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## **Phase II Clinical Data of Peregrine Pharmaceuticals' Bavituximab in Combination With Sorafenib Presented at ASCO Gastrointestinal Cancers Symposium**

### **Positive Trends in Time to Progression, Disease Control Rates and 4-Month Progression-Free Survival Endpoints Were Reported in a Patient Population With Poor Prognosis; Survival Curves Showed Patients With Prolonged Survival Consistent With Those Seen in Other Immunotherapy Studies in Different Indications; Overall Data From Trial Support Bavituximab's Immunostimulatory Mechanism-of-Action**

TUSTIN, CA -- (Marketwired) -- 01/16/15 -- Peregrine Pharmaceuticals, Inc. (NASDAQ: PPHM) (NASDAQ: PPHMP), today announced the presentation of clinical data related to the company's immuno-oncology development program and its lead investigational immunotherapy drug candidate bavituximab at the American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium. This conference is being held January 15-17, 2015 at the Moscone West Convention Center in San Francisco, California.

The clinical presentation titled: "A Phase II Study of Bavituximab and Sorafenib in Advanced Hepatocellular Carcinoma (HCC)" will be presented this afternoon by Adam Yopp, M.D., assistant professor of surgery at the University of Texas Southwestern Medical Center Dallas, Texas.

In this single-center, single-arm, open-label investigator-sponsored trial (IST), 38 patients with advanced HCC received bavituximab (3mg/kg) weekly and sorafenib (400 mg) twice daily until disease progression or toxicity. Data show 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 38 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 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.

"These clinical outcomes of time to progression, disease control rate and 4-month progression-free survival are quite encouraging, especially in this heavily pretreated patient cohort with very poor prognosis due to their unfavorable disease biology including a high rate of macrovascular invasion," said Dr. Yopp. "I was also pleased to see an extended tail in the survival curve that is typical of emerging immunotherapies for cancer. The positive data from this study should be considered as rationale for future randomized trials to further evaluate the potential of bavituximab in liver cancer."

"These data, along with recently reported translational data from this study, continue to build the knowledge base for the bavituximab clinical program and, in particular, highlight the potential immunotherapeutic synergies of bavituximab and sorafenib. We agree with Dr. Yopp that these data warrant further clinical evaluation of this combination in later stage clinical trials," said Joseph Shan, vice president of clinical and regulatory for Peregrine. "We continue to build value in the bavituximab program across multiple programs including the execution of the SUNRISE Phase III trial in second-line, non-small cell lung cancer and from data generated from this and other investigator-sponsored trials as well as other ongoing clinical trials. We look forward to new clinical collaborations with the goal of further exploring the utility of bavituximab in combination with other immuno-oncology drugs."

A link to today's poster can be found from the front page of the company's website at: [www.peregrineinc.com](http://www.peregrineinc.com).

#### Liver IST Clinical Translation Data

Recently presented translational data of six patients from this trial show that half of the patients evaluated had an increase in tumor fighting immune cells following one cycle of bavituximab 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, suggesting the possibility of a clinically meaningful anti-tumor immune response. Three of the six patients evaluated had increased infiltration of activated tumor-fighting T-cells (CD8) into the tumor microenvironment which correlated with a prolonged time to disease progression. In addition, these responding patients initially expressed lower levels of PD-1 positive cells, an established marker of T-cell activation and disease outcome, prior to the initiation of therapy that was followed by a measurable rise post bavituximab treatment.

## About the Phase II Trial

In this Phase II non-randomized, open-label trial, 38 patients with advanced HCC received bavituximab weekly and sorafenib (400 mg) twice daily, until disease progression or toxicity. The primary endpoint of this trial is radiologic time to progression with imaging occurring at 6 week intervals. Secondary endpoints of this trial include overall survival (OS), progression free survival (PFS), safety and response rates. In order to leverage recent understandings surrounding the immune-stimulatory mechanism of action of bavituximab, several additional components have been installed into this portion of the trial. These include plasma and serum collection and tissue biopsies for evaluating changes in immune response following bavituximab treatment to assess whether combination therapy reactivates tumor immunity by changing the tumor microenvironment from immunosuppressive to immunoreactive by changing the tumor infiltrating cell composition or inducing T-cell response to tumor antigens.

More information on this trial can be found at [ClinicalTrials.gov](http://ClinicalTrials.gov) using the Identifier NCT01264705.

## 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 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 third-party 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 data from this trial may not be indicative of the results to be obtained from a future randomized Phase II trial. 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.

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