FOR IMMEDIATE RELEASE

Xeltis starts pivotal clinical trial with first ever restorative synthetic hemodialysis access graft

The aXess graft turns into a living blood vessel, promising an unprecedented, immediate and durable solution for hemodialysis patients

EINDHOVEN, The Netherlands – November 10, 2022 – **Xeltis**, a medtech company with the most advanced polymer-based restorative cardiovascular devices, announced today the initiation of a pivotal trial for the first-ever restorative synthetic hemodialysis access grafts, aXess. The first two patients have been successfully implanted, as part of the AXESS European pivotal trial at AZ Sint-Jan Brugge-Oostende AV in Bruges, Belgium by vascular surgeon Dr. Jan De Letter and discharged from hospital.

The AXESS European pivotal trial is a prospective, single arm study to evaluate the safety and performance of aXess in patients with end-stage renal disease who need hemodialysis. The study will enroll 110 patients in up to 25 centers in Europe and will follow them for five years. The aXess graft has been previously successfully implanted in 20 patients, as part of the AXESS first-in-human (FIH) trial, which completed enrolment in September 2022. AXESS FIH full cohort data are expected in 2023.

“A device that enables immediate use, as seen with the existing synthetic ePTFE grafts, and turns into a living blood vessel that recovers promptly after puncturing from each dialysis session may become the safer and longer lasting solution that patients on hemodialysis need,” explained Dr. De Letter, who also has previous experience with aXess, having implanted it during the FIH trial. “We are encouraged by the promising preliminary experience with this device from the FIH trial and confirmation in a larger trial involving more patients and implanting sites is an important next step.”

The aXess graft is a restorative, synthetic, electrospun blood vessel for arteriovenous hemodialysis access. Once implanted, its porous micro-structure gets colonized by the patient’s own tissue cells through the body’s natural healing process, to turns into a living vessel made of patient’s own tissue over time.

“Life for patients on hemodialysis means multiple hospital visits each week, involving puncturing, bleeding, waiting, healing and risk of infections from all of the above, in addition to poor renal function,” explained Dr. An De Vriese, Head of Nephrology and Infectious Diseases at AZ Sint-Jan Brugge-Oostende AV, and one of the Coordinating Investigators of the AXESS EU pivotal trial. “If a novel device can spare part of this burden through reduced bleeding, prompt coagulation and healing, lower infection risks and longer durability, it would be a life-changing experience for most patients.”

Today, patients with kidney disease that need hemodialysis access may wait for months, or unsuccessfully, for the maturation of a fistula, the first-line treatment involving the creation of an enlarged vessel. When a fistula is not an option, synthetic access grafts may be used but they have generally limited durability and are prone to bleeding after puncturing, infections and clotting, requiring frequent replacements.[1,2]

"Our technology platform has generated restorative devices that may be unlocking unprecedented treatment solutions," said Eliane Schutte, Xeltis CEO. "The initiation of the pivotal phase for the aXess graft confirms our capability to fast-track promising solutions to improve patients' lives and our commitment to substantial evidence."

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Notes to editors

About Chronic Kidney Disease

Chronic Kidney Disease (CKD) affects nine percent of the population, with growing prevalence due to cardiovascular disease (diabetes, hypertension, obesity).[3] Today, CKD accounts for more deaths than breast and prostate cancers combined. Each year, three million patients with chronic kidney disease need hemodialysis and require vascular access to connect to a dialysis machine.

About the AXESS FIH clinical trial

The AXESS trial is a prospective, single arm, non-randomized, multi-center first-in-human feasibility study to evaluate the preliminary safety and performance of the Xeltis hemodialysis access graft in adult patients with end-stage renal disease, who plan to undergo hemodialysis for at least six months and are deemed unsuitable for fistula creation. The trial is ongoing in six implanting centers in Europe, based in Belgium, Italy, Latvia and Lithuania.

About Xeltis

A clinical-stage medical device company, Xeltis has developed the most advanced polymer-based restorative devices for cardiovascular treatment. Xeltis' restorative devices include implantable small diameter blood vessels for hemodialysis vascular access (aXess) and for coronary artery bypass graft (CABG) surgery (XABG), as well as a pulmonary heart valve. These devices are all in clinical trial phase.

Xeltis was formed through the merger of two Dutch/Swiss university spin-offs and it currently has operations in The Netherlands and in the USA. Xeltis' investors include venture capital funds EQT Life Sciences, Kurma Partners, VI Partners and Ysios Capital, as well as the Chinese Grand Pharma Group and a number of public and private investors.

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

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1 Lee T et al. Tradeoffs in Vascular Access Selection in Elderly Patients Initiating Hemodialysis with a Catheter. *American Journal of Kidney Diseases*. Volume 72, Issue 4, October 2018, Pages 509-518

2 Schwab SJ et al. Vascular access for hemodialysis. *Kidney International.* 1999 May;55(5):2078-90. doi: 10.1046/j.1523-1755.1999.00409.x. PMID: 10231476.

3 GBD Chronic Kidney Disease Collaboration. Global, regional, and national burden of chronic kidney disease, 1990–2017: a systematic analysis for the Global Burden of Disease Study 2017. *The Lancet*. Vol 395, Issue 10225, p709-733, DOI:https://doi.org/10.1016/S0140-6736(20)30045-3