January 11, 2016

# Peregrine Pharmaceuticals Provides Update on Planned Expansion of Bavituximab Clinical Program in Lung, Breast and Other Cancers

*-- Phase II Study in NSCLC in Collaboration with AstraZeneca Evaluating Bavituximab Plus Durvalumab to Expand Lung Cancer Program in Q1 2016 --*

*-- Phase II/III Study in HER2-Negative Metastatic Breast Cancer is Now Underway with a Second Phase II Study in Early Stage Triple Negative Breast Cancer to Begin in Q1 2016 --*

*-- Additional Studies to Broaden Evaluation of Bavituximab Immunotherapy and Standard of Care Combinations in Multiple Solid Tumors Planned for 2016 --*

TUSTIN, Calif., Jan. 11, 2016 (GLOBE NEWSWIRE) -- Peregrine Pharmaceuticals, Inc. (NASDAQ:PPHM) (NASDAQ:PPHMP), a biopharmaceutical company focused on developing therapeutics to stimulate the body's immune system to fight cancer, today provided a clinical development update for bavituximab, the company's investigational phosphatidylserine (PS)-targeting immunotherapy.Â  In the first quarter of 2016, Peregrine plans to initiate two new Phase II clinical trials in breast and lung cancer in combination with current standard of care treatments including both chemotherapy and immuno-oncology agents.Â  In addition, the company has entered into a collaboration with the National Comprehensive Cancer Network (NCCN) to evaluate bavituximab in other tumor types and combinations. Â Additionally, the company is nearing completion of enrollment of an ongoing Phase III trial in non-small cell lung cancer (NSCLC) named SUNRISE. Â

The planned trials include a Phase II NSCLC trial in combination with AstraZeneca's investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab (MEDI4736), and a Phase II trial in early stage triple negative breast cancer (TNBC).Â  These are in addition to the recently initiated Phase II/III study in combination with chemotherapy in human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer (MBC). The company expects that initial data from these trials may be available in late 2016 or early 2017.Â  Additionally, the company looks forward to the initiation of additional trials of bavituximab combinations through its ongoing collaborations with AstraZeneca and NCCN.

"As we wrap up enrollment in the SUNRISE trial, we recognize that we are at an ideal juncture to continue expanding the potential of bavituximab with standard of care and immunotherapy combinations in multiple solid tumor types.Â  Combined with the SUNRISE trial, the new studies we have planned can help solidify the potential of bavituximab in NSCLC while significantly expanding the market opportunity in breast cancer," said Steven W. King , president and chief executive officer of Peregrine.Â  "Driving our strategy is the goal of further demonstrating that bavituximab can provide therapeutic benefit to available cancer treatments, regardless of whether those are traditional therapies such as chemotherapy and radiation, or the emerging novel class of immuno-oncology agents. Â In today's update, it is evident that we are moving aggressively to compile a significant body of clinical evidence to support bavituximab's utility in multiple cancers and across a range of treatment regimens.Â  By doing so, we hope to optimally position bavituximab for success."

Bavituximab is an investigational immunotherapy designed to assist the body's immune system by targeting and modulating the activity of phosphatidylserine (PS), a highly immune-suppressive signaling molecule expressed broadly on the surface of cells in the tumor microenvironment.Â  Peregrine's PS targeted inhibitor, bavituximab, is thought to reverse the immunosuppressive environment that many tumors establish in order to proliferate and spread, while also fighting cancer by activating immune cells that target and fight cancer.

Updated details on Peregrine's expanded bavituximab clinical development program include:

**Bavituximab in NSCLC:**

Phase III SUNRISE Trial

Peregrine's Phase III SUNRISE (**S**timulating Imm**U**ne Respo**N**se th**R**ough Bav**I**tuximab in a Pha **SE**Â III Lung Cancer Study) trial is evaluating the use of bavituximab and docetaxel in patients with previously treated locally advanced or metastatic non-squamous NSCLC.Â  Peregrine expects that the first interim analysis (33% of targeted number of deaths) will be conducted in early 2016 and the second interim analysis (50% of targeted number of deaths) in mid-2016.Â  The final

analysis, which will trigger the unblinding of the study data, is currently projected to occur at the end of 2016.

Phase II NSCLC Trial in Combination with AstraZeneca's Durvalumab

Peregrine expects to initiate a global Phase II study of bavituximab in combination with AstraZeneca's durvalumab, an anti-PD-L1 immune checkpoint inhibitor, in patients with previously treated squamous or non-squamous NSCLC during the first quarter of 2016.Â  The goal of this trial is to generate data on the combination of bavituximab and durvalumab to inform the potential advancement of this treatment regimen into later stage clinical trial.Â  The study's primary endpoints are overall response rate (ORR) and safety.Â  The trial is also designed to retrospectively evaluate patients for the correlation between their PD-L1 levels and clinical outcomes, providing further critical data to guide future development.

