



## PRESS RELEASE

### Xenikos B.V. to participate in 3PBio Forum technology transfer panel on September 29 at BIOSPAIN 2016

*Company to also meet with potential pharmaceutical partners for immunotherapy T-Guard™ during BIOSPAIN*

**Nijmegen, the Netherlands, September 20, 2016** – Xenikos B.V., focused on the development of innovative immunotherapies for the treatment of patients suffering from serious immune diseases or rejection after transplantation, announced today that management will participate in the upcoming BIOSPAIN 2016, being held **September 28 - 30, 2016 in Bilbao, Spain**.

CEO Ypke van Oosterhout will participate in the partnering event to meet with potential pharmaceutical partners for Xenikos' product candidate, T-Guard™, which is in clinical development for the treatment of acute graft versus host disease (GVHD). Companies interested in meeting with Xenikos at BIOSPAIN are asked to request a meeting through the event's partnering online system or to contact Ypke van Oosterhout at [y.vanoosterhout@xenikos.com](mailto:y.vanoosterhout@xenikos.com).

Maarten Frijlink, COO of Xenikos, will participate in the annual 3PBio Forum. This year's session, **“Good working relationships, communication and confidence behind successful tech transfer,”** will address the fundamental aspects of technology transfer to achieve the objectives and meet the expectations of all parties involved in the development and manufacture of biologics, from three perspectives: a drug developer, contract manufacturer and technology provider. The session is being led by 3P Biopharmaceuticals, a leading European-based contract development and manufacturing organization, and will include, in addition to Xenikos, two other companies: Ondek Pty Ltd, an Australian biotechnology company developing natural immune modulatory products, and Sartorius, an international leader in pharmaceutical equipment and technology. The forum will take place during the second day of BIOSPAIN, on **Thursday, September 29, 11.00-12.30 in room D of the BEC (Bilbao Exhibition Centre)**.

#### **About BIOSPAIN**

BIOSPAIN is the largest biotech event organized by a national bioindustry association in Europe and one of the largest in the world based on the number of one-on-one meetings (+3,300) and companies participating (+850). BIOSPAIN is organized by ASEBIO, the Spanish Association of Biotech Companies, and each event is co-organized by a local institution from the host city/region. BIOSPAIN 2016 is being co-organized by the Basque government through SPRI, the Basque Business Development Agency.

#### **About T-Guard™**

T-Guard™ is currently in development by Xenikos for the treatment of certain life-threatening immune conditions, such as transplant-related rejection, graft versus host disease (GVHD), acute solid-organ rejection and several severe autoimmune diseases. T-Guard™ consists of a combination of two toxin-loaded anti-T-cell antibodies and shows promise as a therapeutic tool for safely and swiftly resetting the body's immune system in T-cell-mediated diseases. Once injected into the body, T-Guard™ specifically identifies and eliminates adult T cells, with a strong preference for the activated ones. The particular combination of immunotoxins used to construct T-Guard™ was designed to provide a unique blend of synergistic efficacy, narrow specificity and multiple, gentle mechanisms of action. In preclinical testing,



T-Guard™ was shown to be highly effective in killing activated T cells and to act through apoptotic (programmed cell death) mechanisms, which are associated with minimal side effects. T-Guard's targeted action is believed to leave patients less vulnerable to opportunistic infections when compared to historical controls of institutional standard of care. In a clinical proof-of-concept study, T-Guard™ appeared to be well tolerated with strong biological and clinical responses observed. T-Guard™ is currently in clinical Phase 1/2 testing in Europe for the second-line treatment of steroid-resistant acute GVHD. The primary endpoint of the study is response rate at 28 days. Other endpoints include overall survival at 180 days; safety and tolerability are also being evaluated. Preliminary results from this study showed strong clinical responses and indicated a substantial improvement over published institutional historical survival rates, with a well-manageable side effect profile without severe infusion reactions. T-Guard™ has been granted Orphan Drug Designation in both the EU and US. The Company plans to initiate a pivotal clinical study in the second half of 2017.

#### **About Graft versus Host Disease (GVHD)**

Transplantation of allogeneic (donor-derived) blood stem cells is a widely accepted medical procedure to restore normal blood cell production (hematopoiesis) in patients treated for blood or lymphatic cancers or otherwise suffering from defective blood formation or immunity. Today, approximately 30,000 patients worldwide receive allogeneic stem cell transplants every year. Approximately 50% of all blood stem cell transplant patients develop acute GVHD, a complication where donor-derived T cells (immune cells) attack the normal tissues of the patient. Half of these patients do not respond adequately to standard first-line therapy and have a poor long-term prognosis with severe morbidity and high mortality rates. This number is expected to grow substantially as the number of patients receiving high-risk transplants from unrelated donors is expected to double in the next five years. As of today, there is no approved second-line treatment available.

#### **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](http://www.xenikos.com).

#### **For further information, please contact:**

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