



News Release

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Pediatric feasibility study results set stage for clinical trial of world's first bioabsorbable heart valve enabling Endogenous Tissue Restoration

12-month follow-up late-breaking data on bioabsorbable technology presented today at annual meeting of American Association for Thoracic Surgery

- Xeltis is spearheading a revolutionary approach in cardiovascular and regenerative medicine called Endogenous Tissue Restoration
- Xeltis devices are designed to enable natural restoration of complex body parts before these devices are absorbed by the body
- Outstanding feasibility trial results on Xeltis bioabsorbable technology set the stage for initiation of first clinical trial of bioabsorbable heart valve in 2016
- Technology platform has potential to address hundreds of thousands of patients requiring cardiovascular intervention each year worldwide
- Xeltis technology is based on Nobel-prize awarded science

Click [here](#) for video about how the Xeltis technology works

BALTIMORE and ZURICH, Switzerland, May 17, 2016 – One-year follow-up results from a pediatric feasibility study of [Xeltis](#) bioabsorbable cardiovascular pulmonary graft have been presented as late-breaker at the [96th American Association for Thoracic Surgery](#) annual meeting today. All five children, aged 4 to 12 years at study enrollment, had only one functioning heart ventricle as a result of congenital heart defects and showed significant improvement in their general conditions one year after surgery. The 12-month data also showed anatomical and functional stability of the graft and no device-related adverse events.¹

“All patients enrolled are approaching their two-year follow-up, and the results to date are remarkable,” said leading investigator and world-renowned cardiac surgeon, Professor Leo Bockeria, who performed all five cases at the Bakoulev Centers for Cardiovascular Surgery in Moscow. “If further proven,” he added, “this new technology may open up a new therapeutic approach in cardiovascular treatment.”

The success of this feasibility trial has paved the way for Xeltis to develop a bioabsorbable pulmonary heart valve, which will enter clinical trials in Europe this year. Xeltis is developing the first-ever bioabsorbable cardiovascular valves and vessels designed to harness the body's innate healing process and enable Endogenous Tissue Restoration (ETR), the natural restoration of complex anatomical parts within the body. The U.S. FDA has recently granted “Humanitarian Use Device” (HUD) designation for the Xeltis bioabsorbable pulmonary heart valve for the correction or reconstruction of right ventricular outflow tract (RVOT).

“Our technology is designed to enable regenerative medicine via a medical device,” stated Laurent Grandidier, Xeltis CEO. “This is potentially a revolutionary approach in cardiovascular treatment and for the future of medicine.”



Endogenous Tissue Restoration

The feasibility trial was encouraged by excellent results from *in-vivo* studies showing ongoing replacement of the bioabsorbable graft by new, well-vascularized and functioning tissue, as a result of ETR one year after surgery.¹

ETR is enabled by the unique porous structure of Xeltis bioabsorbable implants, which is based on Nobel Prize-awarded science. The implants are designed to harness the body's natural healing process, to pervade them with new healthy tissue, and form complex body parts before the implants get absorbed.

Xeltis bioabsorbable technology has the potential to reduce the risk of complications and of repeated interventions associated with currently available non-bioabsorbable synthetic or animal-derived heart valves. The technology may therefore help reduce the disease burden for patients and the overall costs for healthcare systems.

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About Xeltis

Xeltis is a European-based medical device company spearheading a revolutionary approach in cardiovascular and regenerative medicine called Endogenous Tissue Restoration (ETR). Xeltis is developing the first-ever bioabsorbable cardiovascular valves and vessels designed to harness the body's innate healing process and enable natural restoration of complex anatomical parts within the body.

Xeltis' technology has the potential for broad application across a number of cardiovascular conditions and patient populations, serving as a platform to address hundreds of thousands of patients that require cardiac valve replacements and vascular interventions every year.

For more information, please visit www.xeltis.com

References:

1. Bockeria L, *et al.* A Novel Bioabsorbable Vascular Graft in a Modified Fontan Procedure - the First Clinical Experience. Presented at 96th American Association for Thoracic Surgery annual meeting in Baltimore on 17 May 2016. <http://www.aats.org/annualmeeting/Program-Books/2016/Detail.cgi?d=Tuesday&s=11>