



First patient in the PrimECC study included

PrimECC®, a CE-marked and patent-protected product, is developed to reduce complications after heart surgery. PrimECC® is a solution used to prime the heart-lung machine before open heart-surgery. An earlier study from 2017, which included a total of 80 patients at Sahlgrenska University Hospital, showed that the product is safe. In addition, interesting findings emerged regarding reduced side effects when using PrimECC®. The study that has now begun intends to expand and strengthen the clinical data for PrimECC® and will include a total of 366 patients.

Hundreds of thousands of heart surgeries are performed each year worldwide using a heart-lung machine. The blinded, randomized study conducted with PrimECC® at Sahlgrenska University Hospital 2017 showed, as expected, that patients get a better fluid balance during and after surgery if the heart-lung machine is primed with PrimECC®, but also demonstrated a reduction in the damage to red blood cells that often occurs during surgery with heart-lung machine. Analysis of the results also indicated a reduced risk of kidney damage. The study that has now begun is intended to further explore the interesting findings and potential benefits indicated by the study conducted in 2017, now in a larger group of patients.

"Kidney failure and excess fluid are common and significant problems after heart surgery. Therefore, it feels exciting to have this study started, which may mean a new way to prevent these complications", says Dr. Lukas Lannemyr, responsible for the study at the Thorax department at Sahlgrenska University Hospital.

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

XVIVO Perfusion does not plan any extensive launch of the product before the results from the study have been published. XVIVO Perfusion has been granted patents for PrimECC® in the USA, the EU, China and Japan. PrimECC® is CE-marked and approved for sales in Europe.

"It is gratifying that this important study is now underway. PrimECC® is a very exciting product and my hope is that with this study we will be able to prove that the use of PrimECC® gives less side effects for patients than today's priming solutions ", says XVIVO Perfusion's CEO Dag Andersson.

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Dag Andersson, CEO XVIVO Perfusion AB (publ)

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About Us

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.

Attachments

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