



**Press release**  
May 14, 2018  
Gothenburg

## **Positive findings in the PrimECC study**

**The PrimECC® study was completed during 2017. It included a total of 80 patients and was performed at Sahlgrenska University Hospital. Analysis of the results shows that the product is safe and indicates interesting findings regarding decreased side effects when using PrimECC®. To expand the documentation and spread the use of PrimECC®, the company has decided on further studies. PrimECC® is a CE-marked and patent-protected product, developed to prime the heart-lung machine before open heart surgery.**

Several hundred thousand heart operations are performed in the world each year using a heart-lung machine. As expected the blind, randomized study conducted with PrimECC® at Sahlgrenska University Hospital gives patients a better fluid balance during and after the operation if the heart-lung machine has been primed with PrimECC®. The study also indicates a reduced risk of kidney damage. The results further verify that PrimECC® is a safe product to use. A surprising and positive effect is that the results from the study show that the use of PrimECC® also reduces red blood cell destruction, so-called hemolysis, which occurs when blood is circulated outside the body in a heart-lung machine. Hemolysis releases substances that are harmful to both kidneys and blood vessels and may be a problem during cardiovascular surgery. The study included 80 patients randomized to have the heart-lung machine primed with either PrimECC® or the conventional, simpler solution currently used at the hospital.

"The results are interesting and promising," says Professor Anders Jeppsson, responsible for the study at the thorax department of Sahlgrenska University Hospital. "We want to continue with larger studies at several different thoracic surgery clinics."

The study results are planned to generate four scientific articles. XVIVO Perfusion does not plan any extensive launch of the product before the results from the study have been published. XVIVO Perfusion has applied for a patent for PrimECC® in important markets and has so far been granted a patent in the USA, EU, China and Japan. PrimECC® is CE-marked and approved for sales in Europe.

PrimECC® is a fluid developed in collaboration with Professor Stig Steen in Lund to prime heart-lung machines before use. These machines are used to maintain blood circulation and take over oxygenation of the blood during heart operations. The fluid is used to compensate for the volume of blood that is outside the patient and in the heart-lung machine during the operation. Today simple saline solutions are used which are not optimized for this purpose. The aim of PrimECC® is to minimize adverse effects that may arise during and after use of a heart-lung machine.

"It is very pleasing that the clinical data from the PrimECC® study show that the product is safe. The clinical data show interesting findings regarding reduced side effects. This is exciting as the product has a great clinical and commercial potential. Based on the analysis, the company has decided to proceed in a clinical program with PrimECC® by initiating at least two additional studies to expand the clinical profile of the product," says XVIVO Perfusion's CEO Magnus Nilsson.

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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](http://www.xvivoperfusion.com).

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