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HANCOCK JAFFE LABORATORIES

Hancock Jaffe Submits IDE Application to FDA for VenoValve U.S. Pivotal Trial

IRVINE, CA / ACCESSWIRE / March 8, 2021 /Hancock Jaffe Laboratories, Inc. (NASDAQ:HJLI), a developer of medical devices that restore cardiac and vascular health, today announced that it has submitted an Investigational Device Exemption (IDE) application to the U.S. Food and Drug Administration (FDA) seeking approval to begin a 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.

CVI occurs when valves inside the veins of the leg fail, causing blood to flow in the wrong direction (reflux) and 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 CEO Robert Berman stated, "We look forward to working cooperatively with the FDA as it reviews our IDE application. IDE approval would be a significant milestone for the company and an important step towards our goal of gathering the clinical data necessary to show that the VenoValve is a safe and effective treatment for patients with deep venous CVI. We are hopeful that the pivotal trial data will be similar to the positive outcomes that we experienced in our first-in-human study."

The proposed VALVE (Venous Antireflux Lower extremity Valvular Endoprosthesis) Trial is designed as a prospective, non-blinded, single arm, multi-center study of 75 CVI patients enrolled at up to 20 U.S. centers. The proposed primary endpoint is reflux at six months. Secondary endpoints include disease manifestations (rVCSS), pain perception (VAS), ulcer healing and recurrence, quality of life, and safety.

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

The FDA's first response to an IDE application is generally issued within 30 days of filing, followed by a series of communications between the applicant and the FDA to resolve any questions and comments. The IDE approval process for a class III device like the VenoValve typically takes between three and six months.

Hancock Jaffe has already identified and been in contact with many of the site investigators that will be needed for the VALVE study and has begun the formal site qualification process.

The company will continue to work with the investigational sites while the IDE application is under review by the FDA, with the goal of expediting the internal review board (IRB) approvals that are required for each site following IDE approval by the FDA and completing the training and other site initiation steps that are necessary before a site is eligible to enroll patients in the VALVE study. The company will provide updates on the IDE approval process and site initiation activities when appropriate.

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 VenoValveÒ, 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 CoreoGraftÒ, 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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