Xenikos Secures €40 Million in Convertible Debt Financing, Veloxis Pharmaceuticals Joins as Strategic Investor

Nijmegen, the Netherlands – September 8, 2021 – Xenikos B.V., a clinical-stage biopharmaceutical company currently developing a novel therapy for treating immune related disorders, announced today the closing of €40 million in convertible debt consisting of two equal tranches of €20 million. The financing was led by Veloxis Pharmaceuticals, with participation from existing investors, Medicxi, RA Capital Management, Oost NL and Sanquinnovate. In connection with the financing, Veloxis will obtain two sequential call options to acquire the company and a Board seat.

Xenikos will use the proceeds of the financing to initiate a registrational Phase 3 clinical trial in the US and EU, which is designed to evaluate the efficacy and safety of their flagship product T-Guard® for the treatment of steroid-refractory acute graft-versus-host disease (SR-aGVHD) in patients following allogeneic stem cell transplantation versus ruxolitinib. T-Guard is designed to reset the body's immune system safely and swiftly in life-threatening T cell-mediated conditions, including transplant-related rejection, acute solid-organ rejection and severe autoimmune disease.

Under the terms of this agreement, Xenikos will receive the first tranche at signing and will retain the right to draw down the second tranche upon meeting certain criteria. Concurrent with the issue of each tranche of convertible debt, Veloxis will receive a call option, each becoming active upon the release of its associated tranche, which provides Veloxis the exclusive option to exercise its right to acquire all of Xenikos' outstanding shares. The options will be exercisable for a limited period of time following either i) the successful completion of the safety run-in portion of the Phase 3 study, which is anticipated to be met in 2022, or ii) successful completion of the futility analysis of the Phase 3 study, which is anticipated to be met in 2023.

"Today's announcement highlights Veloxis' confidence in T-Guard's potential in acute graft-versus-host disease," said Dr. Ypke van Oosterhout, Xenikos' CEO. "Effective new treatments for this severe and often-fatal condition are urgently needed, and we believe that T-Guard can fill this void. With their expertise and experience developing and commercializing innovative therapies for transplant patients, Veloxis is an ideal partner to help bring T-Guard to the market following completion of our Phase 3 clinical trial, which we plan to resume during the second half of 2021."

"Veloxis is committed to addressing unmet needs in transplantation and improving outcomes in transplant patients," said Craig A. Collard, CEO of Veloxis. "Finding ways to combat acute GVHD, and SR-aGVHD in particular, is critical to this mission. We are excited to make this strategic investment in Xenikos in hopes of bringing T-Guard through the final phase of development and explore other life cycle opportunities in transplantation such as acute rejection treatment or prevention for solid organ transplant patients."

Xenikos successfully completed a Phase 1/2 study for the second-line treatment of SR-aGVHD in patients following hematopoietic stem cell transplantation, showing that just one week of T-Guard treatment induced a remarkably high complete response rate and a doubling of the six-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 US.

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 immune cells. Preclinical and early clinical testing have shown that T-Guard can specifically identify and eliminate mature T cells and NK cells with tolerable 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. In a Phase 1/2 study, 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 in patients being treated second-line for steroid-refractory acute graft-versus-host disease (SR-aGVHD) following hematopoietic stem cell transplantation (HSCT). These results were published in the peer-reviewed journal Biology of Blood and Marrow Transplantation (Groth, et al. Nov 2018). T-Guard has been granted Orphan Drug Designation in both the EU and the US, and a randomized Phase 3 registration trial evaluating T-Guard for the treatment of SR-aGVHD is expected to commence in the second half of 2021.

About Xenikos

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 randomized Phase 3 registration trial evaluating the Company's flagship product, T-Guard® for the treatment of steroid-refractory acute graft-versus-host disease (SR-aGVHD) is expected to begin in the US and Europe in the second half of 2021.

About Veloxis Pharmaceuticals

Veloxis Pharmaceuticals, Inc, an Asahi Kasei company, is a fully integrated specialty pharmaceutical company committed to improving the lives of transplant patients. Headquartered in Cary, North Carolina, USA, Veloxis is focused on the direct commercialization of immunosuppression medications in the US, expansion of partnerships for markets around the world, and acquisition of assets utilized in transplant patients and by adjacent medical specialties. For further information, please visit www.veloxis.com.

About Asahi Kasei

The Asahi Kasei Group contributes to life and living for people around the world. Since its foundation in 1922 with ammonia and cellulose fiber business, Asahi Kasei has consistently grown through the proactive transformation of its business portfolio to meet the evolving needs of every age. With more than 40,000 employees around the world, the company contributes to sustainable society by providing solutions to the world's challenges through its three business sectors of Material, Homes, and Health Care. Its health care operations include devices and systems for acute critical care, dialysis, therapeutic apheresis, transfusion, and manufacture of biotherapeutics, as well as pharmaceuticals and diagnostic reagents. For further information, please visit www.asahi-kasei.com.

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