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## **Peregrine Pharmaceuticals Reports 61% Objective Response Rate in 46-Patient Bavituximab Phase II Trial in Advanced Breast Cancer**

- 28 of 46 (61%) Patients Receiving Bavituximab in Combination with Docetaxel Achieved Objective Tumor Response by End of Planned Treatment Cycles -**
- Tumor Response Data Compares Favorably with Published Results in a Similar Patient Population Receiving Docetaxel Alone -**

TUSTIN, Calif., Oct 21, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Peregrine Pharmaceuticals, Inc. (Nasdaq:PPHMD) today reported positive results from its Phase II trial evaluating bavituximab in combination with docetaxel in patients with advanced breast cancer. Preliminary data at the end of the six planned treatment cycles in the Phase II study showed that 28 of 46, or 61%, of all patients enrolled in the trial achieved an objective tumor response according to RECIST criteria. This data compares favorably with data from a published study showing an objective tumor response rate of 41% in a similar patient population receiving the same dosing regimen of docetaxel administered as a single agent.

Joseph Shan, vice president of clinical and regulatory affairs at Peregrine commented, "We are very encouraged by the initial results reported today for the full 46 patients enrolled in the bavituximab plus docetaxel Phase II trial. The tumor response data reported in this study exceeded the tumor response data for docetaxel alone that was used as the benchmark for the design of this study. With these positive initial data in hand, we and our expert advisors believe that this combination regimen warrants further clinical evaluation, and we are now assessing possible trial designs for future studies."

The primary objective of the multi-center, open-label Phase II study is to assess the overall response rate to bavituximab and docetaxel. In this trial's Simon two-stage design, 15 patients were initially enrolled in the study followed by an additional 31 patients after the pre-specified primary efficacy endpoint for expanding the study was met, bringing the total to 46 patients. Initial data from the first set of 15 patients in the study was reported in an oral presentation at the 2009 ASCO Annual Meeting. Recent analysis showed the median progression-free-survival (PFS) of patients enrolled in the initial 15-patient cohort of the study was 7.4 months, a promising early result. Patient follow-up in the trial is continuing.

"The data released today continues to reinforce the positive results seen across the five cancer trials to date assessing the potential of bavituximab in different treatment combinations across multiple tumor types," said Steven W. King, president and CEO of Peregrine. "We believe this data in aggregate shows the broad potential of this novel therapeutic compound for the treatment of solid tumors. We look forward to reporting further results from our ongoing bavituximab studies and to providing more details on future clinical development plans as they are finalized over the coming 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. Patients 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 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. Bavituximab acts by binding to externalized PS on tumor blood vessels and inducing immune cell-mediated destruction of these blood vessels. It also restores the immune system's ability to recognize and respond to tumor cells by blocking PS-mediated immunosuppression. 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 have been 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](http://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](http://www.peregrineinc.com).

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