

Leading academic medical center performs first heart transplant in the U.S. utilizing NIHP technology as part of XVIVO's PRESERVE clinical trial

On October 14, 2023 Duke University Hospital in Durham, N.C., performed the first heart transplant in the U.S. using XVIVO's Non-Ischemic Heart Preservation (NIHP) device and solution as part of the PRESERVE clinical trial: A Prospective, Multi-center, Single-Arm, Open-Label Study of Hearts Transplanted after Non-Ischemic Heart PRESERVation from Extended Donors.

The PRESERVE multicenter clinical trial is designed to evaluate the safety and effectiveness of the XVIVO heart technology that will be used in support of a Pre-Market Approval (PMA) with the FDA. The trial will enroll 141 patients across 20 leading transplant centers in the USA. Amongst other inclusion criteria, the trial will allow transplant centers to include extended criteria donor hearts such as hearts from older donors (defined as aged 50 years old or above), from long-distance donors, and hearts from donation after circulatory death (DCD) donors.

"We are delighted that the team at Duke University Hospital successfully performed the first heart transplant using this novel technology in North America as part of our clinical trial. They performed more heart transplants than any other center worldwide in 2022[1] and are a center of research excellence. We are eager to support Duke's efforts and look forward to initiating more heart transplant centers nationwide into the trial to support their mission of providing more patients with life-saving transplantations," says Jaya Tiwari, VP Clinical & Regulatory Affairs USA, XVIVO.

"First and foremost, I would like to extend my congratulations to Duke University Hospital's transplant team for the successful transplantation. The initiation of the U.S. PRESERVE trial marks the fourth clinical trial utilizing our innovative heart technology. We also anticipate the forthcoming publication of promising results from an investor-initiated clinical trial in Australia and New Zealand. The technology is currently being utilized in approximately 30 percent of all heart transplants in that region under special compassionate use permission (i.e. before regulatory approval).

In May, our European randomized controlled clinical trial across 15 leading transplant centers in 8 European countries completed its patient recruitment. Simultaneously, there is an ongoing clinical trial in Lund, Sweden. We firmly believe that XVIVO's groundbreaking heart technology has the potential to change the paradigm in heart preservation, as it will open up for using more available hearts and, consequently, saving more lives," says Christoffer Rosenblad, CEO XVIVO.

Gothenburg

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Christoffer Rosenblad, CEO
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[1] <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/>

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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.

Attachments

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