PRESS RELEASE
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Gothenburg

XVIVO's IDE application for its innovative heart preservation technology has been approved by the US FDA

The US Food & Drug Administration (FDA) has approved XVIVO's Investigational Device Exemption (IDE) application for its´ heart preservation technology. The approval allows XVIVO to start 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 United States is the world's largest heart transplant market, with approximately 4,100 heart transplants performed in 2022. 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 15 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) and from long-distance donors. By including long-distance donors, XVIVO's goal is to further demonstrate what was presented from the investigator initiated NIHP**[1]** study in Australia and New Zealand at ISHLT**[2]** in April, 2023 – that non-ischemic preservation of donor hearts using XVIVO's innovative technology can enable uncompromised organ preservation quality, despite significantly extended transport times.

"I'd like to express my immense appreciation to the team at XVIVO, the PRESERVE Trial lead investigators, and the FDA for their contributions and efforts to ensure that the trial will be high fidelity and address the most urgent need for patients and their clinicians," says Jaya Tiwari, Vice President Clinical & Regulatory Affairs, US, XVIVO. "We are pleased by the enthusiasm of our leading heart transplant centers to be a part of this trial, and we anticipate the first inclusion for the US to be in the late summer as we eagerly await the final inclusion into the European trial."

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“I am delighted that we have approval to start the US heart trial. The technology has the potential to change the paradigm of heart transplantation and is currently used in approximately 25 percent of all heart transplants in Australia and New Zeeland with the special permission of compassionate use i. e. before regulatory approval. Our vision is that nobody should die waiting for a new organ, and therefore it makes me very happy that we can now through the US trial introduce the technology in the largest heart transplant market in the world” says Christoffer Rosenblad, CEO XVIVO.

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[1] NIHP – Non-ischemic Heart Preservation
[2] ISHLT – International Society of Heart and Lung Transplantation

For further information, please contact:

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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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