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## **Peregrine Initiates Second Randomized Phase IIb Lung Cancer Trial Using First-In-Class PS-Targeting Monoclonal Antibody Bavituximab**

### **Promising Tumor Response and Median PFS Data Reported at ASCO Lead to New Phase IIb Trial**

TUSTIN, CA, Jul 14, 2010 (MARKETWIRE via COMTEX News Network) -- 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 second randomized Phase IIb non-small cell lung cancer (NSCLC) trial, this one in front-line patients. The clinical trial will compare bavituximab plus carboplatin and paclitaxel versus treatment with carboplatin and paclitaxel alone. A first-in-class phosphatidylserine (PS)-targeting monoclonal antibody, bavituximab is now being evaluated in combination with standard chemotherapy in two Phase IIb trials, the first in refractory patients and the second in front-line NSCLC patients.

Positive data from a previous Phase II signal-seeking trial which preceded this new Phase IIb trial were recently presented at the ASCO 2010 Annual Meeting. Data from this previous study showed an objective response rate (ORR) of 43% (21 of 49 patients) and median progression-free survival (PFS) of 6.1 months for front-line NSCLC patients treated with bavituximab in combination with carboplatin and paclitaxel. These results exceeded the ORR of 15% and median PFS of 4.5 months following treatment with carboplatin and paclitaxel alone in a separate front-line NSCLC trial.

"Bavituximab represents an entirely new targeted approach to cancer therapy," said David E. Gerber, M.D., assistant professor, Division of Hematology/Oncology at the University of Texas Southwestern Medical Center. "Earlier lung cancer studies combining bavituximab with conventional chemotherapy have shown encouraging response rate and progression-free survival data compared to historical outcomes using chemotherapy alone. Chemotherapy has been shown to increase the exposure of phosphatidylserine on tumor blood vessels, thereby enhancing bavituximab's cancer targeting. Bavituximab has been shown to fight tumors by reactivating the immune system and causing vascular changes. This mechanism of action could provide a new treatment option against this deadly form of cancer."

"Building on the promising data reported at ASCO from our earlier Phase II trial, we are launching this new Phase IIb study to advance the development of bavituximab as a potential new, broad-spectrum therapeutic option for cancer patients," said Joseph Shan, vice president of clinical and regulatory affairs at Peregrine. "Our goal is to complete patient enrollment in this trial by mid-year 2011. As this trial is unblinded, we plan to report interim data as this trial progresses while we continue to monitor median overall survival from our earlier Phase II NSCLC trial."

About the Phase IIb NSCLC Trial Peregrine's randomized, open-label trial is designed to compare the ORR of bavituximab in combination with paclitaxel and carboplatin versus paclitaxel and carboplatin alone. Enrolling up to 86 front-line, non-squamous NSCLC patients, this multi-center study is being conducted in the U.S. and internationally according to International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) guidelines at approximately 20 clinical sites.

The primary objective of the study is ORR and tumor response in the study will be evaluated using Response Evaluation Criteria in Solid Tumors (RECIST) guidelines. Secondary objectives of the study include median PFS, duration of response, median overall survival (OS), and safety parameters.

Patients will be randomized to receive bavituximab (3 mg/kg) or placebo weekly in combination with paclitaxel (200 mg/m<sup>2</sup>) and carboplatin (AUC 6), administered on day one of each 21-day cycle, up to six cycles.

For additional information on Peregrine's two Phase IIb NSCLC trials, please visit [www.clinicaltrials.gov/ct2/search](http://www.clinicaltrials.gov/ct2/search) and type in the key word "bavituximab."

About Lung Cancer Lung cancer is the leading cause of cancer death. According to the American Cancer Society, lung cancer is the second most commonly diagnosed cancer, with approximately 219,440 new cases and 159,000 deaths each year in the U.S. NSCLC is the most common type of lung cancer, accounting for approximately 85-90% of lung cancer cases.

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(R). 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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Contact:

Amy Figueroa

Peregrine Pharmaceuticals

(800) 987-8256

[info@peregrineinc.com](mailto:info@peregrineinc.com)

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<mailto:info@peregrineinc.com>

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