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# Pieris Signs 1st Partnership for Anemia Drug PRS-080, Granting Exclusive Option in Japan to ASKA Pharmaceutical

## Novel Hepcidin Inhibitor Addressing High Medical Need in Anemia of Chronic Disease

BOSTON, MA -- (Marketwired) -- 02/27/17 -- **Pieris Pharmaceuticals, Inc.** (NASDAQ: PIRS), a clinical-stage biotechnology company advancing novel biotherapeutics through its proprietary Anticalin® technology platform, today announced that it has granted ASKA Pharmaceutical Co., Ltd., an independent Japanese pharmaceutical company with annual sales of approximately \$400 million, an exclusive option to license development and commercial rights to Pieris' anemia drug, PRS-080, in Japan and certain other Asian markets following completion of a multi-dose Phase 2a study to be conducted by Pieris in dialysis-dependent anemia patients.

PRS-080 is a highly potent inhibitor of hepcidin, a key regulator of iron metabolism. Elevated hepcidin levels both prohibit iron uptake from dietary consumption and block the release of iron from body storage cells, such as hepatocytes and macrophages. Excess hepcidin is, therefore, often the root cause of iron deficiency and iron-restricted reduction of erythropoiesis, resulting in anemia in patients with chronic kidney disease (CKD) and other conditions. Current treatment options, which include erythropoietin stimulating agents and iron supplements, are associated with side effects, and not all patients respond to those agents. PRS-080 seeks to overcome these limitations by neutralizing hepcidin directly. A Phase 1 study conducted in healthy volunteers demonstrated that a single dose of PRS-080 was well tolerated and resulted in a dose-dependent increase in serum iron. Pieris has completed dosing of all patients in a Phase 1b study in CKD patients on hemodialysis and will next pursue a multi-dose, Phase 2a study in the same patient population, which is scheduled for completion in the second half of 2017.

Under the terms of the option agreement, Pieris will receive an immediate option payment of \$2.75 million USD from ASKA. Following an analysis period after the completion of the planned Phase 2a study conducted by Pieris, ASKA may exercise its option to obtain an exclusive license to develop and commercialize PRS-080 in Japan, South Korea and certain other Asian markets (excluding China). Should ASKA exercise the option, Pieris would be eligible for more than \$80 million USD in combined option exercise fee and milestones associated with development and commercialization of PRS-080 in the first indication in Japan. Pieris may receive further development milestones in additional

indications, as well as in other countries within the ASKA territory. Pieris may also receive double-digit royalties on net sales of PRS-080 up to the mid- to high-teens.

"We are pleased to have found a very committed partner for PRS-080 in a key Asian market," stated Stephen Yoder, President and Chief Executive Officer of Pieris.

"Importantly, this deal enables us to invest in improving drug manufacturing efficiencies while conducting our Phase 2a trial to enable seamless drug supply for future clinical studies by ASKA and other partners we may seek in other territories, as we focus our proprietary pipeline in immunology-related areas for long-term value creation."

"Anemia in hemodialysis patients represents a substantial medical need in Japan, as physicians are not comfortable prescribing high doses of erythropoietin stimulating drugs, such as EPO and iron supplements. PRS-080 is well positioned to address this medical need in the future. We are thus very excited to have secured an option for this highly innovative drug," stated Takashi Yamaguchi, President and Representative Director at ASKA Pharmaceutical.

"We are looking forward to conducting the planned Phase 2a study with PRS-080," stated Dr. Louis Matis, Senior Vice President and Chief Development Officer of Pieris. "At the same time, we continue to focus on readying a highly differentiated pipeline of novel biotherapeutics for clinical development, with our lead Immuno-Oncology bispecific drug candidate, PRS-343, scheduled to enter a first-in patient trial in the first half of 2017, as well as our inhaled drug candidate for the local treatment of asthma, PRS-060, anticipated to begin a first-in-human study around the middle of 2017."

Locust Walk served as transaction advisor to Pieris.

#### ***About Pieris Pharmaceuticals:***

Pieris Pharmaceuticals is a clinical-stage biotechnology company that discovers and develops Anticalin-based drugs to target validated disease pathways in a unique and transformative way. Our pipeline includes immuno-oncology multispecifics tailored for the tumor micro-environment, 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 protein 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](http://www.pieris.com).

#### ***About ASKA Pharmaceutical:***

ASKA Pharmaceutical Co., Ltd. is a leading Japanese pharmaceutical company focused on three fields: Internal medicine, the obstetrics and gynecology and urology. Since its foundation in 1920, it has built up a record of achievement as a pharmaceutical manufacturer and marketing distributor of specialty hormone preparations with technical capabilities that are top-class among Japanese companies. For further information, please visit [www.aska-pharma.co.jp/english/index.html](http://www.aska-pharma.co.jp/english/index.html).

#### ***About Anticalin Therapeutics:***

Anticalin proteins are derived from lipocalins, small human proteins that naturally bind, store and transport a wide spectrum of molecules. Anticalin proteins feature the typical four-loop variable region and a rigidly conserved beta-barrel backbone of lipocalins, which, together, form a shapeable cup-like binding pocket. Proprietary to Pieris, Anticalin proteins are a novel class of protein therapeutics validated in the clinic and by partnerships with leading pharmaceutical companies. Anticalin® is a registered trademark of Pieris.

### ***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; our business and product development plans and timelines; the timing and progress of our studies, development of therapeutic programs; our liquidity and ability to fund our future operations; our ability to achieve certain milestones and receive future milestone or royalty payments; current or future partnerships; or market information. 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; 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](http://www.sec.gov), including without limitation the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2015 and the Company's Quarterly Reports on Form 10-Q.

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