The randomized, open-label trial will evaluate approximately 200 patients at sites in the U.S. and Europe.Â  The company has filed a study protocol to its existing investigational new drug (IND) application for bavituximab in the U.S. and is currently working to open clinical trial sites.

**Bavituximab in Breast Cancer:**

Phase II/III HER2-Negative MBC Trial in Combination with Chemotherapy

In December 2015, Peregrine initiated an open-label, randomized Phase II/III study comparing the efficacy and safety outcomes for taxane monotherapy (paclitaxel or docetaxel at investigator discretion) versus taxane therapy in combination with bavituximab in HER2-negative MBC patients.Â  The goal of the Phase II portion of this study is to generate mature data on the combination of bavituximab and chemotherapy in MBC to guide the design and execution of the trial's Phase III component.Â  The primary efficacy endpoint of the Phase II study is ORR, with secondary endpoints including progression free survival (PFS), overall survival (OS), duration of response and safety.Â  The Phase II portion of the study will enroll approximately 150 patients at sites in the U.S. and Europe.

Phase II Trial in Early Stage TNBC in Combination with Chemotherapy

Peregrine is planning to initiate a Phase II trial of bavituximab in combination with neoadjuvant chemotherapy in early stage TNBC. Â The primary endpoint of this study is to determine the pathologic complete response rate (pCR), an accepted surrogate endpoint in early stage TNBC.Â  The concept for this neoadjuvant setting trial, which will be conducted at a few select U.S. sites, originated from Peregrine's ongoing collaboration with Memorial Sloan Kettering Cancer Center (MSKCC).Â  The company has filed a study protocol to its existing bavituximab IND application in the U.S. and is currently working to open clinical trial sites, including one that will be led by David B. Page, M.D., at the Providence Cancer Center in Oregon.

**Bavituximab in Other Solid Tumor Indications:**

Phase I/Ib Trial in Multiple Solid Tumors in Combination with AstraZeneca's Durvalumab and Chemotherapy

As part of the company's collaboration with AstraZeneca, Peregrine plans to initiate a Phase I/Ib study of bavituximab in combination with durvalumab and chemotherapy in multiple solid tumors in 2016.Â  The Phase I part of the trial is designed to confirm the tolerability of the combination of bavituximab and durvalumab and establish a recommended dose regimen for the Phase Ib part of the trial, which will assess the safety and activity of the combination of bavituximab, durvalumab and chemotherapy.

Multiple Clinical and Translational Studies in Collaboration with NCCN

Peregrine recently announced a new research collaboration with NCCN to expand the company's ongoing clinical research and development of bavituximab for the treatment of a range of tumors.Â  NCCN, a not-for-profit alliance of 26 of the world's leading cancer centers devoted to patient care, research, and education, is dedicated to improving the quality, effectiveness, and efficiency of cancer care so that patients can live better lives.Â  Multiple investigator-initiated clinical and correlative studies with bavituximab in multiple cancers will be initiated at NCCN Member Institutions and their affiliate community hospitals through a $2 million research grant to NCCN's Oncology Research Program (ORP).Â  NCCN will be responsible for oversight and monitoring of the clinical studies through the research grant.Â  The company expects results from this collaboration to further support the ongoing development of bavituximab as a key component of various combination cancer treatments.

**About Bavituximab: A Targeted Investigational Immunotherapy**
Bavituximab is an investigational chimeric monoclonal antibody that targets phosphatidylserine (PS). Signals from PS inhibit the ability of immune cells to recognize and fight tumors. Bavituximab blocks PS and, in turn, is believed to remove this immunosuppressive signal and send an alternate immune activating signal. Â  PS targeting antibodies have been shown to

shift the functions of immune cells in tumors, resulting in robust anti-tumor immune responses.

**About Peregrine Pharmaceuticals, Inc.**
Peregrine Pharmaceuticals, Inc. is a biopharmaceutical company focused on developing therapeutics to stimulate the body's immune system to fight cancer.Â  Bavituximab, the company's lead immunotherapy candidate, is in late-stage clinical development for the treatment of both lung cancer and breast cancer.Â  The company will also evaluate the combination of bavituximab and durvalumab, AstraZeneca's investigational anti-PD-L1 immune checkpoint inhibitor, in a range of cancer types under a clinical collaboration.

In addition to its drug development programs, 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 third-party customers. For more information, please visit 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 may experience delays in initiating planned clinical trials, the risk that enrollment of patients in the company's clinical trials may experience delays, the risk that the results from the Phase III SUNRISE trial may not support a future Biologics License Application (BLA) submission, the risk that interim analyses and data readouts from the clinical trials may not occur within the time frames anticipated, the risk that the company may not have or raise adequate financial resources to complete all of its contemplated clinical trials, and the risk that data from one or more of the Phase II and early stage clinical trials, including ISTs, may not support further development of the combination and/or indication studied. 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, 2015 as well as any updates to these risk factors filed from time to time in the company's other filings with the Securities and Exchange Commission. 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.*

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