January 27, 2005

Peregrine Receives FDA Approval to Proceed With Tarvacin(TM) Phase I Study

TUSTIN, Calif., Jan 27, 2005 /PRNewswire-FirstCall via COMTEX/ -- Peregrine Pharmaceuticals, Inc. (Nasdaq: PPHM) today announced it has received clearance from the U.S. Food and Drug Administration (FDA) to move forward with its clinical program for Tarvacin™, a novel anti-cancer agent. The company and the FDA agreed upon the Phase I study protocol following an exchange of information and discussions centered on Tarvacin™'s novel mechanism of action and the best ways to monitor safety once patient treatment begins. During the discussions with the FDA, Peregrine had finalized the selection of clinical sites to participate in the study. Patient enrollment at each clinical site can begin pending internal review and approval of the protocol.

Peregrine will submit the final revised protocol as agreed upon to the FDA and can initiate the study without waiting for FDA review. The objectives of the Tarvacin™ Phase I clinical study are to (i) determine the safety and tolerability of Tarvacin™ administered intravenously to patients with advanced cancer; (ii) characterize the pharmacokinetic profile of Tarvacin™ and; (iii) define the dose-limiting toxicities, maximum tolerated dose and/or maximum effective dose of Tarvacin™. In addition, patients who demonstrate an objective response to therapy may be offered continued treatment on an extension protocol. Up to 28 patients with advanced solid tumors that no longer respond to standard cancer treatments will be enrolled at three clinical sites.

"We appreciate the FDA's cooperative efforts to understand the novel nature of Tarvacin™ and to work with us in refining the first in-human protocol," said Joseph Shan, director of clinical and regulatory affairs at Peregrine. "We now look forward to initiating patient enrollment and evaluating Tarvacin™ for the treatment of patients with advanced solid tumors."

About Tarvacin™

Tarvacin™ is part of Peregrine's Anti-Phospholipid Therapy (APT) platform, which binds directly to tumor blood vessels to inhibit tumor growth and development. Tarvacin™ is a chimeric monoclonal antibody that binds to the phospholipid, phosphatidylserine. Tarvacin™ was initially discovered by researchers at the UT Southwestern, who have worked closely with Peregrine to explore the potential activity and safety of Tarvacin™ as a treatment for cancer. Peregrine has a sponsored research agreement with researchers at UT Southwestern to study the use of Tarvacin™ and its parent antibody for the treatment of cancer and viral diseases. In addition, the researchers at UT Southwestern have also received grants to study the use of APT agents for the treatment of viral infections and diseases. Peregrine is also collaborating with The Foundation Fighting Blindness to study APT constructs as well as Vascular Targeting Agents (VTAs) for the treatment of eye diseases.

Peregrine and its research collaborators have completed a number of pre- clinical animal experiments using Tarvacin™ to study the safety and efficacy of the compound. In pre-clinical studies, Tarvacin™ binds to tumor blood vessels and demonstrated significant anti-tumor activity in animal cancer models. Enhanced tumor effects were observed when Tarvacin™ was administered in conjunction with chemotherapy and radiation therapy. In addition, in data recently presented at the American Association of Cancer Research (AACR), 3G4, the parent antibody of Tarvacin™, was shown to reduce the growth breast cancer tumors in animal models by 60% when given alone and by 93% when given in combination with the commonly used chemotherapy drug docetaxel. This data, in combination with other data presented during the year, has heightened the company's excitement and commitment to the Tarvacin™ program.

About Phosphatidylserine (PS)

PS is an aminophospholipid or anionic phospholipid. The main function of phospholipids is the formation of cellular membranes. In normal cells, anionic phospholipids are on the inside of the cellular membrane. Exposure of anionic phospholipids on the cell surface occurs during apoptosis (normal cell death), necrosis, cell injury, cell activation and malignant transformation. Factors in the tumor microenvironment cause a breakdown of asymmetry and exposure of anionic phospholipids on the cell surface of the blood vessel and malignant cells.

Anionic phospholipids are attractive as tumor blood vessel targets for several reasons: they are abundant, they are on the surface of the endothelial cells that line tumor vessels that are accessible to VTAs in the blood, they are present on a significant percentage of endothelial cells in diverse solid tumors, and they appear to be absent from vascular endothelium in all normal tissues.

Peregrine has developed an anti-phosphatidylserine (PS) monoclonal antibody named 3G4. When injected into tumor-bearing mice, 3G4 localizes specifically to tumor endothelium. In pre-clinical studies, 3G4 given alone or in combination with chemotherapy significantly inhibits tumor growth in a variety of rodent tumor models. Up to 95% retardation of tumor growth has been seen in syngeneic and human tumors, including human breast carcinomas.

Anti-PS antibodies may also have uses as anti-viral agents. Anti-PS drugs operate on a new principle in virology. When enveloping viruses egress from a host cell after replication, many capture some of the lipids of the host cell for use as their outer membrane. Lacking the natural mechanism for properly aligning the lipids, the outer membranes of these viruses have lipids that are inside-out. The anti-PS antibodies direct the immune responses to the inside- out components of the viral membrane, or envelope. These drugs could potentially be effective against numerous viruses that have similar outer membranes.

About Peregrine Pharmaceuticals

Peregrine Pharmaceuticals is a biopharmaceutical company primarily engaged in the research, development, manufacture and commercialization of cancer therapeutics and diagnostics through a series of proprietary platform technologies. The company is primarily focused on discovering and developing products that affect blood vessels and blood flow in cancer and other diseases. 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).

Peregrine's most clinically advanced therapeutic program is known as Tumor Necrosis Therapy (TNT) and targets dead or dying tumor cells that are common to the majority of different tumor types. The company is developing a radioactive TNT agent that it has trademarked Cotara® for the treatment of cancer. The company is working with New Approaches to Brain Tumor Therapy (NABTT) Consortium to initiate the first part of Peregrine's U.S. Food and Drug Administration (FDA)-approved product registration trial using Cotara® to treat patients with brain cancer. Peregrine has also completed enrollment in a Phase I Cotara® clinical trial for the treatment of colorectal carcinoma at Stanford University Medical Center and is working closely with scientific advisors to design Phase II studies using Cotara® for other solid tumor indications. In addition, a TNT-based agent similar to Cotara® was developed under a licensing agreement in China and has received marketing approval for the treatment of advanced lung cancer.

The company's wholly owned subsidiary, Avid Bioservices, Inc. (http://www.avidbio.com), develops and manufactures monoclonal antibodies and recombinant proteins 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 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. Except for historical information presented herein, matters discussed in this release contain certain forward- looking statements. The inclusion of forward-looking statements should not be regarded as a representation by us, or any other person, that the objectives or plans will be achieved. The words "may," "should," "plans," "believe," "anticipate," "estimate," "expect," their opposites and similar expressions are intended to identify forward-looking statements. We caution readers that such statements are not guarantees of future performance or events and are subject to a number of factors that may tend to influence the accuracy of the statements, including, but not limited to, risk factors discussed in Peregrine's report on Form 10-K for the year ended April 30, 2004 and subsequent quarterly reports on Form 10-Q. Peregrine disclaims any obligation and does not undertake to update or revise the forward-looking statements discussed in this press release.

Investor Inquiries
Hawk Associates, Inc.
Frank Hawkins and Julie Marshall
(800) 987-8256 or
info@hawkassociates.com

Media Inquiries
Lorie Fiber
Edelman
(323) 202-1046/(310) 383-6583 (cell)
lorie.fiber@edelman.com

SOURCE Peregrine Pharmaceuticals, Inc.