Press release
March 21, 2014
Gothenburg

The FDA Advisory Panel voted unanimously that XPS™ with STEEN Solution™ meets the requirements for HDE

The Advisory Panel convened by the FDA voted unanimously, by 10 votes to 0, that the XPS™ System with STEEN Solution™ meets the requirements for HDE (Humanitarian Device Exemption) approval. XVIVO Perfusion will initiate a dialogue with the FDA in the near future to discuss labelling and the post marketing study.

An Advisory Panel meeting was held yesterday, Thursday, March 20, 2014, in Maryland, USA, at which the Advisory Panel discussed XVIVO Perfusion's HDE application for the XPS™ System with STEEN Solution™. The Advisory Panel primarily discussed the clinical data accumulated in the NOVEL study. The NOVEL study is steered by a protocol including XPS™ and STEEN Solution™. After an eight-hour meeting the Advisory Panel voted unanimously that the XPS™ System with STEEN Solution™ meets the requirements for HDE approval.

The Advisory Panel was convened by the FDA and its role is to give advice and a recommendation to the FDA with regard to regulatory questions. The decision on market approval is taken by the FDA. If the HDE approval is granted, XVIVO Perfusion can market STEEN Solution™, XPS™ and the accompanying single-use items in the USA. The NOVEL study with STEEN Solution™ and XPS™ will continue to recruit patients and the results from the study will form the basis of a PMA (Pre-Market Approval) application.

"We are very pleased that the Advisory Panel voted unanimously that STEEN Solution™ and XPS™ meet the requirements for HDE approval. We will now immediately initiate a dialogue with the FDA to discuss the final steps in the application process," says Dr Magnus Nilsson, CEO of XVIVO Perfusion.

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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 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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XVIVO Perfusion is required to publish the information in this press release in accordance with the Swedish Securities Market Act and/or the Financial Instruments Trading Act. The information was submitted for publication on March 21, 2014 at 8:00 a.m.

This is a translation of the Swedish version of the press release. When in doubt, the Swedish wording prevails.