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## **Peregrine Pharmaceuticals Reports Positive Early Results in Phase II Study of Bavituximab in Breast Cancer**

- Pre-Specified Primary Efficacy Endpoint Met in Stage 1 of Two-Stage Study -**
- 100% of Evaluable Patients to Date Continue to Show Objective Tumor Response or Stable Disease -**

TUSTIN, Calif., July 2, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Peregrine Pharmaceuticals, Inc. (Nasdaq: PPHM) today reported that its lead product candidate bavituximab achieved the pre-specified Stage 1 primary endpoint in its ongoing Phase II clinical trial in patients with metastatic breast cancer. The trial is an open-label, Simon two-stage design to evaluate the safety and efficacy of a combination of bavituximab and docetaxel in metastatic breast cancer patients. Fourteen of the 15 patients enrolled in Stage 1 were deemed evaluable for tumor response, with seven achieving partial tumor responses and seven having stable disease at week eight according to RECIST criteria. All 14 of the evaluable patients remain in the study and are continuing to receive treatment, along with continuing assessments of tumor response. With the Stage 1 primary endpoint of six or more objective tumor responses achieved, the design of the clinical trial now allows for an additional 31 study patients to be enrolled.

"We are very pleased with the early positive results from this Phase II breast cancer study," said Steven W. King, president and CEO of Peregrine. "We are particularly encouraged by the fact that at an early time point of eight weeks, half of the patients had achieved objective tumor responses. Equally encouraging is that with patients now out over four months since the start of the study, none have shown tumor growth or disease progression. As these patients continue on treatment, we will continue assessing them for signs of anti-tumor activity. We look forward to sharing more data from this study as patient treatment and follow-up progress."

The primary objective of the multi-center Phase II clinical trial is to assess overall tumor response rate. Secondary objectives include measuring time to tumor progression, duration of response, overall patient survival and safety parameters. All tumor responses in the trial are being evaluated using Response Evaluation Criteria in Solid Tumors (RECIST) criteria. Patients may continue to receive bavituximab as solo therapy after completion of chemotherapy as long as the cancer does not progress and side effects are acceptable. The trial is being conducted in the Republic of Georgia according to International Conference on Harmonization (ICH) and Good Clinical Practices (GCP) guidelines.

According to the RECIST criteria, patients are categorized as having "stable disease" ("SD") if they have less than a 20% increase to a 30% reduction in the sum of the target lesions, and they are categorized as having a "partial response" ("PR") if they experience greater than a 30% reduction in the sum of target lesions. In addition, to be assigned a status of SD or PR, patients cannot have the appearance of any new lesions.

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. The National Cancer Institute estimates that approximately 182,460 U.S. women will be diagnosed with breast cancer in 2008 and 40,480 women will die of the disease in the U.S. alone.

Bavituximab is a monoclonal antibody that binds to 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 binding to PS, bavituximab is believed to help mobilize the body's immune system to destroy the tumor and the tumor blood vessels. Bavituximab currently is in two Phase II combination therapy trials for the treatment of metastatic breast cancer and for the treatment of non-small cell lung cancer (NSCLC). A second Phase II combination therapy study in breast cancer patients is expected to begin soon. Data presented at the 2008 ASCO annual meeting showed that half of evaluable patients in a Phase Ib trial of bavituximab plus chemotherapy achieved an objective tumor response or stable disease after eight weeks of dosing, that the safety profile of bavituximab and chemotherapy appeared consistent with chemotherapy alone and that the pharmacokinetic properties of bavituximab were not affected by co-administration with conventional chemotherapies. A Phase I bavituximab monotherapy trial in advanced solid cancers is continuing.

### **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. ([www.avidbio.com](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 [www.peregrineinc.com](http://www.peregrineinc.com).

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