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Peregrine Pharmaceuticals Doses First Patient in Phase II Clinical Trial of Bavituximab in Patients With Advanced Breast Cancer

TUSTIN, Calif., Feb 12, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Peregrine Pharmaceuticals, Inc. (Nasdaq: PPHM), a clinical stage biopharmaceutical company developing targeted therapies for the treatment of cancer and hepatitis C virus infection (HCV), today announced that patient dosing has begun in its clinical trial designed to evaluate the safety and efficacy of bavituximab in combination with chemotherapy in patients with advanced breast cancer. The primary objective of the study is to assess the overall response rate to the combination of bavituximab with docetaxel, a chemotherapy drug commonly used in breast cancer. The multicenter clinical trial is being conducted in the Republic of Georgia.

"We are now seeing good overall momentum in our bavituximab Phase II cancer program, and we are very pleased that our clinical colleagues in Europe have been so efficient in rapidly moving from protocol approval to trial initiation to patient dosing," said Steven W. King, president and CEO of Peregrine. "We are optimistic that all three bavituximab Phase II cancer trials will proceed well in the coming months and we look forward to reporting on our progress later this year."

In the trial's two-stage design, up to 15 patients with advanced breast cancer will be enrolled initially. The study will then be expanded up to a total of 46 patients if promising results are observed. Secondary objectives include measuring time to tumor progression, duration of response, overall patient survival and safety parameters. Patients may continue to receive bavituximab alone after completion of chemotherapy as long as the cancer does not progress and side effects are acceptable.

"Bavituximab represents a novel strategy for the treatment of cancer that has demonstrated encouraging potential in initial clinical studies," said David Tabagari, M.D., Ph.D., the head of Medulla Immunotherapy and Chemotherapy Clinic and principal investigator of the bavituximab breast cancer trial being conducted in the Republic of Georgia. "We are pleased to have the opportunity to conduct the first Phase II trial of this potentially valuable new approach to treating cancer."

Tumor response in this study will be evaluated using Response Evaluation Criteria in Solid Tumors (RECIST) parameters. The trial is being conducted according to International Conference on Harmonization (ICH) and Good Clinical Practices (GCP) standards.

The National Cancer Institute estimates that approximately 178,480 U.S. women were diagnosed with cancer of the breast in 2007 and about 40,460 women died of the disease. According to the World Health Organization, 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.

Bavituximab is a monoclonal antibody that binds to a phospholipid called phosphatidylserine that is usually located inside normal 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. Bavituximab is believed to help mobilize the body's immune system to destroy the blood vessels needed for tumor growth and spread. In a Phase Ib pilot trial in advanced cancer patients, bavituximab plus chemotherapy appeared to have a safety profile consistent with chemotherapy alone and showed positive signs of clinical activity, achieving objective response or disease stabilization in 50% of the evaluable patients. Peregrine has recently received regulatory approval to conduct three Phase II trials to study the anti-tumor effects of bavituximab in combination with chemotherapy. These include two breast cancer protocols and a non-small cell lung cancer protocol testing bavituximab in combination with chemotherapy. The first bavituximab breast cancer trial is now underway and the two other trials are expected to begin soon. Bavituximab is in clinical trials in the U.S. in patients with advanced solid tumors and in patients co-infected with HCV and HIV.

About Peregrine Pharmaceuticals

Peregrine Pharmaceuticals, Inc. is a biopharmaceutical company with a portfolio of innovative product candidates in clinical trials for the treatment of cancer and hepatitis C virus (HCV) infection. 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. (http://www.avidbio.com), which provides development and bio-manufacturing services for both Peregrine and outside customers. Additional information about Peregrine can be found at http://www.peregrineinc.com.

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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 company will experience delays or difficulties in enrolling patients in the study, the risk that the standard docetaxel response rate will not be improved as a result of the combination therapy, and the risk that the results from this trial will not be consistent with the results of prior trials or preclinical studies. It is important to note that the company's actual results could differ materially from those in any such forward-looking statements. Factors that could cause actual results to differ materially 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, 2007 and the quarterly report on Form 10-Q for the quarter ended October 31, 2007. 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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