



Xeltis completed second feasibility clinical trial on bioabsorbable cardiovascular device technology

Xeltis developing first cardiac valves and vessels designed to allow endogenous tissue restoration

Zurich, Switzerland, 10 November 2015 – Xeltis has successfully completed its second feasibility trial in just over three months, showing positive results in patients a year after surgery for its bioabsorbable cardiovascular device technology. [Xeltis](#) is the first-ever medical device company developing bioabsorbable cardiac valves and vessels designed to allow [Endogenous Tissue Restoration](#) (ETR).

The Xeltis products are made of bioabsorbable polymers structured as a porous matrix that is designed to work as valve or other cardiovascular component once implanted and to allow ETR, as the body's natural healing process pervades it with new functioning tissue. As the natural cardiovascular part forms, the matrix is structured to be absorbed and to leave the patient with its own healthy tissue.

“The positive results of our second feasibility trial confirm the extraordinary potential of our bioabsorbable technology for a number of different cardiovascular applications”, stated Laurent Grandidier, CEO at Xeltis. “We are confident that bioabsorbable cardiovascular devices will be able to replace most commonly used implantable devices, and that ETR will improve patient outcomes while reducing the economic burden for healthcare systems.”

In this study, young children born with only one functioning heart ventricle and requiring a [Glenn procedure](#) have been implanted a Xeltis cardiovascular patch as part of their operation. Results showed that all patients presented no patch-related post-operative complications and no functional impairment requiring intervention a year after surgery. The study was led by Professor Leo Bockeria, a world-renowned cardiac surgeon, at the [Bakoulev Center for Cardiovascular Surgery](#) in Moscow, Russia.

“The results of this study are beginning to build clinical evidence about the feasibility of bioabsorbable cardiovascular devices as new therapeutic options in cardiovascular surgery” stated Professor Bockeria. “A year after surgery, all clinical parameters are positive and provide hope that ETR may offer a more definitive solution to a number of cardiac conditions” he added.

About the Xeltis technology and ETR

The Xeltis technology is based on Nobel prize-winning science of supramolecular chemistry by Professor Jean-Marie Lehn. The first product Xeltis is planning to bring to market in a few years is a bioabsorbable pulmonary valve for pediatric patients.

ETR is a new, transformational therapeutic approach in cardiovascular treatment. It has the potential to help reduce the risk of patient complications generally caused by foreign material in the body, as well as the risk of repeated procedures normally needed for patients with existing replacement parts such as cardiac valves,^{1,2,3,4,5} therefore possibly lowering the overall healthcare costs.



About Xeltis

Xeltis is a European medical device company based in Zurich, Switzerland and in Eindhoven, The Netherlands. Xeltis successfully completed an oversubscribed series B financing round of €27 million in November 2014. Investors include Life Sciences Partners, The Netherlands (LSP), Kurma Partners, France (Kurma), VI Partners, Switzerland (VI) and private shareholders.

- Ends -

For more information, please visit www.xeltis.com

or contact Laura Bertossi Monti +44 755 442 5402; laura.monti@xeltis.com

References:

1. Hammermeister KE, Sethi GK, *et al.* A Comparison of Outcomes in Men 11 Years after Heart-Valve Replacement with a Mechanical Valve or Bioprosthesis. *New England Journal of Medicine*. 1993; 328:1289-1296 [May 6, 1993](#)
2. Hammermeister KE, Sethi GK, *et al.* Outcomes 15 years after valve replacement with a mechanical versus a bioprosthetic valve: final report of the Veterans Affairs randomized trial. *Journal of the American College of Cardiology*. Volume 36, Issue 4, October 2000, Pages 1152–1158
3. Bloomfield P, Wheatley DJ, *et al.* Twelve-year comparison of a Bjork-Shiley mechanical heart valve with porcine bioprostheses. *New England Journal of Medicine*. 1991; 324: 573–579.
4. Lee C, Kim YM, Lee CH., Outcomes of pulmonary valve replacement in 170 patients with chronic pulmonary regurgitation after relief of right ventricular outflow tract obstruction: implications for optimal timing of pulmonary valve replacement. *Journal of the American College of Cardiology*. 2012;60:1005-1014.
5. Lee C, Park CS, Lee CH, Durability of bioprosthetic valves in the pulmonary position: long-term follow-up of 181 implants in patients with congenital heart disease. *Journal of Thoracic Cardiovascular Surgery*. 2011;142:351-358.