

Data Presentations at ASCO Demonstrate the Ability of Peregrine Pharmaceuticals' Bavituximab to Activate Tumor Targeting Immune Cells in PD-L1 Negative NSCLC Tumors

- New Data Show that Bavituximab Alone and in Combination with Docetaxel Elicits a Tumor-Specific Immune Response in PD-L1 Negative Tumors Extracted from NSCLC Patients -
- PS-Targeting Antibodies Combined with Anti-PD-1 Reverses Tumor Immunosuppression and Activates Tumor Fighting CD8+ Immune Cells in Models of Melanoma and Breast Cancer -
 - Encouraging Data in Patients with Advanced Liver Cancer Warrants Further Clinical Study -

TUSTIN, Calif., June 1, 2015 (GLOBE NEWSWIRE) -- Peregrine Pharmaceuticals, Inc. (Nasdaq:PPHM) (Nasdaq:PPHMP), a biopharmaceutical company focused on oncology and the treatment of lung and breast cancers through the development of bavituximab, a novel immunotherapy currently in Phase III, today announced the presentation of preclinical and clinical translation data highlighting its phosphatidylserine (PS) targeting platform and bavituximab at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting, being held May 29-June 2, 2015 in Chicago, Illinois.

"These presentations bridge the preclinical and clinical portions of our Immuno-Oncology Development Program and support our recently announced strategic decision to expand our clinical program aimed at the development of the most promising potential immunotherapy combinations with bavituximab," said Jeff Hutchins, vice president preclinical development of Peregrine. "The data generated to date reinforces the potential of bavituximab to enhance current immuno-oncology treatment modalities aimed at creating a greater group of patients responding to currently available therapies."

In poster #385 titled "Activation of CD8+ tumor infiltrating lymphocytes by bavituximab in a 3D ex vivo system of lung cancer patients", researchers from Nilogen Oncosystems and H. Lee Moffitt Cancer Center presented 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 non-small cell lung cancer (NSCLC). New data generated from additional assays further validates previous data showing that ex vivo drug treatment with bavituximab, alone and in combination with docetaxel, elicits an immune response in tumors from NSCLC patients with negative PD-L1 and low PD-1 expression. Specifically, data showed activation of tumor infiltrating lymphocytes (TILs) by polarization of the tumor microenvironment from immunosuppressive to immuno-stimulatory. Results in this pilot translational study also identified PD-L1 and PD-1 expression as a potential biomarker of response to bavituximab treatment, suggesting that the interruption of the PD-1/PD-L1 axis may enhance the bavituximab effect in lung cancer.

"These preliminary gene profiling data are consistent with previously published data on bavituximab's immunotherapeutic mechanism of action," said Dr. Soner Altiok, M.D, Ph.D., Chief Scientific Officer at Nilogen Oncosystems and Senior Member at the H. Lee Moffitt Cancer Center. "Building upon encouraging translational findings of a cytokine profile previously reported, these new data support the finding that M1 polarization of tumor associated macrophages is involved in bavituximab-mediated activation of tumor infiltrating lymphocytes in the *ex vivo* model of lung cancer."

In poster #386 titled "Phosphatidylserine targeting antibody in combination with anti-PD-1 antibody treatment activates infiltrating T lymphocytes of the spleen and tumor microenvironment in pre-clinical models of melanoma and breast cancer", researchers from The University of Texas Southwestern Medical Center in Dallas, Texas led by Xianming Huang, Ph.D., found that blocking PS with PS-Targeting antibody enhances the anti-tumor activity of combination therapies including anti-PD-1 and anti-CTLA-4 antibodies in an immune competent model of breast cancer and in preclinical models of melanoma. In the breast cancer model, researchers found that the combination of PS blockade and an anti-PD-1 antibody promoted strong and localized anti-tumor responses without the side-effects of systemic immune activation. In models of melanoma, the combination of PS blockade with either an anti-PD-1 or anti-CTLA-4 antibody showed significantly superior tumor growth inhibition over single treatment, with many subjects achieving complete tumor regressions. No toxicity was observed in any of the treatment groups following multiple treatment doses.

Added Dr. Hutchins: "These data support our view of bavituximab as an immunomodulatory treatment in PD-1 sensitive and anti-PD-1 resistant/unresponsive tumors. We look forward to the execution of additional clinical trials aimed at further exploring these potential combinations."

In poster #220 titled: "A phase I/II study of bavituximab and sorafenib in advanced hepatocellular carcinoma (HCC)", researchers led by Adam Yopp, M.D., Assistant Professor of Surgery at the University of Texas Southwestern Medical Center in Dallas, Texas found that the combination of bavituximab and sorafenib is associated with an improved time to progression (TTP) of 6.7 months, a disease specific survival (DSS) of 8.7 months, a disease control rate (DCR) of 58% (22 out of 58 patients) and a 4-month progression-free survival (PFS) of 62%. Two patients (5%) achieved a partial response according to Response Evaluation Criteria In Solid Tumors (RECIST). The secondary endpoint of median overall survival (OS) was 6.2 months. The trial's patient population had unfavorable disease biology as demonstrated by a high rate of previous treatment and macrovascular invasion. The combination of bavituximab and sorafenib was well-tolerated in patients with advanced HCC with no indications of autoimmune adverse events that have been seen with other checkpoint immunotherapies.

A link to copies of these presentations can be found on the home page of Peregrine's website at www.peregrineinc.com.

Webcast Replay: Roundtable Discussion "Raising the Immuno-Oncology Bar"

Last night, Peregrine hosted a roundtable discussion of immunotherapy thought leaders in conjunction with the 2015 Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, Illinois. A link to the replay of this event titled: "Raising the Immuno-Oncology Bar: The Next Wave of Immune Modulating Checkpoint Inhibitors" can be found on the home 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, liver cancer, rectal cancer and advanced melanoma. In January 2014, bavituximab received Fast Track designation by the U.S. Food and Drug Administration (FDA) for the potential second-line treatment of 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. 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.

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