



News Release

Patients implanted with Xeltis bioabsorbable cardiovascular device showed positive functionality results two years after surgery - data at EACTS

Click [here](#) to learn more about how the Xeltis restoring technology works

ZURICH, Switzerland, and EINDHOVEN, The Netherlands, October 5, 2016 – [Xeltis](#), a Swiss-Dutch clinical-stage medical device company, announced today that patients implanted with its bioabsorbable cardiovascular conduit showed positive functionality results two years after surgery. The data have been presented at the 30th European Association for Cardio-Thoracic Surgery (EACTS) annual scientific meeting.

“The two-year data for the Xeltis devices are very impressive,” said **Thierry Carrel, M.D.**, Professor of Surgery at the Clinic for Cardiovascular Surgery, University Hospital Bern (Switzerland). “Ultrasound and MRI examinations have demonstrated anatomical and functional stability in all patients after two years, when Xeltis’ implant will have been gradually absorbed in the body and functionality replaced by components of native tissue formed within and around the implant.”

Xeltis’ feasibility clinical trial was conducted in five patients, aged 4 to 12 years at time of surgery, with only one functioning ventricle. According to the study conclusion, Xeltis’ bioabsorbable technology has the potential to improve cardiac and vascular surgical procedures by reducing implant-related complications.

In another session at EACTS, **Gerardus Bennink, M.D.**, Head and Chief Pediatric Cardio-Thoracic Congenital Surgery, Heart Center of the University of Cologne (Germany) presented positive one-year *in vivo* preclinical data of Xeltis’ bioabsorbable pulmonary heart valve. The study results confirmed the safety and functionality of Xeltis’ valve.

The combination of the successful clinical study on Xeltis technology and the positive outcomes of the preclinical study of Xeltis’ pulmonary valve paved the way for the company to commence its current **Xplore-I clinical study** on a **bioabsorbable pulmonary heart valve**. Xplore-I is a multisite feasibility trial currently enrolling pediatric patients in leading heart centers in Europe. Xeltis announced at the EACTS annual meeting that three pediatric patients have already been successfully implanted as part of the trial.

“The clinical and preclinical data presented at the EACTS meeting validate Xeltis’ seminal contributions to the future of heart valve replacement. We are extremely pleased by the progress we are demonstrating with the first-ever cardiovascular restoration therapy based purely on bioabsorbable medical devices,” said **Laurent Grandidier**, Xeltis CEO.

About Endogenous Tissue Restoration (ETR)

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).

Media Contacts:

Ronald Trahan, APR
Ronald Trahan Associates Inc.
+1 508 359 4005, rtrahan@ronaldtrahan.com

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

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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