Press Release
April 29, 2019
Gothenburg

XVIVO has received market approval (PMA) from the FDA for STEEN Solution™ and XPS™

On April 26, 2019 XVIVO received Premarket approval (PMA) from the FDA for the products XPS™ and STEEN Solution™ for sale on the American market. The approval means that STEEN Solution™, XPS™ and the accompanying single-use articles are the only medical device products that are approved for Ex Vivo Lung Perfusion (EVLP) of initially unacceptable donated lungs at body temperature. This press release is an updated version of the press release sent April 27, 2019 at 12:30 a.m.

Please see FDA press release on the following link:
https://www.fda.gov/news-events/press-announcements/fda-approves-device-help-increase-access-more-lungs-transplant

Extracted from the FDA Press Release:
"Sadly, too many patients on transplant lists die waiting for suitable lungs. Providing patients with access to safe medical devices that have the potential to be lifesaving remains a top FDA priority, and we support the development of innovative technologies that can increase the donor organ pool for transplant patients in need of suitable lungs," said Benjamin Fisher, Ph.D., director of the Division of Reproductive, Gastro-renal, Urological Devices at the FDA's Center for Devices and Radiological Health.

The work on obtaining market approval from the FDA was started in 2009 in close collaboration with experienced transplantation centers, and subsequent comprehensive clinical studies in the USA to verify both product and patient safety, XPS™ and STEEN Solution™ and in August 2014 after the FDA's Advisory Panel voted unanimously that XPS™ and STEEN Solution™ meet the requirements for HDE approval. From 2015 to 2017 a total of 220 patients were included and in June 2018 the study was completed.

The previous HDE approval entailed certain restrictions, amongst other things that no more than 8,000 patients may be treated per year under HDE approval and that separate institutional IRB approval may be required for treatment. These restrictions do not apply to a PMA. Hence, after the FDA announced PMA approval, the products may now be sold in the American market without those restrictions.

The NOVEL Extension study which completed enrollment in June 2017 involves follow-up of the patients for up to one year. XVIVO Perfusion's will perform a PAS (Post Approval Study) as required by the FDA to follow up the long-term characteristics through an official register in the USA comparing traditionally preserved donated lungs with those where EVLP has been performed before transplantation.

"It is a breakthrough for XVIVO that we have now received an PMA from the FDA and can sell STEEN Solution™ and XPS™ in the American market without the HDE restrictions. The approval of the PMA application was the goal of a ten-year effort to bring this device, as a first in kind, to the market and thereby making more lung transplantations possible. It was made through a huge effort from the organization and is a very important milestone for the company" says Dr. Magnus Nilsson, CEO of XVIVO Perfusion AB.

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XVIVO Perfusion AB (publ)
Magnus Nilsson, CEO

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XVIVO Perfusion AB is a medical technology company which develops solutions and systems for assessing and preserving organs outside the body and for selecting usable organs and maintaining them in optimal condition pending transplantation. The company is headquartered in Gothenburg, Sweden, and has one office in Lund, Sweden and one office in the USA. The Xvivo share is listed on Nasdaq Stockholm and has the ticker symbol XVIVO. More information can be found on the website www.xvivoperfusion.com.

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