



Pharmacyclics Submits New Drug Application for Xcytrin for the Treatment of Lung Cancer Brain Metastases

SUNNYVALE, Calif., Dec 22, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- Pharmacyclics, Inc. (Nasdaq: PCYC) today announced that it has submitted a New Drug Application (NDA) for Xcytrin(R) (motexafin gadolinium) Injection with the U.S. Food and Drug Administration (FDA). The company is seeking approval to market Xcytrin for the treatment of non-small cell lung cancer (NSCLC) patients with brain metastases (i.e., cancer that has spread to the brain from another part of the body).

The NDA data packet includes efficacy and tolerability data from two Phase 3 randomized, controlled trials involving 805 patients, which compared the safety and efficacy of whole brain radiation therapy (WBRT) alone to WBRT plus Xcytrin. These studies utilized an innovative clinical benefit endpoint that measured neurologic outcomes.

"The clinical development program with Xcytrin continues on multiple fronts," said Richard A. Miller, M.D., president and CEO of Pharmacyclics. "In addition to the completed trials in brain metastases, which form the basis of our NDA submission, several other ongoing trials are evaluating Xcytrin in non-small cell lung cancer and other cancers. We are also moving forward with several other novel compounds, which are in clinical and preclinical development."

About Lung Cancer and Brain Metastases

According to the National Cancer Institute, over 170,000 patients will be diagnosed with lung cancer this year in the U.S. Lung cancer is the most common cause of brain metastases, which are estimated to occur in up to 50% of lung cancer patients. Spread of lung cancer to the brain may occur early in the course of disease or may be a later complication of this illness.

Brain metastases occur when cancer cells spread to the brain and grow, causing major neurologic complications. Patients with brain metastases usually suffer serious deterioration of neurologic and neurocognitive function such as loss of short-term memory, compromised verbal skills and fine motor coordination, and reduction in cognitive performance. Standard therapy for patients with brain metastases from lung cancer involves the prompt use of cranial radiation, which is used to prevent neurological deterioration and improve neurologic outcomes.

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 for Xcytrin 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 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(R), has completed Phase 3 clinical trials and several ongoing Phase 1 and Phase 2 clinical trials are evaluating Xcytrin as a single agent or in combination with chemotherapy and/or radiation in multiple cancer types. More information about the company, its technology, and products can be found 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, 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," "may," "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 possibility that the FDA refuses to accept or approve any NDA we submit; because our

Phase 3 clinical trial known as the SMART (Study of Neurologic Progression with Motexafin Gadolinium and Radiation Therapy) trial failed to meet its primary endpoint, the FDA may require additional data, analysis or studies before the NDA is accepted for filing or approved by the FDA; the outcome of any discussions with the FDA; the initiation, timing, design, enrollment and cost of clinical trials; unexpected delays in clinical trials and preparation of materials for submission to the FDA as part of our NDA filing; 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 preparation of our NDA filing and the product development of our pipeline; our ability to establish successful partnerships and collaborations with third parties; the regulatory approval process in the United States and other countries; and our 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 annual report on Form 10-K for the period ended June 30, 2006. 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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