PRESS RELEASE

Final results from T-Guard® Phase 1/2 trial in steroid-resistant acute graft-versus-host disease published online in peer-reviewed journal Biology of Blood and Marrow Transplantation

- Overall response rate at 28 days of 60%, complete response rate of 50%
- Overall survival rate of 60% at six months
- Significant improvements seen compared to historical control group
- Company planning to initiate Phase 3 registration trials for US and EU in 2019

Nijmegen, the Netherlands, November 16, 2018 – Xenikos B.V. reported today that final results from a clinical Phase 1/2 trial with T-Guard® for the second-line treatment of steroid-resistant acute graft-versus-host disease (GVHD) were published online in the peer-reviewed journal, *Biology of Blood and Marrow Transplantation* at https://www.bbmt.org/article/S1083-8791(18)30691-8/fulltext.

T-Guard consists of a unique combination of toxin-conjugated monoclonal antibodies that target the CD3 and CD7 molecules on T cells and Natural Killer (NK) cells, and that has been shown in preclinical and early clinical testing to safely and swiftly restore a patient's immune system.

Walter J. F. M. van der Velden, MD, PhD, Radboud University Medical Center Nijmegen, The Netherlands, principal investigator in the study, said: "Effective therapies for treating patients with steroid-refractory acute graft-versus-host disease are urgently needed, especially strategies that reduce the duration of immune suppression following remission. There are currently no approved therapies to treat acute GVHD once a patient becomes resistant to steroids or the disease progresses following steroid treatment. The results published for T-Guard are highly promising from both an efficacy and safety standpoint. If confirmed in the upcoming Phase 3 studies, I believe T-Guard could be a transformational treatment for patients with this life-threatening condition."

The Phase 1/2 trial enrolled a total of twenty adult patients, who all had received an allogeneic stem cell transplant for myeloid or lymphoid malignancies and had Grade II-IV steroid-resistant acute GVHD. The majority of patients were classified as having severe acute GVHD (17/20, 85%); all had visceral involvement (gastrointestinal 18/20, 90%; liver 5/20, 25%); and in 16/20 (80%), two or more organs were involved.

Twelve (60%) of the patients in the trial achieved an overall clinical response (ORR) on day 28, which was the primary endpoint of the trial. Ten patients (50%) achieved a complete response (CR), which is noteworthy considering the severity of the patient population. Twelve (60%) of the 20 patients were alive at six months (achieving six-month overall survival or OS), including 64% (7/11) of those classified as high-risk. The

outcomes compared favorably with the most recent historical controls of the participating centers, which involved a similar cohort of 42 patients treated right before the start of the T-Guard trial. The historical control group achieved an ORR of 52% on day 28, a CR rate of 19% and OS of 29% at six months. Notably, the two-fold difference in OS between T-Guard and the historical controls proved durable during the two-year follow up period.

"We are excited to have the final data from this important clinical study published in a peer-reviewed journal," said **Ypke van Oosterhout, PhD, Chief Executive Officer of Xenikos**. "Following constructive discussions with regulatory authorities in both the US and Europe, preparations are underway to initiate pivotal Phase 3 trials, which are expected to support future regulatory filings for marketing approval."

In the Phase 1/2 trial, the one-week T-Guard treatment course resulted in profound in vivo T and NK cell depletion, followed by a rapid recovery of the immune system starting right after the last T-Guard infusion. Increasing T cell and NK cell numbers and a diverse T cell repertoire suggest a rebalancing of the immune system.

In the trial, T-Guard appeared to be well tolerated. There was a limited number of potentially T-Guard-related adverse events, which consisted of thrombocytopenia, micro-angiopathy and hypoalbuminemia. The adverse events were manageable and reversible after treatment. There were no unexpected serious adverse reactions or serious adverse events related to T-Guard.

The Company is planning to initiate Phase 3 registration trials for the US and EU in 2019.

About Acute Graft-versus-host Disease

Patients who have had an allogeneic stem cell transplant are at high risk of developing graft-versus-host disease (GVHD). The older the person is, the higher the risk for GVHD. GVHD develops when the donor's immune cells mistakenly attack the patient's normal cells. Acute GVHD can occur soon after the transplanted cells begin to appear in the recipient. It ranges from mild or moderate to severe and can be life-threatening if its effects are not controlled. While patients may be successfully treated with steroids, if the disease progresses or if the disease is resistant to treatment, there are currently no approved therapies. The long-term survival of patients with steroid-resistant acute GVHD is only 20% (Calmettes et al., BBMT, 2015); thus, there is an urgent need to develop more effective therapies for this disease.

About T-Guard®

T-Guard is designed to treat steroid-resistant acute graft-versus-host disease (aGVHD), a life-threatening immunological condition that often develops in patients following hematopoietic stem cell transplantation. T-Guard consists of a unique combination of toxin-conjugated monoclonal antibodies that target the CD3 and CD7 molecules on T cells and NK cells. Preclinical and early clinical testing showed that T-Guard can safely and swiftly restore the immune system in patients. T-Guard specifically identifies and eliminates mature T cells and NK cells, with a high preference for activated T cells. In preclinical testing, T-Guard efficiently and selectively targeted these cells by activating non-inflammatory apoptotic mechanisms, with minimal treatment-related side effects. T-Guard's brief, targeted action significantly limits the patient's vulnerability

to opportunistic infection, compared to currently available therapies. Xenikos successfully completed a Phase 1/2 study in 20 patients with severe steroid-refractory aGVHD. The results of this study indicate that T-Guard requires only one week of treatment in order to help restore the immune system's natural balance, offering a curative approach to patients with this severe and often fatal complication. T-Guard has been granted Orphan Drug Designation in both the EU and US. Phase 3 registration trials for the treatment of steroid-resistant aGVHD are planned to begin in the EU and US in 2019. Other potential applications for T-Guard include transplant-related rejection, acute solid-organ rejection, and several autoimmune diseases.

About Xenikos B.V.

Xenikos develops innovative, new immunotherapies, based on conjugated antibodies and designed to improve patient health and quality of life. This powerful therapeutic approach helps reset the immune system in patients with a severe immune disease or post-transplantation rejection. Xenikos' flagship product, T-Guard®, is being prepared to enter Phase 3 testing for the second-line treatment of steroid-resistant acute graft-versus-host-disease in patients following hematopoietic stem cell transplantation.

For more information, visit us at www.xenikos.com.

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