Press Release
August 13, 2014
Gothenburg

XVIVO has received market approval from the FDA for STEEN Solution™ and XPS™.

On August 12, 2014 at 6:03 p.m. CET XVIVO received HDE (Humanitarian Device Exemption) approval from the FDA for the products XPS™ and STEEN Solution™ for sale on the American market. The approval, which is the first in the USA for warm perfusion of organs outside the body pending transplantation, means that STEEN Solution™, XPS™ and the accompanying single-use articles are the only medical device products that may be legally sold for Ex Vivo Lung Perfusion (EVLP) of initially unacceptable donated lungs at body temperature. Just over 40 percent of all lung transplantations worldwide are carried out in the USA. The products have already received a CE mark and are approved for sale in the European market.

After several years of product development in close collaboration with experienced transplantation centers, and subsequent comprehensive clinical studies in Canada and the USA to verify both product and patient safety, XPS™ and STEEN Solution™ have received FDA approval as a Humanitarian Use Device (HUD). The work on obtaining market approval from the FDA was started in 2009 and an HDE application was submitted in July 2012. 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. After yesterday's approval, the products may now be sold in the American market, and together will be labeled for the warm perfusion of initially unacceptable donated lungs.

EVLP with STEEN Solution™ has been used in more than 300 lung transplantations at almost 30 clinics, in Vienna, Paris, Toronto and elsewhere, and has displayed stable results there, similar to those that XVIVO Perfusion published from the American NOVEL study (see press release dated March 21, 2014).

"It is a breakthrough for XVIVO that we have now received approval from the FDA and can initiate sales of STEEN Solution™ and XPS™ in the American market after a time-consuming and comprehensive process with high patient and product safety requirements. The XPS™ machine and STEEN Solution™ mean that XVIVO now has a clinically proven method that is both CE marked and approved by the FDA. This method allows more lungs to be used for transplantation, which will potentially enable more patients with severe lung disease to achieve a greater quality of life as well as a longer life," says Dr. Magnus Nilsson, CEO of XVIVO Perfusion AB.

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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 the USA. The Xvivo share is listed on NASDAQ OMX First North and has the ticker symbol XVIVO. More information can be found on the website www.xvivoperfusion.com. The Certified Adviser is Redeye, www.redeye.se.

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