PRESS RELEASE
April 22, 2026
Gothenburg

XVIVO presents encouraging results from first clinical trial using hypothermic oxygenated perfusion (HOPE) in direct procurement DCD heart transplantation

Today, the results from the HOPE-at-Heart clinical trial (NCT06485596) were presented at the ISHLT Annual Meeting in Toronto. This prospective, multicenter trial, is the first to evaluate direct procurement of donor hearts after circulatory death (DCD) followed by preservation using HOPE with the XVIVO Heart Assist Transport. The trial successfully met its pre-specified primary endpoint.

Donation after circulator death (DCD), now contributes to 50% of the total donor pool in the US and is increasingly used globally. During the DCD donation process the donor heart may be subjected to additional strain and conventional preservation methods may be challenging in this setting. In a single-arm, proof-of-concept trial (NCT06485596) 40 adult heart transplant recipients across four European transplant centers in Belgium and the Netherlands were enrolled.

The results;
- The primary endpoint, patient survival at 30 days, was 98%
- Secondary endpoints demonstrated a 5% incidence of severe primary graft dysfunction (PGD) at 24 hours and a 10% incidence of post-operative mechanical circulatory support the first 30 days.

The mean total preservation time was over 300 minutes. No donor hearts were discarded due to device malfunction or any device-related issue.

“These results are highly encouraging. For the first time, we have prospective clinical evidence supporting the feasibility of direct procurement combined with HOPE in DCD donor hearts, with strong early outcomes and a low rate of severe primary graft dysfunction. This represents an important step forward in expanding the clinical evidence for DCD heart transplantation,” said Filip Rega, Professor of Cardiac Surgery and Transplantation at the University Hospitals Leuven, Belgium, and Coordinating Investigator of the trial.

“What strikes me most is the high utilization rate and how well these DCD hearts performed directly after transplantation. Also, HOPE is giving us a logistical flexibility that can make the difference between a heart being used or declined. For patients on the waiting list, that matters enormously,” said Niels van der Kaaij, MD PhD, Head of Cardiothoracic Transplant Program at the Erasmus Medical Center Rotterdam in The Netherlands, and Principal Investigator of the trial.

“The results from the trial add to the growing global clinical experience with HOPE in heart transplantation. Together, with other studies from Europe and Australia, they continue to inform how HOPE technology may support donor heart preservation in an often challenging clinical environment,” said Christoffer Rosenblad, CEO of XVIVO. “XVIVO’s mission is to support our customers with technologies and services so they can save lives, and the results from this trial reinforce our commitment to that mission as we continue pursuing our vision that nobody should die waiting for a new organ.”

CAUTION—Investigational device. Limited by Federal (United States) law to investigational use. The safety and effectiveness of this device have not been established in the US. The XVIVO heart technology is not commercially available.

April 22, 2026
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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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