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Peregrine Pharmaceuticals Announces Initiation of an Investigator-Sponsored Trial Combining Its Immunotherapy Bavituximab and Ipilimumab (Yervoy®) in Advanced Melanoma

Randomized Trial to Evaluate Immune Activation Following Treatment With Immunotherapy Combination; Open Label Design Will Allow for Ongoing Evaluation of Clinical Results From Study

TUSTIN, CA -- (Marketwired) -- 04/23/14 -- Peregrine Pharmaceuticals, Inc. (NASDAQ: PPHM) (NASDAQ: PPHMP) today announced the opening of an investigator-sponsored trial (IST) of its investigational immunotherapy bavituximab in combination with Bristol-Myers Squibb's ipilimumab (Yervoy®), for the treatment of advanced melanoma. Bavituximab is an upstream immune checkpoint inhibitor that targets phosphatidylserine (PS), a highly immunosuppressive molecule exposed on cells that line tumor blood vessels and tumor cells. Preclinical data in a model of melanoma demonstrate that the combination of a bavituximab equivalent and ipilimumab yield enhanced anti-tumor activity compared to ipilimumab alone. The trial is being conducted at the University of Texas Southwestern Medical Center, Dallas, and led by Arthur E. Frankel, M.D., Professor of Internal Medicine at the Simmons Comprehensive Cancer Center. Bavituximab, Peregrine's lead immuno-oncology candidate, is being evaluated in second-line non-small cell lung cancer (NSCLC), as part of the SUNRISE pivotal Phase III clinical trial.

"We are pleased that this leading melanoma specialist is advancing this program into clinical development, recognizing that there are patients who may not respond to the current standard of care and that the combination of ipilimumab and bavituximab could potentially elicit anti-tumor immune responses in a larger proportion of patients," said Joseph Shan, MPH, vice president of clinical and regulatory affairs at Peregrine. "We are particularly excited as this trial is designed to provide proof-of-concept data for this potentially innovative upstream and downstream checkpoint inhibitor combination. In addition, the trial's open-label design allows for the potential for data readouts throughout the course of the trial."

This is an open label, two-arm, randomized, single-center Phase Ib trial of bavituximab plus ipilimumab (Yervoy®), in patients with advanced melanoma. Up to 24 patients will be randomized into the following two treatment groups:

- Group A will enroll up to 16 patients to receive 2 weekly doses of bavituximab (3mg/kg) followed by combination therapy of ipilimumab (up to four cycles at 3mg/kg every 3 weeks) plus bavituximab (3mg/kg weekly for 12 weeks)
- Group B will enroll up to 8 patients to receive standard ipilimumab alone (up to four cycles at 3mg/kg every 3 weeks)

The primary endpoint of the trial will be safety and secondary endpoints will include measurements of disease control rate (DCR) and overall survival (OS). In addition, tumor biopsies will be collected at screening to measure changes in myeloid-derived suppressor cells (MDSC), tumor-associated macrophages (TAM), T-regulatory cells (Treg) and peripheral blood cytokines. For more information on this trial please visit ClinicalTrials.gov using the identifier NCT01984255.

Preclinical Combination Data of PS-Targeting Antibody and Anti-CTLA-4 Antibody

Preclinical data have shown that phosphatidylserine (PS)-targeting antibodies reactivate tumor immunity at multiple levels and that the combination of a PS-targeting antibody equivalent to bavituximab and an anti-CTLA-4 antibody, an FDA-approved immunotherapy, resulted in superior tumor growth inhibition than with either antibody alone, with no additional toxicity following multiple treatment doses. In addition, histopathological analysis showed the combination produced more inflammatory cell infiltration and tumor destruction than anti-CTLA-4 alone.

About Melanoma

Melanoma is an aggressive and serious form of skin cancer that while generally considered to be preventable and treatable upon early detection, can be fatal if not diagnosed.[1,2] Advanced melanoma occurs when the cancer cells spread through the lymph nodes to other parts of the body. By 2019, worldwide cases of melanoma are expected to double to more than 227,000 from current levels.[3] According to the National Cancer Institute; in 2013 more than 76,000 new cases of melanoma were diagnosed in the United States.[4]

About Bavituximab: A Targeted Immunotherapy

Bavituximab is a first-in-class phosphatidylserine (PS)-targeting monoclonal antibody that represents a new approach to treating cancer. PS is a highly immunosuppressive molecule usually located inside the membrane of healthy cells, but "flips" and becomes exposed on the outside of cells that line tumor blood vessels, creating a specific target for anti-cancer treatments. PS-targeting antibodies target and bind to PS and block this immunosuppressive signal, thereby enabling the immune system to recognize and fight the tumor. These data, detailing the immune-stimulatory mechanism of action of PS-targeting antibodies, such as the company's lead drug candidate bavituximab, are the subject of a manuscript published in the October 2013 issue of the American Association for Cancer Research (AACR) peer-reviewed journal, *Cancer Immunology Research*. As part of the SUNRISE trial, bavituximab is being evaluated in a Phase III, global, randomized, double-blind, placebo-controlled clinical trial designed to evaluate the safety, tolerability and efficacy of bavituximab plus docetaxel as second-line treatment in patients with non-small cell lung cancer. Bavituximab is also currently being evaluated in several solid tumor indications, including breast cancer, liver cancer and rectal cancer. For additional information about the SUNRISE trial please visit www.SunriseTrial.com or ClinicalTrials.gov using Identifier NCT01999673.

About SUNRISE Trial:

SUNRISE is a pivotal Phase III, randomized, placebo-controlled, double-blind, multinational clinical trial evaluating the efficacy and safety of bavituximab (bav i tux' i mab), a novel investigational immunotherapy, plus docetaxel versus placebo plus docetaxel as a second-line treatment for patients with Stage IIIb/IV non-squamous non-small cell lung cancer (NSCLC). For more information about the SUNRISE trial, please visit: www.SunriseTrial.com

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 is developing multiple clinical programs in cancer with its lead immunotherapy candidate bavituximab, while seeking a partner to further advance its novel brain cancer agent Cotara®. 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. Additional information about Peregrine can be found at 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 the results from the Phase Ib trial of bavituximab plus ipilimumab (Yervoy®) in patients with advanced melanoma may not correlate with the data from the preclinical studies. 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, 2013 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.

Yervoy is a registered trademark of Bristol-Meyers Squibb.

1. Leong, S.P. Future perspectives on malignant melanoma. *Surg Clin North Am* 83, 453-456, x (2003).

2. Creagan ET. Malignant melanoma: an emerging and preventable medical catastrophe. *Mayo Clin Proc* 1997;72(6):570-4.

3. Data Monitor Report. Melanoma cases to double. Press release. Available from http://about.datamonitor.com/media/archives/4380 (Accessed March 2014) (2010).

4. National Cancer Institute. http://www.cancer.gov/cancertopics/types/melanoma (Accessed March 2014).

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