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Innovative Administration of Peregrine Pharmaceuticals' Radiolabeled TNT Successfully Treats Inoperable Lung Cancer

TUSTIN, Calif., Jun 19, 2002 (BW HealthWire) --

Tumor Necrosis Therapy Data Presented at Society of Nuclear Medicine's 49th Annual Meeting

Peregrine Pharmaceuticals Inc. (Nasdaq:PPHM) announced today detailed results from clinical research conducted in China that show 56% efficacy was achieved when patients with inoperable lung cancer were treated with the company's 131iodine labeled chimeric Tumor Necrosis Therapy (131I-chTNT) antibody drug using an innovative method of intratumoral injection. Patients treated by this method had a disease control rate of 100%, demonstrating 131I-chTNT can achieve significant therapeutic effects in late stage lung cancer. The results provide substantial validation of Peregrine's proprietary TNT technology, which is a radiolabeled monoclonal antibody that targets the necrotic core of solid tumors. The interim lung cancer data were presented at the Society of Nuclear Medicine's 49th Annual Meeting in Los Angeles, California. The study was independently designed and conducted by researchers at the Shanghai Tumor Hospital.

The Phase I/II study compared the efficacy of three different methods of administration of 131I-chTNT for patients with inoperable late stage lung cancer: intravenous, intratumoral, and a combination of intravenous plus intratumoral injection. The results demonstrated that the method of intratumoral injection alone achieved a 56% complete and partial tumor remission rate. The combined intravenous plus intratumoral injection method achieved 40% and the intravenous method alone achieved 9% tumor remission rate. The disease control rate for all three methods of treatment, including complete and partial remission and stable disease, was 88% for the 43 patients assessed in the study. The highest therapeutic effect was obtained by using common bronchoscopy and computer tomography (CT) scan instruments in a new technique to directly infuse the tumor with lethal doses of 131I-chTNT.

"Peregrine is reviewing the intratumoral injection techniques used to maximize delivery of radiolabeled TNT to the tumor while minimizing healthy tissue exposure. This will assist us in designing a lung cancer study in the United States," said Edward Legere, president and CEO of Peregrine Pharmaceuticals. "By using standardized equipment that is routinely used at medical centers around the world, it is possible the treatment could be widely adopted by oncologists treating late stage lung cancer patients."

"This data highlights the promise of Tumor Necrosis Therapy for the treatment of late stage lung cancer," said Alan L. Epstein, M.D., Ph.D., co-author of the lung cancer research, inventor of the TNT technology, and Peregrine's scientific consultant. "In this study, intratumoral injection caused substantially higher complete and partial remission rates than the other methods of administration. Given there are no effective treatments for inoperable late stage lung cancer, there is a significant unmet need for new therapies. Directly infusing the drug into the tumor mass may also reduce the systemic toxicity often seen with intravaneous administration of radionuclides."

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, with over 7.3 million new cases and just over 3 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. In the United States, there were approximately 170,000 new cases of lung cancer in 1999, making it the most common cancer in the Western world. According to the American Cancer Society and the World Health Organization, since the mid-1990s, about 150,000 Americans have died each year from the disease. Lung cancer is the leading category of cancer death in men, and -- since the late 1980s -- it has surpassed breast cancer as the leading category of cancer death in women.

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    Summary of Clinical Study for Lung Cancer
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The poster summarizing the unaudited results of this Phase I/II study can be accessed on Peregrine's web site at: http://www.peregrineinc.com/Technology.asp?id=Posters+and+Abstracts.

As previously announced, a total of 43 patients enrolled in this study had a cytological and histological confirmed diagnosis of stage IIIb (30/43) or IV (13/43) inoperable lung cancer. As confirmed by fine needle biopsy, 24 patients (56%) had a diagnosis of adenocarcinoma, 12 patients (28%) were diagnosed with squamous carcinoma, six patients (14%) with small-cell lung cancer, and one patient (2%) with adeno-squamous carcinoma.

Twenty-two patients in the first group were administrated 131I-chTNT by intravenous drug infusion, 16 patients in the second group were administrated by intratumoral injection, and five patients in the third group received both treatments. The dose for each patient was 0.8 mCi/kg, which was repeated two weeks later. Patients receiving intravenous administration were given a total dose of 131I-chTNT delivered in 250 ml of normal saline through a free-flowing intravenous line. For the second group, the intratumoral injection of TNT was directed by thoracic CT guided catheter using a multiple-hole needle. The CT images clearly showed tumor localization, the needle pathway, and the site of administration. In the third group, 75% dosage was given by intratumoral injections and 25% by intravenous infusion.

Partial remission (PR) was defined as a greater than 50% reduction in tumor mass in all lesions and complete remission (CR) as no detectable tumor for greater than 10 weeks. Patients receiving intravenous injection alone had two PR (9%), 16 had stable disease (73%), and four progressed (18%). Those receiving intratumoral injection had one CR (6%), eight PR (50%), seven had stable disease (44%), and zero progressed. Finally, those in the third group had one CR (20%), one PR (20%), two had stable disease (40%), and one progressed (20%). Toxicity was limited to mild and reversible bone marrow suppression in 20 cases.

About Tumor Necrosis Therapy (TNT)

Peregrine's TNT targets DNA-associated antigens in the nucleus of necrotic cancer cells. It is being developed in the United States under the trade name Cotara™ and is currently in a multi-center Phase II clinical study for the treatment of brain cancer. Final preparations are being made to start a multi-center, multi-national Phase III study for brain cancer. Cotara is also being studied in four Phase I clinical studies for the treatment of colorectal, pancreas, liver, soft tissue sarcoma and biliary cancers. Cotara has received fast track and orphan drug status from the Food and Drug Administration for the treatment of brain cancer.

About Peregrine Pharmaceuticals, Inc.

Peregrine Pharmaceuticals is a biopharmaceutical company focused on the development, commercialization, and licensing of unique technologies for the treatment of cancer, primarily based on its three "collateral targeting technologies." Peregrine's Tumor Necrosis Therapy (TNT), Vasopermeation Enhancement Agents (VEA), and Vascular Targeting Agents (VTA) target cell structures and cell types that are common among solid tumor cancers, giving them broad applicability across various tumor types. Peregrine's Oncolym®, for the treatment of non-Hodgkin's B-cell Lymphoma, is currently in a multi-center Phase I/II study. Copies of Peregrine press releases, SEC filings, current price quotes and other valuable information for investors may be found on the website http://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, 2001 and on Form 10-Q for the quarter ended January 31, 2002.

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