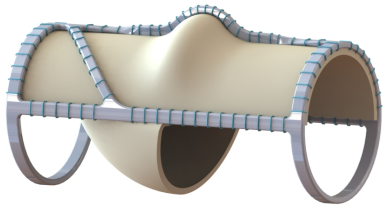
August 3, 2021

Hancock Jaffe's Surgical VenoValve for Treating Chronic Venous Insufficiency Gains FDA Breakthrough Device Designation

August 3, 2021—Hancock Jaffe Laboratories, Inc. announced that the FDA has granted Breakthrough Device designation for the surgically implanted VenoValve as a potential treatment for chronic venous insufficiency. The company advised that the VenoValve is currently set to begin its United States pivotal trial, the Surgical Antireflux Venous Valve Endoprosthesis (SAVVE) trial.



According to Hancock Jaffe, data from the VenoValve first-in-human study were presented in December 2020. At 1-year post-VenoValve surgery compared to presurgery levels, the VenoValve demonstrated average patient improvement in reflux of 54%, in disease manifestations (measured by Venous Clinical Severity Score [VCSS]) of 56%, and in pain (measured by Visual Analogue Scale [VAS] scores) of 76%. In addition, there were no material adverse events (MAEs) at 30 days post-VenoValve implantation.

The company advised that preparations to begin enrollment for the SAVVE pivotal trial are being finalized. The first patient is expected to be enrolled in the study within the next 60 days. The trial will enroll 75 patients at up to 20 centers throughout the United States.

The primary endpoints for the company's SAVVE pivotal trial will be the same as for the first-in-human trial: the primary safety endpoint is the occurrence of MAE in < 10% of patients at 30 days post-VenoValve implantation, and the primary effectiveness endpoint is improvement of reflux ≥ 30% at 6 months after VenoValve surgery. MAEs are defined as the composite of all-cause mortality, deep wound infection, major bleeding, ipsilateral deep vein thrombosis, or pulmonary embolism. Improvement of VCSS and VAS scores are also included in the SAVVE study as secondary endpoints.

In February 2021, the company announced preparations for the pivotal trial.

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 of the FDA's Breakthrough Devices program 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 FDA's mission to protect and promote public health, noted the Hancock Jaffe announcement.