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Peregrine Pharmaceuticals Presents Summary of Clinical Experience of Tumor Necrosis Therapy

Presentation at Strategic Research Institute's Clinical-Stage Product Partnering Summit

TUSTIN, Calif., Mar 25, 2004 /PRNewswire-FirstCall via COMTEX/ -- Researchers for Peregrine Pharmaceuticals (Nasdaq: PPHM) presented today at the Strategic Research Institute's Clinical-Stage Product Partnering Summit in La Jolla, CA a summary of clinical experience with Tumor Necrosis Therapy (TNT). The TNT technology is being developed in the U.S. and Europe by Peregrine under the trade name Cotara™. Over 200 patients have been treated with TNT worldwide and a TNT product has been approved to treat grade III or IV advanced lung cancer in the People's Republic of China. A Cotara registration study for brain cancer has been approved by the U.S. Food and Drug Administration, and a Phase I colorectal cancer study is on-going at Stanford University Medical Center.

The major topics covered in the presentation included a summary of the U.S. brain cancer program for Cotara, data from the U.S. hepatic cancer Phase I clinical study for Cotara and an overview of the China lung cancer product registration clinical trial.

In the Cotara brain cancer Phase II study, 39 patients with high grade brain cancer were treated. The study objectives were to evaluate safety, efficacy and drug distribution. The data showed that tumor coverage and total dose appears to correlate with clinical outcome. The majority of patients treated in the study (n = 28) had recurrent glioblastoma multiforme (GBM). Twenty-five percent (7/28) survived over one year after the Cotara treatment. Expected median survival time of these patients is approximately 24 weeks according to published historical data. Among the 12 patients in this group who received a dose equal to the proposed dose range in the planned registration trial, the median survival time was 37.9 weeks. A manuscript for the Phase II is being generated.

In the hepatic cancer Phase I study, Cotara therapy was administered following Radiofrequency Ablation (RFA). RFA is an accepted form of treatment for metastatic hepatic cancer. Since radiofrequency ablation (RFA) of tumor nodules reliably produces 1-5 cm zones of >99% necrotic tissue, RFA may create abundant binding sites for TNT. In this study, between 12 to 29% (Mean 28.1 +/- 4.0%) of an IV injected dose of Cotara concentrated in the liver. Gamma camera imaging confirmed selective and avid targeting of radioisotope to areas of RFA within the liver. No significant adverse events were observed. The study's investigator concluded, "The chTNT-1/B construct has excellent potential to become useful after RFA. Zones of necrosis that facilitate 131I- chTNT-1/B (Cotara) antibody binding were probably created after RFA. A further improvement in patient convenience and specific targeting with this promising immunoconjugate may also be possible using direct antibody injection at the end of the RFA procedure into the zone of necrosis using temperature monitoring."

According to the clinical data provided by MediPharm Biotech, Inc., the Chinese licensee/developer of TNT, the registration study of advanced lung cancer patients demonstrated that radiolabeled TNT provided significant patient benefit from the therapy. Of the patients treated in the study 3.74% had complete remissions, 30.84% had partial remissions involving at least 50% shrinkage of their tumors, 55.14% had their disease stabilized (representing no change in the tumor mass), and 10.28% had progressive disease. Responses to the therapy were defined according to the World Health Organization criteria for measuring solid tumors. Confirmation of responses was gained by imaging using thoracic radiograph and computer tomography. There are currently no effective treatments for late stage lung cancer patients.

About Tumor Necrosis Therapy (TNT)

Tumor Necrosis Therapy (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.

About Peregrine Pharmaceuticals, Inc.

Peregrine's research and development efforts focus on discovering and developing products that affect blood flow to tumors. Peregrine's vascular research programs fall under several different proprietary platforms including Anti-Phospholipid Therapy (APT), Vascular Targeting Agents (VTAs), anti- Angiogenesis and Vasopermeation Enhancement Agents (VEAs). The company has research collaborations with pharmaceutical and biotechnology companies to develop its VTA platform for therapeutic and diagnostic applications and expects to enter its first APT compound into clinical trials for cancer therapy during calendar year 2004.

Peregrine's vascular agents may also have applications in other angiogenesis-dependent diseases besides cancer such as diabetes, arthritis, skin disorders and eye diseases. Peregrine currently has exclusive rights to over 190 U.S. and foreign patents and patent applications that broadly cover its vascular programs. In addition, the company is currently evaluating its proprietary technology for use in treating non-angiogenesis dependent diseases such as viral infections. The company believes that the pre-clinical data generated by the company and the broad nature of its intellectual property may provide many opportunities for product development, partnering and licensing.

Peregrine's most clinically advanced therapeutic program is based on a targeting platform outside vascular biology. This technology platform is known as Tumor Necrosis Therapy (TNT) and targets dead or dying tumor cells that are common to the majority of different tumor types. Cotara™, the most clinically advanced TNT program, is currently in a Phase I clinical trial for the treatment of colorectal carcinoma at Stanford University Medical Center. In addition, we have received protocol approval from the U.S. Food and Drug Administration ("FDA") to initiate a registration clinical study for the treatment of brain cancer. The company is currently seeking a development or funding partner to move the brain cancer program forward. The company believes that continuing the clinical development of Cotara™ in tumor types other than brain cancer will add significant value t the program. The company has a research collaboration to develop immunocytokines based on the TNT platform and a TNT based agent has been developed and approved for the treatment of lung cancer in China under a licensing agreement.

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). Avid produces clinical trial materials to support Phase I through Phase III clinical trials for biotechnology companies including Peregrine. 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, Peregrine's report on Form 10-Q for the quarter ended January 31, 2004 and on Form 10-K for the year ended April 30, 2003.

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