PRESS RELEASE

Xenikos receives FDA Fast Track designation for T-Guard® for treating steroid-refractory acute graft-versus-host disease

- Xenikos is currently preparing to initiate a U.S. pivotal Phase 3 trial.
- Receiving Fast Track designation from the FDA will facilitate Xenikos' goal of bringing T-Guard to patients as quickly as possible.

Nijmegen, the Netherlands, October 14, 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 U.S. Food and Drug Administration (FDA) has granted Fast Track designation to T-Guard, Xenikos' flagship product designed to treat steroid-refractory acute graft-versus-host disease (SR-aGVHD) in patients following allogeneic stem cell transplantation. Xenikos is currently preparing to initiate a U.S. pivotal Phase 3 trial with T-Guard.

The Fast Track program is designed to facilitate the development of new therapies for treating severe medical conditions in order to fill a currently unmet medical need. Fast Track designation allows for early and frequent communications with the FDA, as well as rolling submission of the market application.

"We are delighted that the FDA has given Fast Track designation to T-Guard, as this will support our goal of getting T-Guard to patients as quickly as possible," said Dr. Ypke van Oosterhout, Chief Executive Officer of Xenikos. "We're also looking forward to starting our Phase 3 pivotal trial in the U.S. Effective new therapies for treating SR-aGVHD are urgently needed, and we believe that T-Guard, which can rapidly and safely reset the patient's immune system, has the potential to provide an important new treatment option to patients with this devastating, potentially fatal condition."

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). The results of this study showed that just one week of T-Guard treatment triggered a strong clinical response and doubled the 6-month overall survival rate. These results were published in the peer-reviewed journal *Biology of Blood and Marrow Transplantation*. A U.S. Phase 3 registration trial involving patients with SR-aGVHD following allogeneic stem cell transplantation will begin soon, and T-Guard has been granted Fast Track designation by the FDA, as well as Orphan Drug Designation status in both the EU and the U.S.

Notes to the editor:

About acute graft-versus-host disease
Following an allogeneic stem cell transplant, 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 normal cells. Acute GVHD occurs early after transplantation and can be relatively mild or quite severe, even becoming life-threatening if not controlled. Although GVHD can often be treated successfully with steroids, limited options are available once the disease progresses or becomes resistant to steroid treatment, and the long-term survival of patients with steroid-refractory acute GVHD is only 20%, highlighting the urgent need for effective therapies to improve patient outcome.

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. Xenikos will soon begin a U.S. Phase 3 registration trial with their flagship product, T-Guard, for treating steroid-refractory acute graft-versus-host disease (SR-aGVHD) in patients following allogeneic stem cell transplantation.

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