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New Translational Data Highlights Bavituximab's Ability to Induce Signs of Immune Activation in Lung Cancer Tumor Samples With Negative PD-L1 Expression

Oral Presentation at IASLC's World Conference on Lung Cancer Provides Rationale for Combining Peregrine Pharmaceuticals' Bavituximab With Chemotherapy and Immune Checkpoint Inhibitors

TUSTIN, Calif., Sept. 08, 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 positive new data from a translational study of bavituximab, the company's investigational phosphatidylserine (PS)-signaling pathway inhibitor. Findings demonstrated the ability of bavituximab, alone or in combination with docetaxel, to induce signs of immune activation in non-small cell lung cancer (NSCLC) patient-derived tumor samples, particularly when there was negative PD-L1 expression in the tumor sample. These data further support the potential mechanistic synergies for bavituximab with chemotherapy and checkpoint inhibitors targeting the PD-1/PD-L1 pathway. Results from the study are being presented as part of a mini-oral presentation at the International Association for the Study of Lung Cancer's (IASLC's) World Conference on Lung Cancer (WCLC), being held this week in Denver, Colorado.

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 macrophages and cytotoxic T cells in tumors.

For the study presented at the WCLC, researchers from Nilogen Oncosystems and the H. Lee Moffitt Cancer Center, in collaboration with Peregrine, evaluated immune changes in 3D tumor microspheres generated from human NSCLC fresh tumors extracted at the time of surgery. These were tumor microspheres were treated with bavituximab alone, docetaxel alone, a combination of bavituximab and docetaxel, and a control. Bavituximab, alone and in combination with docetaxel, induced activation of tumor infiltrating lymphocytes as demonstrated by a statistically significant increase in key immune-stimulating cytokines such as IFN-ɣ , TNF-α, and GM-CSF with a corresponding decrease in secretion of the immunosuppressive cytokine IL-10. Importantly, the bavituximab-affected immune response activity appeared to correlate with low PD-L1 expression on the tumor samples.

"These new translational data suggest 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 immune checkpoint inhibitors. By doing so, it is believed that bavituximab may hold potential to increase the number of patients able to respond to PD-1 and PD-L1 targeting immunotherapies," said Jeff Hutchins, vice president preclinical development of Peregrine. "These findings continue to expand our collection of translational data supporting the mechanism of action for bavituximab and corroborate our wide range of previously published preclinical study results. Taken together, these data provide us with growing confidence for our bavituximab development programs, including the ongoing Phase III SUNRISE clinical trial in NSCLC which is evaluating the same treatment combination used in these studies."

Additional bavituximab-related presentations are also being delivered during the ongoing WCLC. An oral presentation is scheduled to discuss previously announced study findings demonstrating that a combination of bavituximab and an anti-PD-1 antibody was more effective at reducing tumor burden in preclinical lung cancer models than either treatment alone. This oral presentation will be delivered by Rolf A. Brekken, Ph.D., of the University of Texas Southwestern Medical Center, on Wednesday, September 9. In addition, Peregrine is presenting a poster providing a general overview of the company's ongoing SUNRISE (**S**timulating Imm**U**ne Respo**N**se th**R**ough Bav**I**tuximab in a Pha**SE** III Lung Cancer Study) trial at the conference.

"A large and growing body of research continues to support our belief that, as a fundamental checkpoint inhibitor, bavituximab may have the potential to broadly enhance the therapeutic activity of a range of cancer treatments including chemotherapy, radiation and immunotherapies. These latest data being presented at the World Conference on Lung Cancer specifically highlight this synergistic potential in the area of checkpoint inhibitors by clearly illustrating the manner in which bavituximab is able to induce the appropriate immune responses required for a successful therapeutic response to anti-PD-1 and anti-PD-L1 agents," said Steven W. King, president and chief executive officer of Peregrine. "We look forward to continuing our investigation of bavituximab in combination with other immuno-oncology agents through our ongoing collaborations with AstraZeneca, the Memorial Sloan Kettering Cancer Center and UT Southwestern."

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 alter this immunosuppressive signal and send an immune activating signal. Targeting PS with bavituximab has been shown to shift the functions of immune cells in tumors, resulting in 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 previously treated non-small cell 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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