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**HANCOCK JAFFE**  
**LABORATORIES**

# Hancock Jaffe Enrolls Four Additional Patients for First-in-Human VenoValve Study

*Implantations to Take Place by End of April with Initial Data Expected in June 2019*

**IRVINE, CA / ACCESSWIRE / March 21, 2019/ Hancock Jaffe Laboratories, Inc.** (NASDAQ: HJLI), a developer of medical devices that restore cardiac and vascular health, has enrolled four additional patients for its VenoValve first-in-human study in Bogota, Colombia. HJLI expects to implant VenoValves in the four additional patients by the end of April 2019.

Robert Berman, Hancock Jaffe's Chief Executive Officer stated, "We continue to make progress with our VenoValve first-in-human study and are excited to get these implantations underway so that we can continue to receive the feedback and accumulate the data that we need for our U.S. pivotal trial. Today's enrollment milestone represents the midpoint, as half of the first group of patients needed are now in our study."

Following these implantations, five patients will have received VenoValves. The first-in-human Colombian study will initially include five to ten patients who suffer from severe, chronic venous insufficiency (CVI) of the deep vein system, a condition that occurs when the valves in the veins of the venous system of the leg are injured or destroyed, causing blood to flow backwards (reflux) and pool in the lower extremities, and resulting in increased venous pressure (venous hypertension). Severe CVI often results in significant disability which includes swelling, intense pain, and skin ulcerations that become ongoing, open wounds.

Following implantations of the VenoValve, as part of the study patients undergo duplex scans, which are used to measure reflux time - the duration of reflux in the deep venous system. The VenoValve was developed to reduce or eliminate deep venous reflux, a major cause of CVI. The reduction or elimination of reflux would lower venous hypertension and result in greatly improved quality of lives for patients suffering from deep venous CVI. In addition to measuring reflux, endpoints for the first-in-human VenoValve study include VCSS measurements, VAS scores, and VEINES scores, three well known clinical assessments for venous disease and assessments of improvement in the patient's quality of life and reduction in pain.

HJLI has had several Pre-FDA meetings to discuss the pre-clinical and clinical pathway for FDA approval for the VenoValve. Preclinical prototype testing, including in vivo animal studies, and in vitro hemodynamic studies, have demonstrated that the VenoValve mimics the function of a properly functioning native venous valve. Based upon feedback from the FDA, HJLI agreed to conduct a small first-in-human study in Colombia prior to the U.S. pivotal trial. The first-in-human study will provide HJLI with valuable feedback to make any

necessary product modifications or adjustments to the surgical implantation procedures for the VenoValve.

HJLI expects to release preliminary data on the first group of VenoValve recipients at the end of June of 2019 and will continue to follow the patients in Colombia for a period of six months. Approximately 2.4 million patients in the U.S. suffer from CVI due to reflux in the deep venous system, and there are currently no FDA approved treatments for the condition.

### **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. Hancock Jaffe 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. Hancock Jaffe has a third product candidate, which is a porcine tissue-based heart valve, which may be a candidate for pediatric aortic/mitral valve replacement. Hancock Jaffe has a 19-year history of developing and producing FDA approved medical devices that sustain or support life. The current management team at Hancock Jaffe has been associated with over 80 FDA or CE marked medical devices. For more information, please visit [HancockJaffe.com](http://HancockJaffe.com).

### **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, the performance of the new board members described herein) 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.

### **HJLI Press Contacts:**

Amy Carmer  
Tel: 949-261-2900  
Email: [ACarmer@HancockJaffe.com](mailto:ACarmer@HancockJaffe.com)

### **Media & Investor Relations Contact:**

MZ North America  
Chris Tyson  
Managing Director  
(949) 491-8235  
[HJLI@mzgroup.us](mailto:HJLI@mzgroup.us)  
[www.mzgroup.us](http://www.mzgroup.us)

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