June 25, 2021

Pieris Pharmaceuticals Announces Inhaled CTGF Inhibitor PRS-220 for Idiopathic Pulmonary Fibrosis and 17 Million Dollar Grant From Bavarian Government To Accelerate Program Development for Post-COVID-19 Pulmonary Fibrosis

- **PRS-220, an oral inhaled Anticalin protein targeting CTGF, a fully proprietary drug candidate for respiratory disease, is being developed as a local treatment for idiopathic pulmonary fibrosis**
- **Grant to enable the evaluation of PRS-220 for the treatment of post-COVID-19-related pulmonary fibrosis for clinical-readiness in general and initial clinical development of PRS-220 in the post-COVID-19 setting**
- **Clinical development of PRS-220 expected to begin in 2022**

BOSTON, MA / ACCESSWIRE / June 25,2021 / 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 the development of PRS-220, an oral inhaled Anticalin protein targeting connective tissue growth factor (CTGF), also known as CCN2, for the treatment of idiopathic pulmonary fibrosis (IPF). The Company also announced it has been selected to receive a 14.2 million euro (approximately 17 million USD) grant from the Bavarian Ministry of Economic Affairs, Regional Development and Energy for the research and development of PRS-220 for post-acute sequelae of SARS-CoV-2 infection (PASC) pulmonary fibrosis (PASC-PF), also known as post-COVID-19 syndrome pulmonary fibrosis or "long COVID". Clinical development of the program for both indications is expected to begin next year.

PRS-220 follows Pieris' strategy of deploying its proprietary Anticalin proteins for local interventions on clinically validated targets with the objective of developing superior medicines through more efficient biology. CTGF, a protein localized in the extracellular matrix, is a driver of fibrotic tissue remodeling as a consequence of an aberrant wound healing process. Over-expression of this target in lung tissue is observed in patients suffering from IPF, and clinical data indicate inhibition of CTGF reduces the decline in lung function among these patients. IPF affects over three million patients worldwide and roughly 130,000 patients in the United States. Mean survival is two to five years from the time of

diagnosis, with standard of care conferring only modest benefit. The critical function of CTGF in fibrosis, as well as its induced expression upon tissue injury and fibrotic remodeling, render it a compelling intervention for PASC-PF. Persistent symptoms following severe COVID-19 have been reported by different studies in more than one third of hospitalized patients. Pathological changes include impairment of lung function and reduced diffusion capacity of lung for carbon monoxide (DLCO), as well as radiologically detected interstitial lung abnormalities indicative of fibrotic-like impairment of lung tissues. A sub-population of these patients is expected to benefit from an anti-fibrotic treatment, such as PRS-220. There is currently no approved therapy to address PASC-PF.

The grant announced today, intended to support the evaluation of PRS-220 in PASC-PF beyond the intended IPF population, will support clinical-readiness activities and initial clinical development for the program, including GLP tox studies, GMP manufacturing, and phase 1 clinical development. PRS-220 has passed the drug candidate nomination stage within Pieris' pipeline and has several features that reflect its best-in-class potential, including a developability profile demonstrating suitability for inhaled delivery. Pieris intends to present preclinical data for PRS-220 later this year, around which time the Company also plans to provide further program details in IPF and PASC-PF.

"The health consequences of the COVID-19 pandemic will affect our health system for a long time to come. Bavaria's biotech and pharmaceutical companies are at the forefront of developing new therapies to combat the effects of this virus. Through the strategic grants of the Bavarian Ministry of Economic Affairs, we are providing financial support for particularly innovative therapeutic research projects. We are convinced of the great potential of the PRS-220 program and are therefore promoting its development through a grant of 14.2 million euros," said Huber Aiwanger, Bavarian State Minister of Economic Affairs, Regional Development and Energy.

"We are excited to unveil our most advanced proprietary inhaled respiratory program and look forward to sharing more details on this program later this year, while actively working to begin clinical development next year. The Bavarian government's support of innovative drug development is invaluable for both the local biotech ecosystem and broader public health initiatives, and we are grateful for having been selected as a recipient of this grant for PRS-220, which will allow us to accelerate its development and broaden clinical investigation beyond IPF to address an evolving medical need precipitated by the global COVID-19 pandemic that we believe will persist," said Stephen S. Yoder, President and Chief Executive Officer of Pieris. "Pieris is a pioneer in the inhaled biologics space, and it is gratifying to leverage our respiratory platform to improve the lives of those affected by respiratory diseases such as IPF and COVID-19."

***About IPF**:*

Idiopathic pulmonary fibrosis (IPF) is a chronic, progressive, and ultimately fatal type of interstitial lung disease of unknown cause, characterized by a radiological or histopathological pattern of usual interstitial pneumonia. It is the most commonly occurring type of idiopathic interstitial pneumonia, with an estimated mean survival of two to five years from the time of diagnosis. Estimated mortality rates are 64.3 deaths per million in men and 58.4 deaths per million in women.

About PASC-PF:

Post-acute sequelae of SARS-CoV-2 infection (PASC) pulmonary fibrosis (PASC-PF), also known as pulmonary fibrosis secondary to COVID-19 or "long COVID", affects patients who have recovered from acute COVID-19 but continue to suffer from or remain at risk for pulmonary fibrotic abnormalities. Persistent symptoms, reflected by impairment of lung function and reduced diffusion capacity of lung for carbon monoxide (DLCO), as well as radiologically detected interstitial lung abnormalities indicative of fibrotic-like impairment of lung tissues, have been reported following severe COVID-19 in more than a third of hospitalized patients who have recovered from acute COVID-19, according to reported clinical studies. There is currently no approved therapy to address PASC-PF.

***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, the timing for initiation of clinical trials of PRS-220, whether PRS-220 will provide a clinical benefit in the treatment of IPF and PASC-related fibrosis, 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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