



Pharmacyclics Announces Presentation of Preliminary Results From Phase 2 Clinical Trial of Xcytrin(R) With Radiosurgery for Brain Metastases

SUNNYVALE, Calif., Nov 09, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- Pharmacyclics, Inc. (Nasdaq: PCYC) today announced the presentation of preliminary results of an open-label multi-center Phase 2 clinical trial, which suggest that Xcytrin(R) (motexafin gadolinium) Injection may improve stereotactic radiosurgery treatment-planning by enhancing magnetic resonance imaging (MRI) and better defining the treatment field in patients with brain metastases from solid tumors. Xcytrin allowed physicians to identify occult brain metastases that are amenable to stereotactic radiosurgery and that were missed with standard MRI contrast agents. The presentation took place at the 48th American Society for Therapeutic Radiology and Oncology (ASTRO) Annual Meeting taking place this week in Philadelphia, PA.

"These data demonstrate that Xcytrin can be used in combination with radiosurgery and whole brain radiation therapy (WBRT) for patients with brain metastases," said John Suh, M.D., Department Chair of Radiation Oncology at the Cleveland Clinic, and presenter of the Phase 2 results. "Our results showed that, in one-fifth of the patients enrolled in this trial, Xcytrin-based treatment planning for stereotactic radiosurgery identified occult brain metastases that are amenable to radiosurgery and were missed with standard MRI procedures."

The presentation, "Motexafin Gadolinium-Based Treatment Planning MRI Identifies Occult Brain Metastases Amenable to Stereotactic Radiosurgery: Results of a Phase II trial of Motexafin Gadolinium and Whole Brain Radiotherapy with Stereotactic Radiosurgery," described preliminary results from a Phase 2 single-arm trial evaluating the safety, tumor response and time to neurologic progression in 45 patients enrolled at 15 academic medical centers 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 signal obtained with Xcytrin improved detection of tumors compared to standard contrast enhanced MRI procedures. In nine of 43 evaluable patients (21%), lesions were detected with Xcytrin that were not seen with standard MRI. With a median follow-up of approximately five months, it is estimated that 80% of patients are without neurologic progression at one year.

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. 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 tumor response and safety of the radiosurgery procedure.

"This trial suggests that Xcytrin's anti-tumor activity may be combined with its MRI detectability to improve patient outcomes," said Richard A. Miller, M.D., president and chief executive officer of Pharmacyclics. "Xcytrin may provide more precise tumor targeting for radiosurgery and may enhance tumor destruction."

About Brain Metastases

Brain metastases occur when cancer cells spread to the brain and grow, causing major neurologic complications and, in most cases, death. 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.

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 tumor is adequately treated and adjacent normal structures are not injured by the high radiation dose. Xcytrin 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 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; 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 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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