September 4, 2018

Pieris Pharmaceuticals Announces Dosing of First Patient in Phase I Combination Trial for PRS-343 Plus Anti-PD-L1 Immunotherapy

BOSTON, Sept. 04, 2018 (GLOBE NEWSWIRE) -- ***Pieris Pharmaceuticals, Inc.*** **(NASDAQ: PIRS)**, a biotechnology company advancing novel biotherapeutics through its proprietary Anticalin® technology platform for cancer, respiratory and other diseases, announced today that it has dosed the first patient in the Company's Phase 1 combination clinical trial of PRS-343, its lead proprietary immuno-oncology drug candidate targeting HER2 and 4-1BB, plus atezolizumab (Tecentriq®), an approved PD-L1 inhibitor.

The trial, a multicenter, open-label, Phase 1 dose escalation study, is designed to determine the safety, tolerability, and potential synergistic anti-tumor effects of PRS-343 plus anti-PD-L1 immunotherapy in patients with advanced or metastatic HER2-positive solid tumors. Elevated HER2 expression is associated with multiple cancers, including gastroesophageal, bladder, breast, and a range of other tumor types. The trial is fully funded and sponsored by Pieris, while Roche is supplying atezolizumab.

"The initiation of the combination trial of PRS-343 with an anti-PD-L1 immunotherapy marks the beginning of Pieris' investigation into the potential synergistic effects of its 4-1BB-targeted therapy with PD-1/L1 blockade," said Louis Matis, M.D., Senior Vice President and Chief Development Officer of Pieris. "Given evidence from multiple preclinical studies demonstrating synergistic anti-tumor activity from concurrent 4-1BB activation and PD-(L)1 pathway blockade, we believe that combination therapy with PRS-343 and atezolizumab has the potential to provide significant clinical benefit for patients. We are enthusiastic to be initiating this trial and look forward to reporting our findings from this combination study next year."

About PRS-343

PRS-343 is a bispecific monoclonal antibody-Anticalin fusion protein comprised of a HER2 tumor-targeting antibody genetically linked to a potent Anticalin specific for the immune costimulatory TNF family receptor 4-1BB (CD137). PRS-343 is being developed as the first 4-1BB based bispecific therapeutic to mediate the activation of tumor-specific T lymphocytes selectively within the tumor microenvironment (TME). 4-1BB is a potent costimulatory immunoreceptor and an established marker for tumor-specific infiltrating T

lymphocytes, and is, therefore, an attractive target for cancer immunotherapy. In *in vivo* preclinical tumor models, PRS-343 has demonstrated potent T lymphocyte activation localized to the TME of established HER2-positive tumors, indicating the potential for both enhanced safety and efficacy.

About HER2-Positive Malignancies

HER2 is a tyrosine kinase receptor growth-promoting protein found on the surface of some cancer cells and is associated with aggressive disease progression. Multiple tumor types can express HER2 including breast, gastroesophageal, bladder, biliary (cholangiocarcinoma), colorectal, endometrial, ovarian, non-small cell lung, pancreatic, head and neck, and other cancers.

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 immuno-oncology multi-specifics tailored for the tumor microenvironment, an inhaled Anticalin protein to treat uncontrolled asthma and a half-life-optimized Anticalin protein to treat anemia. 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.

Tecentriq® (atezolizumab) is a registered trademark of Genentech, a member of the Roche Group.

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, 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. 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; competition in the industry in which we operate 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, 2017 and the Company's Quarterly Reports on Form 10-Q.

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Source: Pieris Pharmaceuticals, Inc.