PRESS RELEASE
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Gothenburg

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

XVIVO announces FDA receipt of PMA application for the XVIVO Heart Assist Transport System

Today, XVIVO announced that the U.S. Food and Drug Administration (FDA) has received the Premarket Approval (PMA) application for the XVIVO Heart Assist Transport System. The application is supported by clinical data from the PRESERVE IDE trial, as well as additional evidence from the PRESERVE Continued Access Protocol (CAP) trial and clinical experience outside the United States.

The PRESERVE IDE trial, enrolled 141 patients across 14 leading heart transplant centers in the United States. The study evaluated the safety and effectiveness of XVIVO Heart Assist Transport system for the preservation and transport of extended-criteria donor hearts for transplantation into adult recipients. The donor-heart eligibility included donation after circulatory death (DCD) hearts and donation after brain death (DBD) hearts meeting specified extended donor criteria, including anticipated cross-clamp times and defined donor risk factors. The XVIVO Heart Assist Transport system is designed to preserve donor hearts using Hypothermic Oxygenated Perfusion (HOPE).

The PMA application includes supportive information from the PRESERVE Continued Access Protocol (CAP) as well as clinical experience from outside the United States. The CAP trial was established to allow continued clinical use of XVIVO's heart technology while the IDE trials' one-year follow-up data was analyzed. FDA has authorized enrollment of up to 120 patients in the CAP trial, allowing participating transplant centers to continue utilizing the technology while the PMA application is under review.

"The submission of our PMA application marks an important milestone following several years of scientific, clinical and regulatory work," says Christoffer Rosenblad, CEO of XVIVO. "We are grateful to the patients who participated in the PRESERVE trial, as well as the investigators and transplant teams whose dedication helped make this milestone possible. Following the recent CE certification of the XVIVO Heart Assist Transport system in Europe, we are encouraged by the continued progress toward making this technology available to more patients and transplant centers in the US. We believe XVIVO Heart Assist Transport has the potential to support the use of more donor hearts and help more patients gain access to life-saving transplantation. Our vision remains clear: nobody should die waiting for a new organ."

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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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