February 4, 2009

Peregrine Pharmaceuticals' Bavituximab Achieves Primary Endpoint in First Stage of Phase II Lung Cancer Study

TUSTIN, Calif., Feb 04, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- -Preliminary Data Show Seven of 17 Evaluable Patients Achieved an Objective Tumor Response by End of Four Treatment Cycles-

Peregrine Pharmaceuticals, Inc. (Nasdaq: PPHM) today reported that its lead product candidate bavituximab achieved the primary efficacy endpoint in the first stage of its ongoing Phase II clinical trial in patients with non-small cell lung cancer (NSCLC). The open-label, Simon two-stage study is designed to evaluate the safety and efficacy of the combination of bavituximab with the chemotherapy drugs carboplatin and paclitaxel in NSCLC patients. Seventeen of the 21 patients enrolled in Stage A were deemed evaluable for tumor response by the end of four treatment cycles, with six patients achieving partial tumor responses and one patient achieving a complete tumor response, according to RECIST criteria. These preliminary results exceed the pre-specified benchmark criteria established for enrolling an additional 28 patients in Stage B of this trial, up to a total of 49 patients.

"We are very pleased with the promising early results from this pilot Phase II lung cancer trial and will now move forward to initiate the second stage of the study," said Steven W. King, president and CEO of Peregrine. "We are encouraged by the number of tumor responses seen at this early time point of approximately 12 weeks in patients with NSCLC, a leading cause of cancer deaths that responds poorly to current treatments. As these patients continue on treatment, we will be assessing them for further signs of anti-tumor activity, and we look forward to sharing more data from this study as patient treatment and follow-up progress."

The primary objective of the multi-center Phase II clinical trial in patients with previously untreated locally advanced or metastatic NSCLC is to assess the overall tumor response rate. Secondary objectives include measuring time to tumor progression, duration of response, overall patient survival and safety parameters. All tumor responses in the trial are being evaluated using RECIST criteria. Patients may continue to receive bavituximab alone after completion of chemotherapy as long as the cancer does not progress and side effects are acceptable. The trial is being conducted in India according to International Conference on Harmonization (ICH) and Good Clinical Practices (GCP) guidelines.

Lung cancer is a major cause of cancer deaths worldwide. According to the American Cancer Society, in the U.S. lung cancer is the second most commonly diagnosed cancer in men and women and is the leading cause of cancer deaths. It estimates that in the U.S. in 2008, there were approximately 215,020 new cases of lung cancer and an estimated 161,840 lung cancer deaths. NSCLC is the most common type of lung cancer, accounting for approximately 85-90% of lung cancer cases.

Bavituximab is a monoclonal antibody that binds to the cellular membrane component phosphatidylserine (PS) that is usually located inside 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. By binding to PS, bavituximab is believed to help mobilize the body's immune system to destroy the tumor and the tumor blood vessels. Bavituximab currently is in two separate Phase II combination therapy trials for the treatment of advanced breast cancer and a Phase II combination therapy trial for the treatment of non-small cell lung cancer. A Phase I bavituximab monotherapy trial in advanced solid cancers is also continuing.

About Peregrine Pharmaceuticals

Peregrine Pharmaceuticals, Inc. is a biopharmaceutical company with a portfolio of innovative product candidates in clinical trials for the treatment of cancer and hepatitis C virus (HCV) infection. The company is pursuing three separate clinical programs in cancer and HCV infection with its lead product candidates bavituximab and Cotara(R). Peregrine also has in-house manufacturing capabilities through its wholly owned subsidiary Avid Bioservices, Inc. (www.avidbio.com), which provides development and bio-manufacturing 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 forward-looking statements involve risks and uncertainties including, but not limited to, the risk that the company will experience delays or difficulties in enrolling patients in the study, the risk that the standard carboplatin and paclitaxel response rate will not be

improved as a result of the combination therapy and the risk that the results of the subsequent stage for this trial will not be consistent with the results of the first stage. 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, 2008 and the quarterly report on Form 10-Q for the quarter ended October 31, 2008. 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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