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New Preclinical Data Presented at SITC Annual Meeting Highlight Bavituximab's Enhanced Anti-Tumor Activity When Combined With Checkpoint Inhibitors in Breast Cancer and Melanoma

- Bavituximab in Combination with Anti-PD-1 in Breast Cancer Studies Showed a Statistically Significant Improvement in Overall Survival as Compared to Subjects Receiving Anti-PD-1 Therapy Alone -

- New Custom-Designed Immuno-Profiling Clinical Test Provides Further Evidence of Bavituxmab's Immune Modulating Mechanism of Action in the Tumor Microenvironment -

TUSTIN, Calif., Nov. 09, 2015 (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 announced results from multiple new preclinical studies demonstrating enhanced anti-tumor activity and immune activation for combinations of a preclinical bavituximab equivalent and checkpoint inhibitors such as anti-PD-1 and anti-CTLA-4 in preclinical models of breast cancer and melanoma. Additionally, the company announced preliminary results for a new clinical test specifically designed to illustrate how bavituximab, the company's investigational phosphatidylserine (PS)-signaling pathway inhibitor, modulates immune responses in the tumor microenvironment. Results from these studies were presented at the 2015 annual meeting of the Society for Immunotherapy of Cancer (SITC), which was held in National Harbor, MD, on November 4 - 8, 2015.

"The positive data presented at SITC with regard to combinations of bavituximab and checkpoint inhibitors further support our belief that bavituximab has the potential to be a critical component of innovative combination cancer immunotherapies," said Jeff T. Hutchins, vice president preclinical development of Peregrine. "Particularly exciting is the new data in animal models of breast cancer which showed that a significantly greater number of subjects demonstrated anti-tumor activity when treated with the combination of bavituximab and anti-PD-1 as compared to treatment with anti-PD-1 alone. Additionally, combination treatment led to prolonged protection for animals as evidenced by their lack of new tumor development when later re-challenged with the same tumors."

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. Peregrine's PS signaling pathway inhibitor candidates, including bavituximab, reverse the immunosuppressive environment that many tumors establish in order to proliferate, while also fighting cancer by activating immune cells that target and fight cancer. The preclinical equivalent of bavituximab, ch1N11, is used in animal model studies as a guide for clinical development.

Breast Cancer

Researchers from Duke University and Peregrine evaluated the combination of ch1N11 (preclinical bavituximab equivalent) and anti-PD-1 therapy versus anti-PD-1 stand-alone therapy in well-characterized murine breast cancers, including the triple negative breast cancer (TNBC) model E0771. Study data showed that the combination therapy significantly enhanced overall survival ($p=0.0016$) and was capable of mediating complete tumor regressions in a greater number of subjects compared to single agent treatments (60% vs. 20%). Data also demonstrated that animals receiving combination treatment had significant increases in tumor associated indicators of immune system activation, including CD45+, CD8+ and CD3+ T-cells. Importantly, the combination treatment led to a prolonged anti-tumor immune response which protected the animals against a re-challenge with the same tumor. This sustained anti-tumor response suggests the potential of the combination therapy to trigger immune system memory and support adaptive immune responses against reemerging disease in breast cancers. All study animals experienced no signs of adverse effects following repeated doses of all therapeutic agents.

Melanoma

In follow-on work, researchers from the University of Texas, Southwestern and Peregrine evaluated combinations of ch1N11 and checkpoint inhibitors (anti-PD-1 or anti-CTLA-4) versus each agent as a stand-alone therapy in common models of melanoma (B16F10 and K1735). Data showed that the combinations of ch1N11 with either anti-PD-1 or anti-CTLA-4 led to significantly greater levels of tumor infiltrating CD8+ T cells than any of the three agents alone. Additionally, findings demonstrated that the combination therapies were more effective at shifting the tumor microenvironment from immunosuppressive to immune active than the single agents, as shown by greater increases in the ratio of T effector cells to T regulatory cells, reactivation of tumor

infiltrating T cells and restoration of the effector function of the tumor infiltrating T cells. This activity was more pronounced for the ch1N11/anti-PD-1 combination than for the ch1N11/anti-CTLA-4 combination. Based on these data, study investigators concluded that ch1N11 synergizes with checkpoint inhibitors to induce strong tumor specific CD8 T cell immunity.

"There is an extensive and growing collection of data that demonstrates that phosphatidylserine directly triggers broad immunosuppression in the tumor microenvironment and contributes to resistance to checkpoint inhibitor therapy. By targeting and blocking PS, bavituximab appears able to shift the tumor environment from immunosuppressive to immune active and, in turn, enhance the anti-tumor activity of checkpoint inhibitors such as anti-PD-1 and anti-CTLA4," said Bruce Freimark, Ph.D., director of pre-clinical oncology of Peregrine. "This latest data in well validated models of multiple tumor types further support our belief that bavituximab may be able to play an essential role in combination immuno-oncology treatment regimens. With this in mind, we are committed to evaluating the agent's potential in combination with a range of cancer therapies against various cancer types."

ImmunoProfiling

Researchers presented preliminary results for a new custom assay designed to provide detailed profiles of immune activity in patient tumors. The Opal™-6plex quantitative immunofluorescence (IF) assay is specifically designed to measure the level and type of lymphocytes, myeloid and dendritic cell subsets found within the tumor microenvironment. This information is important as it can be used to correlate immune response parameters with bavituximab treatment outcome and patient survival.

Presented results demonstrated that the Opal assay could reliably detect, measure and phenotype lymphocytes and monocytes present in tumor tissues from rectal adenocarcinoma, hepatocellular carcinoma and advanced melanoma patients treated with bavituximab combination therapies. Importantly, the findings were able to show changes in key indicators of immune activation, including CD8+, CD4+ and regulatory T-cells, as well as myeloid and dendritic cells, in the tumor microenvironment following bavituximab treatment. The ability of this new assay to accurately measure specific immune responses is expected to provide important additional information to assist in Peregrine's ongoing development efforts for bavituximab. This will be particularly valuable as the company works to better elucidate the connection between the drug candidate's impact on immunomodulation and patient response to treatment.

"We are very pleased with the performance of the Opal assay, particularly its ability to compare the interaction of up to six phenotypic and functional markers on a single slide of tissue. The power and prognostic value of such immune activity assessments in the area of cancer was initially established by the Immunoscore®, and we believe the Opal assay represents an important evolution of that work," said Bernard A. Fox, Ph.D., Harder Family Endowed Chair for Cancer Research, Member and Chief, Molecular and Tumor Immunology, Earle A. Chiles Research Institute, Providence Cancer Center; a world-renowned translational cancer immunotherapist; a founding member of the Immunoscore steering committee. "I am looking forward to continued collaboration with Peregrine to further optimize and validate this assay to improve our understanding of immune infiltrate in tumors thereby facilitating the rational design and use of bavituximab in combination with novel and standard therapies."

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, the lead compound in Peregrine's immuno-oncology development program, blocks PS to remove this immunosuppressive signal and sends an alternate immune activating signal. 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 with a pipeline of novel drug candidates in clinical trials focused on the treatment 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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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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