

Peregrine Pharmaceuticals Reports Positive Top-Line Results in Bavituximab Combination Therapy Trial in Advanced Cancer Patients

- 50% of All Evaluable Patients Receiving Combination of Bavituximab Plus Chemotherapy Achieved Objective Tumor Response or Stable Disease
- 75% of Patients Receiving Combination of Bavituximab Plus Gemcitabine Achieved Objective Tumor Response or Stable Disease
- 50% of Patients Receiving Combination of Bavituximab Plus Carboplatin/Paclitaxel Achieved Objective Tumor Response
- Trial Results Support Advancing to Exploratory Phase II Efficacy Studies Currently Planned for Later This Year

TUSTIN, Calif., May 31 /PRNewswire-FirstCall/ -- Peregrine Pharmaceuticals, Inc. (Nasdaq: PPHM), a clinical stage biopharmaceutical company developing monoclonal antibodies for the treatment of cancer and hepatitis C virus (HCV) infection, today reported positive top-line results of its Phase Ib open label trial of bavituximab in combination with chemotherapy. This trial was designed to assess the safety and tolerability of bavituximab in combination with common chemotherapy agents in advanced cancer patients with metastatic disease who had failed prior therapy. Patients in the trial were also assessed for tumor response.

In the trial, the safety profile of bavituximab in combination with chemotherapy appeared similar to that seen in advanced cancer patients undergoing chemotherapy alone. The combination of bavituximab and chemotherapy showed positive signs of clinical activity, achieving objective tumor response or stable disease in 50% of the patients who were evaluable for tumor response. Patients receiving bavituximab in combination with gemcitabine demonstrated an even greater response, with 75% achieving an objective tumor response or stable disease, while 50% of patients receiving bavituximab with carboplatin/paclitaxel demonstrated an objective tumor response. Data from this study are being further analyzed to support the initiation of Phase II cancer trials later this year.

"We are encouraged to see objective responses in these patients with refractory advanced solid cancers after only a limited exposure to a regimen of bavituximab plus chemotherapy," said Joseph Shan, executive director of clinical and regulatory affairs at Peregrine. "We look forward to conducting the next set of clinical studies to further explore the potential of bavituximab as a novel cancer treatment."

The Phase Ib open label trial at clinical sites in India was designed to test the safety and tolerability of up to eight weekly doses of bavituximab given in combination with standard chemotherapy regimens including docetaxel, gemcitabine and carboplatin/paclitaxel. Study endpoints included safety, tolerability and pharmacokinetics. Although efficacy assessments were not formal endpoints of the study, patients were evaluated for tumor response according to Response Evaluation Criteria in Solid Tumors (RECIST) parameters, receiving CT or MRI scans prior to therapy and at the end of the combination treatment course. Tumor types in the trial included cancers of the breast, lung and ovary, among others.

"We are very encouraged by these results which indicated that the combination of bavituximab plus chemotherapy appeared to have a safety profile consistent with chemotherapy alone, while demonstrating the ability to shrink tumors or achieve stable disease in half of these very ill patients with advanced cancer," said Steven W. King, president and CEO of Peregrine. "The safety results and signs of anti-tumor activity seen in this combination therapy trial fully support moving bavituximab into exploratory efficacy trials slated for later this year,"

Patients were categorized as having "stable disease" if they had less than a 20% increase in the size of the tumor up to a 30% reduction in tumor size, "partial response" was defined as greater than a 30% reduction in tumor size and "complete response" was defined as disappearance of all lesions. Patients were categorized as having "progressive disease" if they had greater than a 20% increase in tumor size or the presence of new lesions. Patients with objective tumor responses (partial and/or complete responses) were eligible to continue with chemotherapy and bavituximab on a compassionate use basis. The trial was conducted according to International Conference on Harmonization (ICH) and Good Clinical Practices (GCP) guidelines.

Bavituximab is a monoclonal antibody that targets and binds to a phospholipid called phosphatidylserine, which is located on the inside of 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 currently in clinical trials in the U.S. for the treatment of solid tumors

and as a treatment for chronic hepatitis C infection in patients co-infected with HIV. Clinical data to date has shown that bavituximab is generally safe and well tolerated, and extensive preclinical data demonstrate good anti-tumor activity in a variety of tumor types, especially when bavituximab is administered in combination with chemotherapy or radiation.

Peregrine intends to present more complete data from this trial at an appropriate scientific meeting later this year.

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 five separate clinical trials in cancer and HCV infection in the U.S. and India with its lead product candidates bavituximab and Cotara®. 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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