Pharmacyclics Announces Update on IMBRUVICA® (ibrutinib) Waldenstrom's macroglobulinemia (WM) Submission

SUNNYVALE, Calif., Dec. 22, 2014 /PRNewswire/ -- Pharmacyclics, Inc. (NASDAQ: PCYC) announced today that the U.S Food and Drug Administration (FDA) has provided a Prescription Drug User Fee Act (PDUFA) target date of April 17, 2015 by which time the FDA is planning to finalize its review of a supplemental New Drug Application (sNDA) for IMBRUVICA (ibrutinib) as a treatment for patients with Waldenstrom's macroglobulinemia (WM). IMBRUVICA is being jointly developed and commercialized by Pharmacyclics and Janssen Biotech, Inc.

About IMBRUVICA®

IMBRUVICA (ibrutinib) is a first-in-class, oral, once-daily therapy that inhibits a protein called Bruton's tyrosine kinase (BTK). 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 approved for the treatment of patients with chronic lymphocytic leukemia (CLL) who have received at least one prior therapy, and for the treatment of CLL patients with del 17p, a genetic mutation that occurs when part of chromosome 17 has been lost.

IMBRUVICA is also approved for the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. Accelerated approval was granted for the MCL indication based on overall response rate (ORR). Improvements in survival or disease-related symptoms have not been established. Continued approval for the MCL indication may be contingent upon verification of clinical benefit in confirmatory trials.

IMBRUVICA is being studied alone and in combination with other treatments in several blood cancers. Over 4,600 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 55 trials are registered on ClinicalTrials.gov. The overall clinical development program in CLL currently includes seven Phase III trials and covers all lines of therapy and various combinations of treatments.

IMBRUVICA was one 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.

INDICATIONS
IMBRUVICA is indicated to treat people with:

- Chronic lymphocytic leukemia (CLL) who have received at least one prior therapy.
- Chronic lymphocytic leukemia (CLL) with 17p deletion (a genetic mutation that occurs when part of chromosome 17 has been lost).
- Mantle cell lymphoma (MCL) who have received at least one prior therapy
  - Accelerated approval was granted for this indication based on overall response rate. Improvements in survival or disease-related symptoms have not been established. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trials.

Patients taking IMBRUVICA for CLL 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 include hemorrhage, infection, cytophenias, atrial fibrillation, second primary malignancies, and embryo-fetal toxicity.
The most common adverse reactions include thrombocytopenia, diarrhea, neutropenia, anemia, fatigue, musculoskeletal pain, peripheral edema, upper respiratory tract infection, nausea, bruising, dyspnea, constipation, rash, abdominal pain, pyrexia, vomiting, and decreased appetite.

For additional important safety information, please see Full Prescribing Information at www.imbruvica.com/downloads/Prescribing_Information.pdf.

About Pharmacyclics
Pharmacyclics, Inc. (NASDAQ: PCYC) is a biopharmaceutical company focused on developing and commercializing innovative small-molecule drugs for the treatment of cancer and immune mediated diseases. The company’s mission is to build a viable biopharmaceutical company that designs, develops and commercializes novel therapies intended to improve quality of life, increase duration of life and resolve serious unmet medical needs. It will do so by identifying and controlling promising product candidates based on scientific development and administrative expertise, developing its products in a rapid, cost-efficient manner and, pursuing commercialization and/or development partners when and where appropriate.

Pharmacyclics markets IMBRUVICA and has three product candidates in clinical development and several preclinical molecules in lead optimization. The company is committed to high standards of ethics, scientific rigor and operational efficiency as it moves each of these programs to commercialization. Pharmacyclics is headquartered in Sunnyvale, CA. To learn more, please visit www.pharmacyclics.com. Pharmacyclics is on Twitter. Follow us on Twitter @pharmacyclics at http://twitter.com/pharmacyclics.

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.

IMBRUVICA is a registered trademark of Pharmacyclics, Inc.

1 IMBRUVICA Prescribing Information, July 2014.


SOURCE Pharmacyclics, Inc.

News Provided by Acquire Media