



PRESS RELEASE

July 12, 2023

Gothenburg

XVIVO has decided to close the PrimECC® study for further patient inclusions – strategic opportunities will be evaluated

PrimECC is a solution used to prime the heart-lung machine before heart-surgery. It is a CE-marked and patent-protected product and is developed to reduce postoperative complications. In 2020 a study was initiated to expand and strengthen the clinical data for PrimECC. The pace of patient recruitment to the trial has not met expectations and is not projected to be finalized within a reasonable period of time. XVIVO has therefore taken the decision to close the study for further patient inclusions. Study data will be analyzed and strategic opportunities evaluated.

In 2020, an international multicenter study was initiated with the intention to expand the data for PrimECC and demonstrate clinical benefits. The study was designed to target patients with the highest risk of complication after surgery. Initially the COVID-pandemic prevented hospitals from enrolling patients into clinical trials, and more recently, identifying and recruiting sites and patients fulfilling the criteria for entering the trial has proven challenging.

PrimECC is a solution (fluid) developed in collaboration with Professor Stig Steen in Lund intended for use in heart-lung machines. The solution is added to the machine before its attached to a patient to avoid air bubbles entering the circulation when the heart-lung machine is started, and to compensate for lost blood volumes 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 clinical study from 2017 showed that the product is safe. XVIVO has been granted patents for PrimECC in the USA, the EU, China, and Japan.

To date, SEK 15 million has been invested in the PrimECC project. Hence, if XVIVO at a later stage decides to shut down the product, the decision would result in a SEK 15 million impairment in immaterial assets. Such a decision is not deemed to lead to any significant savings in operating expenses in general. XVIVO assess that the future pathway for PrimECC will be determined within the next six months.

“Closing the study recruitment early is the right decision in the current situation. We will now analyze the data and evaluate the strategic and commercial opportunities for PrimECC. With the decision to close the study for further patient inclusions, we will increase focus on our core business within organ transplantation, where the great opportunities deserve our full attention. As an agile company in an ever-changing world, XVIVO stands well-equipped for all our future commitments”, says Christoffer Rosenblad, XVIVO CEO.

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About Us

Founded in 1998, XVIVO is the only medical technology company dedicated to extending the life of all major organs - so transplant teams around the world can save more lives. Our solutions allow leading clinicians and researchers to push the boundaries of transplantation medicine. XVIVO is headquartered in Gothenburg, Sweden, and has offices and research sites on two continents. The company is listed on Nasdaq and has the ticker symbol XVIVO. More information can be found on the website www.xvivogroup.com.

This information is information that XVIVO Perfusion AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2023-07-12 19:16 CEST.

Attachments

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