent Phase 3 study was required, which has resulted in this updated indication for the use of IMBRUVICA in patients with CLL who have received at least one prior therapy and in CLL patients with del 17p.

"The RESONATE data expands our understanding of the efficacy and safety of IMBRUVICA to an even greater degree," 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 RESONATE.† "This approval is particularly exciting for people with del 17p CLL, considering IMBRUVICA is the first treatment to be approved specifically for this difficult-to-treat patient population."

CLL is a slow-growing blood cancer of white blood cells called lymphocytes, most commonly B cells.[4] CLL is predominantly a disease of the elderly, with a median age of diagnosis of 72.[4] 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.[2] Del 17p is reported in seven percent of treatment-naïve CLL cases,[5] with approximately 20 to 40 percent of relapsed/refractory patients harboring the mutation.[6]

"We're very pleased this approval came swiftly," said Peter F. Lebowitz, M.D., Ph.D., Global Oncology Head, Janssen Research & Development, LLC. "These Phase 3 results reinforce the data on which the original approval was granted; they also offer greater clinical understanding of the impact of efficacy related to progression-free and overall survival and, more importantly, the safety of IMBRUVICA in this patient population."

Data from this study were recently presented during an oral session at the 50th annual meeting of the American Society of Clinical Oncology (ASCO), featured in the official ASCO press program and simultaneously published online in the *New England Journal of Medicine*. In January 2014, the RESONATE trial was halted early because results showed a statistically

significant difference in PFS, the primary endpoint of the study, as well as in OS, a key secondary endpoint at the time of this interim analysis.

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

IMBRUVICA in CLL[1]

The safety and efficacy of IMBRUVICA in CLL were evaluated in the randomized, international, multi-center, open-label Phase 3 PCYC-1112 (RESONATE) trial in 391 patients with CLL or SLL, who had received at least one prior therapy. Thirty-two percent of patients in the trial had del 17p. Patients were administered either 420 mg oral ibrutinib (n=195) once-daily until progression or unacceptable toxicity or intravenous ofatumumab for up to 24 weeks (n=196, initial dose of 300 mg followed by 11 doses at 2,000 mg per dose and schedule consistent with local labeling). Data showed single-agent, once-daily IMBRUVICA significantly prolonged PFS (median not reached vs. 8.1 months; HR 0.22, 95% CI, 0.15 to 0.32; P<0.0001) and OS (HR 0.43; 95% CI, 0.24 to 0.79; P=0.05) versus intravenous ofatumumab in previously treated patients with CLL or SLL. The OS results represent a 57 percent statistically significant reduction in the risk of death in patients receiving IMBRUVICA versus those in the ofatumumab arm.

PFS was the primary endpoint of the RESONATE study, with OS, ORR and safety as key secondary endpoints. PFS, as assessed by an independent review committee according to modified International Workshop on Chronic Lymphocytic Leukemia criteria, indicated IMBRUVICA was associated with a 78 percent statistically significant reduction in the risk of death or progression versus ofatumumab. ORR was shown to be 42.6 percent in the IMBRUVICA arm, versus 4.1 percent in the ofatumumab arm.

The Warnings and Precautions for IMBRUVICA include hemorrhage, infections, cytopenias, atrial fibrillation, second primary malignancies and embryo-fetal toxicity.[1] For more information about Warnings and Precautions, please see below in this release.

After an 8.6 month median duration of therapy, the most common Grade 3 or 4 adverse event (AE) was pneumonia* (10%). The most commonly occurring non-hematologic side effects during the RESONATE trial (AEs in 20 percent or more of patients) were diarrhea (48%), fatigue

(28%), musculoskeletal pain* (28%), nausea (26%), pyrexia (fever; 24%) and rash* (24%). Hematologic adverse events included (all grades) platelet decrease (52%), neutrophil decrease (51%) and hemoglobin decrease (36%).[1] **Includes multiple ADR terms.*

Approximately five percent of patients receiving IMBRUVICA in the Phase 3 RESONATE (PCYC-1112-CA) and Phase 1b/2 PCYC-1102-CA studies discontinued treatment due to adverse events. These included infections, subdural hematomas and diarrhea. Adverse events leading to dose reduction occurred in approximately six percent of patients.[1]

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

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®. Twenty-six percent 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.

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

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 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. 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.[1,7] IMBRUVICA targets and blocks BTK, inhibiting cancer cell survival and spread.[1]

Janssen 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 http://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 dedicated to addressing and solving some of the most important unmet medical needs in oncology, immunology, neuroscience, infectious diseases and vaccines, 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 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 Biotech, Inc., 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 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. 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.)

†**Disclaimer**: Dr. Byrd serves as national principal investigator of the Pharmacyclics-sponsored clinical study forming the basis for the IMBRUVICA 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.

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[1] IMBRUVICA Prescribing Information, July 2014
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