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# Data Presented at Society of Nuclear Medicine 2009 Annual Meeting Supports Potential of Peregrine's Cotara(R) for the Treatment of Brain Cancer

# -- -- Dosimetry Study Results Show Greater Than 300-Fold More Radiation Delivered to Tumor as Compared to Other Normal Organs - -- All Patients in the First Two Cohorts Have Met or Exceeded the Expected Median Survival Time for Recurrent GBM Patients -

TORONTO and TUSTIN, Calif., June 16, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Peregrine Pharmaceuticals, Inc. (Nasdaq: PPHM) today reported that researchers will present data at the SNM 2009 Annual Meeting showing that its brain cancer agent Cotara(R) specifically localizes to brain tumors at high concentrations with minimal radiation exposure to other organs. Cotara is a targeted monoclonal antibody linked to a radioisotope being developed as a potential new treatment for glioblastoma multiforme (GBM), a deadly form of brain cancer. The results reported today from an ongoing dosimetry study at U.S. brain cancer centers show 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 have all either met or exceeded the expected median survival time of six months for recurrent GBM patients. Cotara is currently being tested in this Phase I dose response and dosimetry trial and in a Phase II clinical trial in recurrent GBM patients.

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. In this study, lead author Sui Shen, Ph.D., associate professor of radiation oncology at the University of Alabama at Birmingham, and his colleagues assessed the concentration of Cotara in GBM patients' tumors and in their healthy brain tissue, as well as in their thyroid, stomach, heart and bone marrow. He found that Cotara was concentrated in the brain tumor with minimal exposure to the contralateral healthy brain. The thyroid, which can have active uptake of radioiodine, showed only minimal uptake of Cotara. Similarly, uptake of Cotara was very low in the stomach, heart and bone marrow, important potential sites for radiation toxicity. On average, the tumor received more than 300 times the dose of radiation compared to these normal organs.

"These findings confirming Cotara's potential to target its radioactive payload to brain tumors while minimizing radiation exposure to healthy organs, including the thyroid, are very encouraging," said Dr. Shen. "With a mean dose ratio showing 300-fold greater delivery of radiation to the tumor as compared to other organs, Cotara represents a potentially valuable new therapy for GBM patients."

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 this study and in the ongoing Phase II trial, 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. The final planned patient in the dosimetry study is currently being enrolled.

"These positive data analyzed by a leading dosimetry expert validate a key principle underlying the Cotara program, confirming its ability to specifically concentrate in and deliver a high radiation dose to brain tumors," said Joseph Shan, vice president of clinical and regulatory affairs at Peregrine. "In this trial and in our other Cotara clinical trials, Cotara has been well tolerated, and we continue to see longer- term survivors among the treated patients. We are very pleased to have the opportunity to share this promising data from our current U.S.

Cotara clinical trial with experts at this prestigious conference, and we look forward to reporting further data from this study and from our Phase II trial in patients with recurrent GBM."

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 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 six months from the time of disease recurrence.

The Cotara data will be presented today at the 2009 Society for Nuclear Medicine (SNM) Annual Meeting in Toronto, Canada, in a session scheduled from 12:30 PM to 2:00 PM EDT in Room 701B.

Abstract No: 150240; Publication No: 445: S. Shen(1), R. Lustig(2), K. Judy(2), W. Shapiro(3), K. Spicer(4), S. Patel(4), J. Fiveash(1), J. Lai(5), J. Shan(5), "Dosimetry of phase I interstitial 131I-chTNT-1/B MAb (Cotara) for the treatment of recurrent glioma."

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## 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. 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. 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. A Phase I dosimetry trial in GBM patients in the U.S. is in the final stages of patient enrollment and a Phase II safety and efficacy trial in GBM patients in India is ongoing. For more information on the trials, visit www.clinicaltrials.gov.

## **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), which provides development and biomanufacturing services for both Peregrine and outside customers. Additional information about Peregrine can be found at www.peregrineinc.com.

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