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Peregrine Pharmaceuticals Reports Advances in Bavituximab Clinical Program

- Patient Enrollment Completed in 46-Patient Phase II Study Evaluating Bavituximab with Carboplatin and Paclitaxel in Advanced Breast Cancer -
- Peregrine Awarded U.S. Patent Covering Combination Therapies Using Bavituximab and a Broad Range of Anti-Cancer Agents -
- Patent Covers Combination Therapies with Docetaxel, Carboplatin and Paclitaxel that are Showing Promise in Initial Data from Three Ongoing Phase II Studies -

TUSTIN, Calif., Sept 08, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Peregrine Pharmaceuticals, Inc. (Nasdaq: PPHM) today reported completion of patient enrollment in its Phase II trial evaluating bavituximab in combination with carboplatin and paclitaxel in advanced breast cancer patients. The trial's planned total of 46 patients has been enrolled and patients are currently undergoing treatment and follow-up. The primary objective of the multi-center, open-label study is to assess the overall tumor response to the regimen of bavituximab in combination with carboplatin/paclitaxel. Separately, the company announced issuance of a new U.S. patent with claims covering the use of bavituximab in combination with a broad range of cancer therapeutic agents. Peregrine is currently conducting three separate Phase II studies testing bavituximab in combination with docetaxel or carboplatin and paclitaxel in advanced breast and lung cancer patients. These combination therapies, which have shown promising initial results, are all covered under the claims in the newly issued patent.

"It is fitting that this new U.S. patent protecting the use of bavituximab in combination with a variety of anti-cancer therapeutics has issued as enrollment in each of our three Phase II trials of bavituximab in combination with chemotherapy is either completed or nearing completion," said Steven W. King, president and CEO of Peregrine. "There is considerable evidence that bavituximab and other anti-PS antibodies act synergistically with standard cancer treatments, and the additional protection provided by this new patent further strengthens our intellectual property leadership in the field of PS-targeting therapeutics."

U.S. Patent #7,572,448 covers the therapeutic use of bavituximab and related antibodies in combination with a wide range of anti-cancer agents, including many commonly prescribed chemotherapeutic drugs. This patent was granted to the University of Texas System and is exclusively licensed to Peregrine Pharmaceuticals.

The Phase II trial of bavituximab in combination with carboplatin and paclitaxel in advanced breast cancer patients has a Simon two-stage design. In the first stage, 15 patients with advanced breast cancer were enrolled and treated with the combination regimen. Nine of the 14 (64%) evaluable patients in this cohort demonstrated an objective tumor response according to RECIST criteria, exceeding the pre-specified primary efficacy endpoint needed to expand enrollment in the trial. An additional 31 patients were then enrolled to achieve the planned study total of 46 patients overall.

"Completion of patient enrollment in our second Phase II breast cancer study marks another milestone for the bavituximab cancer program, with two of our three ongoing Phase II trials now having completed enrollment," said Joseph Shan, vice president of clinical and regulatory affairs at Peregrine. "We believe the rapid enrollment experienced in all three of these trials is representative of the enthusiasm of our clinical investigators as well as the need for improved cancer therapies. We look forward to reporting further data from these studies in the upcoming months."

Secondary objectives of the study include measuring time to tumor progression, duration of response, overall patient survival and safety parameters. Patients in the study are evaluated regularly for tumor response according to RECIST criteria. They may continue to receive bavituximab as monotherapy after completion of chemotherapy as long as the cancer does not progress and side effects are acceptable. The trial is being conducted in India according to International Conference on Harmonization (ICH) and Good Clinical Practices (GCP) guidelines.

The World Health Organization reports that breast cancer is the most commonly diagnosed cancer in women and is second only to lung cancer as a leading cause of female cancer deaths. The National Cancer Institute estimates that approximately 192,370 U.S. women will be diagnosed with breast cancer in 2009 and 40,170 women will die of the disease in the U.S. alone.

Bavituximab is a monoclonal antibody that targets the cellular membrane component phosphatidylserine (PS) that is usually located inside cells, but which becomes exposed on the outside of the cells that line the blood vessels of tumors, creating a specific target for anti-cancer treatments. By masking PS, bavituximab is believed to help mobilize the body's immune system to destroy the tumor and the tumor blood vessels. Bavituximab is being tested in combination with chemotherapy in Phase II trials

in advanced lung cancer and advanced breast cancer. Interim results in these trials were encouraging, with objective tumor response rates that compare favorably to chemotherapy alone.

About Peregrine Pharmaceuticals

Peregrine Pharmaceuticals, Inc. is a biopharmaceutical company with a portfolio of innovative monoclonal antibodies in clinical trials for the treatment of cancer and serious viral infections. The company is pursuing three separate clinical programs in cancer and HCV infection with its lead product candidates bavituximab and Cotara((R)). Peregrine also has in-house manufacturing capabilities through its wholly owned subsidiary Avid Bioservices, Inc. (www.avidbio.com), which provides development and biomanufacturing services for both Peregrine and outside customers. Additional information about Peregrine can be found at www.peregrineinc.com.

Safe Harbor Statement: Statements in this press release which are not purely historical, including statements regarding Peregrine Pharmaceuticals' intentions, hopes, beliefs, expectations, representations, projections, plans or predictions of the future are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The forward-looking statements involve risks and uncertainties including, but not limited to, the risk that the standard carboplatin and paclitaxel response rate will not be improved as a result of the combination therapy and the risk that the results of the subsequent stage for this trial will not be consistent with the results of the first stage. Factors that could cause actual results to differ materially or otherwise adversely impact the company's ability to obtain regulatory approval for its product candidates include, but are not limited to, uncertainties associated with completing preclinical and clinical trials for our technologies; the early stage of product development; the significant costs to develop our products as all of our products are currently in development, preclinical studies or clinical trials; obtaining additional financing to support our operations and the development of our products; obtaining regulatory approval for our technologies; anticipated timing of regulatory filings and the potential success in gaining regulatory approval and complying with governmental regulations applicable to our business. Our business could be affected by a number of other factors, including the risk factors listed from time to time in the company's SEC reports including, but not limited to, the annual report on Form 10-K for the year ended April 30, 2009 and the quarterly report on Form 10-Q for the quarter ended July 31, 2009. The company cautions investors not to place undue reliance on the forward-looking statements contained in this press release. Peregrine Pharmaceuticals, Inc. disclaims any obligation, and does not undertake to update or revise any forward-looking statements in this press release.

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