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**New Drug Application Filing for Ibrutinib Accepted in Two B-cell Malignancies by the U.S. FDA**

**Priority Review Granted**

SUNNYVALE, Calif., Aug. 29, 2013 /PRNewswire/ -- Pharmacyclics, Inc. (Nasdaq: PCYC) today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing its New Drug Application (NDA) for the investigational oral Bruton's tyrosine kinase (BTK) inhibitor ibrutinib, for two B-cell malignancy indications: previously treated mantle cell lymphoma (MCL) and previously treated chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL). On June 28, 2013 Pharmacyclics submitted a New Drug Application (NDA) under section 505(b) of the Food, Drug & Cosmetic Act for ibrutinib. On Aug 27, 2013 the FDA notified Pharmacyclics that they have completed their filing review and determined that the application is sufficiently complete to permit a substantive review. The FDA’s acceptance of the NDA triggers a $75 million milestone payment to Pharmacyclics under its Collaboration Agreement with Janssen Biotech Inc.

“We are very excited to have received the official FDA acceptance of our first NDA filing for ibrutinib," said Dr. Urte Gayko, Senior Vice President of Global Regulatory Affairs, Pharmacyclics. "We look forward to continuing to work with the FDA as they complete their review of the ibrutinib application which includes the new Breakthrough Therapy Designation process.”

**About CLL / SLL**

CLL, a B-cell malignancy, is a slow-growing blood cancer of the white blood cells (lymphocytes), most commonly from B-cells. CLL is the second most common adult leukemia. Approximately 16,000 patients in the US are diagnosed each year with CLL. The prevalence of CLL is approximately 113,000 in the U.S. CLL is a chronic disease that predominantly occurs in the elderly with a five-year survival of approximately 82 percent. Patients commonly receive multiple lines of treatment over the course of their disease. When cancer cells are located mostly in the lymph nodes, the disease is called SLL. CLL and SLL are considered to be different manifestations of the same underlying disease; they share similarities in signs and symptoms, genetic features, disease progression and treatment.

**About Mantle Cell Lymphoma**

MCL is a B-cell malignancy, an aggressive type of B-cell non-Hodgkin lymphoma (NHL) that usually occurs in older adults. The disease typically begins in the lymph nodes, but can spread to other tissues, such as bone marrow, liver, and spleen. Patients typically survive an average of five years. In the U.S., there are approximately 2,500 new cases of MCL each year and a prevalence of approximately 10,000 (Decision Resources 2012).

**About Ibrutinib**

Ibrutinib is an investigational agent designed to provide potent and sustained inhibition of an enzyme called Bruton's tyrosine kinase (BTK). BTK is a key mediator of at least three critical B-cell pro-survival mechanisms occurring in parallel — regulation of apoptosis, adhesion, and cell migration and homing. Through these multiple signals, BTK regulation helps to direct malignant B-cells to lymphoid tissues, thus allowing access to a micro-environment necessary for survival.

The effectiveness of ibrutinib alone or in combination with other treatments is being studied in several B-cell malignancies, including chronic lymphocytic leukemia/small lymphocytic lymphoma, mantle cell lymphoma, diffuse large B-cell lymphoma, follicular lymphoma, Waldenstrom's macroglobulinemia and multiple myeloma. To date, 7 Phase III trials have been initiated with ibrutinib and a total of 31 trials are currently registered on www.clinicaltrials.gov. Janssen and Pharmacyclics entered a collaboration and license agreement in December 2011 to co-develop and co-commercialize ibrutinib.

**About Pharmacyclics**

Pharmacyclics® is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative small-molecule drugs for the treatment of cancer and immune mediated diseases. Our mission and goal 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 healthcare needs; and to identify promising product candidates.
based on scientific development and administrative expertise, develop our products in a rapid, cost-efficient manner and pursue commercialization and/or development partners when and where appropriate.

Presently, Pharmacyclics 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 viable commercialization.

Pharmacyclics is headquartered in Sunnyvale, California and is listed on NASDAQ under the symbol PCYC. To learn more about how Pharmacyclics advances science to improve human healthcare visit us at http://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 transition report on Form 10-K for the six month period ended December 31, 2012 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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