FOR IMMEDIATE RELEASE

IMBRUVICA® (ibrutinib) Now Approved to Treat Waldenström’s Macroglobulinemia in Europe

First therapy to be approved specifically for this disease in the EU

SUNNYVALE, Calif., July 10, 2015 – Today AbbVie (NYSE: ABBV) announced the European Commission (EC) granted marketing authorization for IMBRUVICA® (ibrutinib) as the first treatment option available in all 28 member states of the European Union (EU) for the treatment of Waldenström’s macroglobulinemia (WM), a rare, slow growing blood cancer, in adult patients who have received at least one prior therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy. Pharmacycics LLC, an AbbVie company, received FDA approval for IMBRUVICA, which is also the first and only FDA-approved treatment for WM in the United States, in January 2015.¹ The approval of IMBRUVICA to treat patients with WM triggers a $20 million milestone payment from Janssen.

IMBRUVICA is jointly developed and commercialized in the United States by Pharmacycics and Janssen Biotech, Inc. In Europe, Janssen-Cilag International NV (Janssen) holds the marketing authorization and its affiliates market IMBRUVICA in EMEA (Europe, Middle East, Africa), as well as the rest of the world. IMBRUVICA is already approved in Europe to treat adult patients with relapsed or refractory mantle cell lymphoma (MCL) and adult patients with chronic lymphocytic leukemia (CLL) who have received at least one prior therapy or in first line use in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy.

“The European Commission approval of IMBRUVICA as the first and only agent approved for patients with Waldenström’s macroglobulinemia across the EU underscores its value for patients with serious medical needs, unaddressed so far,” said Wulff-Erik von Borcke, President of Pharmacycics. “We are happy that IMBRUVICA will now be available to help patients in Europe who are living with Waldenström’s.”
The EC approval was based on data from a Phase II multi-center study, which evaluated the efficacy and tolerability of IMBRUVICA 420 mg once daily in 63 patients with WM who had received a median of two prior therapies (range 1-9). Updated results from the study were published in *The New England Journal of Medicine* and showed IMBRUVICA was associated with a 91% overall response rate (ORR; the primary endpoint) after a median follow up of 19 months (range 0.5-29.7), as assessed by investigators using criteria adopted from the International Workshop of Waldenstrom’s Macroglobulinemia. Eleven patients (17%) achieved a minor response (MR), 36 patients (57%) achieved a partial response (PR) and 10 patients (16%) achieved a very good PR. The median times for patients to achieve at least minor and partial responses with treatment were four weeks and eight weeks respectively.

Secondary endpoints included progression-free survival (PFS) and safety. Estimated PFS and overall survival (OS) rates at 24 months were 69% (95% CI, 53.2 to 80.5) and 95% (95% CI, 86.0 to 98.4), respectively. The most commonly occurring adverse reactions in WM patients treated with IMBRUVICA (>20%) were neutropenia, thrombocytopenia, diarrhea, rash, nausea, muscle spasms, and fatigue. Six percent of patients receiving IMBRUVICA in the WM trial discontinued treatment due to adverse events. Overall, IMBRUVICA was well-tolerated and the safety profile was consistent with previous observations.

**About Waldenström’s macroglobulinemia**

WM (a clinically recognized subset of lymphoplasmacytic lymphoma, or LPL) is a slow-growing and rare blood cancer that most commonly originates from B cells, a type of white blood cell (lymphocyte) that develops in the bone marrow. WM occurs as the result of a malfunction in the healthy lifecycle of a B cell, causing the cell to become malignant and reproduce at an abnormal rate. The malignant B cells produce large amounts of an abnormal type of antibody protein called immunoglobulin M (IgM). Excess IgM causes the blood to thicken and causes many of the symptoms of WM.

**About IMBRUVICA**

IMBRUVICA is currently approved in the US for the treatment of patients with chronic lymphocytic leukemia (CLL) who have received at least one prior therapy, all CLL patients (including treatment-naïve) who have del 17p, a genetic mutation that occurs when part of chromosome 17 has been lost, and all patients (including treatment-naïve) with Waldenström’s
IMBRUVICA (ibrutinib) is a first-in-class, oral, once-daily therapy that inhibits a protein called Bruton's tyrosine kinase (BTK). IMBRUVICA was one of the first medicines to receive U.S. FDA approval via the new Breakthrough Therapy Designation pathway, and is the only product to have received three Breakthrough Therapy Designations.

BTK is a key signaling molecule in the B-cell receptor signaling complex that plays an important role in the survival and spread of malignant B cells. IMBRUVICA blocks signals that tell malignant B cells to multiply and spread uncontrollably.

IMBRUVICA is being studied alone and in combination with other treatments in several blood cancers. Over 6,100 patients have been treated in clinical trials of IMBRUVICA conducted in 35 countries by more than 800 investigators. Currently, 13 Phase III trials have been initiated with IMBRUVICA and 67 trials are registered on www.clinicaltrials.gov.

