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## **Peregrine Initiates Randomized Phase II Trial of Bavituximab in Pancreatic Cancer**

### **U.S. Trial Evaluating Targeted Antibody Bavituximab in Combination With Gemcitabine as Front-Line Therapy**

TUSTIN, CA -- (MARKET WIRE) -- 01/05/11 -- Peregrine Pharmaceuticals, Inc. (NASDAQ: PPHM), a clinical-stage biopharmaceutical company developing first-in-class monoclonal antibodies for the treatment of cancer and viral infections, today announced that it has initiated a randomized Phase II clinical trial in patients with previously untreated stage IV pancreatic cancer. The open-label, multicenter trial is being conducted in the United States and will evaluate Peregrine's bavituximab, a phosphatidylserine (PS)-targeting monoclonal antibody with broad therapeutic potential, in combination with the chemotherapeutic agent gemcitabine versus gemcitabine monotherapy.

"There is a critical need for new therapeutic options for patients diagnosed with metastatic pancreatic cancer, as median overall survival is limited to 6 months with single-agent chemotherapy," said Shuchi (Susan) Pandya, M.D., a principal investigator of this trial and clinical faculty of Hematology and Oncology at the Beth Israel Deaconess Medical Center, a major teaching hospital of Harvard Medical School in Boston. "Prior published data show combining the PS-targeting antibody bavituximab with gemcitabine, a chemotherapy that has been shown to increase PS exposure on tumor blood vessels, enhances anti-tumor effects and controls metastatic growth without added toxicity over gemcitabine alone in animal models of pancreatic cancer. As investigational therapies have yet to prolong survival without causing significant toxicities, we are eager to evaluate this investigational combination therapy in a randomized clinical trial setting."

Currently, Peregrine's bavituximab is being evaluated in combination with chemotherapy in two Phase IIb trials in non-small cell lung cancer, a Phase I/II trial in combination with sorafenib in advanced hepatocellular carcinoma (HCC), as well as a Phase Ib trial for hepatitis C virus (HCV).

"We were inspired to conduct this study based on the encouraging and consistent signs of bavituximab's anti-tumor activity across multiple oncology indications as well as the promising preclinical data supporting the potential of bavituximab in combination with gemcitabine in advanced pancreatic cancer models," said Steven W. King, president and chief executive officer of Peregrine. "With the initiation of our third randomized Phase II oncology trial for bavituximab, we are setting the stage for multiple clinical data reports over the coming year."

#### *About the Phase II Pancreatic Cancer Trial*

Peregrine is conducting this randomized, open-label Phase II trial in up to ten clinical sites in the United States. Approximately 70 patients with previously untreated stage IV pancreatic cancer will be randomly assigned to either gemcitabine alone or gemcitabine with bavituximab.

The primary endpoint of this trial is progression free survival (PFS) of patients with stage IV pancreatic cancer treated with gemcitabine alone versus gemcitabine with bavituximab. Secondary endpoints include overall response rate (ORR), duration of response (DR), and overall survival (OS). For further information about this trial, please visit [www.peregrinetrials.com](http://www.peregrinetrials.com) or <http://www.clinicaltrials.gov/ct2/results?term=bavituximab>.

#### *About Pancreatic Cancer*

According to the National Cancer Institute, pancreatic cancer is the fourth leading cause of cancer-related death in the United States in both men and women. Because it is usually diagnosed at an advanced stage, the survival rate is poor compared with that of other types of cancer. Unfortunately, overall pancreatic cancer incidence and mortality rates have changed very little throughout the past three decades.

#### *About Bavituximab*

Bavituximab is a first-in-class phosphatidylserine (PS)-targeting monoclonal antibody that represents a new approach to treating cancer. PS is a highly immunosuppressive molecule usually located inside the membrane of healthy cells, but "flips" and becomes exposed on the outside of cells that line tumor blood vessels, creating a specific target for anti-cancer treatments. PS-targeting antibodies target and bind to PS and block this immunosuppressive signal, thereby enabling the immune system to recognize and fight the tumor.

#### *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 multiple clinical programs in cancer and hepatitis C virus infection with its lead product candidate bavituximab and novel brain cancer agent Cotara®. Peregrine also has in-house cGMP 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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