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## **Data Presented at AACR Annual Meeting Support Targeted Immune Reactivation Mechanism and Potential of Peregrine's Bavituximab in Solid Tumor Therapy**

### **Imaging Studies Show Docetaxel Strongly Upregulates Bavituximab's PS Target in Tumors, Further Supporting Lead Clinical Indication in Second Line Non-Small Cell Lung Cancer; Preclinical Studies Support Potential of Bavituximab to Induce Cancer-Fighting Changes in Immune Response to Tumors That Have Been Associated With Prolonged Survival in Lung Cancer Patients**

TUSTIN, CA -- (Marketwired) -- 04/10/13 -- Peregrine Pharmaceuticals, Inc. (NASDAQ: PPHM), a biopharmaceutical company developing first-in-class monoclonal antibodies focused on the treatment and diagnosis of cancer, today highlighted data presented at the Annual Meeting of the American Association for Cancer Research (AACR). Data was presented this week from preclinical studies investigating the immune-stimulating mechanism of action of Peregrine's lead phosphatidylserine (PS)-targeting oncology clinical candidate bavituximab and the anti-tumor and imaging potential of other PS-targeting molecules. Bavituximab is currently being evaluated in several oncology clinical trials including the lead indication of second-line non-small cell lung cancer (NSCLC), which is anticipated to advance into a pivotal Phase III trial later this year.

"These studies yield important insights into the fundamental role that exposed PS plays in tumor immune evasion, and further support our lead clinical candidate bavituximab's ability to reactivate tumor immunity. This is now clearly evidenced by several specific measurements of both the immune-stimulating and anti-tumor mechanisms mediated by PS-targeting antibodies as well as imaging studies demonstrating that tumor growth inhibition is correlated with PS expression levels in tumors," said Jeff T. Hutchins, Ph.D., vice president of preclinical research at Peregrine Pharmaceuticals. "Included in these presentations was a compelling finding of a pronounced antibody-mediated increase in tumor-fighting immune cells that is independently correlated with an impressive survival benefit in patients with NSCLC based on a published retrospective study of clinical data(1). When taken together, these results support PS as a promising oncology drug target and provide additional rationale for the impressive Phase II survival data we have seen in bavituximab's lead indication of second-line NSCLC."

Data presented from imaging studies(2) demonstrate that the chemotherapeutic drug docetaxel, a commonly prescribed second-line treatment for patients with advanced NSCLC, increases the exposure of bavituximab's target molecule, phosphatidylserine (PS), on tumor blood vessel cells and tumor cells. Results also showed that PS exposure in tumors is correlated with tumor burden and response to docetaxel treatment, supporting exposed PS as a promising biomarker of cancer and response to therapy. Peregrine's PS-targeting imaging agent I-124-PGN650 is currently being evaluated in a clinical trial to assess its safety and potential to image multiple tumor types in patients with cancer.

Additional data presented from a series of preclinical studies(3) demonstrate that PS-targeting antibodies mediate immunostimulatory changes in tumors resulting in an increase of tumor-fighting (M1) macrophages, immune cells strongly associated with survival benefits in patients with NSCLC(1). Peregrine recently reported promising data from a randomized, double-blind, placebo-controlled Phase II second-line NSCLC clinical trial demonstrating a 60% improvement in median overall survival (OS) in patients receiving 3 mg/kg bavituximab plus docetaxel compared to the control arm. The company plans to meet with the U.S. Food and Drug Administration (FDA) in the second quarter of calendar year 2013 with the goal of initiating a Phase III trial by calendar year-end.

Researchers also presented details of new PS-binding constructs(4). Termed "betabodies," the molecules consist of the PS-binding domain of the serum protein  $\beta$ 2-glycoprotein I ( $\beta$ 2GPI), fused to the constant region of an antibody. Betabodies bind to PS directly, are smaller in size and have a longer serum half-life than natural antibodies. Early studies indicate that betabodies hold potential as next-generation PS-binding agents that have the potential to be used for a broad number of applications including antibody-drug conjugates and next generation therapeutics for oncology and infectious diseases.

(1) The M1 form of tumor-associated macrophages in non-small cell lung cancer is positively associated with survival time. Ma et al. BMC Cancer 2010, 10:112. Open access research article: <http://www.biomedcentral.com/content/pdf/1471-2407-10-112.pdf>

#### *Presentation Details*

(2) Jian Gong(1), Richard Archer(1), Van Nguyen(1), Christopher C.W. Hughes(2), Jeff Hutchins(1), Bruce Freimark(1). 1. Peregrine Pharmaceuticals, Inc., Tustin, CA; 2. University of California, Irvine, Irvine, CA. Predicting anti-tumor responses to

phosphatidylserine targeting antibodies using tumor imaging. In Proceedings of the 104th Annual Meeting of the American Association for Cancer Research (AACR); 2013 Apr 6-10; Washington, D.C. Abstract 2850

(3) Yi Yin, Xianming Huang, Dan Ye, Philip Thorpe. UT Southwestern Medical Ctr., Dallas, TX: Phosphatidylserine-targeting antibody reactivates tumor immunity and destroys tumor vasculature in mice. In Proceedings of the 104th Annual Meeting of the American Association for Cancer Research (AACR); 2013 Apr 6-10; Washington, D.C. Abstract 1244

(4) Xianming Huang(1), Dan Ye(1), Troy Luster(2), E. Sally Ward(1), Philip Thorpe(1). 1. UT Southwestern Medical Ctr., Dallas, TX; 2. Human Genome Science, Maryland, MD. Phosphatidylserine-targeting 'betabodies' for the treatment of cancer. In Proceedings of the 104th Annual Meeting of the American Association for Cancer Research (AACR); 2013 Apr 6-10; Washington, D.C. Abstract 4326

Copies of the AACR posters are available at Peregrine's website at <http://www.peregrineinc.com/technology/bavituximab-oncology/recent-data.html>

#### *About Bavituximab*

Bavituximab is a first-in-class phosphatidylserine (PS)-targeting monoclonal antibody that represents a new approach to treating cancer. Bavituximab is the lead drug candidate from the company's PS technology platform and is currently being tested in eight clinical trials, including three randomized Phase II trials in front-line and second-line non-small cell lung cancer and front-line pancreatic cancer, and five investigator-sponsored trials (ISTs) in additional oncology indications. 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, Inc.*

Peregrine Pharmaceuticals, Inc. is a biopharmaceutical company with a portfolio of innovative monoclonal antibodies in clinical trials focused on the treatment and diagnosis of cancer. The company is pursuing multiple clinical programs in cancer 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 third-party customers. Additional information about Peregrine can be found at [www.peregrineinc.com](http://www.peregrineinc.com).

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