

## Pieris Pharmaceuticals Announces Presentation of Clinical Data for Its Hepcidin Antagonist Program, PRS-080, at the 2015 American Society of Hematology (ASH) Annual Meeting

BOSTON, MA -- (Marketwired) -- 11/05/15 -- *Pieris Pharmaceuticals, Inc.* (NASDAQ: PIRS), a biotechnology company advancing novel biotherapeutics through its proprietary <a href="Anticalin">Anticalin</a>® technology platform, announced today that an abstract summarizing the results from a Phase I clinical study in healthy male volunteers with its PRS-080 Anticalin hepcidin antagonist was selected for an oral presentation at the 57<sup>th</sup> Annual Meeting of the American Society of Hematology (ASH) taking place in Orlando, FL, December 5 - 8, 2015.

The abstract entitled, "A Phase I Study Investigating Safety, Tolerability, Pharmacokinetics and Pharmacodynamic Activity of the Hepcidin Antagonist PRS-080#022. Results from a Randomized, Placebo Controlled, Double-Blind Study Following Single Administration to Healthy Subjects," will be presented on Monday, December 7, 2015 and will be available at <a href="https://www.hematology.org/annualmeeting">www.hematology.org/annualmeeting</a>.

Session Name: 102. Regulation of Iron Metabolism: Iron Metabolism - Clinical and

Translational

Session Time: 10:30 AM - 12:00 PM ET

Presentation Time: 10:45 AM

Room: Orange County Convention Center, W414AB

PRS-080 was well tolerated, with no serious adverse events (SAEs) observed in a single ascending dose (SAD) study at six dose levels administered by intravenous infusion in 48 healthy male subjects ranging from 0.08 to 16.0 mg/kg (clinicaltrials.gov identifier NCT02340572). Reported AEs were of mild to moderate severity with no apparent dose dependency or difference between active and placebo treatment groups. The plasma half-life of PRS-080 ranged between 71 and 81 hours among dose cohorts.

The study also confirmed the mode of action of PRS-080 in the healthy study population. Within one hour of PRS-080 administration, a marked decrease in plasma hepcidin was seen, followed by elevations of both serum iron concentration and transferrin saturation. Moreover, the durations of serum iron elevation and transferrin saturation increased in a dose-dependent manner.

Stephen Yoder, Pieris President and CEO, commented, "We are extremely pleased by the safety profile as well as proof of mechanism demonstrated by our drug in these healthy subjects, and plan to commence a clinical trial of PRS-080 in Q4 this year in anemic patients with chronic kidney disease (CKD) undergoing hemodialysis. The majority of these patients suffer from anemia, which is often associated with increased morbidity and mortality and reduced quality of life. Elevated hepcidin is strongly associated with the severity of anemia in end stage renal disease patients, and has also been proposed to play a role in resistance to erythropoiesis-stimulating agent therapy."

## About PRS-080

PRS-080 is a fully proprietary Anticalin protein that sequesters hepcidin, typically regarded as the master negative regulator of iron metabolism. With a pharmacokinetic profile tuned to remove hepcidin in line with target turnover dynamics, PRS-080 is intended to optimally mobilize iron trapped in iron storage cells, particularly in anemic patients with iron-restricted erythropoiesis due to functional iron deficiency. Funded in part by an EC FP7 health program grant, Pieris' hepcidin antagonist program was supported by the EUROCALIN consortium. Details of the consortium's charter can be found at <a href="https://www.eurocalin-fp7.eu">www.eurocalin-fp7.eu</a>. Patients with ESRD almost invariably develop anemia, which is often associated with increased morbidity and mortality, as well as reduced quality of life.

## About Pieris Pharmaceuticals

Pieris is a clinical stage biotechnology company that discovers and develops Anticalin-based drugs to target validated disease pathways in a unique and transformative way. Our pipeline includes immuno-oncology multi-specifics tailored for the tumor micro-environment, an inhaled Anticalin to treat severe asthma and a half-life-optimized Anticalin to treat anemia. Proprietary to Pieris, Anticalins are a novel class of protein therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies. Anticalin<sup>®</sup>, Anticalins<sup>®</sup> are registered trademarks of Pieris. For more information visit <a href="www.pieris.com">www.pieris.com</a>.

## Forward Looking Statements

This press release contains forward-looking statements as that term is defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, references to novel technologies and methods; our business and product development plans, including the timing of initiation or completion of our clinical trials; our liquidity and ability to fund our future operations; or market information. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, our ability to raise the additional funding we will need to continue to pursue our business and product development plans; the inherent uncertainties associated with developing new products or technologies and operating as a development stage company; our ability to develop, complete clinical trials for, obtain approvals for and commercialize any of our product candidates; competition in the industry in which we operate and market conditions. These forward-looking statements are made as of the date of this press release, and we assume no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law. Investors should consult all of the information set forth herein and

should also refer to the risk factor disclosure set forth in the reports and other documents we file with the SEC available at <a href="www.sec.gov">www.sec.gov</a>, including without limitation the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2014 and the Company's Quarterly Reports on Form 10-Q.

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