PRESS RELEASE
May 18, 2026
Gothenburg

Regulatory derogation and reimbursement in France enable life-saving use of XVIVO's heart technology

Hôpital La Pitié-Salpêtrière (Sorbonne University) in Paris, France, has, since the approval of a regulatory derogation for XVIVO's heart technology back in December 2025, performed 11 heart transplants that would otherwise not have taken place, saving precious lives. In addition, XVIVO's heart technology has now also received reimbursement in France.

A regulatory derogation allows a medical technology to be used under defined conditions of unmet clinical need prior to regulatory approval. It is typically granted to support patient access to promising technologies before obtaining CE marking. In this case, the French regulatory authority, ANSM (Agence Nationale de Sécurité du Médicament), granted derogation for clinical use for XVIVO's heart technology starting in December 2025. Now, French authorities have also approved reimbursement for machine perfusion of donated hearts.

The combination of regulatory derogation and reimbursement enables broad access of XVIVO Heart Assist Transport across France. Professor Guillaume Lebreton at Hopital La Pitié-Salpêtrière (Sorbonne University), France, has been a strong advocate for the derogation and has, as a result of the grant, been able to utilize more donated hearts, allowing more patients to receive the life-saving transplants they need.

"Our team has gained extensive experience with the XVIVO Heart Assist Transport through both the European Randomized Controlled Trial (NIHP2019) and the PEGASUS trial. I am therefore deeply grateful to the French authorities for supporting our mission to help patients who otherwise would not have had the chance to receive a new heart. Now, with both a regulatory derogation and reimbursement in place, broad nationwide use becomes possible," said Professor Guillaume Lebreton, transplant surgeon at Hôpital Pitié-Salpêtrière, Paris, France. "With this technology, we can manage donor hearts with confidence in the outcomes. Heart transplantation has always been a race against time. This innovation changes that, benefiting transplant teams and, most importantly, our patients."

"XVIVO's heart technology has been used in several clinical trials. In Europe, we conducted a randomized controlled trial enrolling 204 patients across 15 institutions in eight European countries. The results demonstrate that use of XVIVO Heart Assist Transport with the HOPE method is associated with improved clinical outcomes and reduced postoperative complications at 12 months after transplantation. The trial is also the first heart trial to demonstrate a direct relationship between perfusion and survival," said Christoffer Rosenblad, CEO of XVIVO. "As we are now awaiting CE marking, I am very pleased that France, as a European leader in heart transplantation, has approved regulatory derogation and reimbursement. It clearly demonstrates that XVIVO's heart technology fills an important gap in the market and addresses a

significant unmet clinical need. Our vision is that ‘nobody should die waiting for a new organ’, and with these approvals we are moving closer to fulfilling that vision.”

CAUTION—Investigational device. Limited by Federal (United States) law to investigational use. The safety and effectiveness of this device have not been established. The XVIVO heart technology is not commercially available.

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Molndal
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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 Stockholm under the ticker symbol XVIVO. More information can be found on the website www.xvivogroup.com.

Attachments

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