

## Data Presented at AACR Demonstrate Peregrine Pharmaceuticals' Bavituximab Induces Immune Activation in PD-L1 Negative NSCLC Tumors

- Bavituximab Alone and in Combination with Docetaxel Elicit a Tumor-Specific Immune Response in PD-L1 Negative Tumors

  Extracted from NSCLC Patients -
  - Immune Modulating Results Consistent with Previously Conducted Translational Studies in Liver Cancer -
- Presented Data Further Support Clinical Studies Evaluating the Effectiveness of Bavituximab Immunotherapy Combinations in Patients with PD-L1 Negative Tumors -

TUSTIN, Calif., April 20, 2015 (GLOBE NEWSWIRE) -- Peregrine Pharmaceuticals, Inc. (Nasdaq:PPHM) (Nasdaq:PPHMP) today announced the presentation of data from clinical translational studies of the company's phosphatidylserine (PS)-targeting immunotherapy bavituximab. Initial data from a pilot study of clinical translational *ex vivo* cultures show that bavituximab, both alone and with docetaxel, elicits evidence of a tumor-specific immune response in patients with human adenocarcinoma of the lung and that bavituximab exhibits an impact on tumors with negative PD-L1 expression. These data were presented yesterday, Sunday, April 19<sup>th</sup>, in a poster presentation at the 106th Annual Meeting of the American Association for Cancer Research (AACR) being held in Philadelphia, Pennsylvania from April 18-22, 2015. Bavituximab is currently being evaluated in second-

line non-small cell lung cancer (NSCLC) as part of the SUNRISE pivotal Phase III clinical trial.

"Our translational findings of a cytokine profile that reflects an immune response following either bavituximab single-agent or combination treatment are encouraging. Furthermore, these preliminary translational data show that tumors with negative PD-L1 expression and low levels of PD-1 expression on CD8+ tumor infiltrating T cells showed immune response to bavituximab treatment *ex vivo*," said Sigrid M. Volko, Ph.D., CLP the lead investigator on the study and President and Chief Executive Officer of Nilogen Oncosystems. "It is an exciting time for the field of immunotherapy and the data we have been generating support that bavituximab has the potential to activate a tumor specific immune response in patients with PD-L1 negative tumors that generally do not respond as well to PD-1 or PD-L1 inhibitors."

In a poster titled: "Bavituximab modulates tumor microenvironment and activates CD8+ tumor infiltrating lymphocytes in a patient-derived 3D ex vivo system of lung cancer," researchers from Moffitt Cancer Center, Nilogen Oncosystems and Peregrine present initial data from a pilot translation study analyzing tumor tissue from six lung cancer patients to evaluate the immunomodulatory effects of bavituximab in a human ex vivo model of NSCLC. Researchers generated 3D tumor microspheres from tumor tissues produced at the time of surgical resection. These microspheres were treated ex vivo for 36 hours with bavituximab, bavituximab and docetaxel, or controls in the presence of Interleukin-2 (IL-2), a cytokine that regulates the activities of white blood cells that are responsible for immunity. Data show that bavituximab as a single agent or in combination with docetaxel induces lymphocyte activation in tumors as demonstrated by a significant increase in interferon-gamma (IFNy), TNF-alpha, and GM-CSF secretion when compared to tumors treated with IL-2 control. Researchers also concluded that the immune response to treatment with bavituximab correlates with negative PD-L1 expression in the resected tumor tissue and low PD-1 expression on CD8+ tumor infiltrates thus serving as a potential prognostic biomarker of positive response to bavituximab treatment.

"These data are exciting as the immune responses seen in this translational lung cancer study mirror what we saw in translational data from a liver cancer clinical trial and is perfectly aligned with what has been seen preclinically to date. It was also encouraging to see how well these data further support our ongoing Phase III SUNRISE trial in that the combination of bavituximab and docetaxel induces immune activity," said Joseph Shan, MPH, vice president of clinical and regulatory affairs at Peregrine. "These data are playing a key role in advancing the clinical portion of an Immuno-Oncology Development Program which has been built upon a growing body of favorable data supporting the potential combination of bavituximab and checkpoint inhibitors. Specifically, these data show that activating the immune system in this negative PD-L1 patient population provides a strong rational for combining bavituximab with inhibitors of the PD-1/PD-L1 pathway. We look forward to detailing our plans for additional immuno-oncology combination clinical trials in the near future."

## Liver Cancer Translational Data

In November, clinical translational data from the company's Immuno-Oncology Development Program were presented assessing changes in immune response pre- and post-treatment in six patients participating in a Phase II IST evaluating bavituximab in

combination with sorafenib in advanced hepatocellular carcinoma. Data from this translational sub-study of patients, show that half of the patients had an increase in tumor fighting immune cells following one cycle of treatment, similar to what has been shown for PS-targeting antibodies in multiple preclinical cancer models. In addition, the increase in immune response was associated with patients that remained on study treatment for longer time periods, consistent with an immunotherapeutic mechanism and suggest the possibility of a clinically meaningful anti-tumor immune response. Immune responding patients also had increased infiltration of CD8 T-cells in the tumor microenvironment which correlated with a prolonged time to disease progression. In addition, these immune responders expressed lower levels of PD-1, an established marker of T cell activation and disease outcome, prior to the initiation of therapy, followed by a measurable rise.

A link to this presentation is located on the front page of Peregrine's website at www.peregrineinc.com.

About Bavituximab: A Targeted Investigational Immunotherapy

Scientific research has shown that tumors evade immune detection due partly to the expression of phosphatidylserine, or PS, a highly immunosuppressive molecule. Peregrine's immuno-oncology development program has developed bavituximab, an investigational monoclonal antibody that targets and binds to PS, blocking its immunosuppressive effects while activating tumor fighting immune cells, thus enabling the immune system with the ability to better recognize and fight cancer. Bavituximab's immune-stimulatory mechanism-of-action data is the subject of a manuscript published in the October 2013 issue of the American Association for Cancer Research's (AACR) peer-reviewed journal, Cancer Immunology Research. Bavituximab is currently being evaluated in several solid tumor indications, including non-small cell lung cancer (the SUNRISE Phase III trial), breast cancer, rectal cancer and advanced melanoma. In January 2014, bavituximab received Fast Track designation by the U.S. Food and Drug Administration (FDA) as a potential second-line treatment in patients with non-small cell lung cancer.

About Peregrine Pharmaceuticals, Inc.

Peregrine Pharmaceuticals, Inc. is a biopharmaceutical company with a pipeline of novel drug candidates in clinical trials for the treatment and diagnosis of cancer. The company's lead immunotherapy candidate, bavituximab, is in Phase III development for the treatment of second-line non-small lung cancer (the "SUNRISE trial") along with several investigator-sponsored trials evaluating other treatment combinations and additional oncology indications. The company is also advancing a molecular imaging agent, 124I-PGN650, in an exploratory clinical trial for the imaging of multiple solid tumor types. Peregrine also has inhouse cGMP manufacturing capabilities through its wholly-owned subsidiary Avid Bioservices, Inc. (<a href="https://www.avidbio.com">www.avidbio.com</a>), which provides development and biomanufacturing services for both Peregrine and third-party customers. For more information, please visit <a href="https://www.peregrineinc.com">www.peregrineinc.com</a>.

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 data from human clinical studies may not correlate with data from translational and pre-clinical studies may not correlate with the results from human clinical studies. 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, 2014 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.

CONTACT: Christopher Keenan

Peregrine Pharmaceuticals, Inc.

(800) 987-8256

info@peregrineinc.com



Source: Peregrine Pharmaceuticals, Inc.

News Provided by Acquire Media