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

BOSTON, MA -- (Marketwired) -- 12/07/15 -- Pieris Pharmaceuticals, Inc. (NASDAQ: PIRS), a biotechnology company advancing its proprietary Anticalin® bio therapeutic technologies, announced today that it will present detailed data today summarizing the results from a Phase I clinical study in healthy male volunteers with its PRS-080 Anticalin hepcidin antagonist at the 57th Annual Meeting of the American Society of Hematology (ASH) taking place in Orlando, FL.

The oral presentation 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," outlined the favorable safety profile of the drug, as well as demonstrable proof of mechanism shown by increased serum iron levels as well as transferrin saturation in treated subjects.

PRS-080 was well tolerated, with no serious adverse events (SAEs) observed in the 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.

Within one hour of PRS-080 administration, a marked decrease in plasma hepcidin was observed, followed by dose-dependent elevations of both serum iron concentration and transferrin saturation. Moreover, the durations of serum iron elevation and transferrin saturation also increased in a dose-dependent manner. Among all subjects receiving PRS-080 doses of 1.2 mg/ml and higher, statistically significant increases in total serum iron mobilization were observed relative to placebo (p = .005).

Louis Matis, M.D., Pieris SVP and Chief Development Officer commented, "We are extremely pleased by the safety profile as well as the pharmacodynamic activity of our hepcidin antagonist in these healthy subjects. Hepcidin is the root cause of and therefore, an attractive target for treating the hypoferremia and iron-restricted reduction of
erythropoiesis seen in anemias of chronic disease (ACD), which are often associated with poor prognosis and lower quality of life. Management of ACD using intravenous iron and erythropoiesis stimulating agents is ineffective for subsets of patients and may have adverse effects, driving the need for new alternative therapies. We expect to soon initiate the dosing of anemic patients with chronic kidney disease (CKD) undergoing hemodialysis, for whom elevated hepcidin is strongly associated with the severity of anemia."

**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 [www.eurocalin-fp7.eu](http://www.eurocalin-fp7.eu). Patients with ESRD almost invariably develop anemia, which is often associated with increased morbidity and mortality, as well as a reduced quality of life.

**About Anemias of Chronic Disease**

Anemia of Chronic Disease (ACD), also known as Anemia of Inflammation (AI), is the most prevalent anemia in hospitalized patients worldwide. It occurs in patients with acute or chronic inflammatory conditions including infections, cancer, rheumatoid arthritis, and chronic kidney disease. ACD is generally characterized by a normocytic anemia, impaired erythropoiesis, low serum iron and low transferrin saturation, but often normal to high body iron stores with iron sequestered in intracellular compartments. The molecular mechanisms and pathogenesis of the iron distribution abnormalities in ACD have been elucidated, and it has now been shown that inflammatory cytokines released during acute infection or chronic disease alter systemic iron metabolism by inducing excess synthesis of the iron regulatory hormone hepcidin. In turn, hepcidin inhibition of iron export from cells by blocking ferroportin activity has been established as the major underlying cause of the hypoferremia and iron-restricted erythropoiesis seen in ACD. Current treatment of the anemia generally includes administration of intravenous iron and erythropoiesis stimulating agents. However, the fact that these approaches do not directly address the high levels of hepcidin responsible for functional iron deficiency, together with concerns over adverse effects from these therapies, have driven the need for alternative treatments.

**About Pieris Pharmaceuticals**

Pieris Pharmaceuticals 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 uncontrolled 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®, Anticalins® are registered trademarks of Pieris. For more
information visit www.pieris.com.

**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; the timing of future clinical trials for our PRS-080 program, our liquidity and ability to fund our future operations; our ability to achieve certain milestones and receive future milestone or royalty payments; 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 www.sec.gov, 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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