PRESS RELEASE
August 3, 2026
Gothenburg

XVIVO granted additional patient enrollment in the US PRESERVE CAP study for XVIVO Heart Assist Transport

XVIVO announces that the US Food and Drug Administration (FDA) has granted the company approval for additional patient enrollment in the Continued Access Protocol (CAP) study of 60 heart transplantations using XVIVO Heart Assist Transport. Last summer, XVIVO received approval to enroll up to 60 patients across 26 US transplant centers, with the final patient enrolled in March. Importantly, the study has once again 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 trial 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 the original IDE study, ensuring continuity in the collection of clinical data collection. The CAP trial will remain active until the FDA completes its PMA review or the maximum number of enrolled patients has been reached.

“The FDA and CMS approvals provide an important mechanism to maintain continued clinical evaluation during this interim period. We are very pleased with the strong interest from participating sites, which further reflects the continued engagement of transplant centers in the ongoing clinical evaluation of the XVIVO Heart Assist Transport,” said Christoffer Rosenblad. “Our vision is that nobody should die waiting for a new organ, and we remain committed to realizing that vision while continuing to support clinicians delivering advanced care with our heart technology.”

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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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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