

# PRESS RELEASE

## Joint press release of WACKER and PIERIS

Number 27

## WACKER Validates Scalability of Anticalin<sup>®</sup> Production With E.coli Secretion Technology and Will Produce Pieris' First Clinical Candidate PRS-050

**Freising-Weihenstephan/Jena, Germany, July 3, 2008 – Pieris AG, a biopharmaceutical company developing Anticalins<sup>®</sup>, a novel class of targeted human protein therapeutics, and Wacker Biotech GmbH, a full-service contract manufacturer of biopharmaceuticals, announced today a significant milestone in the development of Pieris' PRS-050 Anticalin<sup>®</sup> for clinical trials.**

Pieris has developed PRS-050 as a next generation VEGF antagonist and as the first Anticalin<sup>®</sup>-based product in its proprietary pipeline. PRS-050 exemplifies many of the favorable characteristics of Anticalins<sup>®</sup>: compact protein structure, high intrinsic stability, broad formulation flexibility and small molecular size improving the likelihood of effective target access. PRS-050 has already demonstrated potent inhibition of VEGF-induced enhanced vascular permeability and angiogenesis, as well as, anti-tumour activity and is expected to enter the clinic in 2009.

WACKER's proprietary E. coli secretion system is a well-established technology for the cost-efficient production of proteins. At the core of the technology is a proprietary E. coli K12- strain, developed by WACKER, to secrete recombinant proteins in native form. Production of clinically relevant proteins via direct extracellular secretion offers a

Press Release Page 2 of 4 Number 27 July 16, 2008

far more cost effective approach to biopharmaceutical product manufacture than traditional protein refolding technologies.

Andreas Hohlbaum Ph. D., Chief Technology Officer of Pieris, stated: "Pieris has long-established expertise in small scale expression of Anticalins<sup>®</sup> for research use. As we progress our products to the clinic, we have established through our relationship with WACKER that an efficient production scale-up is possible. These excellent results and subsequent agreement with WACKER will expedite process development and GMP manufacture of Anticalins<sup>®</sup> for both proprietary and partnered products."

Thomas Maier Ph.D., Managing Director of Wacker Biotech, commented further: "The Anticalin<sup>®</sup> technology is one of the most exciting 'Beyond Antibody' technologies and we are very proud to support Pieris in its aims to develop this new class of therapeutic proteins. The results obtained to date underscore the power of our E. coli secretion technology and highlight Wacker Biotech's commitment to becoming a leading force as a full-service contract manufacturer of biopharmaceuticals."

#### **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<sup>®</sup> product candidates.

Press Release Page 3 of 4 Number 27 July 16, 2008

### **About Anticalin<sup>®</sup> Technology**

Anticalins<sup>®</sup> are engineered binding proteins derived from the scaffold of natural human lipocalins. Anticalins<sup>®</sup> are selected to have prescribed binding properties with selectivity and affinity fundamentally similar to that of monoclonal antibodies. Being human in origin, Anticalins<sup>®</sup> are predicted to have minimal immunogenicity in man. Furthermore, compared to conventional antibodies Anticalins<sup>®</sup> 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<sup>®</sup> are amenable to further engineering to balance their favorable tissue penetration with adjustable serum half life. Moreover, Anticalins<sup>®</sup> have been developed as Duocalins<sup>®</sup>, whose dual targeting format allows multiple targets to be bound and modulated through a single molecule. Pieris exclusively owns the Anticalin<sup>®</sup> patent estate, which offers complete freedom to operate outside the patent boundaries defined by conventional antibody products. Key patents have already been granted both in the US and in Europe.

### **About PRS-050**

PRS-050 Anticalin<sup>®</sup> has been designed to specifically bind and block the signalling 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.

Press Release Page 4 of 4 Number 27 July 16, 2008

As a next generation VEGF antagonist, PRS-050 exploits several favourable characteristics of Anticalins<sup>®</sup>, 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.

Anticalin<sup>®</sup> and Duocalin<sup>®</sup> are registered trademarks of Pieris AG.

Further information on Pieris AG is available at [www.pieris-ag.com](http://www.pieris-ag.com).

#### **About Wacker Biotech**

Wacker Biotech GmbH is a full-service contract manufacturer of biopharmaceuticals derived from microbial systems. Its portfolio ranges from services in molecular biology, analytical and process development, through the GMP-compliant production of clinical test material, to active pharmaceutical ingredient for commercial market supply. Above all, Wacker Biotech offers proprietary technologies that satisfy market needs for cost-efficient and high-quality production. Two examples are its E. coli-based secretion technology and high-cell-density fermentation process. Wacker Biotech, Jena, is a wholly-owned WACKER subsidiary.

Further information on Wacker Biotech GmbH is available at [www.wacker.com/biologics](http://www.wacker.com/biologics)

**For further information, please contact:**

**Wacker Chemie AG**

**Nadine Baumgartl**

**Media Relations und Information**

**Telephone +49 89 6279-1604**

**Fax +49 89 6279-2604**

**[nadine.baumgartl@wacker.com](mailto:nadine.baumgartl@wacker.com)**

**Pieris AG**

**Andreas Hohlbaum PhD**

**Chief Technology Officer**

**Telephone +49 8161 1411 400**

**Fax +49 8161 1411 444**

**[info@pieris-ag.com](mailto:info@pieris-ag.com)**