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Pieris Pharmaceuticals Announces Successful Completion of Safety Review for 10 mg Dose of Phase 2a Trial of Elarekibep (PRS-060/AZD1402)

BOSTON, MA / ACCESSWIRE / May 4, 2023 / 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 successful safety review of the 10 mg dry powder dose safety cohort from the ongoing multi-center, placebo-controlled phase 2a study of dry powder inhaler-formulated elarekibep (PRS-060/AZD1402). The successful review of the 10 mg dose provides additional data supporting the elarekibep safety profile and enables doses of 10 mg or less to be evaluated in future clinical trials.

Elarekibep is an IL-4 receptor alpha inhibitor under development in collaboration with AstraZeneca for the treatment of moderate-to-severe asthma. Pieris previously announced the successful completion of the safety review for the 1 mg and 3 mg doses, triggering the efficacy portion of the study, which is ongoing at the 3 mg dose. Upon completion of the phase 2a study and availability of topline data, which Pieris expects to be reported by mid-2024, the Company will have a co-development option for this program with AstraZeneca.

For this safety review, 13 asthma patients, controlled on standard of care (medium dose inhaled corticosteroids with long-acting beta agonists), received elarekibep twice daily over four weeks to establish the safety profile and pharmacokinetics of the dry powder formulation of elarekibep at the 10 mg dose. Following completion of enrollment and observation, AstraZeneca evaluated, compared to placebo, the incidence of adverse events, changes in laboratory markers (immuno-biomarkers, clinical chemistry, and hematology), and forced expiratory volume in one second.

"The successful safety review for the elarekibep 10 mg dose cohort provides another data point supporting the potential for this program. Elarekibep offers the potential to significantly improve the standard of care for asthma patients with a superior product profile," said Stephen S. Yoder, President and Chief Executive Officer of Pieris. "We look forward to the completion of the phase 2a study which, if successful, would serve as a key value inflection point in the development of this underserved, large market opportunity and will inform our decision to co-develop elarekibep alongside AstraZeneca."

***About Elarekibep (PRS-060/AZD1402)**:*

Elarekibep is Pieris' lead respiratory Anticalin®-based drug candidate being developed in collaboration with AstraZeneca. Elarekibep blocks the IL-4Rα immunoreceptor, inhibiting small IL-4 and IL-13 proteins that drive a cascade of inflammatory responses in the lungs. The small size and stability of elarekibep allow it to be inhaled directly into the lungs, rather than injected, potentially achieving the same benefits as systemic treatments, but with lower doses and fewer side effects. Phase 1 trials of elarekibep have shown significantly reduced levels of fractional exhaled nitric oxide (FeNO), a biomarker of lung inflammation, in patients with mild asthma. AstraZeneca, as sponsor, is conducting the ongoing phase 2a study of Elarekibep.

***About Pieris Pharmaceuticals**:*

Pieris is a clinical-stage biotechnology company that combines leading protein engineering capabilities and deep understanding into molecular drivers of disease to develop medicines that drive local biology to produce superior clinical outcomes for patients. Our pipeline includes inhalable Anticalin proteins to treat respiratory diseases and locally-activated bispecifics for immuno-oncology. Proprietary to Pieris, Anticalin proteins are a novel class of therapeutics validated in the clinic and by strong partnerships with leading pharmaceutical companies. 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, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, the potential for Pieris' development programs including elarekibep to address our focus areas such as respiratory diseases; the advancement of our proprietary and co-development programs into and through the clinic and the expected timing for reporting data; making IND filings or achieving other milestones related to our programs, including elarekibep; the therapeutic potential, safety profile, and market opportunity of our Anticalin platform; our continued progress in the area of co-stim bispecifics and inhaled therapeutics; and the advancement and funding of our developmental programs generally. Actual results could differ from those projected in any forward-looking statement due to numerous factors. Such factors include, among others, our ability to satisfy any closing conditions for the financing; the amounts of anticipated funding actually received for our continued development programs and our actual reductions in spending as compared to anticipated cost reductions; our ability to raise the additional funding we will need to continue to pursue our business and product development plans; including in collaboration with other parties, 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; competition in the industry in which we operate; the fact that data and results from clinical studies may not necessarily be indicative of future results; delays or disruptions due to COVID-19 or geopolitical issues, including the conflict in Ukraine; 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 Securities and Exchange Commission, or the SEC, available at www.sec.gov, including, without limitation, the Company's most recent Annual Report on Form 10-K, the Company's Quarterly Reports on Form 10-Q, and subsequent filings with the SEC.

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