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Peregrine Pharmaceuticals Receives FDA Approval for its Cotara(TM) Phase III Registration Trial Design for Brain Cancer

TUSTIN, Calif., Feb 24, 2003 /PRNewswire-FirstCall via COMTEX/ -- Peregrine Pharmaceuticals, Inc. (Nasdaq: PPHM) announced today that it has received approval from the U.S. Food and Drug Administration (FDA) to start its Cotara Phase III registration clinical study in recurrent glioblastoma multiforme (GBM). The approved clinical protocol is designed to rigorously evaluate the safety and efficacy of Cotara in a multi-center clinical trial. This single trial will be sufficient for the FDA to evaluate the efficacy and the safety of Cotara for product registration.

"We are pleased to reach this important milestone in the development of the Cotara program. Cotara now has a clear regulatory path for product approval," said Edward J. Legere, Peregrine's president and CEO. "This approved protocol provides a roadmap to product licensure for brain cancer that should make the Cotara program even more attractive to potential licensees or partners. The Company is actively seeking a strategic partner in order to further advance its Cotara program that includes the treatment of brain cancer as well as colorectal carcinoma and other solid tumor types."

About Tumor Necrosis Therapy (TNT)

Cotara is the company's first Tumor Necrosis Therapy (TNT) based product. TNT based drugs directly target and bind to the dead and dying regions of virtually all solid tumors. Rapidly growing tumors contain a significant proportion of degenerating or dead cells in addition to numerous proliferating viable cancer cells. These dead or dying cells result from incomplete formation of tumor blood vessels and impaired immune cell response. The accumulation of dying cells results in the formation of a dead, or necrotic, core present in virtually all solid tumors beyond a very small size. TNT based drugs enter and bind to targets only available for binding in the necrotic areas of cancer. Hence, TNT-based therapeutic agents have the potential to deliver therapeutic agents preferentially targeted to virtually all solid tumors.

TNT antibodies bind to universal intracellular antigens, DNA histone complexes, exposed in the necrotic core of malignant solid tumors. While TNT is capable of binding with nuclear histones found in all cells, preclinical studies indicate that TNT antibodies do not penetrate normal cells with an intact cell membrane, making TNT highly specific to necrotic tumor tissue.

Given TNT's high specificity for necrotic tumor cells, TNT antibodies make excellent delivery molecules for a wide variety of anti-cancer killing agents. To date, the TNT technology platform has been used to deliver various killing agents such as radioactive isotopes, cytokines, chemokines and liposomes to solid tumors. Peregrine believes that many other anti-cancer compounds could potentially benefit from targeted delivery using TNT antibodies.

About Glioblastoma Multiforme

Glioblastoma Multiforme is a grade four brain cancer that is very aggressive and almost universally fatal. Recurrent (patients who have relapsed from their primary treatments) GBM has always been a difficult clinical problem. Recurrence typically occurs in approximately 80% of patients within 6-12 months after resection (primary surgery). Re-treatment for GBM patients often is with a palliative intent. Re-treatment options include radiation therapy, surgical resection or chemotherapy. Since the approval of temozolomide for refractory anaplastic astrocytoma in 1999, use of temozolomide has increased for the treatment of refractory GBM as well. However, data from randomized and non-randomized temozolomide clinical studies show only modest clinical efficacy in this patient population with a median time to progression of 11-17 weeks and a median survival time of 21-28 weeks. New therapies for recurrent GBMs are desperately needed.

About Cotara Phase II

An open-label, Phase II safety-and-efficacy evaluation of Cotara in patients with recurrent malignant glioma (glioblastoma multiforme or anaplastic astrocytoma) or newly diagnosed GBM was conducted at nine U.S. centers. The primary objective of this trial was to determine efficacy as measured by median time to tumor progression. Secondary endpoints included determination of survival, response rates and safety. Patients received Cotara over a 24 or 48 hour time period, by direct intratumoral infusion, via two interstitial catheters. A second administration was given nine weeks later as appropriate.

Among the thirteen (13) patients who received a total dose between 1.5 and 2.5 mCi/cc (the dose range for Phase III) the median time to progression (MTTP) and median survival time (MST) were 16.9 weeks and 44.3 weeks respectively. Although

no statistically significant comparison of these drugs has been performed, this preliminary data suggests that Cotara has a chance to improve survival compared to results achieved with temozolomide. Of interest is Cotara's "long-term" survival data. Of the 28 recurrent GBM patients who have received a Cotara treatment, six (or 21%) have survived over one year. Four patients remain alive from the study with recent survival times of 89+, 100+, 151+ and 165+ weeks at last contact. Interim results of 29 patients show an overall MTTP of 13.9 weeks and a MST of 26.7 weeks. This second analysis includes all patients enrolled in the study regardless of the type of brain cancer, dose received or the duration of their participation in the study. The Phase III study is designed to rigorously evaluate Cotara in patients with first-recurrence of glioblastoma multiforme and compare its safety and efficacy with that of a control arm of patients treated with temozolomide.

Cotara Phase I Colorectal Cancer

Cotara is currently being studied in a Phase I clinical study in advanced colorectal cancer at Stanford University. This study is evaluating the safety and dosimetry (process of calculating the level of radiation exposure) of intravenous delivery of Cotara.

Cotara Is Available for Licensing or Partnering

Cotara is available for licensing or partnering on a world-wide (excluding China) exclusive basis.

About Peregrine Pharmaceuticals

Peregrine Pharmaceuticals is a biopharmaceutical company focused on the development, commercialization and licensing of unique technologies for the treatment of cancer, primarily based on three collateral targeting technologies. Peregrine's Tumor Necrosis Therapy (TNT), Vasopermeation Enhancement Agents (VEA), and Vascular Targeting Agents (VTA) technologies target cell structures and cell types that are common among solid tumor cancers, giving them broad applicability across various tumor types. The company has received approval from the FDA to start a Cotara™ Phase III clinical trial for brain cancer. Cotara is also being studied in a Phase I trial for colorectal, pancreas, soft tissue sarcoma and biliary cancers at Stanford University. The company is focused on licensing collaborations for all of its technologies under development. The company also operates a cGMP contract manufacturing facility for monoclonal antibodies and recombinant proteins through its wholly owned subsidiary Avid Bioservices, Inc. (www.avidbio.com). Copies of Peregrine press releases, SEC filings, current price quotes and other valuable information for investors may be found on the website www.peregrineinc.com.

Safe Harbor Statement: This release may contain certain forward-looking statements that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ from the company's expectations as a result of risk factors discussed in Peregrine's reports on file with the U.S. Securities and Exchange Commission, including, but not limited to, the company's report on Form 10-K for the year ended April 30, 2002 and on Form 10-Q for the quarter ended October 31, 2002.

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