



PRESS RELEASE

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Gothenburg

Patient inclusion completed in European clinical trial with XVIVO's heart preservation technology

XVIVO's innovative heart technology is currently under investigation in a randomized controlled clinical trial across 15 leading transplant centers in 8 European countries. 202 patients have gone through a transplantation in the trial which means inclusion is now completed of all planned participants. The next step is a one-year follow-up phase where patient outcome will be collected and monitored before the trial is closed and data presented. However, the pre-work for initiation of the product approval process has already started and dependent on passing MDR (Medical Device Regulation) requirements, a CE mark can be expected in the first half of 2024.

Developed in collaboration with Professor Stig Steen at Igelösa LifeScience in Sweden, the patented XVIVO heart device and proprietary solution are designed for preservation of donor hearts during transport using cold, non-ischemic perfusion.

The European multicenter clinical trial is XVIVO's first heart preservation trial. A US multicenter clinical trial is expected to start at the end of September.

"We are thankful for the support from patients and clinical trial investigators who chosen to participate in the European clinical trial. We are proud to have been able to engage an exceptional interest in leading heart transplant centers across Europe. Surgeons involved in the study have expressed their enthusiasm for the technology and they are now eagerly waiting for the trial data to be analyzed and presented", says Andreas Wallinder, Chief Medical Officer at XVIVO. "The great initial results recently presented from the Australian/New Zealand study strengthen us in our work to improve outcomes after transplantation using our unique heart technology."

"Especially testimonials from leading transplant surgeons about the immediate positive difference for patients after the use of XVIVO's heart technology make us encouraged, and also confident in seeking regulatory approvals for commercialization. We believe that the new innovative heart technology from XVIVO has the potential to change the paradigm in heart preservation as it will open up for using more available hearts, and in turn saving more lives" says Christoffer Rosenblad, XVIVO CEO.

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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.

Attachments

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