



PRESS RELEASE

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Gothenburg

XVIVO presents 12-month follow-up results from European multicenter heart transplantation trial at ISHLT in Boston

The 12-month follow-up results from XVIVO's European multicenter heart trial, NIHP2019, was presented at the 2025 International Society for Heart and Lung Transplantation (ISHLT) Annual Meeting in Boston, USA. The trial focused on heart transplantation outcomes using XVIVO Heart Assist Transport.

The long-term analysis of the NIHP2019 trial evaluated patient outcomes 12 months post-transplantation. The findings revealed that severe complications occurred in 33 percent of patients who received donor hearts preserved using XVIVO Heart Assist Transport, compared to 47 percent in the control group, where donor hearts were preserved on ice – representing a 38 percent risk reduction. Additionally, the 12-month survival rate was higher among patients in the XVIVO Heart Assist Transport group, at 92 percent, versus 86 percent in the control group.

XVIVO's heart technology, including the XVIVO Heart Assist Transport device and a perfusion solution, provides an alternative to static ice storage. The device pumps an oxygenated perfusion solution, specifically tailored for this purpose, through the organ at low pressure and at 8 degrees Celsius, thereby preserving the heart in a controlled, low metabolic, resting state. This method, which has been extensively proven successful in liver and kidney transplantation, is referred to as hypothermic oxygenated perfusion (HOPE).

"The findings at 12 months validates the significance of the primary end point results reported at 30 days after transplantation, as the large reduction in severe Primary Graft Dysfunction (PGD) we observed then, is now reflected in reduced morbidity and mortality at longer term follow up" says Filip Rega, Professor of Cardiac Surgery and Transplantation at the University Hospitals Leuven, Belgium, and coordinating investigator of the trial. He continues, "the study outcomes reveal an important and clinically relevant reduction in severe post-transplant complications for patients who were transplanted with a donor heart preserved using this novel technology. Also, as this technology can safely extend the time a donated heart can be outside of the body, we now have a tool that can relieve the intense pressure caused by the strict time limits associated with heart preservation and transplantation."

"This is the first randomized controlled trial of a donor heart perfusion device to demonstrate superiority over preservation on ice. Now we can see that the 76 percent risk reduction for severe PGD previously reported is also translated into higher 12-month survival rates. This makes us very proud, as it brings us one step closer to realizing our vision that 'nobody should die waiting for a new organ'. Our heart technology demonstrates XVIVO's dedication as a research-driven and innovative company committed to changing the paradigm of heart preservation," says Christoffer Rosenblad, CEO of XVIVO.

The NIHP2019 trial is a randomized, controlled, open label, multicenter clinical investigation of XVIVO Heart Assist Transport to collect the safety and performance data needed in order to obtain a European CE marking. Between November 2020 and May 2023, the NIHP2019 trial enrolled 204 patients across 15 institutions in 8 European countries.

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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

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