Press Release
April 27, 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.

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

Just over 40 percent of all lung transplantations worldwide are carried out in the USA. The products have already received regulatory approvals on all major markets and was previously sold on the US market under an HDE (Humanitarian Device Exemption) that entailed certain restrictions. A PMA will no longer entail any such restrictions.

After several years of product development 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™ have received FDA Premarket Approval. The work on obtaining market approval from the FDA was started in 2009 and an HDE approval was received in August 2014. During the process, clinical studies have been carried out to demonstrate product and patient safety, and in March 2014 the FDA's Advisory Panel voted unanimously that XPS™ and STEEN Solution™ meet the requirements for HDE approval.

An HDE approval entails 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. A PMA will no longer entail any such restrictions. After yesterday's approval, the products may now be sold in the American market without those restrictions.

EVLP with STEEN Solution™ are used in several hundred lung transplantations over the world every year. 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 any restrictions. The approval of the PMA application was the goal of a ten-year effort with the company's largest multicenter study ever performed in the largest market in the world, a huge effort from the organization and is therefore an 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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This is a translation of the Swedish version of the press release. When in doubt, the Swedish wording prevails.