December 13, 2001

Peregrine Pharmaceuticals Announces It has Agreed Upon the Design of a Phase III Study for Brain Cancer With the FDA; Study Will Treat Patients With Recurrent Glioblastoma Multiforme

TUSTIN, Calif., Dec 13, 2001 (BW HealthWire) -- Peregrine Pharmaceuticals Inc. (Nasdaq:PPHM) today announced that it has concluded a successful meeting with the U.S. Food and Drug Administration (FDA).

Peregrine and representatives from the FDA agreed upon the design of a pivotal Phase III study for the treatment of recurrent glioblastoma multiforme, a deadly form of brain cancer, with the company's Tumor Necrosis Therapy (TNT) drug being developed under the trade name Cotara™.

Cotara is a monoclonal antibody that carries the radioactive isotope Iodine-131 to the necrotic core of solid tumor cancers. The company has plans to expand the study to Canada and Europe. Cotara has received fast track and orphan drug status from the U.S. Food and Drug Administration.

"This is a major milestone in the development of the Cotara project," stated Dr. Terrence Chew, Peregrine's senior vice president of clinical and regulatory affairs. "Glioblastoma multiforme (GBM) is a very aggressive form of brain cancer for which there are few treatment options.

"We believe we have compiled a sufficient body of evidence on the safety and effectiveness of Cotara to advance it into a large multi-center multi-national registration study. We are confident this study will measure the clinical effectiveness of Cotara compared to standard treatment for recurrent glioblastoma multiforme.

"We plan to conduct an investigator meeting for U.S. and Canadian centers in February."

The Phase III study will have an open-label, randomized design comparing Cotara (131I-chTNT-1/B MAb) and temozolomide in patients with recurrent GBM. Approximately 400 patients will be treated in the study upon first recurrence of GBM after receiving primary treatment for their disease. Peregrine plans to conduct the study in the United States, Canada and Europe.

The objective of the study is to compare patients with recurrent GBM treated with 131I-chTNT-1/B monoclonal antibody to those treated with temozolomide. Patients in the Cotara arm of the study will receive up to two doses of the drug administered via interstitial catheters over a 25-hour period.

The dose will be calculated by measuring the size of the tumor using standard gadolinium enhancing tumor volume (GETV). Patients who receive temozolomide will receive the drug in accordance with the package insert. The company expects enrollment to occur over 24 months.

Glioblastoma multiforme is a very aggressive form of primary brain cancer which originates from star-shaped cells called astrocytes and may grow anywhere in the brain or spinal cord. Glioblastoma multiforme is considered one of the fastest growing of all cancers.

Glioblastomas usually have an aggressive and invasive nature and increase the amount of mass in the skull, compressing vital structures, which may cause serious symptoms and complications. According to the American Cancer Society, there will be an estimated 17,200 new cases and 13,100 deaths from brain and central nervous system cancers in 2001.

There are few treatment options for patients with recurrent GBM, so new forms of therapy are desperately needed.

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 its "collateral targeting technologies." These technologies target cell structures and cell types that are common among solid tumor cancers, giving them broad applicability across various tumor types.

In clinical and pre-clinical studies, collateral targeting technologies have been shown to deliver various anti-cancer compounds selectively to the tumor site without causing damage to surrounding healthy tissue.

Peregrine has three collateral targeting technologies: Tumor Necrosis Therapy (TNT), Vasopermeation Enhancement Agents (VEA), and Vascular Targeting Agents (VTA).

The company's lead anti-cancer drug, Cotara™, is currently in a multi-center Phase II clinical study for the treatment of brain cancer and 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 FDA.

The company also has a direct tumor targeting agent called Oncolym® for the treatment of advanced non-Hodgkin's B-cell Lymphoma which is currently in a multi-center Phase I/II. Copies of Peregrine news releases, SEC filings, current price quotes and other valuable information for investors may be found on the Web site at 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 July 31, 2001.

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