Press Release
December 16, 2019
Gothenburg

XVIVO Perfusion granted Breakthrough Device Designation from the FDA for the XVIVO Heart Preservation System

XVIVO Perfusion has been granted 'Breakthrough Device Designation' from the U.S. Food and Drug Administration (FDA) for the XVIVO Heart Preservation System (XHPS), indicated for the hypo-thermic non-ischemic perfusion of excised donor hearts for preservation prior to transplant. The Breakthrough Device Designation is intended to expedite the development and prioritize the review of certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

The Center for Devices and Radiological Health (CDRH) of the FDA has informed XVIVO that the combination product and proposed indication for use has met the criteria and have been granted designation as a Breakthrough Device. The proposed indications for use include The XVIVO Heart Preservation System (XHPS), used in conjunction with Supplemented XVIVO Heart Solution (SXHS), is indicated for the hypothermic non-ischemic perfusion of excised donor hearts for preservation prior to transplant. The device is intended to be used for all standard criteria donor hearts with the intention of transplant into a recipient aged 18 or older on a heart transplant waiting list.

The Breakthrough Devices Program is a voluntary program for certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The overall goal of the Breakthrough Devices Program is to provide patients and health care providers with timely access to these medical devices by speeding up their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization, consistent with the FDA's mission to protect and promote public health.

"The 'Breakthrough Device Designation' granted to XVIVO offers a great opportunity to interact with the FDA and they will also provide XVIVO with a priority review and interactive communication regarding device development through to clinical trial protocols" says Dr. Magnus Nilsson, CEO of XVIVO Perfusion AB.

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XVIVO Perfusion AB (publ)
Magnus Nilsson, CEO

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XVIVO Perfusion AB is a medical technology company which develops solutions and systems for assessing and preserving organs outside the body and for selecting usable organs and maintaining them in optimal condition pending transplantation. The company is headquartered in Gothenburg, Sweden, and has one office in Lund, Sweden and one office in the USA. The Xvivo share is listed on Nasdaq Stockholm and has the ticker symbol XVIVO. More information can be found on the website www.xvivoperfusion.com.

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