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Positive Results From Peregrine Pharmaceuticals' Bavituximab Phase I HCV Trial Presented at AASLD Meeting

- Bavituximab Appeared Generally Safe and Well Tolerated at All Doses Tested -
- Signs of Anti-viral Activity Seen at All Dose Levels -
- Exploratory Analysis of Cytokine Profile Following Treatment Supports Proposed Immunomodulatory Mechanism of Action -

TUSTIN, Calif. and BOSTON, Nov. 5 /PRNewswire-FirstCall/ -- Peregrine Pharmaceuticals, Inc. (Nasdaq: PPHM), a biopharmaceutical company developing monoclonal antibodies for the treatment of cancer and hepatitis C virus (HCV) infection, today announced that results from its Phase Ib study of bavituximab in chronic HCV patients were discussed on Sunday in an oral presentation at the 58th Annual Meeting of the American Association for the Study of Liver Disease (AASLD) -- The Liver Meeting®. The study results were presented by Dr. Eric J. Lawitz, a principal investigator of the Phase Ib study and director of Alamo Medical Research.

The multiple dose, open label study was designed to assess the safety and pharmacokinetic properties of ascending dose levels of bavituximab administered as monotherapy in patients with chronic HCV infection. Other study objectives included evaluation of anti-viral activity as measured by changes in serum HCV virus levels and an exploratory analysis of changes in serum cytokine levels as a measure of bavituximab's ability to stimulate certain components of the immune system.

Results indicate that bavituximab was generally safe and well tolerated, with no dose limiting toxicities or serious adverse events reported. Anti-viral activity (decline of greater than or equal to 0.5 log₁₀ reduction in HCV RNA) was observed at all dose levels and was most consistent in patients receiving 3 mg/kg of bavituximab. In this cohort, 83% of the patients demonstrated anti-viral activity. An assessment of the cytokine profile in this cohort also suggests bavituximab induces a pro-inflammatory cytokine profile, defined as an increase in the ratio of TNF alpha and TGF beta. Stimulating an immune response is a key proposed anti-viral mechanism of action of bavituximab.

"Meeting all of the objectives of this Phase I trial was an important milestone for the bavituximab HCV program," said Steven W. King, president and CEO of Peregrine. "We are particularly pleased with bavituximab's positive safety profile at all doses tested, its predictable and consistent pharmacokinetic characteristics, and the signs of anti-viral activity and immune system stimulation that were observed. Based on these results, we have been able to identify a target dose range of 3 mg/kg for future clinical studies."

Twenty-four patients received bavituximab twice weekly for two weeks at escalating dose levels of 0.3, 1, 3, or 6 mg/kg of body weight. They were followed through week 12 of the study. All study patients had chronic HCV infection based on their medical history and the presence of detectable serum HCV RNA and elevated liver enzymes. More than half of the patients had genotype 1 HCV, the most difficult-to-treat strain. This study included treatment naive patients, patients who were partial responders to standard interferon/ribavirin HCV treatment regimens, and patients who were non-responders or treatment failures when given standard HCV regimens.

"Future hepatitis C therapy will likely require multiple mechanisms of action, including an immune modulating agent," said Dr. Lawitz. "Bavituximab has a novel targeted immunomodulatory mechanism and if proven effective, it has the potential to be complementary to emerging new anti-viral therapies for HCV infection."

Peregrine has initiated a new bavituximab trial in HCV patients co-infected with HIV and is planning additional combination therapy HCV studies.

About Bavituximab

Bavituximab is the first investigational agent in a new class of anti-phosphatidylserine (PS) monoclonal antibody immunotherapeutics that target and bind 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. Since bavituximab's PS target comes from the host and not the virus, bavituximab is expected to be less susceptible to the development of anti-viral resistance than many other therapies. Bavituximab has successfully completed two Phase I clinical trials as monotherapy in patients with chronic HCV infection and is currently being assessed in a trial for the treatment of HCV in patients co-infected with HIV. Similar to the

proposed anti-viral mechanism, anti-PS antibodies also bind to phospholipids exposed on tumor blood vessels in all solid cancers tested to date. Baviximab has successfully completed a Phase I trial in combination with chemotherapy in patients with advanced solid tumors. Protocols for three Phase II cancer trials in combination with chemotherapy are undergoing regulatory review.

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 in the U.S. and India with its lead product candidates baviximab and Cotara[®]. Peregrine also has in-house manufacturing capabilities through its wholly owned subsidiary Avid Bioservices, Inc. (<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 <http://www.peregrineinc.com>.

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