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Peregrine Announces Positive Top-Line Data From Randomized, Double-Blind Bavituximab Phase II Trial in Second-Line Non-Small Cell Lung Cancer

Bavituximab Plus Chemotherapy Demonstrates Doubling of Overall Response Rates Versus Chemotherapy Alone; 50% Improvement in Progression-Free Survival and Overall Survival Trends Support Phase III Development

TUSTIN, CA -- (Marketwire) -- 05/21/12 -- Peregrine Pharmaceuticals, Inc. (NASDAQ: PPHM) today announced positive top-line results from its randomized, double-blind, placebo-controlled Phase IIb trial evaluating two dose levels of bavituximab plus docetaxel versus docetaxel plus placebo (control arm) in patients with second-line non-small cell lung cancer (NSCLC). Data from the trial showed a doubling of overall response rates (ORR), the primary endpoint, and an improvement in progression-free survival (PFS), a secondary endpoint, in patients treated in the bavituximab-containing arms when compared to the control arm. Another secondary endpoint, median overall survival (OS), in the control arm has already been determined at less than 6 months, while the median has not been reached in either bavituximab-containing arm.

Based on independent radiology reviews and current status of patients, top-line data from the trial are as follows:

Treatment Arm	Bavituximab		
	Placebo	(1 mg/kg)	(3 mg/kg)
	plus	plus	plus
	docetaxel	docetaxel	docetaxel
Overall Response Rate (ORR)	7.9%	15.0%	17.9%
Median Progression-Free Survival (PFS)	3.0 months	4.2 months	4.5 months

"The compelling results from this rigorously designed trial clearly demonstrate that the combination of bavituximab and docetaxel is more active than docetaxel alone in treating second-line non-small cell lung cancer. We saw twice as many patients demonstrating an objective tumor response, increased progression-free survival, and already promising survival trends in this refractory setting. These results give us a high level of confidence as we begin planning for Phase III development in this indication," said Joseph Shan, vice president, clinical and regulatory affairs at Peregrine. "We now look forward with heightened enthusiasm to several clinical data points coming this year, including overall survival results from this and potentially two other randomized Phase II trials, as well as data from four ongoing investigator-sponsored trials evaluating new treatment combinations in various cancers."

Based on the review of safety and efficacy of this trial conducted by an independent Data Monitoring Committee, no significant safety issues or concerns were identified when comparing the bavituximab containing arms with the docetaxel alone arm.

This trial enrolled 121 patients with second-line Stage IIIB or IV (TNM Edition 7) non-squamous NSCLC following one prior chemotherapy regimen and were equally randomized to 1 of the 3 treatment arms, with 117 patients included in the top-line analysis. Tumor responses were determined in accordance with Response Evaluation Criteria In Solid Tumors (RECIST 1.1).

Patients received up to 6 cycles of docetaxel (75mg/m²) plus either placebo, 1 mg/kg bavituximab, or 3 mg/kg bavituximab until disease progression.

"After working on over 17 drug approvals, it is data like this that continues to energize and excite me. These robust data will be important in discussions with the FDA regarding advancing bavituximab's clinical development in second-line non-small cell lung cancer," said Robert Garnick, PhD, head of regulatory affairs at Peregrine. "We look forward to working closely with the FDA to identify the most efficient path toward commercialization for this promising candidate in this indication where new therapies are desperately needed."

According to the American Cancer Society, lung cancer is the second most commonly diagnosed cancer in the U.S., with approximately 226,160 new cases and 160,340 deaths each year, representing approximately 28% of all cancer deaths. NSCLC is the most common type of lung cancer, accounting for approximately 85-90% of lung cancer cases. Unfortunately, the five-year survival rate for NSCLC patients is only 1%.

"These data are a significant validation of the clinical potential of bavituximab for patients with few effective treatment options. These data will be instrumental in planning Phase III development in NSCLC and we are excited to share these data as part of ongoing partnering discussions," said Steven W. King, president and chief executive officer of Peregrine. "We look forward to sharing even more clinical data points this year from all seven bavituximab studies aimed at highlighting the broad therapeutic potential of bavituximab across multiple oncology indications and treatment combinations thus potentially building even more value in the program."

About Bavituximab

Bavituximab is a first-in-class phosphatidylserine (PS)-targeting monoclonal antibody that represents a new approach to treating cancer. Bavituximab is the lead drug candidate from the company's PS technology platform and is currently being tested in seven clinical trials including three randomized Phase II trials in front-line and second-line non-small cell lung cancer, front-line pancreatic cancer and four investigator-sponsored trials (ISTs) in additional oncology indications.

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 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 the overall survival data together with the above reported data may not support registration filings with the U.S. Food and Drug Administration ("FDA"), the risk that results from the other randomized Phase II trial will not be consistent with results experienced in the earlier single-arm Phase II trial or support registration filings with the 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.

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Contact :

Christopher Keenan or Jay Carlson

Peregrine Pharmaceuticals

(800) 987-8256

info@peregrineinc.com

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