

## **PRESS RELEASE**

# Xenikos awarded EUR 1 million innovation credit extension to support T-Guard™ development

Nijmegen, the Netherlands, January 3<sup>rd</sup>, 2017 – Xenikos B.V., focused on the development of innovative immunotherapies for the treatment of patients suffering from serious immune diseases or rejection after transplantation, announced today that it has been awarded a EUR 1 million innovation credit extension by the Netherlands Enterprise Agency (Rijksdienst voor Ondernemend Nederland, RVO), part of the Dutch Ministry of Economic Affairs. The funding is to support the next steps in the development of product candidate, T-Guard, which is in clinical Phase 1/2 testing for the treatment of steroid-resistant acute graft versus host disease (GVHD). T-Guard consists of a combination of two toxin-loaded anti-T-cell antibodies and has shown promise as a therapeutic tool for safely and swiftly resetting the body's immune system in T-cell-mediated diseases.

Xenikos was first granted an innovation credit in the amount of EUR 1.9 million in 2012. The innovation credit is a credit facility dedicated to projects that are technologically innovative and unique to the Netherlands, Bonaire, St. Eustatius and Saba. The credit awarded to Xenikos covers 35% of the submitted project costs and becomes repayable only if T-Guard establishes its therapeutic efficacy (proof of concept). In 2015, Xenikos was awarded an extension in the amount of EUR 0.3 million. With the extension announced today, Xenikos will have received a total of EUR 3.2 million under this program.

"The funding provided by the innovation credit is supporting the ongoing development of T-Guard, including the technology transfer of the GMP production to our manufacturing partner and preparations for the pivotal Phase 2 study in steroid-resistant acute graft-versus-host disease," said Ypke van Oosterhout, PhD, Chief Executive Officer. "With our announcement earlier this fall that the last patient has completed treatment in the Phase 1/2 trial evaluating T-Guard for this indication, we are making good progress in advancing this important technology for the treatment of GVHD, a serious disease for which current therapies are often ineffective."

## About T-Guard™

T-Guard is currently in development by Xenikos for the treatment of certain life-threatening immune conditions, such as transplant-related rejection, graft versus host disease (GVHD), acute solid-organ rejection and several severe autoimmune diseases. T-Guard consists of a combination of two toxin-loaded anti-T-cell antibodies and shows promise as a therapeutic tool for safely and swiftly resetting the body's immune system in T-cell-mediated diseases. Once injected into the body, T-Guard specifically identifies and eliminates adult T cells, with a strong preference for the activated ones. The particular combination of immunotoxins used to construct T-Guard was designed to provide a unique blend of synergistic efficacy, narrow specificity and multiple, gentle mechanisms of action. In preclinical testing, T-Guard was shown to be highly effective in killing activated T cells and to act through apoptotic (programmed cell death) mechanisms, which are associated with minimal side effects. T-Guard's targeted action is believed to leave patients less vulnerable to opportunistic infections when compared to historical controls of institutional standard of care. In a clinical proof-of-



concept study, T-Guard appeared to be well tolerated with strong biological and clinical responses observed. T-Guard is currently in clinical Phase 1/2 testing in Europe for the second-line treatment of steroid-resistant acute GVHD. The primary endpoint of the study is response rate at 28 days. Other endpoints include overall survival at 180 days; safety and tolerability are also being evaluated. Preliminary results from this study showed strong clinical responses and indicated a substantial improvement over published institutional historical survival rates, with a well-manageable side effect profile without severe infusion reactions. T-Guard has been granted Orphan Drug Designation in both the EU and US. The Company plans to initiate a pivotal clinical study in the second half of 2017.

#### About Xenikos B.V.

Xenikos B.V. is developing new, innovative immunotherapies to help restore patients' health and save lives. It is developing new therapies based on the action of conjugated antibodies that enables patients suffering from serious immune diseases or rejection after transplantation to reset their immune systems quickly and efficiently. Its lead product candidate T-Guard™ is currently being developed for the second-line treatment of steroid-resistant acute GVHD. Further information is available at www.xenikos.com.

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