June 4, 2017

Pieris Pharmaceuticals Announces Presentation of Clinical Data for Anemia Drug Candidate, PRS-080, at the 54th ERA-EDTA Congress

BOSTON, MA -- (Marketwired) -- 06/04/17 -- ***Pieris Pharmaceuticals, Inc.*** (NASDAQ: PIRS), a clinical-stage biotechnology company advancing novel biotherapeutics through its proprietary Anticalin® technology platform for cancer, respiratory and other diseases, announced today the presentation of Phase 1b study results for its anemia program, PRS-080#022-DP, at the 54th European Renal Association & European Dialysis and Transplant Association (ERA-EDTA) Congress, convening in Madrid, Spain June 3-6, 2017.

The poster presentation, entitled "A phase Ib study investigating the safety, tolerability, pharmacokinetics, and pharmacodynamics of the hepcidin antagonist PRS-080#022-DP in anemic chronic kidney disease patients undergoing hemodialysis", was delivered by Dr. Lutz Renders, Professor at the Klinikum Rechts der Isar, Department of Nephrology, Munich, Germany, and the lead investigator on the clinical trial. The poster is available here.

In this multi-center, placebo-controlled, double-blind study, 24 dialysis-dependent stage 5 chronic kidney disease (CKD5) patients with anemia were treated with single ascending doses of PRS-080#022-DP in 3 cohorts at 2, 4, and 8 mg/kg body weight.

Intravenous administration of PRS-080#022-DP was both safe and well-tolerated at all doses, and resulted in a profound decrease in free hepcidin within one hour after infusion, followed by robust mobilization of serum iron, with dose-proportional increases in both the level and duration of serum iron concentration and transferrin saturation (TSAT) following treatment.

Dr. Renders commented, "PRS-080#022-DP was safe and well tolerated with dose-dependent pharmacodynamic activity. Hepcidin levels are invariably elevated in anemic CKD5 patients, and as the master inhibitory regulator of iron metabolism, hepcidin represents an attractive target for treating the hypoferremia and iron-restricted anemia (IRA) which are often associated with poor prognosis and lower quality of life. Management of IRA using intravenous iron and erythropoiesis stimulating agents is ineffective for a significant subset of patients and may have adverse effects, driving the need for alternative new therapies."

Louis Matis, M.D., Pieris SVP and Chief Development Officer commented, "Based on the favorable profile of PRS-080#022-DP observed in this study, we look forward to the outcome of our upcoming multi-dose study to further explore the clinical potential of PRS-080#022-DP in hemodialysis-dependent anemic patients, for whom elevated hepcidin is associated with the severity of anemia."

About PRS-080#022-DP

PRS-080#022-DP 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. The research leading to these results initially received funding from the European Community's Seventh Framework

Programme (FP7/2007-2013) under grant agreement n° 278408. Patients with end-stage renal disease 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 is a clinical-stage biotechnology company that discovers and develops Anticalin® protein-based drugs to target validated disease pathways in a unique and transformative way. Our pipeline includes immuno-oncology multi-specifics tailored for the tumor microenvironment, an inhaled Anticalin protein to treat uncontrolled asthma and a half-life-optimized Anticalin protein to treat anemia. Proprietary to Pieris, Anticalin proteins are a novel class of therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies. Anticalin is a registered trademark 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 and progress of our studies, 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, 2016 and the Company's Quarterly Reports on Form 10-Q.

Contacts at Pieris:

Company Contact:
Pieris Pharmaceuticals, Inc.
Lance Thibault
Acting Chief Financial Officer
+1-857-246-8998
thibault@pieris.com

Investor Relations Contact:
The Trout Group
Thomas Hoffmann
+1-646-378-2931
thoffmann@troutgroup.com

Media Inquiries:
Mario Brkulj
+49-175-5010575
mbrkulj@macbiocom.com

Source: Pieris Pharmaceuticals, Inc.