



June 7, 2006

## **Peregrine's Bavituximab Shows Promising Anti-Viral Activity and Signs of Prolonged Anti-Viral Effect in Single Dose Monotherapy HCV Trial**

- First Human Efficacy Data From Phase Ia Trial Indicates Encouraging Anti-Viral Activity for First-in-Class Targeted Anti-PS Agent -

- Repeat Dose Phase Ib Trial of Safety and Biodistribution in HCV Patients Underway -

- Enrollment of Additional High Dose Patient Cohort in Phase Ia Trial Complete -

TUSTIN, Calif., June 7 /PRNewswire-FirstCall/ -- Peregrine Pharmaceuticals, Inc. (Nasdaq: PPHM), a biopharmaceutical company developing targeted therapeutics for the treatment of cancer and hepatitis C virus infections, today reported top-line results on the effect of bavituximab (formerly Tarvacin) on viral RNA serum titers when administered as single dose monotherapy in a Phase Ia study in patients with chronic hepatitis C virus (HCV) infection. In this analysis, bavituximab showed signs of anti-viral activity at all four study dose levels, and it also showed evidence of a prolonged anti-viral effect.

These preliminary efficacy data follow positive safety data from the Phase Ia study that Peregrine reported on February 27, 2006, indicating that bavituximab was well tolerated, with no dose limiting toxicities observed. Peregrine also announced today two additional milestones in the bavituximab HCV clinical program. First, the company has completed the treatment phase of an additional, higher dose cohort that was added to the Phase Ia HCV study after the first four cohorts were complete, and second, it has begun dosing patients in a new Phase Ib repeat dose study in HCV patients.

In the Phase Ia study, more than 90% of the subjects were infected with the genotype 1 form of HCV, which is the most common and difficult to treat strain of the virus. All participants had failed or relapsed after receiving standard-of-care treatments. Subjects were administered bavituximab at 0.1, 0.3, 1 or 3 milligram per kilogram (mg/kg) of body weight.

After a single dose of bavituximab, among patients treated with the higher 1mg/kg and 3mg/kg dose levels, 50% achieved a greater than 75% (0.6 log) reduction in serum HCV RNA with a maximum 97% (1.5 log) reduction. These patients had an average reduction in serum HCV RNA levels of 0.8 log during the course of the 12-week follow-up period. Signs of anti-viral activity were seen at all dose levels including the initial dose of 0.1mg/kg. Even at this low dose, one-third of patients experienced a greater than 75% (0.6 log) reduction in serum HCV RNA levels.

Bavituximab also showed signs of durable anti-viral activity after a single dose, with some subjects achieving a greater than 80% (0.7 log) reduction in viral load by day four and maintaining a greater than 60% reduction in serum HCV levels up through the end of the study at week 12.

"This preliminary evidence of anti-viral activity in this first-in-human single dose study of bavituximab is very encouraging," said Dr. Eliot W. Godofsky, principal investigator of the Phase Ia study, and director of the University Hepatitis Center in Sarasota Florida. "Bavituximab is a potentially novel approach to treating chronic hepatitis C infection, one with a unique mechanism of action that should complement both existing and investigational therapies in development. Based on its safety profile to date and these promising signs of anti-viral activity, we look forward to working with Peregrine to assess bavituximab in the repeat dose trial, as well as its potential for use in combination regimens to control and ultimately eradicate HCV."

These initial efficacy findings for a single dose of bavituximab are noteworthy for several reasons. First, the rapid virus production and turnover characterizing HCV infection typically limit the impact of a single dose of any anti-viral drug. Second, preclinical data supports that bavituximab's unique mechanism of action, which mobilizes the body's immune system to attack the hepatitis C virus, is likely to be most effective when administered as part of a multiple dose regimen. Third, most other investigational drugs for HCV infection have reported initial efficacy results following multiple dose or combination regimens that include standard-of-care therapies. In this study bavituximab was administered as monotherapy to patients who had failed standard treatment. In view of these factors, the anti-viral activity demonstrated in this single dose, monotherapy study is all the more encouraging.

"We are delighted with these first positive indicators of bavituximab's anti-viral potential in HCV patients," said Steven W. King, president and CEO of Peregrine. "The initial human results for this first-in-class novel agent are very promising. Its excellent overall safety profile to date, early evidence of anti-viral activity and signs of prolonged duration of activity give additional impetus to our efforts to advance bavituximab as a potential new therapy for the treatment of HCV and other serous viral infections."

