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## **Peregrine Initiates Randomized Phase II Trial of Bavituximab in Chronic Hepatitis C**

### **Open-Label Trial Evaluating 12 Weeks of Therapy With Novel Targeted Antibody Bavituximab in Combination With Ribavirin Versus Standard of Care**

TUSTIN, CA -- (MARKET WIRE) -- 01/10/11 -- Peregrine Pharmaceuticals, Inc. (NASDAQ: PPHM), a clinical-stage biopharmaceutical company developing first-in-class monoclonal antibodies for the treatment of cancer and viral infections, today announced that it has initiated a randomized Phase II clinical trial in patients with previously untreated genotype-1 hepatitis C virus (HCV) infection. This open-label trial will determine the early virologic response (EVR) rate of patients after 12 weeks of therapy with Peregrine's bavituximab, a phosphatidylserine (PS)-targeting monoclonal antibody with immune-modulating potential, in combination with the antiviral drug ribavirin versus standard of care, pegylated interferon alpha 2a and ribavirin. Peregrine expects to complete enrollment shortly in an ongoing Phase Ib HCV trial and report data by mid-year.

"Our fourth randomized Phase II trial evaluating bavituximab for oncology and viral infections is designed to build on our three prior Phase I HCV trials, which have demonstrated our antibody's acceptable safety and promising signs of antiviral activity," said Steven W. King, president and chief executive officer of Peregrine. "Although there are several targeted antiviral drug candidates in development against HCV, immune stimulation with interferon remains a cornerstone of the standard HCV regimen, but unfortunately causes serious side effects and unacceptable toxicity for many patients. With bavituximab's immune reactivation mechanisms and safety profile to date, we are eager to assess this new combination as a potential alternative to interferon-based regimens for patients infected with HCV."

Bavituximab may address a fundamental "immune evasion" mechanism exploited by many infectious pathogens. A growing body of published data from researchers worldwide shows that bavituximab's PS target, exposed on the surface of cells infected by viruses and protozoan parasites, suppresses the immune system's ability to fight disease. PS-targeting antibodies such as bavituximab bind to PS and block the immunosuppressive signals created by the target, thereby allowing the immune system to mount a robust immune response against the pathogen. In prior HCV clinical trials, bavituximab administered as monotherapy in single and multiple doses demonstrated a positive safety profile with no dose-limiting toxicities or serious adverse events. Bavituximab as a monotherapy also showed promising on therapy antiviral activity of up to 1.5 log viral load reduction.

#### *About the Phase II HCV Trial*

In this multicenter Phase II randomized, open-label trial, up to 66 patients with previously untreated genotype-1 chronic HCV infection will be randomly assigned to one of three treatment arms. Patients will receive daily oral ribavirin (1000 mg) with either weekly bavituximab (0.3 mg/kg or 3 mg/kg) or PEG-IFN alpha-2a (180 µg) for up to 12 weeks and will be tested for safety parameters and antiviral activity.

The primary endpoint of the study is the proportion of patients achieving early virologic response (EVR), an early predictor of which patients are likely to clear virus with continued treatment. EVR is defined as a greater than or equal to 2 log reduction in HCV RNA after 12 weeks of treatment. Secondary endpoints include safety, tolerability and HCV viral kinetics. For further information about this trial, please visit [www.peregrinetrials.com](http://www.peregrinetrials.com) or <http://www.clinicaltrials.gov/ct2/results?term=bavituximab>.

#### *About HCV*

According to the U.S. Centers for Disease Control and Prevention, an estimated 3.2 million individuals in the United States have chronic hepatitis C virus (HCV) infection. Chronic HCV infection is a serious disease that can result in long-term health problems, including liver damage, liver failure, liver cancer, or death. It is the leading cause of cirrhosis and liver cancer and the most common reason for liver transplant in the United States. Approximately 8,000 to 10,000 people die every year from HCV-related liver disease.

#### *About Bavituximab's Antiviral Approach*

Bavituximab is the first in a new class of patented antibody therapeutics that target and bind to phosphatidylserine (PS), a specific phospholipid component of cell membranes. Bavituximab helps reactivate and direct the body's immune system to destroy infected cells and virus particles that exhibit this specific phospholipid on their surface. Since their target is host-derived rather than pathogen-derived, PS-targeting antibodies have the potential for broad-spectrum antiviral activity and are also expected to be much less susceptible to the viral mutations that often lead to drug resistance.

Researchers have found that PS is exposed on the outer membrane of cells infected with HCV, HIV, influenza, herpes viruses, hemorrhagic fever viruses, respiratory syncytial virus, measles as well as other viruses. A growing body of scientific publications, including Nature Medicine and The Journal of Experimental Medicine, has highlighted data on the role of PS and Peregrine's PS-targeting therapies in infectious diseases.

#### *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 baviximab 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](http://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](http://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 results from the Phase II HCV trial will not be consistent with results experienced in earlier HCV 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 October 31, 2010. 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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