PRESS RELEASE

Xenikos announces first patient receives T-Guard® for steroid-refractory acute GVHD in pivotal U.S.-based Phase 3 trial

Nijmegen, the Netherlands, December 18, 2019 – The Dutch company Xenikos B.V., which develops innovative immunotherapies for treating patients with severe immune disease and post-transplant rejection, announced today that the first patient has been treated in their U.S.-based Phase 3 registration trial designed to evaluate the use of T-Guard for treating steroid-refractory acute graft-versus-host disease (SR-aGVHD) in patients following allogeneic stem cell transplantation.

This pivotal Phase 3 trial (BMT CTN 1802; clinicaltrials.gov NCT04128319) is designed to evaluate the efficacy and safety of T-Guard in patients who receive an allogeneic stem cell transplant and subsequently develop SR-aGVHD. A total of 47 patients will be enrolled through up to 25 transplant centers in the U.S. The trial is supported by the Blood and Marrow Transplant Clinical Trials Network (BMT CTN) and is co-funded by the National Heart, Lung, and Blood Institute (NHLBI) and the National Cancer Institute (NCI), both part of the National Institutes of Health.

In this single-arm, multi-center study, patients who have been diagnosed with SR-aGVHD will receive four infusions of T-Guard over the course of a week. The primary endpoint of the study is the complete response rate on day 28, and secondary endpoints include duration of complete response, overall response rate, and overall survival rate six months after treatment.

“We are delighted to start this registration trial, which represents a major step forward in helping bring T-Guard to patients,” said **Dr. Ypke van Oosterhout, Chief Executive Officer of Xenikos**. “With the BMT CTN’s vast network of leading transplant centers throughout the U.S., and their experience conducting clinical trials, we believe they will be able to recruit sufficient numbers of patients quickly. Effective new therapies for treating SR-aGVHD are urgently needed, and we believe that T-Guard may provide patients with an effective new option for treating this devastating and potentially fatal condition.”

“Acute GVHD is a life-threatening complication of hematopoietic stem cell transplantation, and better treatments are urgently needed, particularly for patients with steroid-refractory acute GVHD, for which only limited therapeutic options are currently available, resulting in an extremely poor long-term prognosis,” said **Dr. Mehdi Hamadani of the BMT CTN**. “The preliminary data obtained with T-Guard are promising, and we look forward to helping bring this new therapy through the final phase of development and into the clinic.”

T-Guard: helping reset the body’s immune system

T-Guard is designed to safely and swiftly reset the body’s immune system in life-threatening T cell–mediated conditions, including transplant-related rejection, acute solid-organ rejection, and severe autoimmune disease. T-Guard consists of a unique combination of toxin-conjugated monoclonal antibodies that target CD3 and CD7 molecules on T cells and NK cells. Preclinical and early clinical testing have shown that T-Guard can

specifically identify and eliminate mature T cells and NK cells with minimal treatment-related side effects. Importantly, T-Guard's action is short-lived, thereby significantly reducing the patient's vulnerability to opportunistic infections compared to currently available therapies. Xenikos successfully completed a Phase 1/2 study for the second-line treatment of SR-aGVHD in patients following hematopoietic stem cell transplantation (HSCT), showing that just one week of T-Guard treatment induced a remarkably high complete response rate and a doubling of the 6-month overall survival rate as compared to institutional historical controls. These results were published in the peer-reviewed journal *Biology of Blood and Marrow Transplantation*. T-Guard has been granted Orphan Drug Designation status in both the EU and the U.S., and a Phase 3 registration trial evaluating T-Guard for the treatment of SR-aGVHD is currently underway in the U.S (NCT04128319).

About acute graft-versus-host disease

Following allogeneic stem cell transplantation, most patients have a high risk of developing graft-versus-host disease (GVHD), and this risk increases considerably in older patients. With GVHD, the donor's immune cells attack the patient's cells. Acute GVHD occurs early after transplantation and can be relatively mild or quite severe, even life-threatening, if not treated. Although GVHD can often be treated successfully with steroids, few options are available if the disease progresses or becomes resistant to steroid treatment, and the long-term survival of patients with steroid-refractory acute GVHD is less than 20%, highlighting the urgent need for effective therapies.

About Xenikos B.V.

Xenikos develops innovative immunotherapies based on conjugated antibodies. This novel therapeutic approach helps reset the immune system in patients who have a severe immune disease or have developed post-transplantation rejection. A Phase 3 registration trial evaluating the Company's flagship product, T-Guard® for the treatment of steroid-refractory acute graft-versus-host disease is currently underway in the U.S. (NCT04128319).

For more information, visit us at www.xenikos.com.
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About the BMT CTN

The Blood and Marrow Transplant Clinical Trials Network (BMT CTN) conducts rigorous multi-institutional clinical trials of high scientific merit, with a focus on improving the survival and outcome of patients who undergo hematopoietic cell transplantation or receive cellular therapy. The BMT CTN has completed 40 Phase 2 and Phase 3 trials at more than 100 transplant centers, with over 11,000 study participants.

The BMT CTN is funded by the National Heart, Lung, and Blood Institute and the National Cancer Institute at the U.S. National Institutes of Health (NIH) and represents the collaborative efforts of 20 core transplant centers/consortia, the Center for International Blood and Marrow Transplant Research (CIBMTR), the National Marrow Donor Program (NMDP)/Be The Match, and the Emmes Company, LLC, a contract research

organization. CIBMTR is a research collaboration between the NMDP/Be The Match and the Medical College of Wisconsin.

More information about the BMT CTN can be found at www.bmtctn.net.

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