Pieris reports preclinical development progress of its next generation VEGF antagonist

PRS-050 program on track to commence clinical trials as planned

Freising-Weihenstephan, Germany – October 9th, 2009.

Pieris AG, the biopharmaceutical company developing Anticalins as a novel class of targeted human protein therapeutics, today reported continued progress in development of its lead therapeutic program for the clinic.

Under its manufacturing agreement with Wacker Biotech GmbH, a full-service contract manufacturer of biopharmaceuticals, Pieris has successfully completed the first cGMP run of its Anticalin candidate PRS-050, a potent VEGF antagonist with broad therapeutic applicability.

Having established production process parameters for PRS-050 earlier in 2009, Pieris has now met all regulatory CMC requirements to file an IND application by the end of January 2010. With toxicology studies running concurrently, PRS-050 is scheduled to commence first in man studies in the first half of 2010. Progress in the PRS-050 program demonstrates that Anticalin discovery programs can be successfully advanced from lead candidate to GMP production in around twelve months.

Commenting on these developments at Pieris, Claus Schalper, interim-CEO, said: “Sustained progress in development of PRS-050 underscores our commitment to advancing our lead Anticalin program into the clinic as quickly and efficiently as possible. This is in line with Pieris’ strategy to bring Anticalins into the clinics while partnering selected project at an earlier development stage."

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About Pieris AG

Pieris is a biopharmaceutical company engaged in the discovery and development of Anticalins, a novel class of targeted human proteins designed to diagnose and treat serious human disorders. Exploiting extensive know-how in protein engineering as part of a broad intellectual property portfolio, the company applies a balanced risk business model to the development of Anticalin product candidates.

About Anticalin Technology

Anticalins are engineered binding proteins derived from the scaffold of natural human lipocalins. Anticalins are selected to have prescribed binding properties with selectivity and affinity fundamentally similar to that of monoclonal antibodies. Being human in origin, Anticalins are predicted to have minimal immunogenicity in man. Furthermore, compared to conventional antibodies Anticalins benefit from their small size (20 kDa), robust physicochemical properties and simple composition that together allow highly soluble and stable products to be manufactured from bacteria. Anticalins are amenable to further engineering to balance their favorable tissue penetration with adjustable serum half-life. Moreover, Anticalins have been developed as Duocalins, whose dual targeting format allows multiple targets to be bound and modulated through a single molecule.

Pieris exclusively owns the Anticalin patent estate, which offers complete freedom to operate outside the patent boundaries defined by conventional antibody products. Key patents have already been granted in the US, Asia and Europe.

About PRS-050

PRS-050 Anticalin has been designed to specifically bind and block the signaling activity of vascular endothelial growth factor (VEGF) in cancer. Optimised for extended serum half-life, PRS-050 exhibits comparable binding and functional *in vitro* activity to approved VEGF antagonists. Potent inhibition of VEGF-induced enhanced vascular permeability and angiogenesis, as well as anti-tumour activity, have already been demonstrated for PRS-050 in various well-validated *in vivo* preclinical studies.

As a next generation VEGF antagonist, PRS-050 exploits several favourable characteristics of Anticalins, including compact protein structure, high intrinsic stability, broad formulation flexibility and small molecular size with the potential to penetrate neovascularized tumour tissue more effectively. PRS-050 is being developed for a Phase I study in patients with advanced malignancies.

Further information on Pieris AG is available at www.pieris-ag.com.