



Pharmacyclics Announces Presentation of Pooled Analysis of Xcytrin(R) for Lung Cancer Brain Metastases

- Results in 805 Patients Treated on Randomized Trials Presented at Society of Neuro-Oncology Meeting -

SUNNYVALE, Calif., Nov 20, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- Pharmacyclics, Inc. (Nasdaq: PCYC) today announced the presentation of pooled results from two randomized Phase 3 clinical trials, which indicate that Xcytrin(R) (motexafin gadolinium) Injection combined with whole brain radiation therapy (WBRT) significantly prolonged time to neurologic progression in non-small cell lung cancer (NSCLC) patients with brain metastases. The presentation took place at the Society for Neuro-Oncology's 11th Annual Meeting being held this week in Orlando, FL.

"These data demonstrate that Xcytrin, used in combination with whole brain radiation therapy, may significantly improve neurologic outcomes in patients with brain metastases from non-small cell lung cancer," said William R. Shapiro, M.D., chief of the Neuro-Oncology Division of Neurology at the Barrow Neurological Institute, and presenter of the pooled Phase 3 results. "These two large studies both used an innovative and clinically meaningful endpoint and reveal consistent benefit in this patient population."

The presentation, "Motexafin gadolinium (MGd) combined with whole brain radiation therapy prolongs time to neurologic progression in non-small cell lung cancer (NSCLC) patients with brain metastases: pooled analysis of two randomized Phase 3 trials," described pooled results from two Phase 3 trials evaluating the safety and efficacy of WBRT alone to WBRT plus Xcytrin in NSCLC patients with brain metastases. The primary endpoint for both trials was time to neurologic progression (TNP) as determined by a blinded events review committee. In the two trials, 805 NSCLC patients received either WBRT (N = 403) or WBRT plus Xcytrin (N = 402). The treatment arms were well balanced for all known prognostic factors.

In the pooled results analysis, the median TNP determined by a blinded events review committee was 15.4 months for patients receiving WBRT plus Xcytrin compared to 9.0 months for patients treated with WBRT alone (P = 0.016, hazard ratio = 0.73). Secondary endpoints also showed significant benefit for Xcytrin plus WBRT compared to WBRT alone: TNP as determined by investigators, P = 0.015, hazard ratio = 0.76; time to neurocognitive progression, P = 0.02, hazard ratio = 0.78. Xcytrin was well tolerated in the study. The most common drug related grade 3 and 4 adverse events were hypertension (5%) and fatigue (3%), all of which were reversible. Xcytrin did not interfere with the ability to deliver WBRT.

The data used in this pooled analysis are derived from the Phase 3 SMART (Study of Neurologic Progression with Motexafin Gadolinium And Radiation Therapy) trial, which enrolled 554 patients and was designed to compare the safety and efficacy of WBRT alone to WBRT plus Xcytrin in NSCLC patients with brain metastases, combined with the data from an earlier Phase 3 clinical trial in patients with metastatic cancer to the brain resulting either from lung, breast or other types of solid tumors. In that study, 401 patients were enrolled and a treatment benefit was observed in the pre-defined subset of 251 patients with NSCLC. Both Phase 3 trials enrolled patients with NSCLC meeting similar eligibility criteria and having similar baseline disease characteristics. In addition, both studies used identical treatment regimens, and similar clinical assessments were performed. As presented by Dr. Shapiro and his colleagues, the magnitude of the treatment benefit was comparable in each of the trials and in the pooled analysis of the data.

"We are moving forward with preparation of a new drug application (NDA) with the U.S. Food and Drug Administration and anticipate filing by the end of the calendar year," said Richard A. Miller, M.D., president and chief executive officer of Pharmacyclics. "This pooled data from two randomized trials presented at the Society for Neuro-Oncology meeting provides the basis for the integrated efficacy data that will be contained in our NDA."

About Brain Metastases

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. Most patients with brain metastases are treated with WBRT. In some patients, radiosurgery can be performed on a limited number of lesions in an attempt to improve local tumor control. The primary goal of radiation therapy to the brain is to reverse or prevent neurological deterioration and prevent death due to tumor progression in the brain. NSCLC is the most common form of lung cancer, and brain metastases may occur in up to half of these patients. Patients with NSCLC develop brain metastases early in the course of their disease and studies have shown that brain metastases from lung cancer may be among the most amenable to treatments.

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.

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 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 other diseases. 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 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; 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; because the SMART 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; 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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