



Pharmacyclics Announces Positive Final Results of Phase 2 Trial of Xcytrin(R) Plus Radiosurgery for Brain Metastases With Occult Tumors Detected in 24% of Patients

- Efficacy results promising with median time to neurologic progression exceeding 18 months -

CHICAGO and SUNNYVALE, Calif., June 3, 2007 /PRNewswire-FirstCall via COMTEX News Network/ -- Pharmacyclics, Inc. (Nasdaq: PCYC) today announced final results from an open-label multi-center Phase 2 clinical trial, which indicated that Xcytrin(R) (motexafin gadolinium) Injection may improve the efficacy of stereotactic radiosurgery by providing more accurate magnetic resonance imaging (MRI) treatment-planning and better defining the treatment field in patients with brain metastases from solid tumors. Xcytrin allowed physicians to identify occult brain metastases in 24% of patients that were missed with standard MRI contrast agents and were amenable to stereotactic radiosurgery. The data were presented at the 2007 American Society of Clinical Oncology Annual Meeting (ASCO) in Chicago.

"This study suggests that Xcytrin may be used both to enhance the effectiveness of radiation and to improve detection of occult lesions in patients with brain metastases," said Minesh P. Mehta, M.D., professor and chairman of Human Oncology and professor of Neurological Surgery at the University of Wisconsin Medical School, who presented the data. "It appears that a significant number of patients are being under-treated since current imaging and stereotactic radiosurgery techniques fail to identify and treat all the tumors. The efficacy results in this study are promising with a median time to neurologic progression exceeding 18 months."

Brain metastases occur in 20-25% of patients with solid tumors, affecting up to 200,000 patients per year in the U.S. Brain metastases occur when cancer cells spread to the brain and grow, causing major neurologic complications and, in many cases, death. Patients with brain metastases usually suffer serious deterioration of neurologic and neurocognitive function such as loss of motor function, impaired balance, loss of vision, change in mental status, loss of short-term memory, compromised verbal skills, and reduction in cognitive performance. Most patients with brain metastases are treated with whole brain radiation therapy (WBRT). In some patients with a limited number of lesions, radiosurgery can be performed 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. There are virtually no other treatment options available to patients today other than this. A New Drug Application for use of Xcytrin in combination with WBRT for treatment of brain metastases from NSCLC was filed with the Food and Drug Administration in April 2007.

"These results further underscore the potential versatility of Xcytrin in treating a broad range of cancers," said Richard A. Miller, M.D., president and CEO of Pharmacyclics. "The study demonstrates the potential for Xcytrin to improve neurologic outcomes by enhancing both the efficacy of radiation and detection of the tumors -- 24% of the patients in this study were found to have lesions that were missed using standard MRI scans and therefore would have had tumors that remained untreated. Particularly within the context of brain metastases for which there are limited alternative treatments, developing this kind of next-generation drug is a vital step forward -- not only to improve neurologic outcomes, but to also improve diagnostic accuracy."

The Phase 2 single-arm trial evaluated the safety, radiologic response and time to neurologic progression in 45 patients. Patients with brain metastases from cancers of the lung (34), breast (5) and other cancers (6) were enrolled at 14 academic medical centers and treated with Xcytrin plus WBRT followed by stereotactic radiosurgery boost therapy to tumor sites in the brain. The study was also designed to evaluate if the MRI scan obtained with Xcytrin improved detection of tumors compared to standard contrast enhanced MRI procedures. In 11 of 45 patients (24.4%) with MRI data available, lesions were detected with Xcytrin that were not seen with standard MRI. The Xcytrin-based treatment planning MRI detected one occult lesion in seven patients, two occult lesions in one patient, and three occult lesions in three patients. The median survival for patients in this study was nine months, and the median time to neurologic progression or radiologic progression was not reached at 18 months. Xcytrin was well tolerated in this study. One patient in the study suffered radionecrosis of the tumor. The most common treatment related serious adverse events were deep vein thrombosis (13%) and pneumonia (9%).

The trial enrolled patients with one to four brain metastases from solid tumors. Patients in the Phase 2 trial were treated with WBRT in combination with 10 daily doses of 5mg/kg of Xcytrin, followed by stereotactic radiosurgery boost to the tumors with another dose of Xcytrin. MRI scans were obtained at baseline and again after the Xcytrin treatment regimen. Because Xcytrin is designed to localize in tumors and enhance the MRI signal, the post-Xcytrin MRI scan was used to define the field for stereotactic radiosurgery. MRI scans were also obtained at three month follow-up intervals to evaluate radiologic tumor response and safety of the radiosurgery procedure. Follow up assessments of patients included use of neurologic testing and determination of time to neurologic progression.

Stereotactic Radiosurgery and Imaging

Stereotactic radiosurgery involves the delivery of a high dose of radiation to a limited, well-defined treatment volume. This form of radiation usually follows treatment with WBRT to ensure that all tumors within the brain are treated. The delivery of stereotactic radiation requires precise definition of the tumor size, location and adjacent structures. MRI scanning or computerized tomography is typically used to define the treatment field so that the tumors are adequately treated and adjacent normal structures are not injured by the high radiation dose. Xcytrin, in addition to having cooperative activity with radiation, is designed to be MRI detectable and may potentially be used to enhance the tumor image and better define the treatment field.

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, including its MRI detectability, 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, has completed Phase 3 clinical trials and several ongoing Phase 1 and Phase 2 clinical trials are evaluating Xcytrin, either 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>. In addition, more information about advocacy on behalf of Xcytrin(R) can be found at <http://www.yourcanceryourchoice.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 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 possibility that 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; 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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Leiv Lea of Pharmacyclics, Inc., +1-408-774-0330; or Carolyn Bumgardner Wang of WeissComm Partners, Inc., +1-415-225-5050, for Pharmacyclics, Inc.

<http://www.pharmacyclics.com>

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