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## Interim Data From Peregrine's Phase II Trial in Second-Line Non-Small Cell Lung Cancer Demonstrate Doubling of Median Overall Survival in Bavituximab-Containing Arms

TUSTIN, CA -- (Marketwire) -- 09/07/12 --

- *Interim Data from Double-Blind, Placebo-Controlled Trial Presented at Late-Breaking Plenary Session at Leading Oncology Symposium*
- *Data Show Statistically Significant Improvement in Overall Survival for Patients Receiving Bavituximab Plus Docetaxel Versus Docetaxel Alone*
- *Clinical Data Strongly Support Advancing Program into Phase III Clinical Development*
- *Company to Host Conference Call on Monday, September 10, at 11:00 AM EDT*

Peregrine Pharmaceuticals, Inc. (NASDAQ: PPHM), today announced that interim results were presented from its 121 patient randomized, double-blind, placebo-controlled Phase IIb trial in patients with refractory non-small cell lung cancer (NSCLC). The blinded study evaluated two dose levels of bavituximab (bavituximab-containing arms) given with docetaxel versus docetaxel plus placebo (control arm). The interim data showed a statistically significant improvement in overall survival (Hazard Ratio 0.524, p-value .0154) and a doubling of median overall survival (OS) in the bavituximab-containing arms compared to the control arm. The following interim data was presented as part of a late-breaking plenary presentation at the 2012 Chicago Multidisciplinary Symposium in Thoracic Oncology by David Gerber, M.D., Associate Professor of Internal Medicine at the University of Texas Southwestern Medical Center, a principal investigator in the trial.

	Treatment Arm			
	Placebo	Bavituximab (1 mg/kg)	Bavituximab (3 mg/kg)	Bavituximab (Pooled Data)
	plus docetaxel plus docetaxel plus docetaxel plus docetaxel			
Number of patients (per protocol population)	38	40	39	79
Median Overall Survival	5.6 months	11.1 months	13.1 months	12.1 months

Ratio (p-value)	--	.512 (.0286)	.539 (.0714)	.524 (.0154)
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Overall Response	7.9%	15%	17.9%	16.5%
Rate-p-value	--	.3262	.1895	.2069
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Progression Free				
Survival Hazard	3.0 months	4.2 months	4.5 months	4.2 months
Ratio (p-value)	--	.571 (.0794)	.65 (.1921)	.605 (.067)
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"This study was a rigorous trial designed to minimize bias and we are encouraged that this trial yielded such positive results in the most important endpoint, overall survival. The positive overall response rates and progression free survival in both bavituximab-containing arms seen earlier in the study has now translated into a statistically significant extension in overall survival for patients, a result rarely achieved in phase II clinical trials." said Joseph Shan, vice president of clinical and regulatory affairs at Peregrine. "The quality of this data gives us a solid foundation for designing a phase III trial with an increased probability of success. We are planning for an end-of-phase II meeting with the FDA as we plan to initiate this trial by mid-2013."

The trial enrolled 121 patients (117 evaluable per the study protocol) with second-line non-squamous NSCLC following one prior chemotherapy regimen at over 40 clinical centers. Patients were equally randomized to 1 of the 3 treatment arms, docetaxel (75mg/m<sup>2</sup>) plus either placebo, 1 mg/kg bavituximab, or 3 mg/kg bavituximab until disease progression. Approximately 50% of the patients were enrolled in the U.S. and 50% were enrolled internationally with equal distribution between all treatment groups.

"Robust data from this Phase II trial clearly demonstrate a significant benefit in overall survival with a good safety profile in patients receiving bavituximab plus docetaxel compared to those receiving docetaxel plus placebo," said Steven W. King, president and chief executive officer of Peregrine. "We are currently in discussions with several potential pharmaceutical partners who have expressed great interest in our bavituximab oncology program. It is our goal to identify the optimal partner to assist with the design and logistics of a multinational Phase III pivotal trial."

The interim results from the study showed no significant safety differences between the three treatment arms as determined by the trial's independent data monitoring committee. Baseline characteristics were well balanced across all three treatment arms of the study, including performance (ECOG) status, age, gender, and race. Tumor responses were determined in accordance with Response Evaluation Criteria In Solid Tumors (RECIST 1.1) based on blinded central radiology review.

"The median overall survival results from the Proof-of Concept study are truly outstanding and great news for patients. Statistically significant overall survival results at this stage of development are rare and have put us in an excellent position for advancing the program. Our attention is now turned to an end of phase II meeting by year end which will help us define the most efficient path forward to potential regulatory approval," said Robert Garnick, PhD, head of regulatory affairs at Peregrine. "A global Phase III trial designed very similarly to the robust design of this Phase II trial greatly increases bavituximab's likelihood of success."

#### *Audio Webcast*

In conjunction with Dr. Gerber's presentation in Chicago, Peregrine has posted an audio webcast and slide deck to Peregrine's website. The webcast will be hosted by Joseph Shan, vice president of clinical and regulatory affairs. This event will be pre-recorded. Access to the audio and corresponding slides can be found on Peregrine's website.

#### *Conference Call*

Peregrine will host a conference call and webcast to discuss these data and financial results for the first quarter fiscal year 2013 on Monday, September 10, 2012, at 11:00 AM ET (8:00 AM PT). To listen to the conference call, please dial (877) 312-5443 or (253) 237-1126 and request the Peregrine Pharmaceuticals call. A replay of the call will be available starting approximately two hours after the conclusion of the call through September 24, 2012 by calling (855) 859-2056, or (404) 537-3406 and using passcode 27367274.

### *About Lung Cancer*

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%.

### *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 eight clinical trials including three randomized Phase II trials in front-line and second-line non-small cell lung cancer, front-line pancreatic cancer and five 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 focused on the treatment and diagnosis of cancer. The company is pursuing multiple clinical programs in cancer 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](http://www.avidbio.com)), which provides development and biomufacturing 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 the overall survival data together with the above reported data may not support registration filings with the U.S. Food and Drug Administration, the risk that overall survival data from the planned Phase III trial will not be consistent with the results from the randomized, double-blind, placebo-controlled Phase IIb trial, 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, 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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