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Pieris Pharmaceuticals and AstraZeneca Present Multiple Ascending Dose Phase 1b Data for Inhaled IL4-Rα Antagonist AZD1402/PRS-060 at the 2019 European Respiratory Society International Congress

BOSTON, MA / ACCESSWIRE / September 26, 2019/ ***Pieris Pharmaceuticals, Inc. (NASDAQ: PIRS)***, a clinical-stage biotechnology company advancing novel biotherapeutics through its proprietary Anticalin® technology platform for respiratory diseases, cancer and other indications, today announced the presentation on October 1, 2019, of interim data from its placebo-controlled multiple ascending dose phase 1b study for AZD1402/PRS-060, an inhaled IL4-Rα antagonist being developed in collaboration with AstraZeneca intended for the treatment of asthma, at the 2019 European Respiratory Society International Congress.

The poster, available on the Congress Website, is titled "Multiple ascending dose study of the inhaled IL-4Rα antagonist, AZD1402/PRS-060, in mild asthmatics demonstrates robust FeNO reduction and a promising clinical profile for the treatment of asthma," and reported that AZD1402/PRS-060 was safe and well tolerated at all doses, significantly reduced fractional exhaled nitric oxide (FeNO) - a validated biomarker or eosinophilic airway inflammation, and showed dose-dependent systemic target engagement in patients with mild asthma and elevated levels of FeNO (≥ 35ppb). During the treatment period, 30 patients were randomized to receive delivered doses of AZD1402/PRS-060 ranging from 2mg to 60mg (5mg to 150mg administered through a nebulizer) twice a day for nine consecutive days and one final dose on the 10^{th} day, and 12 patients were randomized to receive placebo at the same time points.

Significant and pronounced inhibition of FeNO relative to placebo was observed at all doses. When comparing the 20mg AZD1402/PRS-060 powered cohort (n=12) versus placebo, the primary statistical analysis using the emax model demonstrated a 36% relative reduction in FeNO (Figure 1). Systemic target engagement was dose-dependent and closely aligned with systemic exposure of the drug, consistent with results of the Phase 1a single ascending dose study. No systemic target engagement and minimal systemic exposure was observed at the 2mg dose, suggesting that local target engagement by the drug is sufficient to reduce airway inflammation.

AZD1402/PRS-060, mg (delivered)	**n**	**Reduction vs. placebo, % (95% CI)**	**p-value**
2	6	24.0 (1.8-41)	0.04
6	6	24.3 (2.7-41)	0.03
20	12	36.4 (22-48)	<0.0001
60	6	30.5 (10-46)	0.005
Placebo	12	--	--

Figure 1: Estimated relative percentage reduction in FeNO
CL, confidence interval

"As sponsor of this trial, Pieris is executing with a high degree of efficiency, and I am proud of our team's ability to

drive to these results," said Stephen S. Yoder, President and Chief Executive Officer of Pieris Pharmaceuticals. "Beyond PRS-060, I also look forward to advancing the several other respiratory programs we are developing in collaboration with AstraZeneca, in addition to our fully proprietary respiratory pipeline, which currently comprises three programs."

About PRS-060:

PRS-060 is an inhaled IL4-Rα antagonist intended for the treatment of asthma being developed as part of a five-program respiratory collaboration with AstraZeneca. AstraZeneca will be responsible for all subsequent clinical development of PRS-060 following the completion of a Phase 1b study. Pieris will have separate options to co-develop and, subsequently, to co-commercialize the drug candidate following the completion of a Phase 2a study.

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 inhalable Anticalin proteins to treat respiratory diseases, immuno-oncology multi-specifics tailored for the tumor microenvironment, 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 Statement:

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, the expected timing of the reporting by the Company of key clinical data from its lead programs, references to novel technologies and methods and our business and product development plans, including the advancement of our proprietary and co-development programs into and through the clinic and the expected timing for reporting data or making IND filings related to our programs, and partnering prospects for any such programs. 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, including our ability to recruit and enroll patients in our studies; our ability to address the requests of the FDA; 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, 2018 and the Company's Quarterly Reports on Form 10-Q.

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