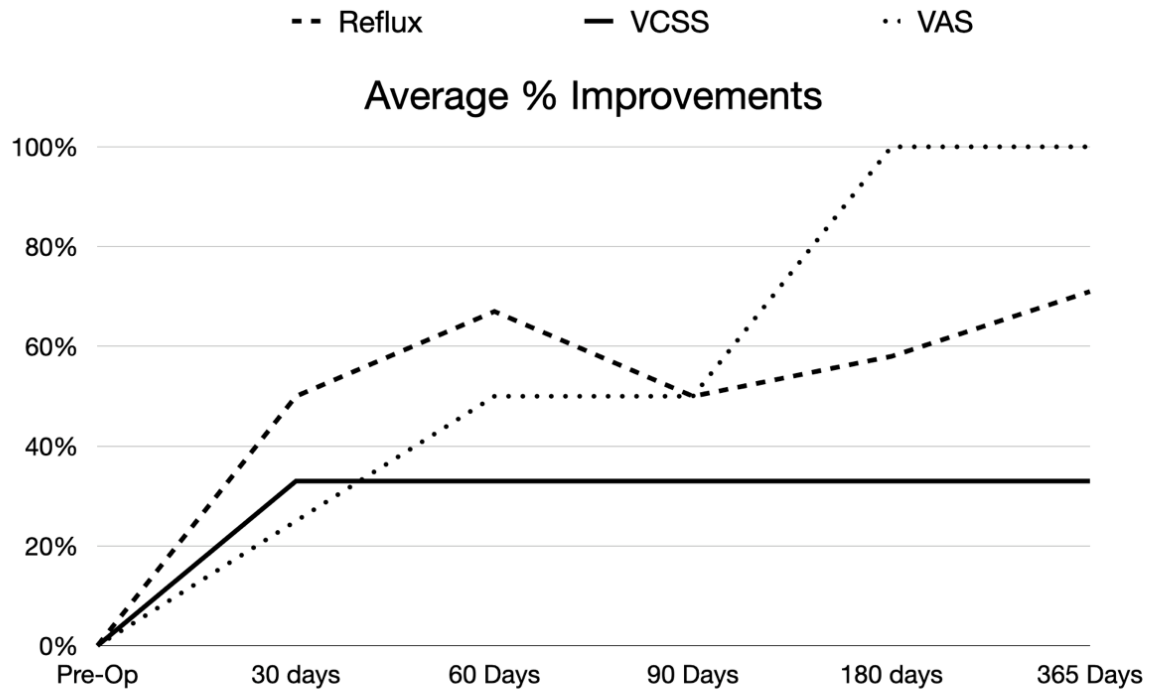
December 1, 2020

HANCOCK JAFFE LABORATORIES

Hancock Jaffe Announces One Year Follow-up Data on Tenth VenoValve Patient

Patient Shows Significant Improvement at One Year

IRVINE, CA / ACCESSWIRE / December 1, 2020/ Hancock Jaffe Laboratories, Inc. (NASDAQ:HJLI, HJLIW), a developer of medical devices that restore cardiac and vascular health, announced today that the tenth VenoValve patient in HJLI's first-in-human, clinical study has successfully reached the one-year milestone. Patient 10's chronic venous insufficiency ("CVI") has dramatically improved when compared to pre-surgery levels, with reflux (the backwards flow of blood) improving 71%, disease manifestations, as measured by a venous clinical severity scores ("VCSS"), improving 33%, and pain, as measured on a visual analog scale ("VAS"), improving 100%.



VenoValve First-In-Human Trial Patient 10

The patient's presurgery levels for reflux, VCSS, and VAS were 2.4, 6, and 8, respectively. At one-year post-surgery, those levels were 0.7, 4, and 0, respectively. The improvement in reflux is significant, as the patient now has reflux in the range that you would expect in a normal patient without CVI. A VAS score of 0 means the patient is completely pain-free. Overall, ten VenoValve patients have now completed the one-year first-in-human trial. HJLI expects to release the results on the eleventh and final patient, and the cumulative,

aggregated results from the first-in-human trial by the end of December.

Robert Berman, Hancock Jaffe's CEO stated, "The numbers for Patient 10 are impressive, but what is equally as important is the difference the VenoValves are making in the lives of our patients. When you have a patient who is experiencing pain at a level of 8 out of 10 and for whom simple tasks like putting on a shoe and bathing are very difficult, and can reduce or eliminate the pain, swelling, suffering that are often associated with CVI, it is life-altering for the patient and we hope will be transformative in how doctors treat deep venous CVI."

CVI occurs when the valves in the veins of the leg are injured or destroyed, causing blood to flow backwards, which is known as reflux. Reflux results in increased venous pressure (venous hypertension), damage to the veins, and results in the pooling of blood in the lower leg. Deep venous CVI is a serious condition, often resulting in debilitating pain, swelling, and open sores (venous ulcers) on the lower leg. HJLI has implanted VenoValves in 11 patients over the course of a year as part of its first-in-man, Colombian study, which is the pre-cursor to the U.S. pivotal trial.

Next steps for the VenoValve include the continued monitoring of the final VenoValve patient in Colombia, a Pre-IDE meeting with the U.S. Food and Drug Administration ("FDA"), the completion of a series of functional tests and a GLP study mandated by the FDA, and the filing of an IDE application with the FDA, seeking approval to begin the U.S. pivotal trial, which HJLI expects to file in the first quarter of 2021.

A paper containing preliminary results from the VenoValve first-in-human trial were recently published in the *Journal of Vascular Surgery Venous and Lymphatic Disorders,* the premier peer-reviewed journal for vascular surgeons and other health care professionals engaged in the treatment of vascular disease. A copy of the paper can be accessed at https://doi.org/10.1016/j.jvsv.2020.10.017.

Approximately 2.4 million people in the U.S. suffer from CVI due to reflux in the deep venous system. Estimates indicate that direct medical costs from CVI in the U.S. exceed $38 Billion a year. There are currently no FDA approved devices, or effective treatments for deep venous CVI.

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 20-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 50 FDA or CE marked medical devices. For more information, please visit 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 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.

SOURCE: Hancock Jaffe Laboratories, Inc.

View source version on accesswire.com:
https://www.accesswire.com/618887/Hancock-Jaffe-Announces-One-Year-Follow-up-Data-on-Tenth-VenoValve-Patient