**PRESS RELEASE**
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Gothenburg

# Delay in CE approval for XVIVO's perfusion solution for heart preservation

**The XVIVO Heart Assist Transport and the XVIVO Heart Assist Transport Perfusion Set have received CE approval. At the same time XVIVO estimates delays of approximately 6-12 months for the CE approval of XVIVO's heart perfusion solution and supplement, which are part of its´ innovative heart preservation technology. The delay is due to the consultation process at an EU competent authority.**

XVIVO Heart Assist Transport system consists of several medical devices. XVIVO Heart Assist Transport and XVIVO Heart Assist Transport Perfusion Set have both received CE approval. Due to the composition of the perfusion solution used in XVIVO's heart preservation technology, the notified body must seek a scientific opinion from the European Medicines Agency (EMA) and another EU competent authority before issuing the CE certificate. Even if the CE-mark for main components of the heart technology have been reached, and the Heart Solution has passed the consultation at one of the competent authorities (EMA) the company estimates that the additional scientific consultation procedure will take approximately another 6-12 months due to additional request for information. The exact time of delay will be pending submission slot times available for consultation.

XVIVO's European multicenter heart trial is the first Randomized Control Trial with superiority design. The recently presented 12-month follow-up results from The European multicenter heart trial were presented and showed a 76 percent risk reduction in severe PGD, which is the leading cause of early and late mortality. The reduction in severe PGD showed an improved one-year survival in the XVIVO group with 92 percent survival in the XVIVO group vs 86 percent in the control arm, corresponding to additionally six lives saved in the XVIVO group. The outstanding results were reflected in the significant interest of surgeons around the world that hope to use the technology on patients as soon as possible.

"We are very disappointed by this delay, as it deprives many European patients the chance to a life-saving transplant until the technology is regulatory approved", says Christoffer Rosenblad, CEO of XVIVO. "We have spent a year on this regulatory process and made significant achievements. One final step remains and XVIVO will continue working closely with the relevant authorities. Achieving CE approval for our heart technology would be a significant step towards transforming the paradigm of heart preservation and that one day nobody should die waiting for a new organ. We are deeply grateful to the patients, clinicians, transplant teams, and partners across Europe whose dedication has brought us this far. The XVIVO Heart Assist Transport system is not just a technological breakthrough — it is a symbol of hope for the thousands of patients waiting for a new heart."

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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.

*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 2025-07-28 22:10 CEST.*

## Attachments

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