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New Study Shows Combining Peregrine's Bavituximab With an Apoptosis-Inducing Agent Can Eradicate Tumors in a Model of Advanced Breast Cancer

Study Published in Breast Cancer Research and Treatment Shows Combination Therapy Eradicated 30% of Tumors in Advanced Breast Cancer Model

TUSTIN, CA, Apr 15, 2010 (MARKETWIRE via COMTEX News Network) -- Peregrine Pharmaceuticals, Inc. (NASDAQ: PPHM) today announced the publication of new data highlighting the tumor-killing potential of its lead phosphatidylserine (PS)-targeting antibody bavituximab in combination with an agent that induces apoptosis, or programmed cell death. In this study published in the journal Breast Cancer Research and Treatment, bavituximab combined with an investigational apoptosis-inducing drug produced powerful anti-tumor effects, completely eradicating 30% of tumors in a model of advanced breast cancer. More than half of human breast cancers involve suppression of normal apoptosis. Bavituximab in combination with chemotherapy is in ongoing Phase II clinical trials for the treatment of advanced breast cancer and non-small cell lung cancer.

"The combination therapy with a PS-targeting antibody and an apoptosis-inducing agent was extremely effective in suppressing tumor growth, completely eradicating 30% of tumors without producing toxicities at any dose level," commented Dr. Philip Thorpe, co-author of the study, professor of pharmacology at University of Texas Southwestern Medical Center and scientific advisor to Peregrine. "Suppression of the p53 gene that controls normal cell death is an important feature in half of all breast cancers. In this study, PRIMA-1 acted both to restore normal p53 function and upregulate bavituximab's PS target, producing powerful synergistic results by further enhancing the immune-stimulating, anti-tumor activity of the PS-targeting antibody. These synergistic mechanisms may represent a promising new approach for treating advanced breast tumors."

In these two preclinical breast tumor studies conducted at the University of Missouri-Columbia, scientists evaluated a bavituximab-equivalent antibody 2aG4 in combination with PRIMA-1, a small molecule investigational drug that targets abnormal p53, a protein present in half of all breast cancer cases that suppresses apoptosis, or normal cell death. Among its multiple anti-tumor effects, PRIMA-1 increases tumor cell apoptosis which in turn exposes PS, the target for Peregrine's antibodies.

Results showed the combination therapy was more effective than either treatment alone at reducing the tumor growth rate and the incidence of lymph node metastasis in two different tumor models. In one of the models, 30% of the tumors were completely eradicated following combination therapy, compared to none in the control group animals.

"Our PS-targeting antibodies have broad-spectrum potential and fit very nicely with existing and emerging cancer treatments, showing consistent increases in anti-tumor effects when used in combination with cancer treatments with different mechanisms of action, including chemotherapy, radiation and now PRIMA-1," said Marvin R. Garovoy, M.D., head of clinical science at Peregrine. "Through preclinical studies, we continue to understand new combination therapy and possible clinical indications for our PS-targeting antibodies and look forward to advancing this knowledge in an expedited fashion into clinical research through our new investigator-sponsored trials program."

Targeting Mutant p53 Protein and the Tumor Vasculature: An Effective Combination Therapy for Advanced Breast Tumors, Yayun Liang et al., Breast Cancer Research and Treatment. Published Online First March 27, 2010.

The PS-targeting antibody 2aG4 used in these studies was provided by Peregrine Pharmaceuticals. These studies were conducted by researchers at the University of Missouri-Columbia and UT Southwestern and were supported by grants and funding provided by the Department of Defense Breast Cancer Program, NIH, RADIL (University of Missouri), and Susan G. Komen for the Cure.

About PS-Targeting Antibodies Peregrine's lead phosphatidylserine (PS)-targeting antibody is bavituximab, a first-in-class monoclonal antibody that targets the cellular membrane phospholipid PS. Usually located inside cells, PS becomes exposed on the outside of cells that line tumor blood vessels and on certain viruses and the cells they infect, creating a specific target for treatments while sparing healthy cells that do not express PS. Bavituximab induces immune cell-mediated destruction of cells with exposed PS and is also believed to restore the immune system's ability to recognize and respond by blocking PS-mediated immunosuppression. Initial results from Phase II cancer trials of bavituximab in combination with chemotherapy have been encouraging, with objective tumor response rates that compare favorably to historical results with chemotherapy alone.

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 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 biomanufacturing services for both Peregrine and outside customers. Additional information about Peregrine can be found at www.peregrineinc.com.

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