To learn more about the medical terminology used in this news release, please visit http://stedmansonline.com/.

INDICATIONS
IMBRUVICA is indicated in the US to treat people with:

- Chronic lymphocytic leukemia (CLL) who have received at least one prior therapy
- Chronic lymphocytic leukemia (CLL) with 17p deletion
- Waldenström’s macroglobulinemia
- 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.

Patients taking IMBRUVICA for CLL or WM should take 420 mg taken orally once daily (or three 140 mg capsules once daily).
Patients taking IMBRUVICA for MCL should take 560 mg taken orally once daily (or four 140 mg capsules once daily).

Capsules should be taken orally with a glass of water. Capsules should be taken whole. Do not open, break, split or chew the capsules.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS FOR U.S. PRESCRIBERS

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 (e.g., 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* (57%, 52%, 43%), neutropenia* (47%, 51%, 44%), diarrhea (51%, 48%, 37%), anemia* (41%, 36%, 13%), fatigue (41%, 28%, 21%), musculoskeletal pain (37%, 28%**, NA***), bruising (30%, 12%**, 16%**), nausea (31%, 26%, 21%), upper respiratory tract infection (34%, 16%, 19%), and rash (25%, 24%**, 22%**).

*Based on adverse reactions and/or laboratory measurements (noted as platelets, neutrophils, or hemoglobin decreased).

**Includes multiple ADR terms.

***Not applicable; no associated ADRs.

The most common Grade 3 or 4 non-hematological adverse reactions (> 5%) in MCL patients were pneumonia (7%), abdominal pain (5%), atrial fibrillation (5%), diarrhea (5%), fatigue (5%), and skin infections (5%).

Approximately 6% (CLL), 14% (MCL), and 11% (WM) of patients had a dose reduction due to adverse events.

Approximately 5% (CLL), 9% (MCL), and 6% (WM) of patients discontinued due to adverse events. Most frequent adverse events leading to discontinuation were infections, subdural hematomas, and diarrhea in CLL patients and subdural hematoma (1.8%) in MCL patients.

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:

About Pharmacyclics, An AbbVie Company
Pharmacyclics, a wholly-owned subsidiary of AbbVie (NYSE: ABBV), is focused on developing and commercializing innovative small-molecule drugs for the treatment of cancer and immune-mediated diseases. Pharmacyclics’ mission is to develop and commercialize novel therapies intended to improve quality of life, increase duration of life and resolve serious unmet medical needs.

Pharmacyclics markets IMBRUVICA and has three product candidates in clinical development and several preclinical molecules in lead optimization. Pharmacyclics is committed to high standards of ethics, scientific rigor and operational efficiency as it moves each of these programs toward commercialization. To learn more, please visit www.pharmacyclics.com.

About AbbVie
AbbVie is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott Laboratories. The company’s mission is to use its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world’s most complex and serious diseases. Together with its wholly-owned subsidiary, Pharmacyclics, AbbVie employs more than 28,000 people worldwide and markets medicines in more than 170 countries. For further information on the company and its people, portfolio and commitments, please visit www.abbvie.com. Follow @abbvie on Twitter or view careers on our Facebook or LinkedIn page.
NOTE: This announcement may contain forward-looking statements made in reliance upon the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements, among others, relating to our future capital requirements, including our expected liquidity position and timing of the receipt of certain milestone payments, and the sufficiency of our current assets to meet these requirements, our future results of operations, our expectations for and timing of ongoing or future clinical trials and regulatory approvals for any of our product candidates, and our plans, objectives, expectations and intentions.

Because these statements apply to future events, they are subject to risks and uncertainties. When used in this announcement, the words “anticipate”, “believe”, “estimate”, “expect”, “expectation”, “goal”, “should”, “would”, “project”, “plan”, “predict”, “intend”, “target” and similar expressions are intended to identify such forward-looking statements. These forward-looking statements are based on information currently available to us and are subject to a number of risks, uncertainties and other factors that could cause our actual results, performance, expected liquidity or achievements to differ materially from those projected in, or implied by, these forward-looking statements. Factors that may cause such a difference include, without limitation, our need for substantial additional financing and the availability and terms of any such financing, the safety and/or efficacy results of clinical trials of our product candidates, our failure to obtain regulatory approvals or comply with ongoing governmental regulation, our ability to commercialize, manufacture and achieve market acceptance of any of our product candidates, for which we rely heavily on collaboration with third parties, and our ability to protect and enforce our intellectual property rights and to operate without infringing upon the proprietary rights of third parties. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, performance or achievements and no assurance can be given that the actual results will be consistent with these forward-looking statements. For more information about the risks and uncertainties that may affect our results, please see the Risk Factors section of our filings with the Securities and Exchange Commission, including our Form 10-K for the year ended December 31, 2013 and quarterly reports on Form 10-Q. We do not intend to update any of the forward-looking statements after the date of this announcement to conform these statements to actual results, to changes in management's expectations or otherwise, except as may be required by law.

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1 IMBRUVICA Prescribing Information, January 2015