PRESS RELEASE January 4, 2016

Phase 1/2 Trial of T-Guard™ in the Treatment of Steroid-Resistant, Acute, Graft versus Host Disease (GVHD) Delivers Promising Interim Results

Nijmegen, the Netherlands, January 4, 2016 – **Researchers in the Netherlands and Germany have reported positive interim results of a Phase 1/2 clinical study evaluating T-Guard™ for treatment of steroid-resistant, acute, Graft versus Host Disease (GVHD), a frequent and potentially life-threatening complication of bone marrow and blood stem cell transplantation.**

T-Guard™ is a combination of two toxin-loaded anti-T-cell antibodies that shows promise as a therapeutic tool for safely and swiftly resetting the body's immune system in T cell mediated diseases. It is currently being developed for the treatment of acute Graft versus Host Disease (GVHD), a feared and potentially life-threatening complication of hematopoietic stem cell transplantation. There are presently no registered therapies for acute GVHD patients, who have failed standard first-line corticosteroid therapy and the prognosis for these patients is very poor.

Towards investigation of T-Guard's potential as a medicine, the first full clinical trial (a 20-patient Phase 1/2 trial to explore its safety and efficacy) began in 2014 at the Radboud University Medical Center in Nijmegen, the Netherlands. It was extended to the University Hospital of Muenster, in Germany, in 2015.

Researchers from both institutes have reported positive interim results from the first 13 patients in the trial, who were predominantly suffering from the notoriously difficult-to-treat, steroid-resistant, acute form of GVHD in the gut. Compared to the results of an independently-conducted retrospective study on the institutional standard of care in the period immediately preceding this trial, both the 28-day overall and complete response rate had substantially improved (the majority of patients were complete responders, representing an almost doubling of the complete response rate). This translated into a two-fold higher overall survival rate in the subset of patients, who completed the six-month follow-up period at the time of the interim analysis. T-Guard was also generally well-tolerated and safe. Investigators reported that any adverse events that were potentially treatment-related were all clinically well-manageable. Detailed and final study results will be published upon completion of the study.

While these interim outcomes met the pre-defined criteria of the independent Data and Safety Monitoring Board to recommend the continuation of the study, the results have also generated interest in extending this second phase of the Phase 1/2 study with an additional 20 patients, to explore the benefits of providing an additional T-Guard treatment course to those patients that showed at least a partial response to the first course, and who could benefit from a 'last push' towards a complete response.

Xenikos' current shareholders, Dutch Blood Supply Foundation, Sanquin (Amsterdam, the Netherlands), and regional development company, PPM Oost (Apeldoorn, the Netherlands), have provided additional financial support for this study extension. It is anticipated to position T-Guard optimally for a subsequent, randomized active-controlled pivotal study in the European Union (EU)/United States (US). Based on initial discussions with regulators, it is believed that such a study, if successful, may qualify T-Guard for accelerated approval (US) and conditional marketing authorization (EU).

The primary safety and efficacy outcomes of the extended Phase 1/2 study are expected in Q1 2017.

"We are very pleased by this positive outcome of the interim analysis. These encouraging results, along with the constructive and positive feedback obtained from the key regulatory bodies, bring us a step closer to better treatment of severe acute GVHD." said Ypke van Oosterhout, Chief Executive Officer of Xenikos B.V. - the company behind the development of T-Guard. *"They also mean that discussions regarding the possibility to bring T-Guard's development further towards early market access for treatment of acute GVHD can be advanced."*

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Notes to Editors:

About Graft versus Host Disease

Graft versus Host Disease (GVHD) is a common complication following allogeneic (donor-derived) blood stem cell transplantation. Transplantation of allogeneic blood stem cells is a widely accepted procedure to restore normal blood cell production (hematopoiesis) in patients treated for blood- or lymphatic cancers, or otherwise suffering from defective blood formation, or immunity. For it to be successful, the blood stem cell graft must contain a minimum number of donor-derived T cells (immune cells), which are beneficial in fighting any residual cancer cells. However, sometimes they can attack the normal tissues of the patient, causing Graft versus Host Disease (GVHD). Approximately 25% of blood stem cell transplant patients develop severe acute GVHD that does not respond adequately to standard first-line therapy. In the last twenty years, there has been a steady increase in the number of allogeneic blood stem cell transplants performed annually in the EU and the US, mainly driven by a sharp increase of unrelated donor (high risk) transplantation (1) (2). This trend is expected to continue. There are currently no registered treatment options, for GVHD patients, who have failed standard corticosteroid therapy. The prognosis without treatment is very poor. All these factors combined emphasize the importance of finding new, effective treatment options for GVHD.

About T-Guard™

T-Guard™ is currently under development by Xenikos B.V. for 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. It 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™ provides a unique blend of synergistic efficacy, narrow specificity and multiple, gentle mechanisms of action. Its action is unparalleled by any immunosuppressive product currently available commercially. T-Guard™ is not only very effective in killing activated T cells, but also acts through mechanisms associated with minimal side effects (via apoptosis). Its targeted action leaves patients less vulnerable to opportunistic infections as compared to currently available treatment options.

The safety and efficacy of the new medicine were first evaluated in 2001 in a clinical pilot study at the Radboud university medical center in Nijmegen, the Netherlands. T-Guard™ was granted EU Orphan Drug Designation in 2005 and US Orphan Drug Designation in September 2013.

About Xenikos B.V.

Xenikos B.V. strives to develop new, innovative immunotherapy medicines to help restore patients' health and save lives. It is developing new medicines, based on the action of conjugated antibodies that enables patients suffering serious immune diseases, or rejection after transplantation, to reset their immune system quickly and efficiently. Further information is available at www.xenikos.com

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