December 2, 2009

Peregrine Completes Patient Enrollment in Cotara(R) Dose Confirmation and Dosimetry Brain Cancer Trial

-Dosimetry Data Objectives Have All Been Met and Final Data from the Trial Is Expected By Mid-2010-
-Completion of Patient Enrollment in the Study Allows the Company to Expand Its Ongoing Cotara Phase II Glioblastoma Clinical Trial-

TUSTIN, Calif., Dec 02, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Peregrine Pharmaceuticals, Inc. (Nasdaq: PPHM) today reported completion of patient enrollment in a dose confirmation and dosimetry trial of Cotara(R) in patients with relapsed glioblastoma multiforme (GBM), the deadliest form of brain cancer. Cotara is a targeted monoclonal antibody linked to a radioisotope being developed as a potential new treatment for GBM. Cotara specifically targets cells at the center of brain tumors, so its radioactive payload is able to kill cancer cells while leaving healthy tissue largely unaffected. Cotara is also being tested in a Phase II clinical trial in patients with recurrent GBM.

In the ongoing dose confirmation and dosimetry study, patients received a single treatment of Cotara and were evaluated for specificity of drug localization to the tumor, as well as for progression-free survival and overall patient survival. Initial data from the trial show that all of the patients in the first two completed study cohorts have survived longer than the expected six-month median survival time for GBM patients and they confirm Cotara's targeting capabilities, indicating that it delivers more than 300-fold higher radiation levels to the tumor than to normal organs.

"Completion of patient enrollment in this study is a significant regulatory milestone for Cotara, representing an important component of the Cotara clinical development program," said Dr. Robert Garnick, head of regulatory affairs at Peregrine. "With enrollment in this trial now completed, we are turning our attention to expanding the ongoing Cotara Phase II GBM trial to further advance the program. Given the encouraging data seen to date in the Cotara brain cancer trials, we plan to explore available clinical and regulatory options for expediting Cotara development."

The main objectives of the open label dosing and dosimetry study are to confirm the maximum tolerated dose of Cotara, to determine radiation dosimetry and to assess overall patient survival, progression-free survival and the proportion of patients alive at six months following Cotara administration. In both ongoing clinical trials, Cotara is delivered using convection-enhanced delivery (CED), a method developed by the U.S. National Institutes of Health that targets the specific tumor site in the brain.

"We believe the data generated from this dosimetry trial will be an important and necessary part of our Cotara regulatory package as we continue to advance the program," said Joseph Shan, vice president of clinical and regulatory affairs at Peregrine. "The trial design the regulatory authorities asked us to implement was necessarily complex and therefore challenging to enroll, requiring a significant commitment from both patients and the participating health care institutions. We are grateful for their successful efforts and our plan is now to expand the ongoing 40-patient Phase II Cotara GBM trial to these clinical sites, which should help expedite timely completion of the ongoing Phase II clinical trial."

Interim data from the dosimetry trial presented at the Society of Nuclear Medicine 2009 Annual Meeting in June showed that in patients dosed in the first two cohorts of the study, the concentration of Cotara in brain tumors was on average more than 300-fold higher than in other normal organs. In addition, these patients had all either met or exceeded the expected median survival time for recurrent GBM patients. Interim data from a Phase II study of GBM patients who have experienced a first relapse was presented at the XIV World Congress of Neurological Surgery in September. It highlighted a subset of 10 GBM patients and included follow-up durations ranging from seven weeks to over 73 weeks, showing an interim median recurrence-free survival of 33 weeks and an interim median overall survival of 41 weeks. Patient enrollment in this trial has surpassed the half-way mark.

More than 70 patients with recurrent GBM have received Cotara in the current and previous clinical studies. Localization and accumulation of the drug to the tumor have been excellent and longer-term survivors (greater than one year from the time of Cotara treatment) have been observed in all of the trials, with long-term surviving patients from early GBM clinical studies now alive more than 8.5 years after treatment with Cotara. Expected survival for patients with GBM is approximately six months from the time of disease recurrence.

Overall, Cotara has been administered to a total of more than 120 patients with brain, colon, liver or other cancers. Promising data from these studies support Cotara's ability to specifically target solid tumors and its anti-tumor activity, as well as its acceptable safety profile.

About Cotara(R)

Cotara is an experimental treatment for brain cancer that links a radioactive isotope to a targeted monoclonal antibody designed to bind to the DNA histone complex that is exposed by dead and dying cells found at the center of solid tumors. Cotara's targeting mechanism enables it to bind to the dying tumor cells, delivering its radioactive payload to the adjacent living tumor cells and essentially destroying the tumor from the inside out, with minimal radiation exposure to healthy tissue. Cotara is delivered using convection-enhanced delivery (CED), an NIH-developed method that targets the specific tumor site in the brain. Cotara has been granted orphan drug status and fast track designation for the treatment of glioblastoma multiforme and anaplastic astrocytoma by the U.S. Food and Drug Administration.

About Peregrine Pharmaceuticals

Peregrine Pharmaceuticals, Inc. is a biopharmaceutical company with a portfolio of innovative monoclonal antibodies in clinical trials for the treatment of cancer and serious viral infections. The company is pursuing three separate clinical programs in cancer and HCV infection with its lead product candidates bavituximab and Cotara*(R)*. Peregrine also has in-house manufacturing capabilities through its wholly owned subsidiary Avid Bioservices, Inc. (www.avidbio.com), which provides development and biomanufacturing services for both Peregrine and outside customers. Additional information about Peregrine can be found at www.peregrineinc.com.

Safe Harbor Statement: Statements in this press release which are not purely historical, including statements regarding Peregrine Pharmaceuticals' intentions, hopes, beliefs, expectations, representations, projections, plans or predictions of the future are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. It is important to note that the company's actual results could differ materially from those in any such forward-looking statements. Factors that could cause actual results to differ materially include, but are not limited to, the risk that that the results of future clinical studies will not correlate or be consistent with the results of the completed studies to date and the risk that the company will experience delays or difficulties in enrolling patients in any planned future clinical studies. Factors that could cause actual results to differ materially or otherwise adversely impact the company's ability to obtain regulatory approval for its product candidates include, but are not limited to, uncertainties associated with completing preclinical and clinical trials for our technologies; the early stage of product development; the significant costs to develop our products as all of our products are currently in development, preclinical studies or clinical trials; obtaining additional financing to support our operations and the development of our products; obtaining regulatory approval for our technologies; anticipated timing of regulatory filings and the potential success in gaining regulatory approval and complying with governmental regulations applicable to our business. Our business could be affected by a number of other factors, including the risk factors listed from time to time in the company's SEC reports including, but not limited to, the annual report on Form 10-K for the year ended April 30, 2009 and the quarterly report on Form 10-Q for the quarter ended July 31, 2009. The company cautions investors not to place undue reliance on the forward-looking statements contained in this press release. Peregrine Pharmaceuticals, Inc. disclaims any obligation, and does not undertake to update or revise any forward-looking statements in this press release.

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