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## **Peregrine Pharmaceuticals Reaches Agreement With FDA on a Phase III Trial Design for Baviximab in Second-Line Non-Small Cell Lung Cancer**

### **Phase III Registration Trial of Investigational Immunotherapy Expected to Start by Year-End**

TUSTIN, CA -- (Marketwired) -- 05/20/13 -- Peregrine Pharmaceuticals (NASDAQ: PPHM), a biopharmaceutical company developing first-in-class monoclonal antibodies focused on the treatment and diagnosis of cancer, today announced that it has reached agreement with the U.S. Food and Drug Administration (FDA) on a Phase III registration trial design of the company's lead clinical immunotherapeutic candidate baviximab in second-line non-small cell lung cancer (NSCLC). The trial design was supported by promising data from a Phase IIb trial in patients treated with baviximab plus docetaxel. Final data from the study will be presented at the upcoming ASCO Annual Meeting on Saturday, June 1, 2013.

"We are very pleased with the outcome from this highly collaborative effort with the FDA which allows us to proceed with our proposed Phase III clinical trial," said Robert Garnick, Ph.D, head of regulatory affairs at Peregrine. "We believe this trial, when combined with baviximab's supporting data to date, could be sufficient to support a future BLA submission."

The Phase III clinical trial will be a randomized, double-blind, placebo-controlled trial evaluating baviximab plus docetaxel versus docetaxel alone enrolling approximately 600 patients at sites worldwide. The trial will enroll Stage IIIB/IV non-squamous, NSCLC patients who have progressed after standard front-line treatment. The primary endpoint of the trial will be overall survival (OS).

"The promising survival and safety data from the Phase IIb clinical trial in second-line NSCLC combined with the safety profile from over 400 patients treated to date with baviximab provide strong support for this Phase III clinical trial," said Joseph Shan, vice president of clinical and regulatory affairs of Peregrine. "We look forward to finalizing the clinical protocol and initiating the global Phase III trial by year-end."

Baviximab is a novel investigational immunotherapy that activates the maturation of dendritic cells and cancer-fighting (M1) macrophages leading to the development of cytotoxic T-cells that fight solid tumors. Baviximab has been studied in 17 clinical trials including lung, breast, pancreatic, liver and rectal cancers. Data from three of these clinical trials will be presented at the ASCO Annual Meeting beginning June 1, 2013.

"This agreement on a Phase III trial design with the FDA is a critical milestone for the baviximab program," said Steven King, president and chief executive officer of Peregrine. "We will now focus on starting the Phase III trial while continuing ongoing partnering discussions. With immunotherapies at the forefront of new approaches to treating cancer, we are well positioned with baviximab's novel immune activation mechanism to help advance this rapidly evolving field."

#### ***About Baviximab: A Targeted Immunotherapy***

Baviximab 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, causing the tumor to evade immune detection. Baviximab targets PS and blocks this immunosuppressive signal, resulting in the maturation of dendritic cells and cancer-fighting (M1) macrophages leading to the development of cytotoxic T-cells that fight solid tumors. Baviximab is the lead drug candidate from the company's PS-targeting technology platform and is currently being evaluated in several solid tumor indications, including non-small cell lung cancer, breast cancer, liver cancer and rectal cancer.

#### ***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 baviximab 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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future are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The forward-looking statements involve risks and uncertainties including, but not limited to, the risk that the company may not be able to initiate the Phase III trial within its anticipated timeline, the risk that the results from the Phase III trial may not support a future BLA submission, the risk that the company may not have or raise adequate financial resources to complete the Phase III trial and the risk that the company may not find a suitable partner for the Phase III trial or the PS program. It is important to note that the company's actual results could differ materially from those in any such forward-looking statements. Factors that could cause actual results to differ materially include, but are not limited to, uncertainties associated with completing preclinical and clinical trials for our technologies; the early stage of product development; the significant costs to develop our products as all of our products are currently in development, preclinical studies or clinical trials; obtaining additional financing to support our operations and the development of our products; obtaining regulatory approval for our technologies; anticipated timing of regulatory filings and the potential success in gaining regulatory approval and complying with governmental regulations applicable to our business. Our business could be affected by a number of other factors, including the risk factors listed from time to time in our reports filed with the Securities and Exchange Commission including, but not limited to, our annual report on Form 10-K for the fiscal year ended April 30, 2012 and our quarterly report on Form 10-Q for the quarter ended January 31, 2013. The company cautions investors not to place undue reliance on the forward-looking statements contained in this press release. Peregrine Pharmaceuticals, Inc. disclaims any obligation, and does not undertake to update or revise any forward-looking statements in this press release.

Contact:

Christopher Keenan or Jay Carlson  
Peregrine Pharmaceuticals, Inc.  
(800) 987-8256  
[info@peregrineinc.com](mailto:info@peregrineinc.com)

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