

February 3, 2009



Pieris reports development progress for Anticalin® PRS-050, a next generation VEGF antagonist

Expansion of management team announced to support program success

Freising-Weihenstephan, Germany - February 3rd, 2009.

Pieris AG, a biopharmaceutical company developing Anticalins[®], a novel class of targeted human protein therapeutics, reports today that it has made significant progress in the development of its Anticalin[®] candidate PRS-050, a potent VEGF antagonist with broad therapeutic applicability.

Having successfully demonstrated the mode of action of PRS-050 in vitro and in vivo, Pieris has now validated the efficacy of the Anticalin[®] product candidate in several preclinical models. Amongst those tested, DCE-MRI (Dynamic Contrast-Enhanced Magnetic Resonance Imaging) has been established and validated to monitor immediate treatment effects in the upcoming Phase I clinical trial. Production process parameters for GMP manufacture of PRS-050 have also been clearly defined. Initial toxicology results have shown that PRS-050 is very well tolerated.

Progress in the PRS-050 program demonstrates that Pieris has fulfilled critical speed and capacity goals in producing Anticalins[®] as clinical product candidates. Discovery programs can be advanced from lead candidate to GMP production in less than twelve months. Furthermore, several grams per liter production of Anticalins[®] in Wacker Biotech's proprietary bacterial secretion system ESETEC[®] supports broad therapeutic application of the Anticalin[®] technology.

In light of the progress in its lead proprietary program, the Company also announced the expansion of its Management Team with the appointment of Dr Kristian Jensen as Chief Operating Officer. Dr Angelika Stern will henceforth be fully dedicated to management of the PRS-050 program in her new function as Head of Project Management Angiogenesis.

Kristian Jensen joins Pieris from Merck Serono, where he spent almost three years establishing and managing its phage display antibody facility in Geneva, Switzerland. Prior to Merck Serono, he obtained his research management experience during four years as Group Leader in discovery at Xerion Pharmaceuticals AG, and more recently while responsible for key external collaborations at Pieris. Dr Jensen has a background in chemistry and holds a PhD in molecular biology from the University of Aarhus, Denmark.

Commenting on these developments at Pieris, Evert Kueppers, Chief Executive Officer, stated: "I am delighted to welcome Kristian to head up research activities at Pieris. With his extensive experience in the discovery and development of biologics, together with his knowledge of the demands of product-focused biopharmaceutical companies, he will provide invaluable research direction to both our partnered and proprietary Anticalin[®] programs."

Kristian Jensen commented further: "Pieris has made remarkable progress over the past three years and together with its current financial strength, offers an exciting opportunity to further develop the Anticalin[®] portfolio, thereby combining conventional antibody advantages with key features of small molecule drugs".

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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.

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 currently being prepared for a Phase I study in patients with advanced malignancies.

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

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