PRESS RELEASE

Xenikos announces data from phase I/II trial with T-Guard™ for treatment of steroid-resistant acute GVHD presented at ASH Annual Meeting

- Fifty percent (50%) day 28 complete responses (CR) and 60% overall survival (OS) at six months in high-risk patient population with 90% lower gastrointestinal tract involvement
- Rapid recovery of the immune system with a diverse T cell repertoire

Nijmegen, the Netherlands, December 11, 2017 – Xenikos B.V. today reported that detailed efficacy and safety data from a clinical phase I/II trial with T-Guard for the second-line treatment of steroid-resistant acute graft-versus-host disease (GVHD) were presented at the 59th Annual Meeting of the American Society of Hematology (ASH) in Atlanta, GA.

Walter J. F. M. van der Velden, MD, PhD, Radboud University Medical Center Nijmegen, The Netherlands gave an oral presentation, entitled, "**A Phase I/II Study on the Anti-CD3/CD7 Immunotoxin Combination (T-Guard™) for the Treatment of Steroid-Refractory Acute GVHD**." Seventeen of the 20 patients in this study (85%) suffered from severe steroid resistant-acute GVHD (Grade III-IV), and all had involvement of visceral organs; gut (18/20; 90%) and liver (5/20; 25%). Twelve of these patients (60%) achieved an overall clinical response (ORR) on day 28, with 10 patients (50%) achieving a complete response (CR). Twelve of the 20 patients were alive at six months (6-months overall survival, OS, 60%). The outcomes compared favorably with the most recent historical controls of the participating centers, receiving either infliximab (N=21) or inolimomab/etanercept (N=21), where an ORR and CR was achieved in 52% and 19% of patients, respectively, and OS at six months was 29%. The one-week 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 with increasing T- and NK-cell numbers and a diverse T cell repertoire, suggesting a rebalancing of the immune system.

Dr. van der Velden said: "With a long-term survival rate of only 20%, there is an urgent need for more effective therapies for steroid-refractory acute graft-versus-host disease, especially for those that limit the level of immune suppression after achieving a remission. Indeed, today there are no approved therapies to treat acute GVHD once a patient becomes resistant to or the disease progresses following treatment with steroids. T-Guard has demonstrated promising response rates and overall survival results, allowed for a swift immune reconstitution and proved to be safe and well tolerated. I look forward to the initiation of the pivotal trial with T-Guard, which, if proven safe and effective, I believe could be a potentially game-changing therapy."

"We are excited about the data from this important clinical study, providing further evidence for the potential of T-Guard to effectively treat stem cell transplantation patients with this life-threatening medical complication," said **Ypke van Oosterhout, PhD, Chief Executive Officer of Xenikos**. "We look forward to discussing the results from the phase I/II trial with FDA soon and gaining their input on the design of the pivotal international phase III trial, which we plan to initiate in the first half of 2018 and that is expected to support a future regulatory filing for marketing approval in both the US and Europe."

The study enrolled twenty adult patients with a median age of 53, who all had received an allogeneic stem cell transplant for myeloid or lymphoid malignancies and had Grade II-IV steroid-resistant acute GVHD. Patients were treated with T-Guard administered as a four-hour intravenous infusion every 48 hours for a total of four infusions (4 mg/m^2 each). The primary efficacy endpoint was defined as overall clinical response (ORR) on day 28. Main secondary endpoints were CR rate at day 28 and 6-month overall survival (OS), as well as safety and tolerability.

Treatment with a short course of T-Guard was generally well tolerated with no significant infusion reactions. 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.

The Company is planning to initiate a pivotal multi-center global active-controlled trial, comparing T-Guard with best-available therapy for steroid-resistant acute GVHD in the first half of 2018.

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 and 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, once the disease progresses or if a 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 in development for the treatment of steroid-resistant acute graft-versus-host disease (GVHD), a life-threatening immune condition. T-Guard consists of a combination of two toxin-loaded antibodies that target CD3 and CD7 on T and NK cells and shows promise as a therapeutic tool for safely and swiftly rebalancing the body's immune system in T-cell-mediated diseases. Once injected into the body, T-Guard specifically identifies and eliminates adult T- and NK-cells, with a strong preference for the activated T cells. In preclinical testing, T-Guard was shown to be highly effective in killing these cells through non-inflammatory apoptotic mechanisms (programmed cell death), which are associated with minimal side effects. T-Guard's brief but targeted action is believed to leave patients less vulnerable to opportunistic

infections when compared to current best available but not yet approved therapies. T-Guard has been granted Orphan Drug Designation in both the EU and US.

Xenikos recently completed a phase I/II study in 20 patients with severe steroid-refractory acute GVHD. Based on the results, the Company believes that T-Guard has the potential to offer a curative approach with a one-week treatment. Unlike other approaches, which only address symptoms, T-Guard actively restores the immunological balance, providing a durable remedy for patients with this devastating and potentially fatal disease. A registration trial for this indication is expected to start in the first half of 2018. Other areas of future development may include transplant-related rejection, acute solid organ rejection and various severe autoimmune diseases.

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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