PRESS RELEASE
November 25, 2024
Gothenburg

Enrollment completed five months early in the US clinical trial evaluating XVIVO's heart preservation technology

XVIVO's innovative heart technology is currently under investigation in the US clinical trial "PRESERVE: A Prospective, Multi-center, Single-Arm, Open-Label Study of Hearts Transplanted after Non-Ischemic Heart PRESERVation from Extended Donors." This marks the enrollment completion of the Investigational Device Exemption (IDE) trial which was intended to enroll patients at an ambitious pace of 18 months, but was instead completed in 13 months – 5 months ahead of schedule. To date, 141 patients have undergone transplantation with the XVIVO heart technology at 14 leading heart transplant hospitals in the US. The next milestone will be one year follow-up, where patient outcomes will be collected and monitored before the data is analyzed and presented to the US Food & Drug Administration (FDA) via the Pre-Market Approval (PMA) process.

The United States is the world's largest heart transplant market, with approximately 4,500 heart transplants performed in 2023. With an increasing number of patients in need of a transplant, the ability to safely utilize, preserve, and transport more donated organs is critical to address the growing organ shortage. Developed in collaboration with Professor Stig Steen at Igelösa LifeScience in Sweden, the XVIVO heart device and proprietary solution are designed for preservation of donor hearts using Hypothermic Oxygenated Perfusion (HOPE). The PRESERVE multicenter clinical trial is intended to evaluate the safety and effectiveness of the XVIVO heart technology to support a PMA Application to the FDA. Amongst other inclusion criteria, the trial allows transplant centers to include donor hearts from older donors (defined as aged 50 years old or above), Donation after Circulatory Death (DCD), and from long-distance donors.

The shorter inclusion time reflects the enthusiasm and commitment of trial centers to evaluate the ability of cold, oxygenated technology to make more hearts available for transplant. This has been made possible by the dedication of the XVIVO clinical team to ensure trial sites were provided 24/7 support, resulting in strong momentum throughout the 13 months.

"We are excited about the potential of the XVIVO heart preservation system to transform heart transplantation. By providing controlled moderate hypothermia and oxygenated low-pressure perfusion during storage and transport, the system mitigates ischemia and its negative effects. This technology not only expands the donor pool by making higher-risk hearts viable but also enhances patient safety during logistical challenges such as long-distance transport or surgical delays. Anecdotally, we've observed improved heart function post-transplant, with patients often weaning from bypass with minimal support. We eagerly await the detailed analysis of the PRESERVE trial data to validate these promising outcomes with rigorous scientific evidence", says Dr. Victor Pretorius, MBChB – National PI, UC San Diego Health, the

US*.

“I am extremely impressed by the level of engagement we have seen in the PRESERVE trial. Conducting such a trial within 18 months would have been an achievement, but completing it in less time is a testament to the commitment and efficiency of the trial sites' transplant teams and the XVIVO team. I’m confident that this innovative technology will change the paradigm in heart preservation. We eagerly anticipate the one-year follow-up data that will enable us to bring this groundbreaking technology to the US market once the FDA process is complete. This heart technology brings us closer to our vision that ‘nobody should die waiting for a new organ”, says Christoffer Rosenblad, CEO of XVIVO.

November 25, 2024
Gothenburg
Christoffer Rosenblad, CEO
XVIVO Perfusion AB (publ)

The opinions expressed in this release are the author's own and do not reflect the view of XVIVO or constitute an endorsement. The XVIVO Heart Technology is regulated in the US under an Investigational Use Exemption (IDE), and the safety and efficacy have not been established.

For further information, please contact:

Christoffer Rosenblad, CEO, +46 73 519 21 59, e-mail: christoffer.rosenblad@xvivogroup.com
Kristoffer Nordström, CFO, +46 73 519 21 64, e-mail: kristoffer.nordstrom@xvivogroup.com

About Us

Founded in 1998, XVIVO is the only medical technology company dedicated to extending the life of all major organs - so transplant teams around the world can save more lives. Our solutions allow leading clinicians and researchers to push the boundaries of transplantation medicine. XVIVO is headquartered in Gothenburg, Sweden, and has offices and research sites on two continents. The company is listed on Nasdaq Stockholm under the ticker symbol XVIVO. More information can be found on the website www.xvivogroup.com.

Attachments

Enrollment completed five months early in the US clinical trial evaluating XVIVO’s heart preservation technology