PRESS RELEASE
January 21, 2022
Gothenburg

XVIVO's Kidney Assist Transport receives 510 (k) clearance by US FDA, which is XVIVO's first regulatory cleared product for abdominal transplantation in the US

Today XVIVO proudly announces that the US Food & Drug Administration (FDA) has granted clearance for Kidney Assist Transport. Organ donors and organ recipients are rarely at the same hospital, and therefore organs need to be transported in a safe and reliable manner. The device is a transportable organ perfusion system that allows for continuous oxygenated perfusion for up to 24 hours and has been shown to improve preservation compared to cold storage.

According to the World Health Organization (WHO) kidney disease is the world's 10th most common cause of death. Patients suffering from end-stage kidney disease need regular dialysis or a kidney transplant to survive. Transplantation is the preferred treatment as it improves the patient's quality of life and survival. Kidney transplant is also a far more cost-effective treatment option than dialysis. Today the US is the largest market with approximately 18,700 kidney transplants from deceased donors in 2021, and there are currently more than 90,000 patients on the waitlist for a new kidney. The need for organs available for transplantation far exceeds the supply.

A recent article in the scientific journal The Lancet suggests that hypothermic machine perfusion with oxygen using Kidney Assist Transport can reduce severe complications, additional diagnostic procedures, hospital readmission and cost for chronic dialysis**[1]**.

"Already before launch there has been a huge interest for Kidney Assist Transport, and we as an organization are thrilled to take this unique device to market. We will initiate the launch regionally and continue to scale up throughout the year", says Managing Director North America Fredrik Dalborg.

"We are now establishing a strong commercial presence in the US within abdominal transplantation, with a firm focus on kidneys. Our strategy is to become the global leader within abdominal where Kidney Assist Transport is a true enabler. I feel honored that we today can launch this fantastic device after years of dedicated development and several clinical trials. Kidney Assist Transport will make more kidneys available for transplantation", says Dag Andersson, CEO of XVIVO.

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Dag Andersson, CEO
XVIVO Perfusion AB (publ)

[1] Johmanns I, et al. Oxygenated versus standard cold perfusion preservation in kidney transplantation (COMPARE): a randomised, double-blind, paired, phase 3 trial. The Lancet. November 2020;396 (10263):1653-1662.

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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.

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 2022-01-21 22:50 CET.

Attachments

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