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Peregrine Pharmaceuticals Announces Significant Progress in Advancing Its Cotara Program Into a Pivotal Phase III Trial

Agreement Reached With FDA on Pivotal Trial Design for Its Novel Targeted Therapy Cotara for the Treatment of Recurrent Brain Cancer; Agreement Allows for Phase III Trial Planning While Advancing Partnering Discussions

TUSTIN, CA -- (Marketwire) -- 12/05/12 -- Peregrine Pharmaceuticals (NASDAQ: PPHM), a biopharmaceutical company developing first-in-class monoclonal antibodies focused on the treatment and diagnosis of cancer, today announced that it has made significant progress in advancing its Cotara program into late-stage development through its agreement with the U.S. Food and Drug Administration (FDA) on the design of a single registration trial for Cotara in patients with recurrent glioblastoma multiforme (GBM). The FDA has agreed with the company's proposed randomized trial design comparing two dose levels of Cotara in up to 300 patients. The trial design allows for multiple interim data analyses with the potential to stop patient accrual early based on predicted success or futility. Cotara has been granted orphan drug status and Fast Track designation for the treatment of GBM and anaplastic astrocytoma by the U.S. Food and Drug Administration (FDA) and orphan drug designation by the European Medicines Agency (EMA).

"We appreciate the input that the FDA has provided to us during the course of our discussions in order to arrive at this mutually agreed upon design, that, if successful, should be sufficient to support a full marketing submission," said Robert Garnick, Ph.D., Peregrine's head of regulatory affairs. "Our next steps include the engagement of other regulatory agencies, where we plan to run the trial as part of a global registration study."

Cotara is a targeted loco-regional therapy that delivers a high dose of radiation directly into the brain tumor while sparing radiation exposure to healthy brain tissue. Cotara is being studied as a one-time treatment that in previous clinical trials has shown promising overall survival in patients with recurrent GBM.

"Our goal going into these discussions with the FDA was to agree upon a clinical trial design that would be appropriate for this orphan indication and one which we could enroll within a two-year timeframe," said Joseph Shan, vice president of clinical and regulatory affairs at Peregrine. "Having achieved this goal, we are now beginning to plan for this global registration study while continuing partnering discussions."

"Having established a clear clinical path forward for this novel and targeted delivered drug candidate, we can now escalate our business development activities to secure a partnership, recognizing the great interest by companies in drug candidates within the orphan and rare disease space," said Steven W. King, president and chief executive officer of Peregrine. "Cotara and our lead oncology therapeutic candidate, bavituximab both represent significant opportunities. With key data from Phase II bavituximab clinical trials in several oncology indications set to read out in the coming months and the opportunity to advance Cotara into a pivotal trial, we have number of potentially significant value drivers on the horizon. We look forward to updating you further as we continue to make progress in our late stage clinical programs."

About Cotara
Based on Peregrine's Tumor Necrosis Therapy (TNT) platform, Cotara is a novel therapy for the treatment of recurrent GBM. Cotara links a radioactive isotope (iodine 131) to a monoclonal antibody that targets DNA/histone H1 complex which 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 in a single dose using convection-enhanced delivery (CED), an NIH-developed method that targets the specific tumor site in the brain.

Data from Peregrine's prior Phase II clinical trial of a single intratumoral infusion of Cotara in 41 patients with recurrent GBM demonstrated promising median overall survival (OS) of 9.3 months, with 4 patients surviving at least 3 years.

About Brain Cancer
According to the Central Brain Tumor Registry of the United States, an estimated 24,620 new cases of primary malignant brain and CNS system tumors are expected to be diagnosed in the United States in 2013. The most common type of brain cancer is glioblastoma multiforme (GBM), which accounts for 60% of all malignant brain cancers. An aggressive form of cancer, GBM is the deadliest form of brain cancer, with a five-year survival rate of only 3%.

About Peregrine Pharmaceuticals, Inc.
Peregrine Pharmaceuticals, Inc. is a biopharmaceutical company with a portfolio of innovative monoclonal antibodies in clinical trials, focused on the treatment and diagnosis of cancer. The company is pursuing multiple clinical programs in cancer with its lead product candidate bavituximab and novel brain cancer agent Cotara®. Peregrine also has in-house cGMP 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. The forward-looking statements involve risks and uncertainties including, but not limited to, the risk that data from the pivotal trial may not support BLA submission or registration, the risk that the company does not have, or is unable to raise, sufficient capital to fund a pivotal trial and the risk that the company is unable to find a suitable partner to advance the Cotara program. 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, 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 our SEC reports including, but not limited to, the annual report on Form 10-K for the fiscal year ended April 30, 2012 and quarterly report on Form 10-Q for the quarter ended July 31, 2012. 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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