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## **Interim Phase II Data Presented at XIV World Congress of Neurological Surgery Supports Potential of Peregrine's Cotara(R) for Treatment of Brain Cancer**

- Interim Data from Lead Clinical Site in Ongoing Phase II Study Evaluating Cotara in Patients with Recurrent Glioblastoma Shows It is Generally Well Tolerated with Encouraging Signs of Efficacy-**
- Recurrent GBM Patients Treated with a Single Dose of Cotara as Monotherapy Had Interim Median Recurrence-Free Survival of 33 Weeks and Median Overall Survival of 41 Weeks-**
- Expected Survival for Patients with GBM is Approximately 24 Weeks from Time of Disease Recurrence-**

BOSTON, Mass. and TUSTIN, Calif., Sept 02, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Peregrine Pharmaceuticals, Inc. (Nasdaq: PPHM) today reported that clinical investigators are presenting interim Phase II data showing that its brain cancer agent Cotara(R) appeared well tolerated and demonstrated encouraging signs of efficacy in patients with glioblastoma multiforme (GBM), the deadliest form of brain cancer. The data from an ongoing Phase II study of Cotara in patients with recurrent GBM is being presented today at the XIV World Congress of Neurological Surgery Annual Meeting by Dr. Deepak Gupta, assistant professor of neurosurgery at the All India Institute of Medical Sciences (AIIMS) in New Delhi on behalf of the Cotara study team that includes Drs. A.K. Mahapatra, Ashish Suri and C.S. Bal.

Dr. Gupta will present interim data for 10 recurrent GBM patients at first relapse treated at AIIMS as part of an ongoing 40 patient Phase II clinical trial. Eight males and two females with a mean age of 51 years received a single intratumoral infusion of Cotara. Currently, follow-up duration ranges from between seven to over 73 weeks with an interim median recurrence-free survival of 33 weeks and an interim median overall survival of 41 weeks. Expected survival for patients with GBM is approximately 24 weeks from time of disease recurrence. Based on this interim data, the study authors conclude that Cotara appears to be feasible, tolerable and has encouraging signs of efficacy in recurrent GBM patients.

"This interim data from our Phase II trial suggests that Cotara has the potential to be a valuable new therapy for patients with glioblastoma, a devastating disease with few treatment options," said Dr. A.K. Mahapatra, professor of neurosurgery at AIIMS and principle investigator on the Cotara study. "Our experience to date with Cotara shows that it is feasible to administer and is quite well tolerated in these very ill patients. Most importantly, Cotara has demonstrated promising signs of efficacy. We look forward to enrolling more GBM patients in the Cotara trial over the coming months and to further assessing the experience of the patients treated to date."

The Cotara Phase II multi-center open label study is designed to enroll up to 40 glioblastoma patients who have experienced a first relapse. The primary objective of the trial is to confirm the maximum tolerated dose of Cotara in GBM patients at first relapse. Secondary objectives include estimates of overall patient survival, progression-free survival and the proportion of patients alive at six months. Patients in the trial are receiving a single infusion of Cotara by convection-enhanced delivery (CED), a technique that delivers the agent to the tumor with great precision. Brain scans are administered at eight-week intervals post-treatment. The study is being conducted according to internationally accepted ICH and GCP guidelines.

"The interim data being presented today for the GBM patients treated at AIIMS supports the meaningful signs of clinical activity seen in prior Cotara trials as measured by median overall survival," said Joseph Shan, vice president of clinical and regulatory affairs at Peregrine. "Previous clinical data presented earlier this year has shown the ability of Cotara to specifically deliver high doses of radiation to GBM tumors, resulting in significant anti-tumor effects. The early data from this ongoing Phase II study is providing further evidence that Cotara's ability to target tumors with great specificity may provide clinical benefit to patients with this devastating disease. We look forward to completing enrollment and reporting data on the entire trial as soon as possible."

More than 65 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 some recurrent GBM patients from early clinical studies now alive more than 8.5 years after treatment with Cotara. Expected survival for patients with GBM is approximately 24 weeks from time of disease recurrence.

Overall, Cotara has been administered to a total of more than 125 patients with brain, colon or liver cancer. 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.

The presentation, Efficacy of Intratumoral Radioimmunotherapeutic Agent Cotara in Recurrent GBM: Initial Experience with 10 Cases, is being presented today at 2:54 pm EDT at the XIV World Congress of Neurological Surgery Annual Meeting at the Hynes Convention Center in Boston, MA.

#### 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. In a previous clinical study, a subset of patients with recurrent glioblastoma treated with Cotara achieved a median survival of 38 weeks, a 58% increase over the historical median survival time of 24 weeks for patients treated with standard of care therapy. In this study, 25% of 28 recurrent patients survived for more than a year post-treatment and 10% of patients survived for more than three years. These data are considered a promising development in this deadly disease. In addition to the Phase II trial now underway in India, a dosimetry and dose confirmation trial in glioblastoma patients at leading U.S. academic brain cancer centers is nearing completion. 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 hepatitis C virus 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](http://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](http://www.peregrineinc.com).

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