Press release
July 9, 2013
Gothenburg

All patients included in the NOVEL trial in the USA with STEEN Solution™

In June all the patients were included in the clinical study with STEEN Solution™ according to plan. Interim results confirms previous single center experience, that initially rejected lungs evaluated with Ex Vivo Lung Perfusion (EVLP) perform similarly to standard criteria lungs after transplantation and that the use of EVLP to screen the marginal donor pool is safe. The patients will be followed up for one year after transplantation.

The NOVEL trial is a multicenter study performed at 6 sites in USA and was designed to safely increase the percentage of usable lungs from the donor pool. In the study, clinical outcomes associated with ex-vivo lung perfusion (EVLP) of initially rejected or marginal lungs were compared with contemporary matched controls. A total of 42 patients received transplants using the STEEN Solution™ method and was matched with 42 control patients. The initial results indicate that initially rejected lungs that were perfused with Steen Solution™ perform as well as lungs that initially were deemed good for use. This is in line with experiences from centers in Europe and Canada where EVLP with STEEN Solution™ is in clinical practice.

At the International Society of Heart and Lung Transplantation (ISHLT) conference in Montréal, the interim results were presented and confirmed previous single center experiences that initially rejected lungs evaluated with Ex Vivo Lung Perfusion (EVLP) perform similarly to standard criteria lungs after transplantation. The results also indicate that the use of EVLP to screen the marginal donor pool is safe. At the same conference, the combined outcome data from Toronto (Canada), Vienna (Austria) and Paris (France) were presented with 140 assessed and 114 transplanted lungs. More than 240 patients have now received lungs evaluated with STEEN Solution™ method which would have otherwise remained unused without this technology.

“The clinical results from the study are very encouraging and demonstrates that STEEN Solution™ safely makes many more organs available for this life-saving treatment of patients with end-stage lung deceases” says Dr Magnus Nilsson, CEO of 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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This is a translation of the Swedish version of the press release. When in doubt, the Swedish wording prevails.