Press release
September 20, 2013
Gothenburg

NOVEL trial recruitment of patients complete, FDA has decided that an expert panel meeting will be held Q1 of 2014.

All 42 planned patients in Xvivo Perfusion's American clinical trial using STEEN Solution™ have received transplants. In the ongoing follow-up good clinical results have been obtained. The patients are being followed up over a period of one year. During a meeting with the FDA it was decided that the expert panel meeting preceding the decision on HDE registration (Humanitarian Device Exemption) will be held within four to five months. During the meeting the FDA's remaining questions were also discussed. Following the advice of the FDA, the clinics taking part in the trial are continuing to transplant lungs that have been perfused outside the body using STEEN Solution™ and so far 52 patients have received transplants at the centers taking part in the trial.

The NOVEL trial is being performed at 7 centers in the USA and was designed to safely increase the number of usable lungs from the donor pool. In the study, clinical outcomes associated with ex-vivo lung perfusion (EVLP) of organs initially assessed to be unusable were compared with a control group consisting of lungs that were transplanted after having been initially assessed to be usable. A total of 42 patients received transplants using the STEEN Solution™ method and these were matched with 42 control patients. The results so far from the study continue to indicate that lungs evaluated using STEEN Solution™ perform as well as lungs transplanted directly.

"It is a big step forward for XVIVO Perfusion that the FDA has now decided to hold an expert panel meeting. Such meetings precede decisions on registration. Unfortunately the FDA is not able to hold this meeting until after the turn of the year. We continue to note that clinics in the USA continue to show great interest in STEEN Solution™," says Dr Magnus Nilsson, CEO at XVIVO Perfusion.

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Gothenburg
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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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