



Pharmacyclics Announces FDA Filing of New Drug Application for Xcytrin(R) Injection to Treat Lung Cancer Brain Metastases

SUNNYVALE, Calif., April 23, 2007 /PRNewswire-FirstCall via COMTEX News Network/ -- Pharmacyclics, Inc. (Nasdaq: PCYC) today announced that the U.S. Food and Drug Administration (FDA) has filed the company's New Drug Application (NDA) for Xcytrin(R) (motexafin gadolinium) Injection. The Prescription Drug User Fee Act (PDUFA) date for completion of review by FDA is December 31, 2007. The Company is seeking approval to market the drug 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).

"We are very eager to work with the Agency to complete a thorough and fair review of the extensive data in our NDA," said Richard A. Miller, MD, President and CEO of Pharmacyclics. "We and our investigators, outside experts and patient advocates believe our data support the efficacy and safety of Xcytrin for the treatment of brain metastases for patients with non-small cell lung cancer and justify a comprehensive review by the Agency. We believe it is in the best interests of patients to do everything we can to make this drug available for patients with this terrible disease for which few treatment options exist."

According to the National Cancer Institute, over 200,000 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 late complication of this illness. This is a disease that causes devastating and deadly neurologic problems and is increasing in incidence. No drug has ever been shown to provide neurologic benefit to these patients.

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 paralysis, loss of vision, disturbances of gait and speech, decrease in mental status, loss of short-term memory, compromised verbal skills and reduction in cognitive ability. 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.

In December 2006, the Company submitted an NDA to the FDA's Division of Drug Oncology Products requesting marketing clearance for Xcytrin in combination with radiation therapy for the treatment of brain metastases from NSCLC. In February 2007, it received a refuse to file letter from the FDA citing failure to demonstrate statistically significant differences between treatment arms in the primary endpoint of the pivotal study to support approval. The Company filed the NDA over protest, a procedure permitted by regulation that allows sponsors to have their NDA filed and reviewed when there is disagreement over the acceptability of the NDA. There can be no assurance that the NDA will be approved or that there will be an advisory panel meeting to review the data.

"After consultation with investigators, experts and patient groups, we decided to have our NDA filed over protest because clinical evaluation of Xcytrin for the brain metastases indication required use of a novel but clinically meaningful endpoint, which should be carefully reviewed by the Agency. Moreover, there are other examples of NDAs for oncology drugs that have been accepted for filing without meeting the primary endpoint with statistical significance. In some cases this has led to product approvals, particularly in cases where the unmet need is great, the drug is well tolerated and there are few if any other treatment options available," added Dr. Miller.

The NDA submission was based on the results of two randomized trials and an integrated analysis of both trials. These trials utilized an innovative neurologic progression endpoint designed with FDA to assess the clinical benefit of treatment. The first of these trials, which included 251 NSCLC patients and 150 patients with brain metastases from other solid tumors, did not show a statistically significant benefit overall but did show a clinically and statistically significant improvement in time to neurologic progression in the subset of patients with NSCLC.

The follow up pivotal 554-patient SMART trial showed a 5.4 month improvement in time to neurologic progression, the primary pre-specified endpoint, with a median time to neurologic progression of 15.4 months for Xcytrin compared to 10.0 months for the control (with a p-value equal to 0.12). While not statistically significant, this represented a very strong and promising treatment effect in a disease for which nothing has worked beyond radiation therapy.

An integrated analysis of the 805 lung cancer patients in these two large Phase 3 studies demonstrated a statistically significant 6.4 month improvement in time to neurologic progression for patients receiving Xcytrin plus whole brain radiation therapy compared to those receiving radiation alone. The median time to neurologic progression was 15.4 months compared to 9.0 months, respectively, with a p-value equal to 0.016. Several secondary endpoints also showed a significant benefit for Xcytrin plus whole brain radiation compared to radiation alone: time to neurologic progression as determined by investigators, P = 0.015 and time to neurocognitive progression, P = 0.02. In addition to this consistent treatment effect, Xcytrin plus radiation

therapy was generally well tolerated across all studies.

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.

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 <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 plans for our NDA filing, 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 declines to schedule an advisory panel meeting to review our NDA; the FDA refuses to approve our NDA; 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 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 and its subsequently filed quarterly reports on Form 10-Q. 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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