



Press release
January 7, 2016
Gothenburg

PrimECC has been granted CE mark

XVIVO Perfusion has been granted a CE mark for a patent-protected product, PrimECC[®], developed to prime the heart-lung machine before open heart surgery. The company will expand the clinical documentation for PrimECC[®] through additional clinical studies in 2016.

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 avoid air bubbles coming into the patient's blood circulation when the heart-lung machine is started, and 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 for this purpose. The aim of PrimECC[®] is to minimize adverse effects that may arise during and after use of a heart-lung machine.

A "proof of concept" study performed using PrimECC[®] has shown interesting clinical results. In order to expand the documentation, the company will perform a randomized clinical study on 80 patients at Sahlgrenska University Hospital in Gothenburg in 2016. XVIVO does not plan any extensive launch of the product before this study is complete. XVIVO Perfusion has applied for a patent for PrimECC[®] in important markets and has so far been granted a patent in the USA and EU.

"Several hundred thousand heart operations are performed in the world each year using a heart-lung machine and the 'proof of concept' study performed using PrimECC[®] indicates that the patient has an improved fluid balance after the operation if the heart-lung machine is primed with PrimECC[®] rather than the simpler solutions that are often used. Work on broadening the clinical documentation is ongoing, as the product has interesting clinical and commercial potential," says XVIVO Perfusion's CEO, Magnus Nilsson.

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XVIVO Perfusion AB (publ)

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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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