



## **Peregrine Completes Patient Enrollment in Second-Line Non-Small Cell Lung Cancer Trial; Data to Be Unblinded in First Half 2012**

### **Third Randomized Phase II Trial Enrolled in Last 30 Days Sets Timeline for Multiple Upcoming Clinical Data Points in 2011 and 2012**

TUSTIN, CA -- (MARKET WIRE) -- 10/06/11 -- 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 the completion of enrollment and randomization of 121 patients in a double-blind, placebo-controlled Phase II trial evaluating bavituximab in combination with docetaxel in patients with previously treated locally advanced or metastatic non-small cell lung cancer (NSCLC). Bavituximab is a phosphatidylserine (PS)-targeting monoclonal antibody with broad therapeutic potential also being evaluated in randomized Phase II trials for front-line NSCLC, pancreatic cancer, and hepatitis C virus (HCV) infection as well as in several investigator-sponsored trials (ISTs) in additional oncology indications.

"Completing patient enrollment in three randomized Phase II trials over the last month sets the stage for reporting early results from all three trials over the coming months. We look forward to evaluating and reporting interim data from an earlier completed randomized Phase II trial in front-line NSCLC and data from an HCV study later this year as we await unblinding data from this second-line NSCLC trial in the first half of next year," said Steven W. King, president and chief executive officer of Peregrine. "In our prior Phase II trials, we have seen encouraging tumor response data, which have correlated with promising survival for patients treated with bavituximab in combination with chemotherapy. This latest trial's rigorous design is intended to determine if bavituximab may improve tumor response rates when given in combination with the commonly used second line chemotherapy treatment docetaxel. Unfortunately treatment with docetaxel alone is expected to result in less than a 6%(1) tumor response rate, but since docetaxel increases exposure of bavituximab's PS target, we believe the combination has a good chance to improve on these results and hopefully improve overall survival for patients who have already failed a prior treatment for this deadly form of cancer. We greatly appreciate the patients and investigators who have participated in our studies and our dedicated team at Peregrine working hard to advance our multiple Phase II trials."

#### *About Peregrine's Trial*

Peregrine's randomized, double-blind, placebo-controlled Phase II trial is designed to evaluate docetaxel with bavituximab or placebo and enrolled 121 patients with previously treated locally advanced or metastatic NSCLC. All patients have confirmed Stage IV (TNM Edition 7) non-squamous NSCLC and have progressed following one prior chemotherapy regimen.

Patients were randomized to receive up to 6 cycles of docetaxel with placebo, 1 mg/kg bavituximab, or 3 mg/kg bavituximab until disease progression. The primary endpoint of this trial is to compare the objective response rate (ORR) measured in accordance with RESIST criteria. Secondary objectives of the study include progression-free survival (PFS), duration of response, overall survival (OS), and safety. More information about this trial can be found at <http://www.clinicaltrials.gov/ct2/show/NCT01138163?term=bavituximab&rank=5>.

#### *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.

(1) Docetaxel package insert

#### *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).

Safe Harbor Statement: Statements in this press release which are not purely historical, including statements regarding

Peregrine Pharmaceuticals' intentions, hopes, beliefs, expectations, representations, projections, plans or predictions of the 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 will not be in a position to report data for the Phase II trial in the first half of next year, the risk that results from the randomized Phase II trial will not be consistent with results experienced in the earlier single-arm Phase II trials, the risk that results from the randomized Phase II trial may not support registration filings with the U.S. Food and Drug Administration, and the risk that Peregrine may not have or raise adequate financial resources to complete the planned clinical programs. Factors that could cause actual results to differ materially or otherwise adversely impact the company's ability to obtain regulatory approval for its product candidates 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 the company's SEC reports including, but not limited to, the annual report on Form 10-K for the year ended April 30, 2011 and quarterly report on Form 10-Q for the quarter ended July 31, 2011. 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.

[Add to Digg](#) [Bookmark with del.icio.us](#) [Add to Newsvine](#)

Contact:

Amy Figueroa or Jay Carlson

Peregrine Pharmaceuticals

(800) 987-8256

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

Source: Peregrine Pharmaceuticals

News Provided by Acquire Media