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**PHARMACYCLICS ANNOUNCES INITIATION OF SINGLE AGENT  
XCYTRIN PHASE 2 CLINICAL TRIAL IN RECURRENT, METASTATIC  
NON-SMALL CELL LUNG CANCER**

**Sunnyvale, Calif. -- September 8, 2005** -- Pharmacyclics, Inc. (Nasdaq: PCYC) today announced that it has initiated an open-label Phase 2 clinical trial of Xcytrin<sup>®</sup> (motexafin gadolinium) Injection, the company's lead cancer therapeutic candidate, as a second-line treatment for patients with recurrent, metastatic non-small cell lung cancer (NSCLC). The trial is planned to enroll 108 patients at 12 sites across the U.S. and Canada.

"The purpose of this trial is to evaluate the safety and efficacy of single agent Xcytrin in recurrent NSCLC," said Markus Renschler, M.D., vice president of Oncology Clinical Development at Pharmacyclics. "Xcytrin has shown promising activity in other lung cancer trials when used in combination with chemotherapy or radiation. Lung cancer is difficult to treat, and evaluation of novel new therapies for this disease is critical."

The Phase 2 trial will enroll patients with metastatic disease who have failed one platinum-based chemotherapy regimen. The primary endpoints are safety and efficacy, as measured by tumor response rate and duration of response. Tumor response rate will be evaluated using Response Evaluation Criteria in Solid Tumors (RECIST), the standard parameters used to document response for solid tumors. Patients will be randomized to receive either a 10mg/kg dose of Xcytrin every week, or a 15mg/kg dose every three weeks.

"Our strategy is to build upon the experience and activity we have seen with Xcytrin in other lung cancer trials," said Richard A. Miller, M.D., president and chief executive officer of Pharmacyclics. "We believe that there is an opportunity to expand the use of Xcytrin to the systemic treatment of patients with metastatic disease in addition to its use in treating patients with brain metastases from lung cancer."

### **About Non-Small Cell Lung Cancer**

The American Cancer Society predicts that there will be more than 172,000 new cases of lung cancer in the U.S. in 2005. Lung cancer is the leading cause of cancer death, and accounts for over 160,000 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. Recently, Tarceva<sup>®</sup> (erlotinib) was approved for treatment of patients with recurrent lung cancer.

### **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). Xcytrin is a redox active drug that disrupts redox dependent pathways in cells and inhibits oxidative stress related proteins. Its multifunctional mode of action provides the opportunity to be used in a broad range of cancers. 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 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, atherosclerosis and other diseases. 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).

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Tarceva<sup>®</sup> is a registered trademark of OSI Pharmaceuticals, 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.

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