PRESS RELEASE
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Gothenburg

Results from XVIVO's clinical trial NIHP2019 for heart preservation presented at ISHLT in Prague

Today, at the 2024 International Society of Heart and Lung Transplantation meeting in Prague, Czech Republic, the results from XVIVO's clinical trial, NIHP2019, in heart transplantation were presented.

The results showed that the primary endpoint, representing severe complications after heart transplantation, was registered in 18.8% of the subjects who received a donor heart preserved with the XVIVO Heart Assist Transport and in 30.1% of subjects in the control group who received a donor heart transported on ice, the current gold standard.

The rates of severe primary graft dysfunction (PGD) after heart transplantation were also lower for patients who received a donor heart preserved with the XVIVO Heart Assist Transport (11% compared to 28%).

"This trial represents a significant evolution in donor heart preservation," says Filip Rega, Professor of Cardiac Surgery and Transplantation at the University Hospitals Leuven, Belgium, and coordinating investigator of the trial. "Primary graft dysfunction is a feared complication after heart transplantation associated with serious morbidity and mortality. The study outcomes reveal an important and clinically relevant reduction in primary graft dysfunction for patients who were transplanted with a donor heart preserved using this novel technology."

"The NIHP2019 trial is the result of many years of hard work and collaboration, marking one of the greatest achievements in the history of XVIVO. It brings us one step closer to realizing our vision that nobody should die waiting for a new organ. Currently, only 30 percent of available donated hearts are utilized for transplantation - that needs to change. Our heart technology demonstrates XVIVO's dedication as a research-driven and innovative company committed to changing the paradigm in heart preservation," says Christoffer Rosenblad, CEO of XVIVO.

The NIHP2019 trial is a randomized, controlled, open label, multicenter clinical investigation of the XVIVO Heart Assist Transport to collect the safety and performance data to support CE marking. The NIHP2019 trial enrolled 203 patients in 15 institutions across 8 European countries between November 2020 and May 2023.

In the US, XVIVO has obtained Investigational Device Exemption (IDE) approval by FDA for a heart preservation trial (PRESERVE) to collect the safety and effectiveness data required to support future PMA applications. Recruitment in the PRESERVE trial is ongoing.

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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 and has the ticker symbol XVIVO. More information can be found on the website www.xvivogroup.com.

This information is information that XVIVO Perfusion AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2024-04-11 10:10 CEST.

Attachments

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