Joseph Shan, Peregrine's executive director of clinical and regulatory affairs, added, "These first efficacy results in humans are particularly exciting because researchers did not expect to see much anti-viral activity after a single dose of drug, based on our experience in lethal animal disease models such as Lassa fever. Bavituximab demonstrated good anti-viral activity in these studies, but only after administration of multiple doses. Based on the results reported today, the drug's anti-viral potential may be even more promising in humans than the animal models suggest."

Patients in the fifth dosing cohort (6mg/kg) of the Phase Ia HCV study are currently in the 12-week follow-up period, and data from this group will be available later this year. The repeat dose Phase Ib HCV study that is underway is designed to evaluate multiple doses of bavituximab for safety as well as assessing changes in serum HCV RNA levels. Enrollment in this study is expected to be completed by the end of the year.

#### About the Bavituximab Phase Ia Clinical Trial

The primary objective of the Phase Ia study was to determine safety and pharmacokinetic (PK) properties of bavituximab single dose monotherapy. Changes in viral HCV RNA levels were monitored as a secondary goal of the trial. Under the initial protocol, a total of 24 HCV infected patients were treated in cohorts of six with a single intravenous dose of bavituximab as a monotherapy at 0.1, 0.3, 1 or 3mg/kg, and the patients were monitored for safety, pharmacokinetics and viral load changes for 12 weeks. Based on the positive safety profile at the highest planned dose, a fifth cohort of six patients at 6mg/kg was added. Dosing at 6mg/kg has been completed and subjects are currently in the 12-week follow-up period. Bavituximab appears to be well tolerated to date at all dose levels, including the 6mg/kg dose level.

#### About the Bavituximab Phase Ib Clinical Trial

The primary objective of the multi-center Phase Ib study is to determine safety and pharmacokinetic properties of bavituximab as a multiple dose monotherapy. Changes in serum HCV RNA levels and selected cytokines will be monitored. The trial will enroll up to 24 patients (4 cohorts of 6 patients) with each cohort receiving 4 doses of bavituximab over a 14-day period. Patients will then be followed for 12 weeks. The dosing regimen for this study was based on safety, PK and viral load data collected during the Phase Ia clinical trial. Patient treatment in the Phase Ib trial has been initiated.

#### About Bavituximab

Bavituximab (formerly Tarvacin) is the first investigational agent in a new class of anti-phosphatidylserine (PS) immunotherapeutics that targets and binds to cellular components that are normally not present on the outside of cells, but which become exposed on certain virally infected cells and on the surface of enveloped viruses. Bavituximab helps stimulate the body's immune defenses to destroy both the virus particles and the infected cells. Similar to the proposed anti-viral mechanism, anti-phospholipid immunotherapeutic agents also bind to phospholipids exposed on tumor blood vessels in all solid cancers tested to date, having shown promise in a number of preclinical cancer models. Bavituximab is in Phase I clinical trials for the treatment of advanced refractory solid tumor cancers.

#### About Peregrine

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 trials in cancer and HCV infection with its lead product candidate bavituximab (formerly Tarvacin) and Cotara®. Peregrine also has in-house manufacturing capabilities through its wholly owned subsidiary Avid Bioservices, Inc. ([www.avidbio.com](http://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](http://www.peregrineinc.com).

#### Safe Harbor Statement:

Statements in this press release which are not purely historical, including statements regarding Peregrine Pharmaceutical's 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 bavituximab's safety profile in a repeat dose trial or in a combination therapy trial will not be at the same safety level as was found in the phase Ia trial, the risk that the results of future trials will not correlate to the results from the phase Ia trial, and the risk that bavituximab will not be as well tolerated at ascending doses. 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, 2005, and the quarterly report on Form 10-Q for the quarter ended January 31, 2006. 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.

SOURCE Peregrine Pharmaceuticals, Inc.

CONTACT: Investors, Brod & Schaffer, +1-800-987-8256, [ir@peregrineinc.com](mailto:ir@peregrineinc.com); or Media, Stephen Gendel, or Barbara Lindheim, both of GendeLLindheim BioCom Partners, +1-212-918-4650, all for Peregrine Pharmaceuticals, Inc.