

Peregrine Pharmaceuticals Provides Update on the Internal Review of Its Phase II Second-Line Non-Small Cell Lung Cancer Trial

Preliminary Analysis Supports Advancing Bavituximab Into Phase III Development

TUSTIN, CA -- (Marketwire) -- 01/07/13 -- Peregrine Pharmaceuticals, Inc.(NASDAQ: PPHM), a biopharmaceutical company developing first-in-class monoclonal antibodies focused on the treatment and diagnosis of cancer, today provided an update from its internal review of discrepancies from its Phase II randomized, double-blind placebo-controlled trial of bavituximab in second-line non-small cell lung cancer (NSCLC) in 121 patients. The review was prompted by the discovery of vial coding discrepancies while preparing for an end of Phase II meeting with the FDA. The internal review included a thorough operational review of multiple third-party vendor operations at sites worldwide, testing of investigational product used in the trial, additional patient sample testing to determine drug levels and a review of immunogenicity testing results from the trial. The results of the extensive internal review indicate that discrepancies are isolated to the placebo and 1 mg/kg treatment arms of the trial and that there was no evidence of discrepancies in the 3 mg/kg treatment arm of the trial.

"Our goal in undertaking such a comprehensive review was to understand every aspect of this clinical trial," said Jeffrey L. Masten, vice president, quality of Peregrine. "Due to the complex nature of this trial, this was an enormous effort involving multiple third-party vendors and thousands of product and patient samples obtained from three different continents. Specifically, we sought to determine the cause and the impact of any discrepancies within the trial and to verify every step within the drug product distribution process. We believe we have accomplished our goals in obtaining a more thorough understanding of the trial and we are very pleased with the outcome."

Based on the results of the internal review, Peregrine is taking a very conservative approach toward analyzing the results from the trial which included combining the placebo and 1mg/kg arms into one treatment arm (control arm), and comparing those results to the 3mg/kg arm. This analysis indicates that the 3 mg/kg arm continues to show favorable tumor response rates, progression-free survival and overall survival (OS) over the new combined control arm. Peregrine expects to announce more detailed results from the analysis in the near term when it is completed.

"The results from this comprehensive review have provided a better understanding of the outcome of this trial. We believe that these results of our internal review and subsequent data analysis support advancing bavituximab into Phase III development for the treatment of second-line non-small cell lung cancer," said Joseph S. Shan, vice president, clinical and regulatory affairs of Peregrine. "We are now preparing for discussions with the FDA and worldwide regulatory agencies."

"With the results of this review in hand, we are now in the process of updating potential partners and moving the program forward," said Steven W. King, president and chief executive officer of Peregrine. "Looking ahead, we anticipate data from seven ongoing bavituximab trials in different indications as well as results from an imaging study based on the same novel target."

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), which provides development and biomanufacturing services for both Peregrine and outside customers. Additional information about Peregrine can be found at 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 forwardlooking statements involve risks and uncertainties including, but not limited to, the risk that the final OS data from the randomized, double-blind, placebo-controlled Phase IIb trial may be less compelling than the data as presently calculated thereby creating uncertainty with respect to the future development in second-line NSCLC, the risks that partnering discussions may not result in a partnering transaction or that such discussions could be hindered or delayed as a result of the existing class action lawsuits, the risk that results from the front-line NSCLC trail will not be consistent with results experienced in earlier trials and may not support advancing this indication into later stage trials. 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 the our SEC reports including, but not limited to, the annual report on Form 10-K for the fiscal year ended April 30, 2012 and quarterly report on Form 10-Q for the quarter ended October 31, 2012. 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. Our business could be affected by a number of other factors, including the risk factors listed from time to time in the our SEC reports including, but not limited to, the annual report on Form 10-K for the fiscal year ended April 30, 2012 and quarterly report on Form 10-Q for the quarter ended October 31, 2012. 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

Source: Peregrine Pharmaceuticals

News Provided by Acquire Media