PRESS RELEASE
September 20, 2022
Gothenburg

XVIVO granted Breakthrough Device Designation from the FDA for the Liver Assist device

XVIVO has been granted Breakthrough Device Designation from the U.S. Food and Drug Administration (FDA) for their Liver Assist device, indicated for ex-vivo oxygenated machine perfusion for preservation of donor livers prior to transplantation. The FDA's Breakthrough Device Program is intended to expedite the development and prioritize the regulatory review of certain medical devices that provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions than previous therapies.

The US is the largest liver transplant market globally with more than 8,600 livers transplanted in 2021**[1]**. In that year, the US performed more transplants than the next three largest markets combined (China, Brazil and Italy)**[2]**. The total US liver transplant market is expected to grow at an annual rate of 6 percent until 2030**[3]**. Additionally, the donation after circulatory death (DCD) segment of the market is expected to grow faster at approximately 15 percent per year in the same time frame**[4]**. An article published last year in The New England Journal of Medicine, shows that oxygenated hypothermic perfusion of DCD donor livers before transplantation has a significant positive impact on post-transplant clinical outcomes**[5]**.

The overall goal of the Breakthrough Devices Program is to provide patients and health care providers with timely access to life-saving technologies by expediting their development, assessment, and review, through the FDA. As part of this program, the FDA will provide XVIVO with priority review and interactive communication ("sprint discussions") which provide a faster mechanism for communication with FDA compared to Pre-Sub meetings. This enables device development and review to move forward in an efficient manner and achieve a faster path to market access. The Breakthrough Devices Program not only expedites FDA review but also has the potential to facilitate Centers for Medicare and Medicaid Services (CMS) payment and positively affect future coverage benefits.

"In line with our strategy to become the market leader within abdominal transplantation we have taken a decision to commercialize our liver technology in the US. FDA's decision to grant a breakthrough designation indicates that the technology is innovative with the potential to be an improvement upon what is available on the market today. With more than 10 years of clinical experience, the Liver Assist is the most used device globally for machine perfusion of livers. As we believe in the extended life of organs we are very much looking forward to expanding this technology in the US after an FDA approval" says Dag Anderson, CEO of XVIVO.

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Gothenburg
Dag Andersson, CEO
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[1] OPTN (Organ procurement and transplantation network – USA)
[2] GODT (Global observatory on organ donation and transplantation)
[3] XVIVO Market Intelligence & Forecast
[4] XVIVO Market Intelligence & Forecast
[5] https://www.nejm.org/doi/full/10.1056/NEJMoa2031532

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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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