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HANCOCK JAFFE LABORATORIES

Hancock Jaffe Announces End Points for First-in-Human VenoValve Study

IRVINE, Calif., Jan. 09, 2019 (GLOBE NEWSWIRE) -- Hancock Jaffe Laboratories, Inc. (Nasdaq: HJLI, HJLIW), a Company specializing in medical devices that restore cardiac and vascular health, today announced end-points for its upcoming VenoValve first-in-human study in Bogota, Colombia. Endpoints for the study will include improvements in reflux time, as well as rVCSS, VAS and VEINES scores, three well known clinical measurements for venous disease. Patients will be monitored at regular intervals during the study with the 90 day and 180 day results being of particular importance to the Company and the U.S. Food and Drug Administration ("FDA"). Knowledge gained from the Colombian study will be used to make any necessary design modifications to the VenoValves in preparation for the Company's U.S. pivotal trial.

Duplex scans will be administered to measure reflux time - the duration of reflux in the deep venous system. Reflux occurs when a series of one-way valves in the leg begin to fail, resulting in the backflow of blood. A duplex scan, also known as a doppler test with ultrasound, is a non-invasive evaluation of blood flow through veins and arteries and is the mainstay for evaluating chronic venous insufficiency ("CVI"). On average, patients without CVI have reflux times of about 1 second, with reflux times increasing with the increasing severity of the disease. Improvements in reflux times will be expressed as a percentage of the original duplex measurement.

The rVCSS is used to measure changes in venous disease severity and response to treatment and includes ten descriptors or subcategories of venous disease which are rated from 0 to 3 by the clinician. Once an initial baseline rVCSS is established for each patient, changes in rVCSS scores will be tracked and may be expressed as a percentage change from the original or previous scoring.

The VAS or Visual Analogue Scale is widely used in clinical research to measure intensity and frequency of pain. Scores are marked along a continuum between "no pain" and "worst pain".

VEINES is a disease specific, quality of life measurement associated with venous ulcers. The VEINES instrument consists of 35 items in two categories that generate two summary scores: a quality-of-life questionnaire (VEINES-QOL) comprising of 25 items that quantify disease effect on quality of life; and a symptom questionnaire (VEINES-Sym) which consists of 10 items that measure physical symptoms. In addition to being painful, prone to infection, and hampering mobility, venous ulcers are known to impact work capacity, social activity, self-care and personal hygiene, and to cause depression, anxiety, and social isolation.

On December 17, 2018, HJLI announced that it had received approval for its first-in-human trial from INVIMA, the Colombian equivalent of the FDA. The Company is making arrangements to import the VenoValves to Colombia, and has begun to screen patients for

the study.

"We have already received more than 100 inquiries from patients in Colombia wanting to participate in our study," said Robert Berman, Hancock Jaffe's CEO. "Patients will be carefully screened under the supervision of Dr. Jorge Hernando Ulloa, our primary investigator in Bogota, and Dr. Marc H. Glickman, Hancock Jaffe's Chief Medical Officer. Because results from the study will come relatively quickly, now is the appropriate time to begin to explain the terminology that we will be using to measure our success."

Once initial patient enrollment is completed, HJLI will announce the expected date for the first VenoValve implantations. The Company expects to provide another update shortly after the first implantations, and a further update part of the way through the study after compiling sufficient preliminary data. Following the completion of the 6 month study, the Company will seek to present its data at worldwide vascular conferences and publish the data in a peer reviewed journal.

Patients will have follow-up visits and assessments approximately 14 days, 30 days, 60 days, 90 days, and 180 days after implantations of the VenoValves. HJLI will monitor patients for potential serious adverse events related to the device, which include thromboses (blood clots) leading to obstruction, stenosis (narrowing) of the vein, inflammation (neointimal hyperplasia) leading to device failure, device migration, bleeding due to native vein injury or anticoagulation, and infection.

The first-in-human Colombian study will initially include 5 to 10 patients who suffer from severe CVI, a condition that occurs when the valves in the veins of deep venous system of the leg are injured or destroyed, causing blood to pool in the lower extremities. Severe CVI often includes swelling, debilitating pain, and skin ulcerations that become ongoing, open wounds. The VenoValve is a potential treatment and cure for severe CVI, a condition that effects approximately 4.5 million people in the U.S. and tens of millions of additional patients worldwide. There are currently no FDA approved treatments for deep venous CVI.

About Hancock Jaffe Laboratories, Inc.

HJLI specializes in developing and manufacturing bioprosthetic medical devices to establish improved standards of care for treating cardiac and vascular diseases. HJLI currently has three product candidates: the porcine tissue based VenoValve®, which is intended to be surgically implanted in the deep venous system of the leg to treat Chronic Venue Insufficiency; the CoreoGraft®, a bovine tissue based off the shelf conduit intended to be used for coronary artery bypass surgery, and a porcine tissue based heart valve, which based upon its relatively small size and increased output, is an ideal candidate for pediatric aortic/mitral valve replacement.

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.

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