PRESS RELEASE

Xenikos partners with the Blood and Marrow Transplant Clinical Trials Network (BMT CTN) to conduct a U.S.-based Phase 3 trial to test T-Guard® in acute graft-versus-host disease

- Study will be conducted at up to 20 leading transplant centers in the U.S.
- Xenikos intends to file an Investigational New Drug application in 2019

Nijmegen, the Netherlands, December 20, 2018 – Xenikos B.V. announced today that they have partnered with the Blood and Marrow Transplant Clinical Trials Network (BMT CTN) to conduct a U.S.-based Phase 3 registration trial to test the efficacy of T-Guard in treating steroid-refractory acute graft-versus-host disease (SR-aGVHD) in patients following an allogeneic stem cell transplant. Funded by the National Heart, Lung, and Blood Institute and the National Cancer Institute, both part of the National Institues of Health, the BMT CTN includes leading transplant centers in the United States (U.S.) and will provide a total of USD 1.37 million in funding for the T-Guard trial.

"At Xenikos, we see BMT CTN's access to major transplant centers in the U.S., as well as their established track record for successfully recruiting patients with acute GVHD, and vast knowledge and expertise in this field, as aiding in the development of innovative new immunotherapies for improving patient outcomes" said **Dr. Ypke van Oosterhout, CEO of Xenikos**. "We are therefore confident that our partnership with BMT CTN will help bring T-Guard to transplant patients as quickly as possible."

"Our network often conducts large, multi-institutional clinical trials in order to test new treatments designed to improve outcomes associated with hematopoietic stem cell transplantation or HSCT," said **Dr. Mehdi Hamadani of the BMT CTN**. "Acute GVHD is a life-threatening complication of HSCT and better treatments are needed for our patients. The preliminary data obtained with T-Guard is quite promising, and we believe that the Phase 3 trial is the next logical step."

The U.S.-based Phase 3 trial will be a multi-center study involving patients who have received an allogeneic stem cell transplant for a myeloid or lymphoid malignancy and subsequently developed SR-aGVHD. Importantly, the Phase 3 trial design is based on input received from the U.S. Food and Drug Administration at the End-of-Phase 2 meeting. Xenikos plans to file an Investigational New Drug application in 2019.

About BMT CTN

The Blood and Marrow Transplant Clinical Trials Network was established in October 2001 to conduct large multi-institutional clinical trials. The trials address important issues in hematopoietic stem cell transplantation (HSCT), thereby furthering understanding of the best possible treatment approaches. The Network is funded by the National Heart, Lung, and Blood Institute and the National Cancer Institute both part of the National Institutes of Health.

About T-Guard®

T-Guard is designed to treat steroid-resistant acute graft-versus-host disease (SR-aGVHD), a life-threatening condition common in patients following a hematopoietic stem cell transplantation. 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 safely and swiftly restore the immune system by specifically identifying and eliminating 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 in 20 patients with severe SR-aGVHD, showing that only one week of T-Guard treatment is sufficient to help restore the immune system, offering a potentially curative therapy to patients with this severe and often fatal complication. T-Guard has been granted Orphan Drug Designation in both the EU and the U.S., and other potential applications for T-Guard include transplant-related rejection, acute solid-organ rejection, and various autoimmune diseases.

About Xenikos B.V.

Xenikos develops innovative new immunotherapies based on conjugated antibodies. This novel therapeutic approach helps reset the immune system in patients who have a severe immune disease or developed post-transplantation rejection. Xenikos' flagship product, T-Guard®, is now ready to enter Phase 3 testing for the second-line treatment of steroid-resistant acute graft-versus-host disease (SR-aGVHD) in patients following hematopoietic stem cell transplantation.

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