PRESS RELEASE September 18, 2013

T-Guard™ Receives Orphan Drug Designation for Treatment of Graft versus Host Disease (GVHD) in the US

Nijmegen, the Netherlands, September 18, 2013 - **Xenikos B.V. today announced that T-Guard™ has been granted Orphan Drug Designation by the United States (US) Food and Drug Administration (FDA) for the treatment of Graft-versus-Host Disease (GVHD), a frequent and potentially life-threatening complication of bone marrow or blood stem cell transplantation.**

The designation made by the FDA's Office of Orphan Products Development (OOPD) is an important regulatory step towards making T-Guard™ available to patients in the US with GVHD. The OOPD designates orphan status to drugs and biologic products under development that it considers are promising in the safe and effective treatment, diagnosis or prevention of rare diseases or disorders that affect less than 200,000 people in the US. The approval confers several benefits and incentives on Xenikos B.V. These include a seven year period of marketing exclusivity, if regulatory approval for T-Guard in the treatment of GVHD is also received.

"We are delighted with the FDA's decision to grant orphan drug designation for T-Guard™ for treatment of Graft-versus-Host-Disease in the US," remarked Ypke van Oosterhout, Chief Executive Officer of Xenikos. *"Alongside the receipt of orphan drug designation in the European Union (EU), this important regulatory milestone enables us to further strengthen our commitment to patients facing this life-threatening condition worldwide, as well as to others with serious immune diseases."*

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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 (riskier) unrelated donor 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 a medicine 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 T-Guard™ were evaluated in a clinical pilot study at the Radboud University Nijmegen Medical Center in the Netherlands. The results were encouraging, showing a clear therapeutic window in the treatment of severe acute GVHD. Xenikos B.V. is now preparing for T-Guard™'s Phase Ib/IIa Trial, involving 20 patients with severe acute GVHD, who have failed standard corticosteroid therapy. The trial is scheduled to be initiated in hospitals in the Netherlands and Germany during the last quarter of 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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(2) Pasquini MC, Wang Z. Current use and outcome of hematopoietic stem cell transplantation: CIBMTR Summary Slides, 2012. Available at www.cibmtr.org.