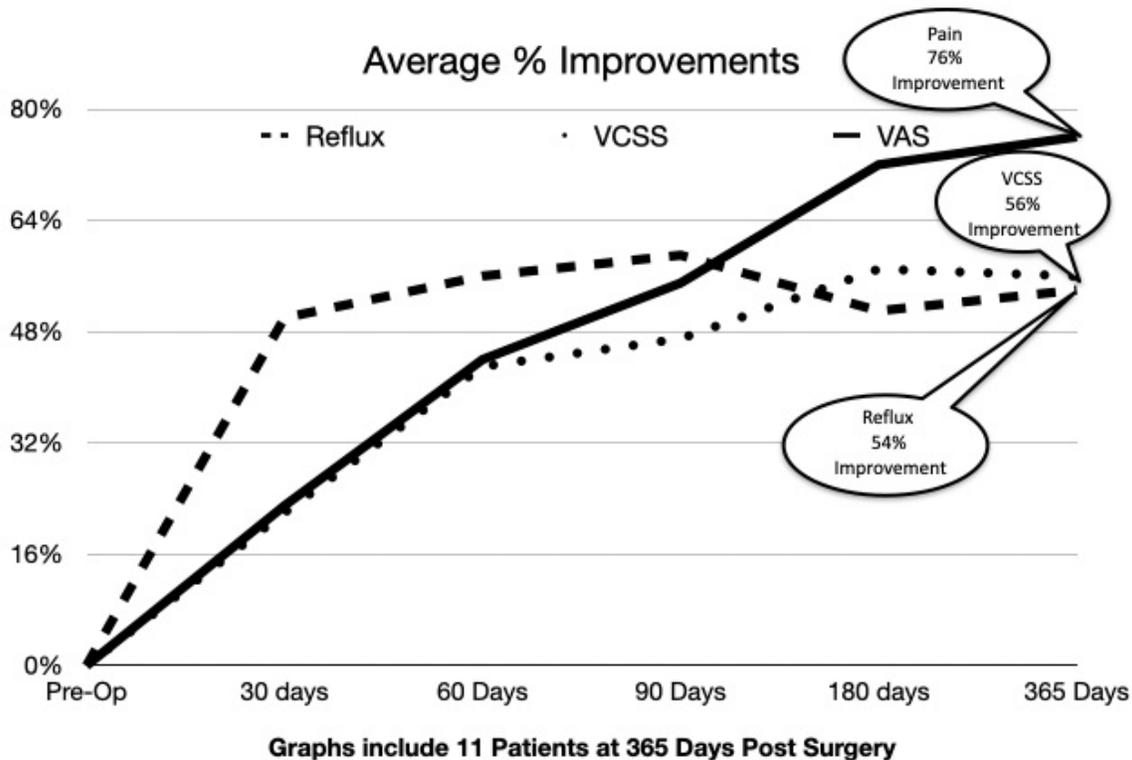


# Hancock Jaffe Announces Significant Improvements in all Study Endpoints For Final VenovValve First-in-Human Data

## *Patients Show Significant Improvements in Reflux, VCSS, and VAS Scores*

**IRVINE, CA / ACCESSWIRE / December 15, 2020/ Hancock Jaffe Laboratories, Inc.** (NASDAQ:HJLI)(NASDAQ:HJLIW), a developer of medical devices that restore cardiac and vascular health, announced today that the final aggregated data for the VenovValve first-in-human trial shows significant improvements in all study endpoints. For the eleven patients in the first-in-human study, reflux (the backwards flow of blood) improved an average of 54%, disease manifestations as measured by a venous clinical severity scores ("VCSS") improved 56%, and pain, as measured on a visual analog scale ("VAS"), improved 76%, all at one-year post VenovValve surgery when compared to pre-surgery levels. Safety for all patients was assessed as well at one year.



Ten of the eleven VenovValve patients in the first-in-human study went from having severe Chronic Venous Insufficiency ("CVI") to having either a mild form of the disease or no disease. The VenovValve in one patient stopped working at 90 days post-surgery when the patient stopped taking anti-coagulation medication.

Dr. Marc H. Glickman, Hancock Jaffe's Senior Vice President and Chief Medical Officer stated, "Overall, our final first-in-human results far exceed my expectations. We had no significant safety issues at one year and no evidence of any detriment to these patients at one year. First-in-human trials are informative in nature, and help guide our Pivotal trial expectations and goals. We have been very encouraged with this data and look forward to starting our pivotal trial in the US."

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 implanted VenoValves in 11 patients over the course of a year as part of its first-in-human, Colombian study, which is the pre-cursor to the U.S. pivotal trial.



**Pre-Op**



**30 Days**

Robert Berman, Hancock Jaffe's CEO stated, "I am extremely proud of Dr. Glickman and the rest of the Hancock Jaffe team for our VenoValve clinical achievements during what has been a very challenging year. Like the rest of the world, the healthcare system in Bogota was taxed beyond limits because of the COVID-19 pandemic, and our extraordinary first-in-human results are a testament to the dedication and ingenuity of our team both in Irvine and in Colombia."

HJLI also recently successfully completed a six-month GLP animal safety study, which is required by the U.S. Food and Drug Administration ("FDA"), in order to proceed with a U.S. pivotal trial. HJLI is currently working to complete a series of additional functional tests mandated by the FDA, and is currently scheduled to meet with the FDA for a Pre-IDE meeting on January 11, 2021. HJLI expects to file its IDE application seeking approval to begin the U.S. pivotal trial by the end of the first quarter of 2021. An investigational device exemption or IDE from the FDA is required for a medical device company to proceed with a pivotal trial in the U.S. for a class III medical device.

Additional information about the results from the first-in-human trial, including presentations by Dr. Marc Glickman and Dr. Jorge Ulloa, the principal investigator for the first-in-human

trial, will take place during a webinar hosted by Ladenburg Thalmann on Wednesday, December 16, 2020, at 1:00 Eastern time. A limited number of live participation slots for the Webinar are available at [https://zoom.us/webinar/register/5816075333364/WN\\_4GVCQ7GiTWKBxiYpbBXQGw](https://zoom.us/webinar/register/5816075333364/WN_4GVCQ7GiTWKBxiYpbBXQGw). For those unable to attend the webinar live, a link to a replay of the webinar will be available after Thursday, December 17, 2020 in the Investor section of the Hancock Jaffe website.

#### **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](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 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.

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