



Pieris Pharmaceuticals Presents Data Demonstrating Monotherapy Clinical Benefit with 4-1BB/HER2 Bispecific PRS-343 in Phase 1 Escalation Study at the Society for Immunotherapy of Cancer (SITC) 2019 Annual Meeting

BOSTON, MA / ACCESSWIRE / November 9, 2019 /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 presentation of data from the phase 1 dose-escalation monotherapy study of PRS-343, a 4-1BB/HER2 bispecific for the treatment of HER2-positive solid tumors, in a late-breaking oral presentation at the Society for Immunotherapy of Cancer (SITC) Annual Meeting. PRS-343 demonstrated single-agent anti-tumor activity, including partial responses, in heavily pre-treated patients across multiple HER2-positive tumors. Beyond demonstrating clinical benefit, PRS-343 showed a potent increase in CD8+ T cell numbers and proliferative index in the tumor microenvironment of responders, indicative of 4-1BB agonism on T cells. PRS-343 was safe and well tolerated at all doses and schedules tested.

"The data presented today demonstrate PRS-343's potential to make a meaningful difference for patients with tumors that are difficult to treat with currently-available therapies," said Geoffrey Y. Ku, medical oncologist at Memorial Sloan Kettering and the principal investigator for the PRS-343 monotherapy trial. "Beyond today's presentation, I look forward to sharing some of these case studies at Pieris' upcoming R&D day alongside emerging data from the study of PRS-343 in combination with atezolizumab."

The ongoing phase 1 first-in-human, open-label multicenter trial has enrolled 53 patients, including 19 patients with gastric cancer, 14 patients with breast cancer, 6 patients with gynecological cancers, and 14 patients with other tumor types. Eleven dose cohorts have been evaluated at a Q3W dosing schedule, with the 11th dose level (8 mg/kg) also being evaluated at a Q2W dosing schedule. Pre- and post-treatment biopsies were obtained from many of the patients. Trial objectives include evaluation of safety and tolerability, characterizing the pharmacokinetic profile, assessing pharmacodynamic and potential immunogenicity effects, and investigating clinical response.

As of the cut-off date of October 23, 2019, 18 patients were evaluable for a response at active dose levels, which began at cohort 9 (2.5 mg/kg).

- At the 8 mg/kg Q2W dose level, one patient with stage 4 gastric adenocarcinoma and one patient with stage 4 gynecological carcinoma achieved confirmed partial responses; the remaining patients experienced stable disease, for an overall disease control rate of 100% in this cohort as best response.
- Across the remaining active dose levels and schedules, an additional five patients experienced stable disease.
- Biomarker data from post-treatment tumor biopsies in patients receiving active dose levels and showing clinical benefit reflected a pronounced increase in CD8+ T cell numbers.
- As of the cutoff date, treatment duration across active dose levels is over 30 weeks.
- Treatment-related adverse events (AEs) were primarily grade 1 and 2. The most common AEs were infusion related reactions and fatigue. No patients experienced a dose-limiting toxicity and a maximum tolerated dose has not been reached.

"In addition to being the first 4-1BB bispecific to enter the clinic, PRS-343 is our lead immuno-oncology asset, and we believe this dataset serves as early clinical validation of our 4-1BB-targeting immuno-oncology approach and the Anticalin bispecific platform," said Stephen S. Yoder, President and Chief Executive Officer of Pieris. "PRS-343 shows promising signs of efficacy linked to clear biomarker evidence of 4-1BB agonism, in addition to being safe and well tolerated. We look forward to concluding this escalation trial in the near term and initiating an expansion trial informed by the emerging data. We also look forward to initiating clinical development of our 4-1BB/PD-L1 bispecific, PRS-344, with Servier in the first half of next year."

A copy of the presentation is available at this [link](#).

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 Statement:

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 expected timing of the reporting by the Company of key clinical data from its lead 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 or making IND filings related to our programs, and partnering prospects for any such programs. 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, 2018 and the Company's Quarterly Reports on Form 10-Q.

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