PRESS RELEASE
July 25, 2023
Gothenburg

US FDA grants XVIVO approval to include DCD hearts in IDE Clinical Trial

The US Food & Drug Administration (FDA) has approved XVIVO's Investigational Device Exemption (IDE) supplement for its heart preservation clinical trial to now include Donation after Circulatory Death (DCD) hearts. This permits clinical trial sites to utilize XVIVO's heart technology to preserve hearts from DCD donors in the PRESERVE Clinical Trial. The study is a "Prospective, Multi-center, Single-Arm, Open-Label Study of Hearts Transplanted after Non-Ischemic Heart PRESERVation from Extended Donors". The number of patients to be enrolled are 141 at up to 20 US hospitals. The number of patients are unchanged, but this change will allow for five additional clinics to participate in the trial.

The United States is the world's largest heart transplant market, with approximately 4,100 heart transplants performed in 2022. During the same year, DCD donors consisted of approximately one third of the total donor pool in the United States. With an increasing number of patients in need of a transplant, the ability to safely utilize, preserve, and transport more donated organs is critical to address the growing organ shortage. Developed in collaboration with Professor Stig Steen at Igelösa LifeScience in Sweden, the patented XVIVO heart device and proprietary solution are designed for preservation of donor hearts during transport using cold, non-ischemic perfusion. In 2022, XVIVO´s heart technology was featured in the global news as a crucial component for the success of the first xeno (pig to human) heart transplant that was performed at the University of Maryland in the US.

The PRESERVE multicenter clinical trial will evaluate the safety and effectiveness of the XVIVO heart technology to be used in support of a Pre-Market Approval (PMA). The trial will enroll 141 patients across 20 leading transplant centers in the US. Amongst other inclusion criteria, the trial will allow transplant centers to include donor hearts from older donors (defined as aged 50 years old or above), Donation after Circulatory Death donors, and long-distance donors.

"We are pleased that we now can include DCD hearts in the US clinical trial, considering that almost one third of the total donor pool consists of DCD donors. Furthermore, the ability to include up to 20 clinics will provide more US clinics the opportunity to use the innovative heart technology. We are committed to supporting US patients with end-stage heart disease and their clinicians by providing an additional opportunity to facilitate a heart transplant in pursuit of our vision 'that no one should die waiting for an organ" says Christoffer Rosenblad, CEO XVIVO.

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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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