



News Release

FOR IMMEDIATE RELEASE

Xeltis' Technology for Natural Heart Valve Restoration Featured as the Future of Valve Therapy at EuroPCR

--Dedicated plenary session on Endogenous Tissue Restoration (ETR) previews first data from aortic valve preclinical studies--

PARIS, May 17, 2017 – A pioneering approach to heart valve therapy from Swiss-Dutch clinical stage company Xeltis was the focus of plenary session “Bioresorbable valve therapy: tomorrow's world” at EuroPCR 2017 in Paris today. Global thought leaders in interventional cardiology discussed the unique science, early data and potential benefits of Endogenous Tissue Restoration (ETR), a new restorative therapeutic approach. ETR enables the patient's own body to naturally restore a heart valve that is defective or no longer works.

“Xeltis' initial trial results to date support ETR's promise to enable the body's natural restoration of heart valve function,” said Martin B. Leon, M.D., director at the Center for Interventional Vascular Therapy at Columbia University Medical Center and New York-Presbyterian Hospital, one of the speakers at the session. “This innovative treatment approach has the potential to reduce complications, re-interventions and healthcare costs, while improving quality of life for patients with heart valve disease. This would represent a major leap forward in heart valve therapy.”

With ETR, the patient's natural healing system develops tissue that pervades Xeltis' heart valve, forming a new, natural and fully functional valve within it. As ETR occurs, Xeltis' implants are gradually absorbed by the body. ETR is enabled by the porous structure of Xeltis' heart valves, which are made of bioabsorbable polymers, based on Nobel prize awarded science. RestoreX, Xeltis' new technology platform, is the world's first polymer-based technology designed to enable natural restoration of heart valve function.

Preview of First Data from Xeltis Aortic Valve Pre-Clinical Program

The first study results from Xeltis preclinical aortic valve program have been presented today during the same plenary session. The promising data showed good hemodynamic performance and fully functional valves *in vivo* six months after implantation.

“We are delighted by the high level of interest in our solution,” said [Martijn Cox, Ph.D., chief technology officer and co-founder of Xeltis](#), “and, more importantly, that the new aortic valve data presented today further validate our vision to naturally restore heart valves using ETR.”

The first feasibility clinical trial for Xeltis' pulmonary valve, [Xplore-I](#), is underway in Europe and Asia. Patient enrollment was completed in December 2016.

In January, the U.S. Food and Drug Administration (FDA) approved an Investigational Device Exemption (IDE) for Early Feasibility Study (EFS) to implant Xeltis' pulmonary valve in 10 patients. This [Xplore-II study](#) is expected to begin later this year. Additionally, the agency granted Humanitarian Use Device (HUD) Designation for Xeltis' pulmonary heart valve for the correction or reconstruction of right ventricular outflow tract (RVOT) in children.

Previously, Xeltis shared one- and two-year data from a pediatric feasibility study of a vascular graft developed with RestoreX technology, which showed positive functionality results with no device-related adverse events, and significant improvement in patients' general conditions. In the study, all five children, age 4 to 12 years at enrollment, had only one functioning heart ventricle as a result of congenital heart defects (CHDs).

Xeltis is currently investigating additional applications of its innovative approach to restore other heart valves and blood vessels.

Millions of people are diagnosed with heart valve disease each year globally, but current replacement valves have significant limitations. Today, patients with artificial heart valves generally endure repeated replacement procedures and complications from chronic inflammation or take long-term medication with potentially severe side effects.

About Xeltis

Xeltis is a clinical-stage medical device company developing the first heart valves and blood vessels enabling the body's natural restoration of heart valve function through a therapeutic approach called Endogenous Tissue Restoration (ETR).

The company's cardiovascular implants are made of bioabsorbable polymers based on Nobel Prize-awarded science.

Xeltis has closed a \$33 million series B financing (\$30 million in 2014, extended by \$3 million in 2015). For more information, please visit www.xeltis.com.

Media Contacts:

Laura Bertossi Monti
Xeltis
+44 75544 25402
laura.monti@xeltis.com

Katie Hogan
tWist
202 549 0557
khogan@w2ogroup.com

CAUTION: The Xeltis technology is an investigational device and NOT approved for sale.

--End--