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# Peregrine Announces Initiation of Phase I/II Prostate Cancer Investigator-Sponsored Trial (IST)

# New Trial Supported by Preclinical Data Showing Bavituximab-Equivalent Antibody Plus Taxane-Based Chemotherapy Reduced Castration-Resistant Prostate Cancer Primary Tumor Burden by 95% and Completely Inhibited Metastatic Disease Fourth IST to Evaluate Bavituximab's Broad Therapeutic Potential for Oncology Indications

TUSTIN, CA and IRVINE, CA -- (MARKET WIRE) -- 05/25/11 -- Peregrine Pharmaceuticals, Inc. (NASDAQ: PPHM), a clinicalstage biopharmaceutical company developing first-in-class monoclonal antibodies for the treatment of cancer and viral infections, today announced the initiation of an investigator-sponsored trial (IST) for patients with castration-resistant prostate cancer (CRPC). Peregrine's fourth IST, this Phase I/II trial will treat up to 31 second-line CRPC patients with Peregrine's investigational monoclonal antibody bavituximab in combination with the chemotherapeutic agent cabazitaxel.

"Once prostate cancer patients have failed treatment with docetaxel-based chemotherapy, options are unfortunately limited," said Michael Lilly, M.D., principal investigator and professor of clinical medicine, Division of Hematology-Oncology at The University of California, Irvine. "As the first approved agent for second-line CRPC, cabazitaxel provides modest survival benefits, but there remains significant room for improvement in the treatment of this patient population. We look forward to evaluating whether the combination of bavituximab and cabazitaxel can extend progression-free survival in these patients."

In multiple clinical trials, bavituximab combined with taxane-based chemotherapies has demonstrated promising signs of antitumor activity and a positive safety profile. In a preclinical model of CRPC, a bavituximab-like antibody combined with taxanebased chemotherapy yielded potent anti-tumor effects, reducing primary tumor burden by 95% and completely inhibited metastatic development.

Bavituximab is also being evaluated in randomized Phase II trials in non-small cell lung cancer (NSCLC), pancreatic cancer, and hepatitis C virus (HCV) infection, as well as multiple ISTs in different oncology indications.

# About the Phase I/II Prostate Cancer Trial

This Phase I/II single-arm, open-label trial will include up to 31 CRPC patients who have been previously treated with docetaxel or a docetaxel-containing regimen. Patients will receive weekly bavituximab with up to eight 21-day cycles of the drug cabazitaxel administered on day one of each cycle. The primary endpoint of the study is to determine the progression-free survival (PFS) frequency after 12 weeks. Secondary endpoints include measurement of PSA response rate, objective response rate by RECIST for patients with measurable disease, overall survival, and safety parameters.

This trial is being conducted by the Chao Family Comprehensive Cancer Center at the University of California, Irvine, through a nationwide consortium of investigators.

For further information about this trial, please visit <u>http://www.peregrinetrials.com</u> or <u>http://www.clinicaltrials.gov/ct2/show/NCT01335204?term=bavituximab&rank=6</u>.

#### About Bavituximab

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.

# About Peregrine's Investigator-Sponsored Trials (IST) Program

Peregrine's IST program offers oncologists the opportunity to conduct clinical trials with bavituximab. To apply for Peregrine's IST program, please visit <u>http://www.peregrineinc.com/pipeline/investigator-sponsored-trials.html</u>.

#### About Prostate Cancer

According to the American Cancer Society, prostate cancer is the second leading cause of cancer death in American men,

behind only lung cancer. In 2010, roughly 217,000 new cases of prostate cancer were diagnosed in American men and roughly 32,000 men died of the disease.

### About Peregrine Pharmaceuticals

Peregrine Pharmaceuticals, Inc. is a biopharmaceutical company with a portfolio of innovative monoclonal antibodies in clinical trials for the treatment of cancer and serious viral infections. The company is pursuing multiple clinical programs in cancer and hepatitis C virus infection with its lead product candidate bavituximab and 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 outside 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 forwardlooking statements involve risks and uncertainties including, but not limited to, the risk that results from investigator-sponsored trials will not be consistent with results experienced in earlier clinical trials and preclinical studies, the risk that investigators may experience delays in patient enrollment, risk that results may not support registration filings with the U.S. Food and Drug Administration, and the risk that Peregrine may not have or raise adequate financial resources to complete the planned clinical programs. Factors that could cause actual results to differ materially or otherwise adversely impact the company's ability to obtain regulatory approval for its product candidates 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 the company's SEC reports including, but not limited to, the annual report on Form 10-K for the year ended April 30, 2010 and the quarterly report on Form 10-Q for the quarter ended January 31, 2011. 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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