Press release
July 6, 2017
Gothenburg

Recruitment completed for NOVEL study in the US on STEEN Solution™ and XPS™

Inclusion of all 220 (110 + 110) patients is now completed in the NOVEL study which is being carried out in the US on STEEN Solution™ and XPS™. This clinical study will form the basis of the company's PMA (Pre-market Approval) application to the FDA. Approximately 40 percent of all lung transplantations in the world are done in the US and STEEN Solution™ and XPS™ have already been approved for sales in the US under an HDE (Humanitarian Device Exemption) approval.

In March 2014 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. In August 2014 the company received HDE approval from the FDA for the products XPS™ and STEEN Solution™ for sales on the American market. HDE approval entails certain restrictions, amongst other things that no more than 4,000 patients may be treated per year under HDE approval and that separate ethical approval may be required for treatment. The study that has now been completed will form the basis of the company's PMA application, which means that if it is approved, there will no longer be any such restrictions.

The NOVEL study is continuing with follow-up of the patients for up to one year. XVIVO Perfusion has an ongoing dialogue with the FDA about the design and the time for submission of the PMA application and will post information when this has been done. The PAS (Post Approval Study) required by the FDA, which is a compulsory safety follow-up after all approvals, will include a total of 126+126 patients that will be followed for 3 years. Sixteen more patients in each group are required to complete enrollment into the PAS.

XPS™ is the only CE-marked and FDA-approved (HDE approval) normothermic lung perfusion integrated system on the market today, that provides the clinician the flexibility to evaluate lungs before transplantation by means of a standardized and simplified procedure. XPS™ is used worldwide with good clinical results. The XPS™ and STEEN Solution™ have already been CE-marked and thus approved for sales on the European market, and are also approved for sales in Canada and Australia.

"We are delighted that the PMA study on XPS™ and STEEN Solution™ in the US has now been completed. This will mean that as soon as recruitment for the PAS study is complete, some of the restrictions that were part of the clinical trial will disappear and more patients will have an option to receive an EVLP lung. This will also mean that the company can focus more in the US on tailoring the technology for customers, building up the market and customer service," says Magnus Nilsson, CEO of XVIVO Perfusion.

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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.