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HANCOCK JAFFE LABORATORIES

Hancock Jaffe Receives IDE Approval To Begin VenoValve U.S. Pivotal Trial

IRVINE, CA / ACCESSWIRE / April 5, 2021 / Hancock Jaffe Laboratories, Inc. (NASDAQ:HJLI), a developer of medical devices that restore cardiac and vascular health, today announced that the U.S. Food and Drug Administration (FDA) has approved the company's Investigational Device Exemption (IDE) application to begin the U.S. pivotal trial for the VenoValve®. The VenoValve is an implantable valve designed to restore proper directional blood flow for patients with Chronic Venous Insufficiency (CVI) of the deep veins of the leg, a condition that afflicts approximately 2.4 million patients in the U.S. and for which there are currently no effective treatments.

"We are delighted that the FDA has approved our IDE application to begin the VenoValve pivotal trial, which should allow us to begin to gather the clinical data necessary to demonstrate that the VenoValve is a safe and effective treatment for patients with deep venous CVI," said Hancock Jaffe CEO Robert Berman. "This approval brings us one step closer to achieving our goal of establishing a new standard of care with the VenoValve for the millions of patients suffering from the debilitating effects of CVI who have no effective treatment options today."

The SAVVE (Surgical Anti-reflux Venous Valve Endoprosthesis) Trial is a prospective, non-blinded, single arm, multi-center study of 75 CVI patients to be enrolled at up to 20 U.S. centers. The trial's primary effectiveness endpoint is a reduction in reflux at six months, and the primary safety endpoint is the absence of a major adverse event (MAE), defined as mortality, deep wound infection, major bleeding, ipsilateral deep vein thrombosis or pulmonary embolism, at 30 days post-implantation. Secondary endpoints include disease manifestations (rVCSS), pain perception (VAS), ulcer healing and recurrence, quality of life, and the absence of MAEs throughout the study. The FDA has recommended that the company provide one year safety and effectiveness data from the pivotal trial to support a pre-marketing authorization (PMA) application for commercialization. Patients enrolled in the SAVVE Trial will be followed for a period of five years.

These are the same endpoints that Hancock Jaffe used for its successful VenoValve first-in-human trial. One-year results from this trial, released in December 2020, demonstrated that patients treated with VenoValve experienced significant improvement in all study endpoints, and the device showed a good safety profile. Interim results from the study were recently published online in the Journal of Vascular Surgery.

CVI occurs when valves inside the veins of the leg fail, causing blood to flow in the wrong direction (reflux) and creating venous hypertension. This results in leg swelling, pain, open sores (venous ulcers) and reduced mobility for patients. CVI is a debilitating condition that can make everyday tasks such as bathing, sleeping and walking extremely difficult for patients. The current standard of care for deep venous CVI sufferers consists of compression garments and leg elevation.

Hancock Jaffe has begun to qualify sites that have expressed interest in participating in the SAVVE study. The company will immediately begin to fulfill conditions for study initiation outlined by the FDA and seek Institutional Review Board (IRB) and other necessary approvals from potential SAVVE sites. The company expects sites to join the SAVVE study on a rolling basis following receipt of the necessary site approvals and documentation and appropriate site training. The company expects to begin patient enrollment in the third quarter of 2021 and will provide periodic updates.

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 current product candidates include: 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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