



Press release
March 14, 2014
Gothenburg

Progress made in the NOVEL study in the USA

Indiana University Health in Indianapolis, USA has performed its first transplantation using lungs from a DCD (Donation after Circulatory Death) donor within the framework of the NOVEL-study. This has been made possible by using STEEN Solution™ and the XPS™ to evaluate the lung function outside the body. The FDA advisory committee meeting will be held on March 20, 2014.

The number of lungs from DCD donors used in lung transplantation is limited today, but using the STEEN Solution™ method, these lungs can also be used for transplantation to a greater extent than would otherwise be possible. It is XVIVO Perfusion's assessment that the number of lung transplants can be many times greater in the future when the use of lungs from DCD donors is more extensively employed.

Dr Thomas Wozniak, Lung Transplant Surgical Director at IU Health stated recently that "Despite the fact that most DCD lungs satisfy standard criteria for transplantation, changes can occur during the DCD process that can render some of these organs suboptimal. Prior to the availability of XVIVO, there was no way to determine which of these lungs would fail other than implanting them into recipients. For this reason, we have not previously utilized DCD lungs. With XVIVO perfusion, we are now more able to predict which of these lungs will be suitable for implantation into a recipient. To date, our program has transplanted 2 patients utilizing XVIVO technology that otherwise would not have been considered for DCD lungs."

The FDA process is proceeding according to plan and XVIVO Perfusion has submitted material for the advisory committee meeting to be held on March 20, 2014. The expert panel consists of external experts and it primarily assesses the results from the NOVEL study in the USA. The expert panel gives advice and recommendation to the FDA regarding regulatory questions.

"It is good news that IU Health has performed its first transplantation of lungs from a DCD donor using STEEN Solution™ and the XPS™. As the donor pool can become many times greater if there is access to DCD donors' lungs and the STEEN Solution™ EVLP method enables more patients with severe lung disease improved access to lung transplantation and therefore to enjoy a longer and better life." says Dr Magnus Nilsson, CEO of XVIVO Perfusion.

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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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