August 3, 2021

FDA Grants Breakthrough Device Designation Status for Hancock Jaffe's VenoValve

- Goal of FDA Breakthrough Device Program is to speed up development by giving priority to devices that treat life-threatening or irreversibly debilitating conditions

- Company preparing to begin SAVVE U.S. pivotal trial for VenoValve

- VenoValve is a potential treatment for approximately 2.4 million U.S. patients that suffer from severe Chronic Venous Insufficiency in the deep veins of their legs

IRVINE, CA / ACCESSWIRE / August 3, 2021 /Hancock Jaffe Laboratories, Inc. (NASDAQ:HJLI) ("Hancock Jaffe" or the "Company"), a developer of medical devices that restore cardiac and vascular health, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation status to the VenoValve®, the Company's lead product, which is currently set to begin its U.S. 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 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.

"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."

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.

The primary endpoints for the Company's SAVVE (Surgical Anti-reflux Venous Valve Endoprosthesis) U.S. pivotal trial will be the same as for the first-in-human trial: the primary safety endpoint is the occurrence of MAE in less than 10 percent of patients at 30 days post-VenoValve implantation, and the primary effectiveness endpoint is improvement of reflux equal to or greater than 30 percent at six months following VenoValve surgery. MAEs are defined as the composite of all-cause mortality, deep wound infection, major bleeding, ipsilateral deep vein thrombosis (DVT), or pulmonary embolism. Improvement of VCSS and VAS scores are also included in the SAVVE study as secondary endpoints.

Preparation to begin enrollment of 75 patients at up to 20 centers throughout the U.S. for the SAVVE pivotal trial are being finalized, with the first patient expected to be enrolled in the study within the next 60 days. Interested patients can learn more about the SAVVE trial by visiting www.venovalve.com.

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 Agency's mission to protect and promote public health.

About Hancock Jaffe Laboratories, Inc.
Hancock Jaffe Laboratories (NASDAQ:HJLI) specializes in developing and manufacturing bioprosthetic (tissue-based) medical devices to establish improved standards of care for treating cardiac and vascular diseases. HJLI currently has two lead product candidates: the VenoValve®, a porcine-based valve which is intended to be surgically implanted in the deep venous system of the leg to treat reflux associated with Chronic Venous Insufficiency, and the CoreoGraft®, a bovine tissue-based off-the-shelf conduit intended to be used for coronary artery bypass surgery.

Cautionary Note on Forward-Looking Statements
This press release and any statements of stockholders, directors, employees, representatives and partners of Hancock Jaffe Laboratories, Inc. (the "Company") related thereto contain, or may contain, among other things, certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements identified by words such as "projects," "may," "will," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential" or similar expressions. These statements are based upon the current beliefs and expectations of the Company's management and are subject to significant risks and uncertainties, including those detailed in the Company's filings with the Securities and Exchange Commission. Actual results (including, without limitation, with respect to our liquidity and future cash position, the timing of filing of our IDE application and beginning patient enrollment, and the VenoValve's ability to fill the unmet medical needs of CVI sufferers) may differ significantly from those set forth or implied in the forward-looking statements. These forward-looking statements involve certain risks and uncertainties that are subject to change based on various factors (many of which are beyond the Company's control). The Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future presentations or otherwise, except as required by applicable law.

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SOURCE: Hancock Jaffe Laboratories, Inc.

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