PRESS RELEASE
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Gothenburg

XVIVO submits an IDE application to US FDA for its innovative heart technology – a significant milestone

XVIVO proudly announces the filing of an Investigational Device Exemption (IDE) application to the US Food & Drug Administration (FDA). It will support an initial FDA regulatory approval to conduct the "PRESERVE Clinical Trial: A Prospective, Multi-center, Single-Arm, Open-Label Study of Hearts Transplanted after Non-Ischemic Heart PRESERVation from Extended Donors".

This is being done under the previously announced FDA Breakthrough Designation granted for the XVIVO heart technology which is a Non-Ischemic Heart Preservation (NIHP) device. In pre-submission meetings, XVIVO worked constructively with the FDA to discuss questions and concerns and has used FDA's feedback to determine the path forward for its IDE application. An IDE allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data that XVIVO will use in support of a Pre-Market Approval (PMA).

In 2019 there were 112,000 Americans on the national transplant waiting list while only 39,718 transplants were performed. With a growing organ shortage, the importance of preservation of available organs is magnified. The XVIVO heart technology is designed for preservation of donor hearts during transport using cold, non-ischemic perfusion for use in transplant surgery.

The technology was invented by Professor Stig Steen at Igelösa Lifescience and has been developed in collaboration with XVIVO. The device and the proprietary solution is patented by XVIVO.

"We are very pleased with the investigational plan, set forth in the IDE filing, that we believe accurately reflects the spirit of the Breakthrough Designation and are looking forward to the Agency's feedback" says Jaya Tiwari, XVIVO's Vice President Clinical & Regulatory Affairs, USA. "We expect that our discussions with FDA will complete in the first half of 2022, with the goal of beginning patient enrollment during the summer across multiple leading US institutions that have already expressed their keen interest to participate in this trial. We plan to discuss more detail on the trial upon approval of our IDE application."

"This significant milestone is proof of our dedication that nobody should die waiting for a new organ. The US is our largest market and therefore the IDE application for our heart technology will be an important extension to the ongoing clinical trails in Europe, Australia and New Zealand. As XVIVO is a research-driven company it is very rewarding when hard work turns into solid results" says Dag Andersson, CEO of XVIVO.

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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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