PRESS RELEASE
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Gothenburg

Preliminary one-year follow-up data from the US PRESERVE trial for XVIVO's heart technology presented at ISHLT in Toronto

Today, preliminary one-year follow-up data from the US PRESERVE trial of XVIVO's investigational heart technology, 'PRESERVE: A Prospective, Multi-center, Single-arm, Open-label Study,' were presented by the trial's principal investigator, Dr. Victor Pretorius, at the annual ISHLT conference in Toronto, Canada. The PRESERVE trial was designed to assess pre-specified safety and effectiveness endpoints for hypothermic oxygenated perfusion (HOPE) using the XVIVO Heart Assist Transport in the preservation and transport of extended criteria donor (ECD) hearts. The trial met its pre-specified primary endpoints.

A total of 141 transplant recipients were enrolled at 14 US transplant centers. The trial (NCT05881278) included adult recipients of hearts from donors meeting specific risk criteria: estimated cold ischemic time ≥4 hours, or ≥2 hours with one or more extended-criteria risk factors (such as donor age ≥ 50, down-time ≥ 20 mins, hypertrophy/septal thickness >12- ≤16mm, or angiographic luminal irregularities with no significant CAD), or donation after circulatory death (DCD) donors.

The preliminary data;
- The primary efficacy endpoint of overall success rate at 30 days (defined as absence of severe primary graft dysfunction (PGD), death, re-transplant, or mechanical support at Day 30) was 92.1%
- The primary safety endpoint of patient survival at day 365 was 91.4%
- Secondary endpoint analysis demonstrated an incidence of severe PGD at 24 hours of 7.9%

Additionally, the median out-of-body time was 291 minutes, with 73.8% of hearts preserved more than four hours.
"As static cold storage remains the standard for donor heart preservation and ischemic time remains a critical limitation, particularly for extended-criteria donor and donation after circulatory death hearts, it is encouraging to see these preliminary trial results and that the study met its pre-specified primary endpoints," said Victor Pretorius, M.D., Cardiothoracic and Thoracic Surgery at Emory Healthcare, and Principal Investigator of the PRESERVE trial.

"It has been a great honor to oversee the PRESERVE trial and to witness the dedication and engagement of all the participating transplant centers. A reflection of that commitment is that patient enrollment was completed in just 13 months, five months ahead of schedule," said Jaya Tiwari, Senior Vice President of Global Medical Affairs at XVIVO. "These preliminary findings represent an important step in the ongoing evaluation of HOPE for the preservation of extended criteria DBD and DCD donor hearts."

“Today’s late-breaking data represent an important step in advancing research in organ preservation,” said Christoffer Rosenblad, CEO of XVIVO. “Our long-term vision is to support transplant teams with technologies that may broaden preservation possibilities and help address some of the longstanding challenges in organ transplantation. We are encouraged by the preliminary findings from the PRESERVE trial and we look forward to submitting the PRESERVE data to the U.S. Food and Drug Administration for their review later this year.”

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 U.S.

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Toronto, Canada
Christoffer Rosenblad, CEO
XVIVO Perfusion AB (publ)

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.

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 2026-04-22 21:24 CEST.

Attachments

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