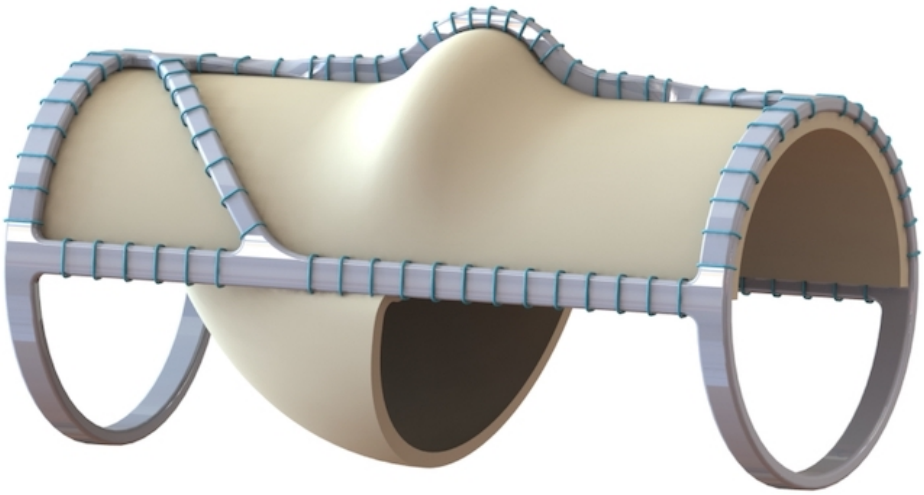
FDA Breakthrough Device Status for Hancock Jaffe VenoValve®



Cardiac and Vascular device developer **Hancock Jaffe Laboratories, Inc.**, tells us that the U.S. FDA has granted Breakthrough Device Designation status to the **VenoValve®**, the Company's lead product. VenoValve is currently set to begin its U.S. pivotal trial.

Background

Hancock Jaffe Laboratories specializes in developing and manufacturing bioprosthetic (tissue-based) medical devices to establish improved standards of care for treating cardiac and vascular diseases. The porcine-based VenoValve® is intended to be surgically implanted in the deep venous system of the leg to treat reflux associated with Chronic Venous Insufficiency.

The FDA's Breakthrough Devices Program was established to enable priority review for devices that provide more effective treatment or diagnosis of life threatening or irreversibly debilitating diseases or conditions. The goal is to provide patients and health care providers with timely access to medical devices by speeding up their development, assessment, and review, while preserving the Agency's mission to protect and promote public health.

The VenoValve is a potential treatment for a condition called Chronic Venous Insufficiency (CVI), a disease that afflicts approximately 2.4 million people in the U.S. CVI occurs when valves inside of the veins of the leg fail, causing blood to flow in the wrong direction (reflux) and creating increased pressure inside of the veins of the leg (venous hypertension). CVI is a debilitating

condition that can make everyday tasks such as bathing, sleeping, and walking extremely difficult for patients. There are currently no effective treatments for deep venous CVI.

Data from the VenoValve first-in-human study, presented in December of 2020, indicated that average patient improvement in reflux was 54 percent, average improvement in disease manifestations (measured by rVCSS scores) was 56 percent, and average improvement in pain (measured by VAS scores) was 76 percent, all at one-year post-VenoValve surgery compared to pre-surgery levels. In addition, there were no material adverse events (MAEs) at 30 days post-VenoValve implantation.

Company comments

“We are very pleased to have the opportunity to work with the FDA on an expedited basis as we try to bring relief to the millions of patients who suffer from deep venous CVI and who currently have no effective treatment options,” said Hancock Jaffe CEO Robert Berman. “The VenoValve significantly improved the lives of the patients in our first-in-human study, and we hope to replicate that success in our SAVVE U.S. clinical trial.”

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