

Peregrine Pharmaceuticals Presents Preliminary Correlative Analysis of PD-L1 Expression from SUNRISE Trial at ASCO 2017

- -- Negative PD-L1 Expression was Associated with a Significantly Longer Median Overall Survival Compared to Positive PD-L1 Expression in Patients Receiving Docetaxel Plus Bavituximab --
- -- Presented Results Support Hypothesis that Bavituximab May Demonstrate Greater Effect in "Cold" Tumors Expressing
 Low to No PD-L1 --

TUSTIN, Calif., June 05, 2017 (GLOBE NEWSWIRE) -- Peregrine Pharmaceuticals, Inc. (NASDAQ:PPHM) (NASDAQ:PPHMP), a biopharmaceutical company committed to improving patient lives by advancing its proprietary R&D pipeline and manufacturing high quality products for biotechnology and pharmaceutical companies, today announced the presentation of promising new data from its Phase III SUNRISE trial of bavituximab in patients with previously treated locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC). Presented results demonstrated that patients in the study's bavituximab treatment arm who had low baseline PD-L1 expression levels had a statistically significant improvement in median overall survival (mOS) as compared to patients in the same treatment arm who had higher baseline levels of PD-L1. Data were presented by Peregrine scientists at the Annual Meeting of the American Society of Clinical Oncology (ASCO), being held June 2 - 6, 2017 in Chicago.

Data presented demonstrated that patients in the study's docetaxel plus bavituximab (D+B) treatment arm with a pretreatment PD-L1 expression level on tumor cells of < 1% (TC0) had a mOS of 12.1 months compared to a mOS of 6.1 months for patients with PD-L1 expression \geq 1% (TC1/2/3) (HR = 0.42 p=0.007). There was no difference in mOS based on PD-L1 expression levels observed in the study's docetaxel plus placebo (D+P) control arm (10.7 months for TC0 vs. 11.1 months for TC1/2/3; HR = 0.87; p=0.609).

"We believe that these latest observations from the SUNRISE trial further support the hypothesis that bavituximab, through its immune modulating mechanism, may have more effect on tumors without pre-existent immunity. These 'cold' tumors suppress normal anti-tumor immune response and are categorized by very low to no PD-L1 expression on tumor cells," said Joseph Shan, vice president of clinical and regulatory affairs at Peregrine. "These latest findings, along with other recently announced clinical and preclinical data from our PS-targeting program, inform our clinical development strategy going forward and provide additional rationale for combining bavituximab with checkpoint inhibitors."

As part of the SUNRISE clinical study protocol, researchers requested but did not require that patients provide a tumor tissue sample at the time of diagnosis. In total, tissue samples were collected from 129 of the trial's 597 patients and were assessed retrospectively for baseline PD-L1 expression levels on tumor cells. Of the 129 tissue samples collected, 122 were evaluable for PD-L1 expression on tumor cells (54 in D+B arm and 68 in D+P control arm). Of the evaluable samples in the D+B arm, 69% demonstrated PD-L1 expression levels < 1%, as compared to 59% in the D+P arm.

Bavituximab is an investigational immune-modulatory monoclonal antibody that targets phosphatidylserine (PS). PS inhibits the ability of immune cells to recognize and fight tumors. Bavituximab is believed to reverse PS-mediated immunosuppression by blocking the engagement of PS with its receptors as well as by sending an alternate immune activating signal. PS-targeting antibodies have been shown to shift the functions of immune cells in tumors, resulting in multiple signs of immune activation and anti-tumor immune responses.

Peregrine's clinical development strategy for bavituximab currently focuses on small, early-stage, proof-of-concept trials evaluating the drug in combination with other cancer treatments. This approach includes grants awarded by the National Comprehensive Cancer Network (NCCN) to support three different clinical trials of bavituximab treatment combinations. These trials will evaluate novel bavituximab combinations in glioblastoma, head and neck cancer, and hepatocellular carcinoma including an immunotherapy combination. Additionally, Peregrine continues to advance its pre-clinical collaboration with Memorial Sloan Kettering Cancer Center (MSK) with the goal of evaluating combinations of PS targeting antibodies with checkpoint inhibitors and other immune stimulatory agents. Peregrine's intent behind this strategy is to focus its research and development spending to further validate bavituximab's combination potential as the company seeks to advance the program though a pharmaceutical or biotechnology partner.

Peregrine Pharmaceuticals, Inc. is a biopharmaceutical company committed to improving the lives of patients by delivering high quality pharmaceutical products through its contract development and manufacturing organization (CDMO) services and through advancing and licensing its investigational immunotherapy and related products. Peregrine's in-house CDMO services, including cGMP manufacturing and development capabilities, are provided through its wholly-owned subsidiary Avid Bioservices, Inc. (www.avidbio.com), which provides development and biomanufacturing services for both Peregrine and third-party customers. The company is also working to evaluate its lead immunotherapy candidate, bavituximab, in combination with immune stimulating therapies for the treatment of various cancers, and developing its proprietary exosome technology for the detection and monitoring of cancer. 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 data from future bavituximab clinical trials may not show a statistically significant increase in median overall survival for bavituximab treated patients with PD-L1 expression levels of < 1%. 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, 2016 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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