



July 16, 2012

Peregrine Announces Initiation of a Phase I Rectal Adenocarcinoma Investigator-Sponsored Trial

Fifth IST to Evaluate Baviximab's Broad Therapeutic Potential for Oncology Indications

TUSTIN, CA and DALLAS, TX -- (Marketwire) -- 07/16/12 -- Peregrine Pharmaceuticals, Inc. (NASDAQ: PPHM), a clinical-stage biopharmaceutical company developing first-in-class monoclonal antibodies for the diagnosis and treatment of cancer and viral infections, today announced the initiation of an investigator-sponsored trial (IST) for patients with stage II or stage III rectal adenocarcinoma. This open-label Phase I trial will treat up to 18 patients with Peregrine's investigational monoclonal antibody baviximab in combination with the chemotherapeutic agent capecitabine and radiation therapy. Peregrine's lead clinical candidate, baviximab, is a phosphatidylserine (PS)-targeting antibody that has demonstrated promising tumor response and survival trends in randomized Phase II trials in non-small cell lung cancer (NSCLC).

"Preclinical studies have repeatedly shown that radiation increases the exposure of baviximab's target molecule, PS, on the surface of tumor blood vessel cells. Additionally, baviximab in combination with radiation therapy has demonstrated potent anti-tumor effects in models of lung and brain cancer, with evidence of enhanced immunity," said Jeffrey Meyer, M.D., principal investigator of the study and assistant professor of radiation oncology at the University of Texas Southwestern Medical Center. "We look forward to evaluating this promising treatment combination in patients with advanced rectal cancer."

Baviximab is also being evaluated in randomized Phase II trials in NSCLC, and pancreatic cancer, as well as multiple ISTs in additional oncology indications.

"Building on consistently promising data in multiple preclinical tumor models, this trial represents our first clinical study of baviximab combined with radiation," said Joseph Shan, vice president of clinical and regulatory affairs of Peregrine. "We intend for this trial to be the first step in assessing baviximab's potential benefit in several additional oncology indications commonly treated with radiation therapy."

About the Phase I Rectal Cancer Trial

This Phase I single-arm, open-label, dose-escalation trial will enroll up to 18 patients with stage II or III rectal adenocarcinoma, with Eastern Cooperative Oncology Group (ECOG) performance status of 0-1. Patients will receive weekly baviximab for a total of 8 weeks with administration of capecitabine (825 mg/m²) on each of the 28 days of radiation therapy (1.8 Gy/fraction) over 6 weeks, followed by 2 weeks of baviximab administration by itself. Surgery will follow the last baviximab administration by 4-8 weeks (i.e., 6-10 weeks following completion of radiation therapy). The primary endpoint is to determine the safety, feasibility and tolerability of combining baviximab with a standard platform of capecitabine and radiation therapy. Secondary endpoints include the assessment of any anti-tumor activity by objective response as determined by MR imaging and histopathological response in patients.

This trial is being conducted by the University of Texas-Southwestern Medical Center.

For further information about this trial, please visit <http://www.peregrineinc.com/pipeline/currently-enrolling-trials.html>

About Baviximab

Baviximab is a first-in-class phosphatidylserine (PS)-targeting monoclonal antibody that represents a new approach to treating cancer. PS is a highly immunosuppressive molecule usually located inside the membrane of healthy cells, but "flips" and becomes exposed on the outside of cells that line tumor blood vessels, creating a specific target for anti-cancer treatments. PS-targeting antibodies target and bind to PS and block this immunosuppressive signal, thereby enabling the immune system to recognize and fight the tumor.

About Peregrine's Investigator-Sponsored Trials (IST) Program

Peregrine's IST program offers oncologists the opportunity to conduct clinical trials with baviximab. To learn more about Peregrine's IST program, please visit <http://www.peregrineinc.com/pipeline/investigator-sponsored-trials.html>.

About Rectal Adenocarcinoma

According to the National Cancer Institute, approximately 50,000 new cases of rectal adenocarcinoma will be diagnosed in 2012. The 5-year survival rate for Stage IV rectal cancer is estimated to be 6%.

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 infectious diseases with its lead product candidate bavituximab 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), which provides development and biomanufacturing 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 results from this trial may not be consistent with other clinical trial results of bavituximab to date, the risk that data from this trial may not support registration filings with the U.S. Food and Drug Administration ("FDA"), 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, 2011 and the quarterly report on Form 10-Q for the quarter ended January 31, 2012. 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.

[Add to Digg](#) [Bookmark with del.icio.us](#) [Add to Newsvine](#)

Contact:

Christopher Keenan or Jay Carlson

Peregrine Pharmaceuticals, Inc.

(800) 987-8256

info@peregrineinc.com

Source: Peregrine Pharmaceuticals

News Provided by Acquire Media