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Pieris Pharmaceuticals Receives Orphan Drug Designation for Cinrebafusp Alfa for the Treatment of Gastric Cancer

BOSTON, MA / ACCESSWIRE / June 24,2021 / ***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 the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to cinrebafusp alfa (PRS-343), a 4-1BB/HER2 bispecific, for the treatment of HER2-high and HER2-low expressing gastric cancers.

"The granting of orphan drug designation to cinrebafusp alfa underscores the high unmet medical need that persists in the treatment of gastric cancer and reinforces our conviction in the importance of developing this program while setting a high bar for success to help patients with limited therapeutic options," said Stephen S. Yoder, President and Chief Executive Officer of Pieris. "We look forward to beginning the phase 2 trial of cinrebafusp alfa later this summer."

FDA grants orphan drug designation to promote the development of a drug that targets a condition affecting 200,000 or fewer U.S. patients annually. Orphan drug designation provides qualifying therapies with development and commercial incentives, including FDA assistance in clinical trial design, tax credits for eligible clinical trials, waiver of application fees, and market exclusivity for seven years following FDA approval, in addition to other available regulatory exclusivities.

About Cinrebafusp Alfa:
Cinrebafusp alfa (PRS-343) is a 4-1BB/HER2 fusion protein comprising a 4-1BB-targeting Anticalin protein and a HER2-targeting antibody. Based on encouraging phase 1 study results, which demonstrated clinical benefit as single agent and biomarker data indicative of a 4-1BB-driven mechanism of action, the Company is actively working towards initiating a phase 2 study of cinrebafusp alfa in combination with ramucirumab and paclitaxel for the treatment of HER2-high expressing gastric cancer and in combination with tucatinib for the treatment of HER2-low expressing gastric cancer.

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 respiratory and immuno-oncology focused 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, whether the combination of cinrebafusp alfa with other therapies could address a high medical need in HER2 gastric cancer patients who do not respond to traditional HER2-targeted therapies; whether the effects of the combination of cinrebafusp alfa with other therapies seen in preclinical studies will be observed in clinical trials; 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 cinrebafusp alfa 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 Company's cash resources, 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, cinrebafusp alfa, PRS-344, and PRS-352 and the expected timing of the initiation of the next stage of cinrebafusp alfa'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 U.S. Food and Drug Administration; 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 Securities and Exchange Commission available at www.sec.gov, including without limitation the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and the Company's Quarterly Reports on Form 10-Q.

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