

# Pieris Pharmaceuticals and Servier Announce Dosing of First Patient in Phase 1/2 Trial of 4-1BB/PD-L1 Bispecific PRS-344/S095012

BOSTON, MA and PARIS, FRANCE / ACCESSWIRE / November 8, 2021 *IPieris Pharmaceuticals, Inc. (NASDAQ:PIRS)*, a clinical-stage biotechnology company advancing novel biotherapeutics through its proprietary Anticalin<sup>®</sup> technology platform for respiratory diseases, cancer, and other indications, and Servier, a global pharmaceutical group, today announced that the first patient has been dosed in the phase 1/2 study of PRS-344/S095012, a next generation 4-1BB/PD-L1 Anticalin-based bispecific for the treatment of solid tumors, triggering an undisclosed milestone payment to Pieris. The global, open-label phase 1/2 dose escalation study will evaluate the safety, tolerability, potential optimal dosage, and potential anti-tumor activity of PRS-344/S095012 in patients with advanced solid tumors whose cancer progressed on standard-of-care treatment.

PRS-344/S095012 is a tetravalent bispecific fusion protein comprising 4-1BB-targeting Anticalin proteins and a PD-L1-targeting antibody. Preclinical studies showed that PRS-344/S095012 is superior to the combined administration of separate PD-L1- and 4-1BB-targeting molecules. Further, in anti-PD-L1-resistant mouse models, the bispecific induces a dose-dependent anti-tumor response and significantly extends survival. In vitro, PRS-344/S095012 enhances effective CD8+ T cell response and proinflammatory cytokine release. Furthermore, preclinical models reflect that PRS-344/S095012-mediated 4-1BB activation is PD-L1 dependent, reducing the risk of peripheral toxicity, and 4-1BB costimulation only occurs in combination with simultaneous TCR signaling, restricting its activity to antigen-specific T cells.

"This marks an important step in our development of PRS-344/S095012, our broader 4-1BB bispecifics franchise, and our strategic alliance with Servier. Our 4-1BB/PD-L1 bispecific has been designed to address localized 4-1BB agonism while driving PD-L1 antagonism benefit, thereby facilitating a meaningful therapeutic window," said Tim Demuth, M.D., Ph.D., Chief Medical Officer of Pieris.

"PRS-344/S095012 has shown clear synergistic benefit in preclinical studies thanks to its bispecific format. We are excited to have begun clinical development of PRS-344/S095012, which may provide patients with a new treatment option and significant clinical impact. The dosing of the first patient in this study marks a meaningful step to developing a potential

future treatment for cancer patients with limited options," said Patricia Belissa-Mathiot, Director of Clinical Development and R&D Chief Medical Officer at Servier.

# **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 <a href="https://www.pieris.com">www.pieris.com</a>.

#### **About Servier**

Servier is a global pharmaceutical group governed by a Foundation. With a strong international presence in 150 countries and a total revenue of 4.7 billion euros in 2020, Servier employs 22,500 people worldwide. Servier is an independent group that invests over 20% of its brand-name revenue in Research and Development every year. To accelerate therapeutic innovation for the benefit of patients, the Group is committed to open and collaborative innovation with academic partners, pharmaceutical groups, and biotech companies. It also integrates the patient's voice at the heart of its activities, from research to support beyond the pill.

A leader in cardiology, the ambition of the Servier Group is to become a renowned and innovative player in oncology. Its growth is based on a sustained commitment to cardiovascular and metabolic diseases, oncology, neuroscience and immuno-inflammatory diseases. To promote access to healthcare for all, the Servier Group also offers a range of quality generic drugs covering most pathologies.

More information: servier.com

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## 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 benefits of PRS-344 in treating solid tumors demonstrated in preclinical studies will be seen in the phase 1/2 study, 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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