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Tumor Necrosis Therapy Receives Marketing Approval for Advanced Lung Cancer In The People's Republic of China

Registration Study Demonstrated a 34.6% Overall Response Rate and An

89.7% Disease Control Rate in Advanced Lung Cancer Patients

TUSTIN, Calif., Aug. 13 /PRNewswire-FirstCall/ -- Peregrine Pharmaceuticals, Inc. (Nasdaq: PPHM) and MediPharm Biotech, Inc. today announced that MediPharm has received marketing approval for Iodine-131 radiolabeled Tumor Necrosis Therapy (TNT) monoclonal antibody in the Peoples Republic of China. The issuance of the "Certificate of New Drug from the State Food and Drug Administration (SFDA) of China for Iodine-131 radiolabeled Tumor Necrosis Therapy (TNT) monoclonal antibody for the treatment of advanced lung cancer" represents the first radiolabeled monoclonal antibody approved for cancer therapy in China. Prior to commencement of market launch, the SFDA must inspect and approve the cGMP manufacturing facility which will manufacture the TNT drug for marketing launch, the timing and specific requirements of which are uncertain to Peregrine.

Iodine 131 labeled TNT was approved for the treatment of stage III and IV advanced lung cancer through either intravenous or intratumoral administration of two doses (0.8 mCi/kg per dose) given two to four weeks apart.

According to the clinical data provided by MediPharm, the registration study of advanced lung cancer patients demonstrated that radiolabeled TNT provided significant patient benefit from the TNT 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.

Of the patients treated in the registration study, 69% were male and 31% were female. The mean age of patients in the study was 58 years old. At study entry 13% patients had stage II, 58% patients had stage III and 29% patients had stage IV lung cancer. Histology revealed 9% patients had small cell lung cancer and 91% had non-small cell lung cancer. All patients had failed prior therapies and had aggressive disease. Peregrine has not independently audited the above clinical data.

"This initial approval represents a significant validation of the TNT technology for the treatment of cancer and the culmination of over a decade of research and development. I am extremely pleased that TNT is one step closer to being used to help lung cancer patients in an approved setting," said Alan L. Epstein, M.D., Ph.D., professor of pathology, Keck School of Medicine of the University of Southern California, collaborator on the lung cancer studies in China, inventor of the TNT technology, and Peregrine's scientific consultant in the TNT area. "Given that there are no effective treatments for late stage lung cancer, there is a significant unmet need for new therapies in China and the rest of the world."

"We view the approval of radiolabeled TNT in China along with the FDA acceptance of our TNT registration trial design as significant milestones in the development of TNT as a cancer treatment." said Steven King, Peregrine's president and CEO. "We look forward to helping MediPharm develop its commercial manufacturing capabilities as it prepares for its market launch in China."

"We are very gratified to receive marketing approval of Tumor Necrosis Therapy for lung cancer in China," said Dian Wen Ju, M.D., Ph.D., senior vice president of MediPharm Biotech. "We are very optimistic about the commercial potential of TNT in China. TNT is a 'first class new drug' approved in China, and we believe market acceptance will be promising upon launch. Our next step in preparing for market launch is getting cGMP manufacturing facilities approved by the SFDA. We plan to work closely with the SFDA to gain this approval and launch the product in China. As we make preparations for market launch of TNT for lung cancer, we will continue with further clinical testing of TNT for other cancer indications. We are optimistic we will be able to file for additional TNT cancer indications with the Chinese State Food and Drug Administration in the future, thus expanding the commercial potential of the drug."

With a population of approximately 1.3 billion, China is a vast market for cancer therapy. Cancer became the main cause of death in China in 1996. According to the Globoscan 2000 cancer database, there are about 1.9 million new cases and about 1.4 million deaths annually from cancer in China. The explosion in the number of cases of lung, breast, colon and rectal cancer was caused partly by the aging of China's population.

The main causes of lung cancer are related to smoking, family history, air pollution and a lack of vitamin A. According to a survey conducted in 92 countries by the World Health Organization, China has a high prevalence of smokers that accounts for about 85 percent of the lung cancer cases in China. In Shanghai, more than 60 percent of the city's male adult population smokes, according to Dr. Tan Binyou, the executive vice president of the Chinese Medical Association in Shanghai. He added that 12 percent of the city's youngsters are addicted to tobacco. According to statistics released at the International 2003 Lung Cancer Forum organized by the Chinese Anti-Cancer Society, about 400,000 people die from lung cancer in China every year. If the smoking problem isn't curbed soon, about 800,000 to 1 million people will suffer from lung cancer every year by 2020 in China, these experts warned.

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 MediPharm Biotech

MediPharm is a private biopharmaceutical company focused on the research, development and commercialization of antibody based pharmaceuticals for the treatment of cancer, infection, autoimmune diseases and related disorders. Since 1996, the company has conducted its new product research and development at the University of Southern California under Alan L. Epstein, M.D., Ph.D and all of its clinical development at leading hospitals throughout the People's Republic of China. The company's first approved product, Tumor Necrosis Therapy (TNT), was developed in and licensed from the USA. The company successfully designed, funded and conducted all human clinical studies of TNT in China. Since attaining marketing approval for TNT for the treatment of lung cancer, the company is planning to perform additional clinical trials for brain, colon, liver, and stomach cancers in order to expand the clinical application of this approved product. The company also plans to start clinical testing in China of two new antibody based drugs in 2004. The company's business strategy is to license or partner cutting-edge technologies from companies in the U.S. and Europe, which can be rapidly tested clinically in China to take advantage of large patient populations and lower costs of clinical trials. The company's goal is to become a fully integrated biopharmaceutical company that is a leader in the development, manufacturing and marketing of monoclonal antibody based therapies in the People's Republic of China while being the preferred partner for multinational companies wanting to gain access to the vast Chinese marketplace.

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's Oncolym® technology to treat non-Hodgkin's B-cell lymphoma in Phase I/II of development is available for licensing. The company 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, 2003.

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