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Pieris and Lilly Enter Into a Clinical Trial Collaboration to Evaluate Combination of PRS-343 With Ramucirumab and Paclitaxel in Gastric Cancer

BOSTON, MA / ACCESSWIRE / August 10, 2020 / ***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 that it has entered into a clinical trial collaboration and supply agreement with **Eli Lilly and Company** to evaluate the safety and efficacy of combining Pieris' PRS-343, a 4-1BB/HER2 bispecific for HER2-positive tumors, with Lilly's ramucirumab, a VEGFR2 antagonist FDA-approved for multiple types of solid tumors, and paclitaxel for the second-line treatment of patients with HER2-positive gastric cancer in a phase 2 study.

Under the terms of the agreement, Lilly will supply Pieris with ramucirumab for the study as well as collaborate on data from the trial. Pieris is working towards initiation of a phase 2 single-arm combination study for the second-line treatment of HER2-positive gastric cancer later this year.

"We have seen impressive single-agent activity in the phase 1 trial of PRS-343, including a complete response and many patients experiencing a clinical benefit, and believe there is a compelling biology and clinical rationale to adding PRS-343 to the current standard of care regimen for advanced or metastatic gastric cancer in the second line, ramucirumab and paclitaxel," said Stephen S. Yoder, President and Chief Executive Officer of Pieris. "Today's announcement further supports exploring this clinical rationale while managing costs efficiently."

***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 and immuno-oncology multi-specifics tailored for the tumor microenvironment. 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, the timing for, and outcome of, the additional in-use and compatibility study for PRS-343 as requested by the FDA; whether data from patients enrolled to date will be sufficient to inform the recommended phase 2 dose for the Company's planned proof of concept study of PRS-343 in gastric cancer; the expected timing and potential outcomes of the reporting by the Company of key clinical data from its 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, making IND filings or achieving other milestones related to our programs, including PRS-060/AZD1402, PRS-343, PRS-344, and PRS-352 and the expected timing of the initiation of the next stage of PRS-343's development in gastric cancer. 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, including with respect to the additional in-use and compatibility study for PRS-343, and the resolution of the partial clinical hold relating to that drug candidate; competition in the industry in which we operate; delays or disruptions due to COVID-19; 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, 2019 and the Company's Quarterly Reports on Form 10-Q.

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