

PRESS RELEASE January 13, 2014

New Clinical Study of T-Guard™ in the Treatment of Graft versus Host Disease (GVHD) Begins in The Netherlands

Nijmegen, the Netherlands, January 13, 2014 - Xenikos B.V. today announced the start of a new clinical study in the Netherlands of T-Guard™ for treatment of Graft versus Host Disease (GVHD), a frequent and potentially life-threatening complication of bone marrow and blood stem cell transplantation. The Phase I/II trial began on January 6, 2014 following approval from the relevant Dutch authorities late in 2013.

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. T-Guard 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. The new Phase I/II clinical trial will explore the safety and efficacy of T-Guard™ in 20 patients with severe steroid-refractory acute GVHD.

The study is being conducted at Radboud university medical center in Nijmegen, the Netherlands – a leading Dutch academic medical center that incorporates specialist hematology capabilities. Experts at the hospital carry out approximately 60-70 transplants per year and are eager to find a new, effective treatment option that can reduce the significant negative impacts of acute GVHD on outcome and transplant patients' Quality of Life. The study will be managed by a team of dedicated hematology specialists, nurses, and data analysts, lead by Dr. Walter van der Velden, MD., PhD. Internist-Hematologist and Principal Investigator of the study.

The primary endpoint of the study will be the overall response rate at Day 28, (the current standard primary endpoint of acute GVHD trials). Secondary endpoints include: six months overall survival and the safety and tolerability of T-Guard™. An interim analysis, evaluating both T-Guard™'s efficacy and safety, is anticipated in the third quarter of 2014. The final trial outcomes are expected during mid 2015.

Xenikos plans to expand the study into Germany, at the University Hospital Münster, Germany, upon receipt of approval for the trial by the relevant German authority, the Paul Ehrlich Institute.

"The start of our latest trial means we can take another major step forward in bringing T-Guard™ to patients to rectify the current lack of registered treatment options for GVHD," said Ypke van Oosterhout, Chief Executive Officer of Xenikos. "We anticipate that the results will strengthen the evidence of T-Guard™'s promise in the treatment of severe acute GVHD."

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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

About the Radboud university medical center

The Radboud university medical center advances human knowledge by conducting biomedical, translational and clinical research in order to improve treatment outcome and patient wellbeing. Its key strength is medical life-sciences and clinical practice, with an impressive infrastructure comprising state-of-the-art technology platforms and (translational) research facilities. The Center is uniquely positioned in the emerging Euregio and Dutch healthcare infrastructure to play a leading role in the new healthcare paradigm of prediction, prevention and personalized medicine. The Center focuses on scientific health challenges of today, with an eye on emerging diseases of the future. Further information is available at: www.radboudumc.nl

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(2) Pasquini MC, Wang Z. Current use and outcome of hematopoietic stem cell transplantation: CIBMTR Summary Slides, 2012. Available at www.cibmtr.org.

T-Guard™ is a registered trademark of Xenikos B.V.