News Release

FOR IMMEDIATE RELEASE

First Heart Valve That Enables Cardiovascular Restoration Successfully Implanted in Three Patients in "Xplore-I" Clinical Trial

"Three children's hearts are now beating with a Xeltis Valve." Laurent Grandidier, CEO, Xeltis

Click **here** for video about how the Xeltis restoring technology works

ZURICH, Switzerland/EINDHOVEN, The Netherlands, October 3, 2016 – **Xeltis**, a Swiss-Dutch clinical-stage medical device company, announced today that three pediatric patients have been successfully implanted with the world's first heart valve enabling cardiovascular restoration. The children have been enrolled in the "Xplore-I" clinical study of **Xeltis bioabsorbable pulmonary heart valve**, a multi-centered feasibility trial currently enrolling pediatric patients from 2 to 21 years of age in leading heart centers in Europe.

The primary objective of the Xplore-I clinical feasibility study is to assess the survival rate of patients undergoing Right Ventricular Outflow Tract (RVOT) reconstruction at six months following implantation of the bioabsorbable heart valve. RVOT reconstruction is an open-heart surgery often involving pulmonary heart valve replacement. It is normally performed in children born with congenital heart defects. The first three trial implants have been conducted at Gottsegen György Hungarian Institute of Cardiology's Pediatric Cardiac Centre in Budapest (Hungary) and University Children's Hospital in Krakow (Poland).

"The Xplore-I patients are doing well and have been discharged from hospital," said **Dr. Zsolt Prodan, M.D.,** Head of Congenital Heart Surgery at Paediatric Cardiac Centre in Budapest, who performed the first two interventions in July. "The bioabsorbable implant is performing according to expectations," he added. **Dr. Prodan will present trial details at the 30th Annual Meeting of the European Association of Cardio-Thoracic Surgery (EACTS) on Tuesday, October 4.**

"Reconstruction and replacement of diseased heart valves in children using patients' own tissue could help reduce the risk of complications and of re-interventions observed with animal and human donor implants," stated **Thierry Carrel, M.D.**, principal investigator of the 'Xplore-I' study, and Professor of Surgery at the Clinic for Cardiovascular Surgery, University Hospital Bern (Switzerland). "We are quite confident regarding this technology, since children from the precursor feasibility study on bio-absorbable blood vessels demonstrate excellent results over two years after implantation," he continued.

"Initiating the clinical trial on our first bioabsorbable heart valve is a pivotal event for Xeltis. The extensive number of presentations on our technology at this year's EACTS meeting confirms our company's fast advancement," **Laurent Grandidier**, Xeltis CEO. "We are reinventing the heart valve with the goal of making better solutions available to patients," he added.

About Endogenous Tissue Restoration
Endogenous Tissue Restoration (ETR) is a novel therapeutic approach in cardiovascular regenerative medicine enabling the restoration within the body of complex cardiac parts with patient's own tissue. The porous structure of a Xeltis' bioabsorbable heart valve enables

cardiovascular restoration by harnessing the body's natural healing process to pervade it with new healthy tissue once implanted. As a new healthy heart valve or blood vessel made of patient's own tissue forms around the structure of the implant and takes over functionality, the implanted valve gets absorbed in the body.

About Xeltis
Xeltis is a clinical-stage medical device company developing the first heart valves and blood vessels enabling cardiovascular restoration, through a therapeutic approach called Endogenous Tissue Restoration (ETR). Xeltis' cardiovascular implants are made of bioabsorbable polymers based on Nobel Prize-awarded science. Xeltis technology is the first-ever cardiovascular regenerative medicine therapy based purely on a bioabsorbable medical device implant.

The US FDA has granted Humanitarian Use Device Designation (HUD) for Xeltis pulmonary valve as a bioabsorbable pulmonary heart valve for the correction or reconstruction of RVOT in children. Xeltis has closed a $33 million series B financing ($30 million in 2014, extended by $3 million in 2015).

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For more information, please visit www.xeltis.com

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

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