Xenikos signs representation contract with Tytonis
June 24th, 2011, Nijmegen, The Netherlands, and Alkmaar, The Netherlands

Xenikos BV ("Xenikos", or the "Company") and Tytonis B.V. ("Tytonis") announces today that they have signed a representation contract under which Tytonis will support Xenikos in its ongoing financing round and to support the Company furthermore in the out-licensing of its lead clinical product, T-Guard™, for the treatment of various severe immunological disorders related to T cell deregulations. The undisclosed contract contains a risk sharing provision under which Tytonis is participating in the commercial risk involved with the product transaction process.

Xenikos, founded in 2009 in Nijmegen by Dr. Ypke van Oosterhout, is a privately owned company. The company was founded after a strategic restructuring of the previous owner of the T-Guard™ product Henogen, following its acquisition by NovaSep. As a result of this merger, the product rights were entirely transferred to Xenikos.

Tytonis, founded in 2006 by Dr. H. Luessen, is a privately owned company providing advisory services to a selected group of pharmaceutical companies to support them in Corporate/Business Development, Licensing, Valuation, Portfolio Strategy, Pharmaceutical Product Development and Drug Delivery related topics. Tytonis also operates within a highly distinguished expert network of former industrial executives and internationally known experts, called “Pharma at Work”.

T-Guard™ is an antibody-based medicine that has originally been developed at the UMC St Radboud (Nijmegen). Its mechanism of action is based on a swift and efficient removal of adult T cells within the patient's body: the so-called ‘resetting of the immune system’. This principle might prove useful in several serious conditions that are caused by over-reactive and/or misdirected T cells. So far, T-Guard has been clinically tested in a small group of patients in an investigational trial suffering from life-threatening rejection following a blood stem cell transplantation (so-called Graft-versus-Host Disease, GVHD). This pilot-study delivered a convincing ‘proof of principle’. Impressive biological and clinical improvements could be noted without serious toxicities occurring. Most importantly, it was demonstrated that T-Guard was indeed capable of ‘rebooting the immune system’: i.e. the generation of new T cells was not accompanied with a recurrence of the GVHD disease.

T-Guard has obtained the European Orphan Drug Designation (August 2005), a full GMP-production has been established, and a Protocol Assistance Procedure had been started with the European Medicines Agency (EMA) and the Dutch National Institute for Public Environment and Health (RIVM), resulting in the performance of additional pre-clinical studies, including a sub-acute toxicity study in 28 Cynomolgus monkeys. Moreover, all preparations for performing a clinical Phase Ib/Ia multicenter study have been completed, including the finalization of study documents, the drafting of the contracts with the CRO and participating centers, and the obtaining of the approval of the Ethics Committee.
Dr. Ypke van Oosterhout, CEO of Xenikos, says: “T-Guard has gone a long way since its initial ‘discovery’ at the UMC St Radboud. Based on the promising clinical results obtained thus far, we really think that this product can make a difference in treating severe acute GVHD and, potentially, also other serious diseases in which misbehaving T cells are implied. The eagerness of several renowned Hematologists to further evaluate T-Guard in their transplant centers, together with the commitment of Tytonis to help us finding the right partner for meeting our development goals, makes us confident about T-Guard’s future.”

Dr. Henrik Luessen, CEO of Tytonis, says: “We followed the development of this T-Guard project already when it was early developed with the UMC St. Raadboud in Nijmegen in 2000 as we considered the approach to address deregulated T/NK-cells with this novel conjugated antibody approach highly interesting. When getting aware of the clinical results of T-Guard™ at the end of 2010 for the first time we found out that our earlier expectations concerning the therapeutic potential of the drug have been entirely fulfilled. We are very delighted to represent this highly exciting product opportunity, which may impact the quality of life of many seriously affected Graft-versus-Host disease patients even if there is not much hope for a cure or prolongation of their life span in sight. It should be noted that many other diseases based on deregulated T cells such as rheumatoid arthritis may benefit from T-Guards ability to reset the T cell balance into a healthy condition. This product deserves to be brought to the market quickly. This is also the opinion of the Pharma at Work expert network that supports the T-Guard™ product with full commitment. We invite both investors to participate in Xenikos to develop the product to the next valuation point demonstrating efficacy in clinical phase IIa and/or phase II studies, and qualified pharmaceutical companies in the immunological area to partner the T-Guard™ project together with Xenikos. We are open and flexible in our negotiations and focus on time efficient impact to bring the product to the medical community.”

For further information, please contact:
Henrik L. Luessen, Tytonis BV, telephone number +31 (6) 215 66 415 or e-mail henrik.luessen@tytonis.com. A non-confidential factsheet providing further detailed information can be downloaded from the Tytonis website: www.tytonis.com/licensing.htm.

This document may contain certain forward-looking statements relating to the business, financial performance and results of Tytonis B.V., Xenikos B.V. and the industry in which it operates. These statements are based on Tytonis’ and Xenikos’ current plans, estimates and projections, as well as its expectations of external conditions and events. In particular the words “expect”, “anticipate”, “predict”, “estimate”, “project”, “plan”, “may”, “should”, “would”, “will”, “intend”, “believe” and similar expressions are intended to identify forward-looking statements. We caution investors that a number of important factors, and the inherent risks and uncertainties that such statements involve, could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements.