



Pharmacyclics Announces Publication of Interim Data From Study Evaluating Single Agent Xcytrin for Advanced Renal Cell Carcinoma 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 2 clinical trial of Xcytrin(R) (motexafin gadolinium) Injection, the company's lead anti-cancer agent, for the treatment of patients with advanced, recurrent renal cell carcinoma. 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.

Researchers at the Methodist Hospital Research Institute in Houston, TX, measured the clinical benefit rate and tumor response rate in 22 metastatic renal cell cancer patients with treatment-refractory disease who were treated with Xcytrin daily for five days every two weeks until disease progression.

"Our preliminary results indicate that Xcytrin is active in patients with advanced, recurrent renal cell carcinoma," said Robert Amato, D.O., associate professor and director of the Genitourinary Oncology program in the Methodist Hospital Research Institute and principal investigator of the clinical trial. "Future trials will examine optimized dosing schedules in less-heavily previously-treated patients."

So far, the study has enrolled 22 patients, including 17 males and 5 females with a median age of 63 years and who have failed a median of 2 prior therapies. Five of the patients enrolled had one site of metastasis, eight enrolled had two sites of metastases and nine enrolled had more than two sites. These clinical features are known to be associated with poor prognosis.

Following treatment with Xcytrin, five patients have exhibited clinical benefit, defined as stable or regressing disease, through at least six months of follow-up, with two of these patients continuing on treatment and exhibiting clinical benefit through nine months. Three patients showed tumor responses including complete regression of pulmonary metastases. Side effects of Xcytrin therapy were mild (Grade 1 and 2) and included fatigue, headache, nausea and blistering on the fingers. Each of these side effects was observed in more than 25% of patients.

"We continue to observe single agent activity with Xcytrin in a range of tumor types," said Richard A. Miller, M.D., president and chief executive officer of Pharmacyclics. "We believe Xcytrin may have a role in the treatment of many kinds of cancer when used alone or with other agents."

About Renal Cell Carcinoma

Approximately 31,000 patients are diagnosed with renal cell carcinoma each year in the U.S. Approximately 12,000 will die from the disease every year. The cancer metastasizes readily, most often to the lungs and other organs, and about one-third of patients have metastases at the time of diagnosis. There is no cure for metastatic renal cell cancer, which is generally unresponsive to standard chemotherapy agents.

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. Pharmacyclics(R), Xcytrin(R) and the "pentadentate" logo(R) are registered trademarks of Pharmacyclics, Inc.

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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