March 19, 2015

New ibrutinib (IMBRUVICA®) Data to be Presented at American Association for Cancer Research (AACR) Meeting

Pre-clinical data to be presented in solid tumor and blood cancer models

SUNNYVALE, Calif., March 19, 2015 /PRNewswire/ -- Pharmacyclics, Inc. (NASDAQ: PCYC) today announced that new pre-clinical and clinical data for ibrutinib (IMBRUVICA®) will be highlighted at the 2015 American Association for Cancer Research (AACR) Annual Meeting to be held April 18 - 22, 2015, in Philadelphia, PA. Several company-sponsored and investigator-initiated abstracts have been accepted for presentation as oral and poster sessions highlighting data in solid tumor and blood cancers. IMBRUVICA is jointly developed and commercialized by Pharmacyclics and Janssen Biotech, Inc.

"We are very encouraged by the ibrutinib data we are seeing both as a single agent and as a synergistic combination with other treatment options across solid tumor and new hematologic histologies," said Betty Chang, Ph.D., Head of Research at Pharmacyclics. "Based on the success to date within ibrutinib’s approved and investigational uses, we remain committed to exploring the further potential of ibrutinib as a backbone of therapy within the broader oncology and hematology arenas."

A select list of accepted ibrutinib abstracts is included below. A full list of accepted ibrutinib data abstracts is available on the AACR website.

Presentations:

Oral Presentation
Long-term treatment with single-agent ibrutinib 420 mg leads to durable responses including complete responses in CLL (Abstract CT132)
Clinical Trials Minisymposium. Sunday, April 19 at 3:15 p.m. ET in Room 103
Lead Author: Steven Coutre, Stanford University, Stanford, CA

Poster Presentations

Combining ibrutinib with immune checkpoint blockade to induce therapeutic antitumor immune response in solid tumors (Abstract 251; Poster 9)
Immune Checkpoints. Sunday, April 19, 2015 at 1:00 - 5:00 p.m. ET in Section 12
Lead Author: Idit Sagiv-Barfi, Stanford University, Stanford, CA

Ibrutinib enhances the anti-tumor efficacy of CTLA-4 blockade in lymphoma and colon cancer models (Abstract 259; Poster 17)
Immune Checkpoints. Sunday, April 19, 2015 at 1:00 - 5:00 p.m. ET in Section 12
Lead Author: Patrick Ng, Pharmacyclics, Inc., Sunnyvale, CA

Ibrutinib exerts potent antifibrotic activity in a mouse model of pancreatic adenocarcinoma (Abstract 396; Poster 5)
Crosstalk of the Microenvironment and the Tumor Clone. Sunday, April 19, 2015 at 1:00 - 5:00 p.m. ET in Section 17
Lead Author: Daniel Masso-Valles, Vall d'Hebron Institute of Oncology (VHIO), Barcelona, Spain

Ibrutinib plus proteasome or MALT1 inhibitors overcome resistance to BCR antagonists in CARD11 mutant-expressing B-lymphoma cells (Abstract 1742; Poster 15)
Inhibitors of UPS and HSP90 Pathways and Other Targets. Monday, April 20, 2015 at 8:00 a.m. - 12:00 p.m. ET in Section 31
Lead Author: Ling Xue, Pharmacyclics, Inc, Sunnyvale, CA

Ibrutinib significantly improves survival in a human Burkitt lymphoma (BL) xenograft NSG mouse model: Ibrutinib may be a potential adjuvant agent in the treatment of BL (Abstract 2608; Poster 30)
MAPK, EGFR, and BTK Inhibitors. Monday, April 20, 2015 at 1:00 - 5:00 p.m. ET in Section 29
Lead Author: Sanghoon Lee, New York Medical College, Valhalla, NY

Synergistic effect of ibrutinib and inhibitors targeting TLR signaling in ABC subtype of diffuse large B-Cell lymphoma (Abstract 2598; Poster 20)
MAPK, EGFR, and BTK Inhibitors. Monday, April 20, 2015 at 1:00 - 5:00 p.m. ET in Section 29
The BTK inhibitor ibrutinib (PCI-32765) overcomes paclitaxel resistance resulting from the overexpression of ABCB1 and ABCC10 transporters (Abstract 2697; Poster 19)

Resistances to Pathway-Targeted Therapeutics 1. Monday, April 20, 2015 at 1:00 - 5:00 p.m. ET in Section 33

Lead Author: Hui Zhang, Shandong Cancer Hospital and Institute, Jinan, China

Specific antitumor activity of the splicing modulator sudemycin and cooperation with ibrutinib in chronic lymphocytic leukemia (Abstract 2584; Poster 6)

MAPK, EGFR, and BTK Inhibitors. Monday, April 20, 2015 at 1:00 - 5:00 p.m. ET in Section 29

Lead Author: Silvia Xargay-Torrent, IDIBAPS, Barcelona, Spain

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, CLL patients with del 17p, a genetic mutation that occurs when part of chromosome 17 has been lost, and patients with Waldenstrom's macroglobulinemia.

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). 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 5,100 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 58 trials are registered on www.clinicaltrials.gov.

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.

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

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
- Waldenstrom'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

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.

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

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, January 2015


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