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Peregrine Pharmaceuticals Submits Clinical Protocol for New Phase II Trial of Baviximab in Patients With Metastatic Breast Cancer

TUSTIN, Calif., Oct. 22 /PRNewswire-FirstCall/ -- Peregrine Pharmaceuticals, Inc. (Nasdaq: PPHM), a clinical stage biopharmaceutical company developing monoclonal antibodies for the treatment of cancer and hepatitis C virus (HCV) infection, today announced that it has submitted a Phase II clinical protocol with the Ministry of Health of the Republic of Georgia to study baviximab in combination with the chemotherapy drug docetaxel in patients with metastatic breast cancer. The open label, multi-center safety and efficacy trial will begin enrolling patients pending regulatory and ethics committee approvals.

The new trial has a two-stage design. Up to 15 patients with metastatic breast cancer will be enrolled initially and the study will be expanded up to a total of 46 patients if promising results are observed in the first cohort. The primary objective is to assess the overall response rate to the combination of baviximab with docetaxel, a chemotherapy drug commonly used in the treatment for metastatic breast cancer. Secondary objectives include measuring time to tumor progression, duration of response, overall patient survival and safety parameters. The study is expected to enroll patients at a minimum of three clinical trial sites.

"The filing of this second breast cancer protocol continues our strategy of evaluating baviximab in Phase II combination studies in specific cancer indications," said Steven W. King, president and CEO of Peregrine. "This study also marks our first clinical initiative in Eastern Europe, which has become a major venue for global clinical trials conducted according to International Conference on Harmonization (ICH) and Good Clinical Practices (GCP) standards. The sites we are working with have solid experience in conducting mid and late stage cancer trials that adhere to FDA and international standards. We have been impressed to date by the professionalism of their operations, the efficiency of their patient recruitment infrastructure and their commitment to patient welfare."

Tumor response in this new study will be evaluated using Response Evaluation Criteria in Solid Tumors (RECIST) parameters. The trial is being conducted according to ICH and GCP guidelines.

According to the World Health Organization, metastatic breast cancer is the most commonly diagnosed cancer in women, and is second only to lung cancer as a leading cause of female cancer deaths. The National Cancer Institute estimates that 178,480 U.S. women will be diagnosed with cancer of the breast in 2007 and 40,460 women will die of the disease.

Baviximab is a monoclonal antibody that binds to a phospholipid called phosphatidylserine that is normally located inside normal cells, but which becomes exposed on the outside of the cells that line the blood vessels of tumors, creating a specific target for anti-cancer treatments. Baviximab is believed to help mobilize the body's immune system to destroy the blood vessels needed for tumor growth and spread. In a Phase Ib trial in advanced cancer patients, baviximab plus chemotherapy appeared to have a safety profile consistent with chemotherapy alone and showed positive signs of clinical activity, achieving objective response or disease stabilization in 50% of the evaluable patients. A protocol for a Phase II trial of baviximab in combination with the chemotherapy drugs paclitaxel and carboplatin in patients with metastatic breast cancer is currently undergoing regulatory review in India. A protocol for a Phase II trial of baviximab in combination with chemotherapy in patients with non-small cell lung cancer (NSCLC) is also under regulatory review in India. Baviximab is in clinical trials in the U.S. in patients with advanced solid tumors and in patients co-infected with HCV and HIV.

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 protocol will not be approved, the risk that the company will experience delays or difficulties in enrolling patients in the study, and the risk that the results from this trial will not be consistent with the results of prior trials or pre-clinical 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 the company's SEC reports including, but not limited to, the annual report on Form 10-K for the year ended April 30, 2007 and quarterly report on

Form 10-Q for the quarter ended July 31, 2007. 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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