



## **Pieris validates the use of Anticalins<sup>®</sup> as ophthalmologic biotherapeutics**

**Freising-Weihenstephan, Germany – September 5<sup>th</sup> 2007.** Pieris AG, a biopharmaceutical company developing Anticalins<sup>®</sup>, a novel class of targeted human protein therapeutics, today announced successful completion of a series of preclinical studies validating the use of Anticalins<sup>®</sup> in ophthalmologic disease.

The studies reported by Pieris relate to PRS-055, an Anticalin<sup>®</sup> specific for VEGF. VEGF is a key factor in the regulation of neovascular permeability and is implicated in debilitating eye diseases such as age-related macular degeneration (AMD), proliferative diabetic retinopathy and retinopathy of prematurity. Intravitreal injection of PRS-055 has been shown to inhibit VEGF-induced breakdown of the blood-retinal barrier in a rabbit *in vivo* model. The antagonistic effect of PRS-055 has been shown to be of equivalent potency to that of the approved ophthalmology product Lucentis<sup>®</sup> (ranibizumab; Genentech / Novartis).

“These exciting results have demonstrated that Anticalins<sup>®</sup> are viable candidates as potent biotherapeutics for diseases of the eye” said Dr Andreas Hohlbaum, Director of Science and Preclinical Development of Pieris. “Based on the success of the PRS-055 program to date, we are now selecting technologies for depot and/or non-invasive drug delivery that will exploit the favorable size and excellent stability characteristics of Anticalins<sup>®</sup>.”

The preclinical data on PRS-055 will be presented on September 8<sup>th</sup>, 2007, at the IV. International Symposium of the German Ophthalmological Society (DOG) in Baden-Baden, Germany.

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## Notes to editors

### About Pieris AG

Pieris is a biopharmaceutical company engaged in the discovery and development of Anticalins<sup>®</sup>, 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<sup>®</sup> Technology

Anticalins are engineered by Pieris from the scaffold of human lipocalins, a family of natural ligand binding proteins. 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. Where Anticalins benefit compared to conventional antibodies is in their small size (20 kDa), their robust physicochemical properties and their simple composition that together allow highly soluble, predictably stable products to be manufactured from bacteria. Anticalins are amenable to further engineering to balance their favorable tissue penetration with adjustable serum clearance. Moreover, Anticalins have been developed as Duocalins<sup>®</sup>, whose dual targeting format allows multiple targets to be bound and modulated through a single molecule.

Pieris and its collaborators are not only able to develop superior biotherapeutics, but can do so outside the complex patent landscape that encumbers the development of conventional antibody products.

### About VEGF and PRS-055

Angiogenesis is the development of new blood vessels from pre-existing vasculature and as a pathologic process plays an important role in several diseases. Although various pro- and anti-angiogenic factors have been identified, Vascular Endothelial Growth Factor (VEGF) has been implicated as the key pro-angiogenic factor both in cancer and in neovascular eye disorders.

The PRS-055 program has been designed to develop Anticalins that specifically bind to and block the signaling activity of VEGF. Targeting VEGF provides for inhibition of both neovascularization and blood vessel hyperpermeability. PRS-055 exhibits a favorable binding and functional *in vitro* activity profile comparable to certain approved VEGF antagonists. Complete inhibition of VEGF-induced enhanced vascular permeability and angiogenesis, as well as, its promotion of tumor growth, has previously been demonstrated *in vivo* using systemic administration of a half-life extended version of PRS-055.

PRS-055 exploits the compact structure, intrinsic stability, broad formulation flexibility and small molecular size of Anticalins to develop products with enhanced penetration of neovascularized tissues in indications such as age-related macular degeneration (AMD) and diabetic retinopathy. Pieris is currently exploring innovative depot formulation and non-invasive delivery methods for future application to this program.

Further information is available at <http://www.pieris-ag.com>

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