



## **Pharmacyclics Announces Publication of Interim Data From Study Evaluating Xcytrin Plus Taxotere for Advanced Recurrent Tumors at ASCO 2005**

ORLANDO, Fla., May 13, 2005 /PRNewswire-FirstCall via COMTEX/ -- Pharmacyclics, Inc. (Nasdaq: PCYC) today announced the publication of interim data from a Phase 1 dose escalation study of Xcytrin(R) (motexafin gadolinium) Injection, the company's lead anti-cancer agent, in combination with Taxotere(R) (docetaxel) for the treatment of patients with advanced refractory tumors. The published abstract is part of the proceedings at the 2005 American Society of Clinical Oncology (ASCO) Annual Meeting being held May 13-17, 2005, at the Orange County Convention Center in Orlando, FL.

The ongoing study has enrolled 13 patients of which 12 are evaluable for response at this time, including patients with metastatic cancer of the lung (9), ovary (2), prostate (1), and breast (1). Six patients receiving Xcytrin and Taxotere have achieved a partial response including four of the nine patients suffering from non-small cell lung cancer (NSCLC), the breast cancer patient, who was previously treated with taxol, and the prostate cancer patient. Two additional NSCLC patients achieved stabilization of their tumors. All of the patients in this study had failed one to five prior treatment regimens, which in three of the responding patients (two with NSCLC) included treatment with a member of the taxane family. Among the NSCLC patients whose tumors responded to the study treatment, the duration of response lasted for a median of 15 weeks (range 6-18 weeks).

"Our data demonstrate objective tumor responses in patients who have failed multiple previous therapies including treatment with taxanes," said Kishan Pandya, M.D., professor of medicine and oncology, James P. Wilmot Cancer Center at the University of Rochester, and principal investigator of the trial. "Xcytrin's novel mechanism of action and non-overlapping toxicity with chemotherapy make it a potentially appealing new agent for cancer therapy."

The Phase 1 dose-escalating study is designed to evaluate the safety and tumor response rate for the combination of Xcytrin with Taxotere. Successive cohorts of patients are given increasing doses of Xcytrin together with a standard dose of Taxotere and treatment is repeated every 21 days. No significant toxicity, other than that normally attributable to Taxotere, has been observed.

"These early results show promise for combining Xcytrin with chemotherapy drugs, such as Taxotere," said Richard A. Miller, M.D., president and chief executive officer of Pharmacyclics. "The activity in NSCLC is consistent with activity demonstrated in other trials involving patients with lung cancer. We will be pursuing additional trials with Xcytrin in NSCLC as a single agent and in combination with chemotherapy."

### **About Non-Small Cell Lung Cancer (NSCLC)**

The American Cancer Society predicts that there will be more than 173,000 new cases of lung cancer in the U.S. in 2004. Lung cancer is the leading cause of cancer death, and accounts for over 150,000 deaths in the U.S. each year. The most common form of lung cancer, non-small cell, is incurable in advanced stages. Lung cancer frequently spreads to other body parts including the brain. Advanced lung cancer is usually treated with combination chemotherapy using drugs such as Cisplatin, Carboplatin, taxanes and others.

### **About Xcytrin**

Pharmacyclics is developing Xcytrin as an anti-cancer agent with a novel mechanism of action that is designed to selectively concentrate in tumors and induce apoptosis (programmed cell death). Pharmacyclics has been granted Fast-Track status by the U.S. Food and Drug Administration (FDA) for Xcytrin for the treatment of brain metastases (cancer that has spread to the brain from another part of the body) in non-small cell lung cancer (NSCLC) patients. Xcytrin is currently being evaluated in a randomized Phase 3 clinical trial (the SMART trial) that recently completed enrollment and is designed to compare the effects of whole brain radiation therapy (WBRT) alone to WBRT plus Xcytrin for the treatment of brain metastases in patients suffering from NSCLC. Xcytrin also is currently under investigation in several Phase 1 and Phase 2 clinical trials in various cancers evaluating its use as a single agent and in combination with chemotherapy and/or radiation therapy.

### **About Pharmacyclics**

Pharmacyclics is a pharmaceutical company developing innovative products to treat cancer and atherosclerosis. The company's products are rationally designed, ring-shaped small molecules called texaphyrins that are designed to selectively target and disrupt the bioenergetic processes of diseased cells, such as cancer and atherosclerotic plaque. More information about the company, its technology, and products in development can be found on its website at [www.pharmacyclics.com](http://www.pharmacyclics.com). Pharmacyclics(R), Xcytrin(R) and the "pentadentate" logo(R) are registered trademarks of Pharmacyclics, Inc.

Taxotere(R) is a registered trademark of Aventis.

NOTE: Other than statements of historical fact, the statements made in this press release about enrollment and future plans for our clinical trials, progress of and reports of results from preclinical and clinical studies, including results from our SMART trial, clinical development plans and product development activities are forward-looking statements, as defined in the Private Securities Litigation Reform Act of 1995. The words "believe," "will," "continue," "plan," "expect," "intend," "anticipate," variations of such words, and similar expressions also identify forward-looking statements, but their absence does not mean that the statement is not forward-looking. The forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that may cause actual results to differ materially from those in the forward-looking statements. Factors that could affect actual results include risks associated with the initiation, timing, design, enrollment and cost of clinical trials; the fact that data from preclinical studies and Phase 1 or Phase 2 clinical trials may not necessarily be indicative of future clinical trial results; our ability to collect complete and audited data from clinical sites participating in our SMART trial, our ability to establish successful partnerships and collaborations with third parties; the regulatory approval process in the United States and other countries; and future capital requirements. For further information about these risks and other factors that may affect the actual results achieved by Pharmacyclics, please see the company's reports as filed with the U.S. Securities and Exchange Commission from time to time, including but not limited to its quarterly report on Form 10-Q for the period ended March 31, 2005. Forward-looking statements contained in this announcement are made as of this date, and we undertake no obligation to publicly update any forward- looking statement, whether as a result of new information, future events or otherwise.

SOURCE Pharmacyclics, Inc.

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