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HANCOCK JAFFE  
LABORATORIES

# Hancock Jaffe to Begin CoreoGraft First-in-Human Study

*First Two Surgeries Scheduled to Take Place by End of October*

**IRVINE, CA / ACCESSWIRE / October 14, 2020/ Hancock Jaffe Laboratories, Inc.** (NASDAQ:HJLI), a developer of medical devices that restore cardiac and vascular health, today announced that the first two surgeries for its CoreoGraft first-in-human study are scheduled to take place by the end of October. Hancock Jaffe will provide an update on the first two patients once the surgeries are completed, with additional updates expected 30 days, 90 days, 180 days, and 365 days after the surgeries.

The CoreoGraft first-in-human trial, which will take place at Italian Hospital Asuncion in Paraguay, will consist of up to 5 patients. CoreoGrafts will be implanted in patients requiring coronary artery bypass grafting ("CABG") for severe coronary artery diseases.

The 3 mm CoreoGraft conduit will be used as a substitute for saphenous vein grafts (SVGs) in patients needing CABG surgeries. Saphenous vein grafts are known to have high, short-term and long-term failure rates. Once the CoreoGrafts are implanted, they will be evaluated at each interval of the follow-up period for signs of failure including "openness" or "patency", blood clots ("thrombus") and other changes commonly associated with graft failure.

Robert Berman, Hancock Jaffe's CEO stated, "The CoreoGraft first-in-human study is an important milestone for the company and we are excited to get the study started. For many years Doctors have been searching for a reliable small diameter conduit that can be used for CABG surgeries and we are hopeful that the CoreoGraft can be used to fill the clinical void".

A first-in-human study is a critical developmental step in testing the feasibility of a medical device. The purpose of a first-in-human study is to obtain valuable feedback both on the device itself, and the surgical procedure used to implant the device, so that any necessary changes and improvements can be implemented to increase the chances of clinical success.

In January of 2020, HJLI released positive results from its six (6) month CoreoGraft animal feasibility study. At thirty (30), ninety (90), and one hundred and eighty (180) days post CoreoGraft bypass surgeries, all grafts were patent (open), when the implantations went smoothly and there were no technical errors. At the conclusion of the study, pathology examinations of the CoreoGrafts and surrounding tissue showed no signs of thrombosis, infection, aneurysmal degeneration, changes in the lumen, or other problems that are known to plague SVGs. In addition, the pathology examinations indicated a thin layer of endothelial cells in the CoreoGrafts that were implanted for 90 days, and more complete endothelialization was observed for grafts implanted for 180 days, both throughout the CoreoGrafts and into the left anterior descending arteries. Endothelialization is thought to be a critical step in establishing the long-term [biocompatibility](#) of cardiovascular devices.

For patients with suitable veins, the current standard of care for most CABG surgeries is to

harvest the saphenous vein from the leg of the patient, dissect the saphenous veins into multiple grafts, and to use the dissected SVGs to revascularize the heart. In addition to the vein harvest procedure being invasive, painful, and subject to its own complications for the patient, SVGs are also known to have high short-term and long-term failure rates when used as grafts around the heart. Studies indicate that up to 40% of SVGs fail within one year of CABG surgeries, with a significant percentage failing within the first 30 days. Eight to ten years after surgery, SVG failure rates are known to be as high as 75%. Eventually, the CoreoGraft could become a viable alternative to using SVGs.

Approximately 200,000 CABG surgeries are performed each year in the U.S., representing more than 55% of all cardiac surgeries and accounting for between \$15 Billion and \$25 Billion in annual expenditures. With an average of three grafts used per surgery, HJLI estimates the potential U.S. addressable market for the CoreoGraft to be more than \$2 Billion per year. There are currently no FDA approved prosthetic grafts for CABG surgeries.

HJLI will provide periodic updates on CoreoGraft patients following the surgeries, as well as additional patient enrollments and scheduled surgeries for the CoreoGraft first-in-human study.

#### **About Hancock Jaffe Laboratories, Inc.**

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. 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 (including, without limitation, with respect to our first-in-human VenoValve study) 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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