



## **Pharmacyclics to Submit New Drug Application for Xcytrin(R) for Treatment of Lung Cancer Patients With Brain Metastases**

### **New Analyses and Additional Data from Phase 3 SMART Trial to be Presented at ASCO 2006**

SUNNYVALE, Calif., May 9, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- Pharmacyclics, Inc. (Nasdaq: PCYC) today announced that the company plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) to market Xcytrin(R) (motexafin gadolinium) Injection for the treatment of non-small cell lung cancer (NSCLC) patients with brain metastases (i.e., lung cancer that has spread to the brain from another part of the body).

The company also announced that new analyses and additional data from its Phase 3 SMART (Study of Neurologic Progression with Motexafin Gadolinium And Radiation Therapy) trial will be presented at the upcoming Annual Meeting of the American Society of Clinical Oncology (ASCO) in Atlanta. Details on the oral presentation are as follows:

Abstract #7014: "Motexafin gadolinium (MGd) combined with prompt whole brain radiation therapy (RT) prolongs time to neurologic progression in non-small cell lung cancer (NSCLC) patients with brain metastases: Results of a Phase 3 trial," Minesh P. Mehta, M.D., Dept. of Human Oncology, University of Wisconsin, Madison, Saturday, June 3, 2006, 5:30 - 5:45 p.m.

The presentation will be followed by a discussion by Laurie E. Gaspar, M.D., Professor and Chair of Radiation Oncology at the University of Colorado.

The SMART trial was conducted at 94 centers in North America, Europe and Australia and enrolled 554 patients with brain metastases from NSCLC. This randomized, controlled Phase 3 trial compared the safety and efficacy of whole brain radiation therapy (WBRT) alone to WBRT plus Xcytrin. The primary endpoint of the study was time to neurologic progression as determined by a blinded events review committee.

"We plan to file an NDA for Xcytrin primarily based on the data from our pivotal SMART trial," said Richard A. Miller, M.D., president and CEO of Pharmacyclics. "New data from the SMART trial, which will be included in the NDA filing, will be presented and discussed at ASCO. We anticipate filing the Xcytrin NDA by the end of 2006."

#### 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 has been shown to disrupt redox-dependent pathways in cells and inhibit oxidative stress related proteins. Its multifunctional mode of action provides the opportunity to be used in a broad range of cancers. Xcytrin has been granted Fast Track designation by the FDA for use in the treatment of lung cancer brain metastases. This designation is reserved for new drugs that demonstrate the potential to address an unmet medical need and are intended for the treatment of a serious or life-threatening condition.

#### About Pharmacyclics

Pharmacyclics is a pharmaceutical company developing innovative products to treat cancer, atherosclerosis and other serious diseases. The company is leveraging its small-molecule drug development expertise to build a pipeline in oncology and other diseases based on a wide range of targets, pathways and mechanisms. Its lead product, Xcytrin, has completed Phase 3 clinical testing in lung cancer brain metastases and several Phase 1 and Phase 2 clinical trials are ongoing with Xcytrin, either as a single agent or in combination with chemotherapy and/or radiation in multiple cancer types. Pharmacyclics has other product candidates in earlier-stage development for cancer and inflammatory diseases. More information about the company, its technology, and products can be found at [www.pharmacyclics.com](http://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 "potential," "project," "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; unexpected delays in and unanticipated increases in costs related to our preclinical studies and 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 obtain future financing and fund the product development of our pipeline; the outcome of our discussions with the FDA; our ability to prepare and submit an NDA on a timely basis or at all; the possibility that the FDA refuses to accept any NDA we submit; the possibility that additional data or studies may be required before the NDA is accepted for filing or approved by the FDA; 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 December 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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