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HANCOCK JAFFE
LABORATORIES

Hancock Jaffe Principal Investigator Dr. Jorge Hernando Ulloa Presents Ven Valve One Year First-In-Human Data at Charing Cross International Symposium

IRVINE, CA / ACCESSWIRE / April 23, 2021 / [Hancock Jaffe Laboratories, Inc.](#)

(NASDAQ:HJLI), a developer of medical devices that restore cardiac and vascular health, today announced that Dr. Jorge Hernando Ulloa, the Principal Investigator for HJLI's first-in-human [Ven Valve](#)® study in Bogota, Colombia, presented one year data this past week at the Charing Cross International Symposium. The Charing Cross International Symposium is the longest-running vascular and endovascular global symposium in Europe and is attended by the world's leading experts in vascular and endovascular medicine.

Patients in the first-in-human study demonstrated significant improvement in all study endpoints including an aggregate 54% improvement in reflux (the backwards flow of blood), a 56% improvement in disease manifestations, as measured by venous clinical severity scores ("rVCSS"), and a 76% improvement in pain, as measured on a visual analog scale ("VAS"), all one-year post Ven Valve surgery when compared to pre-surgery levels. Patients also experienced dramatic venous ulcer healing, with no ulcer recurrences. Quality of life scores for the first-in-human patients showed statistically significant improvement as measured by VEINES, and safety incidences were non-device related and were minimal.

Dr. Marc H. Glickman, Hancock Jaffe's Senior Vice President and Chief Medical Officer stated, "There continues to be significant worldwide interest in the Ven Valve and the progress we are making in treating Chronic Venous Insufficiency. As the world emerges from the COVID pandemic, we will continue to update our progress at leading vascular conferences whether virtually or in person."

Chronic Venous Insufficiency (CVI) occurs when valves inside the veins of the leg fail, causing blood to flow in the wrong direction (reflux) and venous hypertension. This results in leg swelling, pain, open sores (venous ulcers) and reduced mobility for patients. CVI is a debilitating condition that can make everyday tasks such as bathing, sleeping and walking extremely difficult for patients. The current standard of care for deep venous CVI sufferers consists of compression garments and leg elevation.

The U.S. Food and Drug Administration (FDA) recently approved Hancock Jaffe's Investigational Device Exemption (IDE) application to begin the U.S. pivotal trial for the Ven Valve. The SAVVE (Surgical Anti-reflux Venous Valve Endoprosthesis) trial will be a prospective, non-blinded, single arm, multi-center study of 75 CVI patients enrolled at up to 20 U.S. centers. Primary effectiveness and safety endpoints for the SAVVE study will mirror those used in the first-in-human trial including a reduction in reflux at six months, and the absence of major adverse events (MAEs) (mortality, deep wound infection, major bleeding,

ipsilateral deep vein thrombosis, pulmonary embolism) at thirty (30) days post implantation. Secondary endpoints include disease manifestations (rVCSS), pain perception (VAS), ulcer healing and recurrence, quality of life measurements and the absence of MAEs throughout the study.

Following IDE approval, Hancock Jaffe has begun to seek institutional review board (IRB) and other necessary approvals from the potential SAVVE sites and will soon begin site training. The company expects the first implantation for the SAVVE study to occur at the beginning of the third quarter.

The VenoValve is an implantable valve designed to restore proper directional blood flow for patients with CVI of the deep veins of the leg, a condition that afflicts approximately 2.4 million patients in the U.S. and for which there are currently no effective treatments.

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 [VenoValveÒ](#), 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 [CoreoGraftÒ](#), 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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