NEWS RELEASE

Phase 3 Study with IMBRUVICA® (ibrutinib) Combination Demonstrates Significant Delay in Disease Progression

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Phase 3 Study with IMBRUVICA® (ibrutinib) Combination Demonstrates Significant Delay in Disease Progression RARITAN, NJ, March 16, 2015 - Janssen Research & Development, LLC (Janssen) announced today that a pre-planned interim analysis of the Phase 3 HELIOS (CLL3001) study investigating the combination of IMBRUVICA® (ibrutinib) plus bendamustine and rituximab (BR) versus placebo plus BR in patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), showed the trial has met its primary endpoint, demonstrating a statistically significant improvement in progression-free survival (PFS). An Independent Data Monitoring Committee (IDMC) recommends that the study be unblinded and patients receiving placebo plus BR should be offered the option to receive IMBRUVICA as their next treatment. IMBRUVICA is jointly developed and commercialized by Janssen Biotech, Inc. and Pharmacyclics, Inc.

"This is the second randomized, controlled study in patients with previously treated CLL or SLL to show a significant improvement in progression-free survival, further underscoring the potential of IMBRUVICA," said Sen Zhuang, M.D., Ph.D., Vice President, Oncology Clinical Research, Janssen. "The data from the Phase 3 **RESONATE** trial demonstrated that IMBRUVICA as a single agent significantly improved both progression-free and overall survival compared to ofatumumab. Now, the interim data from HELIOS demonstrate that IMBRUVICA may be incorporated into a regimen with bendamustine and rituximab to improve outcomes for patients."

HELIOS is a Janssen-sponsored, randomized, double-blind, placebo-controlled, international, multicenter Phase 3 study conducted in 21 countries, which evaluated the safety and efficacy of IMBRUVICA in combination with BR in 578 patients with relapsed or refractory CLL/SLL who had received at least one prior therapy. Patients were randomized to receive either the combination of 420 mg IMBRUVICA orally once daily and six cycles of BR, or a

matching regimen of placebo orally once daily and six cycles of BR, with IMBRUVICA or placebo continued until disease progression or unacceptable toxicity.

The primary endpoint of the HELIOS study is PFS, with secondary endpoints including safety (adverse events), overall response rate (ORR), overall survival (OS), rate of minimal residual disease (MRD)-negative responses and other improvements in hematologic values, disease-related symptoms and patient-reported outcome scores.

These topline results are planned to be submitted for presentation at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting, as well as for publication in a peer-reviewed journal. A full study report is being prepared and planned to be submitted to health authorities for future labeling considerations. For additional study information, visit **ClinicalTrials.gov**.

About IMBRUVICA

IMBRUVICA was one of the first therapies to receive U.S. approval after having received 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.[1,2] IMBRUVICA targets and blocks BTK, inhibiting cancer cell survival and spread.[1] For more information, visit **www.IMBRUVICA.com**.

Additional Information about IMBRUVICA®

INDICATIONS

IMBRUVICA is indicated to treat people with:

- Mantle cell lymphoma (MCL) who have received at least one prior therapy
    - Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trials.
- Chronic lymphocytic leukemia (CLL) who have received at least one prior therapy
- Chronic lymphocytic leukemia (CLL) with 17p deletion
- Waldenström's macroglobulinemia (WM)

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hemorrhage - Fatal bleeding events have occurred in patients treated with IMBRUVICA®. 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 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. Grade 3 or greater infections occurred in 14% to 26% of patients. Cases of progressive multifocal leukoencephalopathy (PML) have occurred in patients treated with IMBRUVICA®. Monitor patients for fever and infections and evaluate promptly.

Cytopenias - Treatment-emergent Grade 3 or 4 cytopenias including neutropenia (range, 19 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 14%) including non-skin 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 11%).

Tumor Lysis Syndrome - Tumor lysis syndrome has been reported with IMBRUVICA® therapy. Monitor patients closely and take appropriate precautions in patients at risk for tumor lysis syndrome (e.g. high tumor burden).

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 (≥25%) in patients with B-cell malignancies (MCL, CLL, WM) were thrombocytopenia, neutropenia, diarrhea, anemia, fatigue, musculoskeletal pain, bruising, nausea, upper respiratory tract infection, and rash. Seven percent of patients receiving IMBRUVICA® discontinued treatment due

to adverse events.

DRUG INTERACTIONS

CYP3A Inhibitors - Avoid co-administration with strong and moderate CYP3A inhibitors. 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 moderate or severe baseline hepatic impairment. In patients with mild impairment, reduce IMBRUVICA® dose.

Please see full prescribing information:

http://www.imbruvica.com/downloads/Prescribing_Information.pdf

About Chronic Lymphocytic Leukemia

Chronic Lymphocytic Leukemia (CLL) is a slow-growing blood cancer that most commonly arises from B cells, a type of white blood cell (lymphocyte) that originates in the bone marrow.[3,4] CLL is predominantly a disease of the elderly, with a median age of 71 at diagnosis.[3]

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. Please visit **oncology.janssenrnd.com**.

(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 and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in product development, including obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; challenges to patents; changes to applicable laws and regulations, including global health care reforms; and 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, 2014, including in Exhibit 99 thereto, and the company's 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]IMBRUVICA Prescribing Information, January 2015

[2]Genetics Home Reference. Isolated growth hormone deficiency. Available at: **http://ghr.nlm.nih.gov/condition/isolated-growth-hormone-deficiency**. Accessed March 2015.

[3]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 2015.

[4]Shaffer AL, Rosenwald A, Staudt LM. Lymphoid malignancies: the dark side of B-cell differentiation. Nat Rev Immunol. 2002;2(12):920-932.

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