



**PRESS RELEASE**

July 21, 2025  
Gothenburg

## First patient enrolled in US PRESERVE CAP study for XVIVO Heart Assist Transport device

**Today, XVIVO announces that the first patient has been enrolled as part of the Continued Access Protocol (CAP) study for its heart technology, XVIVO Heart Assist Transport, in the United States. This CAP study follows the successful PRESERVE Trial and allows for the enrollment of up to 60 patients across 26 US transplant centers. Importantly, the study has received continued cost recovery approval from the Centers for Medicare & Medicaid Services (CMS), providing essential access and support for both participating centers and patients.**

The CAP, approved by the US Food and Drug Administration (FDA), allows for continued clinical use of the XVIVO Heart Assist Transport device while XVIVO collects and analyzes one-year follow-up data from the PRESERVE trial in preparation for submitting its Pre-Market Approval (PMA) application. The protocol closely mirrors that of the original IDE study, ensuring continuity in safety and efficacy data collection. The CAP will remain active until the FDA completes its PMA review or the maximum number of enrolled patients is reached.

"The Continued Access Protocol (CAP) study ensures that patients awaiting heart transplants can continue to benefit from XVIVO's heart technology, even as the FDA receives and evaluates our PMA submission," says Jaya Tiwari, SVP Clinical and Regulatory Affairs. "The FDA and CMS approvals provide an important mechanism to maintain clinical use during this interim period, supporting continuity of care while the technology's safety and efficacy continue to be formally evaluated. The strong interest from participating sites further underscores the need for ongoing access to the XVIVO Heart Assist Transport."

"The initiation of the PRESERVE CAP study and enrollment of the first patient marks another important step in our mission to bring innovative, life-saving technologies to patients in need," says Christoffer Rosenblad, CEO of XVIVO. "We are proud to see such strong interest from US transplant centers. Our vision is that nobody should die waiting for a new organ, and we remain committed to both realizing this vision and supporting clinicians as they continue delivering advanced care with our heart technology."

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Christoffer Rosenblad, CEO

XVIVO Perfusion AB (publ)

**For further information, please contact:**

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**About Us**

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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](http://www.xvivogroup.com).

**Attachments**

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