August 19, 2021

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# Hancock Jaffe Presents New Positive Two-Year VenoValve Data at the Society for Vascular Surgery Annual Meeting

***Two-year VenoValve® data shows average improvements in reflux, disease manifestations and pain, of 63%, 60%, and 93%, respectively***

***Patients with venous ulcers who experienced dramatic ulcer healing had no venous ulcer recurrences***

***No safety issues occurred during the one-year reporting period following the study completion***

**IRVINE, CA / ACCESSWIRE / August 19, 2021 /**Hancock Jaffe Laboratories, Inc. (NASDAQ:HJLI) ("Hancock Jaffe" or the "Company"), a developer of medical devices that restore cardiac and vascular health, announced that promising two-year post-VenoValve® implantation data is being presented today at the Society for Vascular Surgery® (SVS) Annual Meeting in San Diego, CA by Dr. Jorge Ulloa, who was the Principal Investigator for the Company's first-in-human VenoValve trial.

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Key highlights from Dr. Ulloa's presentation indicate that:

- Reflux (the backwards flow of blood) decreased from an average of 1.95 to an average of .72 (a 63% improvement)
- Disease manifestations (measured by rVCSS scores) decreased from an average of 13.38 to an average of 5.38 (a 60% improvement)
- Pain (measured by VAS scores) decreased from an average of 7.25 to an average of .50 (an improvement of 93%)
- There were no safety issues or venous ulcer recurrences

The data reported is for a group of eight patients that participated in the VenoValve first-in-human study and who agreed to participate in a one-year post study follow-up. Three additional first-in-human patients elected to not participate in the one-year post study follow-up, but reported no negative VenoValve-related events during the one-year follow-up period. The average post-VenoValve implantation time for this cohort of patients is two years, and the comparative results are based on pre-VenoValve levels compared to the patients' most recent office visit.

Dr. Ulloa's SVS slide presentation will be available on the Hancock Jaffe website.

Dr. Marc Glickman, Hancock Jaffe's Senior Vice President and Chief Medical Officer stated, "This data is exactly the result that we were looking for as we begin our VenoValve SAVVE pivotal trial. Our patients are continuing to benefit from the VenoValve, with no safety issues and no ulcer recurrences. Chronic Venous Insufficiency in the deep venous system has frustrated patients and physicians for decades and our primary investigators for the SAVVE study are as excited and enthusiastic as we are about the upcoming study."

The VenoValve is a potential treatment for a condition called Chronic Venous Insufficiency (CVI), a disease that afflicts approximately 2.4 million people in the U.S. CVI occurs when valves inside of the veins of the leg fail, causing blood to flow in the wrong direction (reflux) and creating increased pressure inside of the veins of the leg (venous hypertension). CVI is a debilitating condition that can make everyday tasks such as bathing, sleeping, and walking extremely difficult for patients. There are currently no effective treatments for deep venous CVI.

"This long-term data is very encouraging and should be a helpful addition to our SAVVE trial data when we are ready to seek U.S. regulatory approval for the VenoValve," said Robert Berman, Hancock Jaffe's CEO. "We are excited about the progress we are making and the potential for the VenoValve to establish our Company as the preeminent provider of innovative products for the treatment of venous disease."

The SAVVE (Surgical Anti-reflux Venous Valve Endoprosthesis) U.S. pivotal trial for the VenoValve will include 75 patients at up to 20 sites. The primary endpoints for the SAVVE trial will be the same as for the first-in-human trial: the primary safety endpoint is the occurrence of MAE in less than 10 percent of patients at 30 days post-VenoValve implantation, and the primary effectiveness endpoint is improvement of reflux equal to or greater than 30 percent at six months following VenoValve surgery. MAEs are defined as the composite of all-cause mortality, deep wound infection, major bleeding, ipsilateral deep vein thrombosis (DVT), or pulmonary embolism. Improvement of VCSS and VAS scores are also included in the SAVVE study as secondary endpoints.

The Company plans to begin enrollment for the SAVVE pivotal trial within the next 60 days. Interested patients can learn more about the SAVVE trial by visiting www.venovalve.com.

As recently announced, the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation status to the VenoValve.

**About the Society for Vascular Surgery**
The Society for Vascular Surgery® (SVS) seeks to advance excellence and innovation in vascular health through education, advocacy, research and public awareness. The organization was founded in 1946 and currently has a membership of more than 6,000. SVS membership is recognized in the vascular community as a mark of professional achievement.

**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 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.

**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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**SOURCE:** Hancock Jaffe Laboratories, Inc.