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HANCOCK JAFFE LABORATORIES

Hancock Jaffe Receives Approval for First-in-Human VenoValve Study

IRVINE, Calif., Dec. 17, 2018 (GLOBE NEWSWIRE) -- Hancock Jaffe Laboratories, Inc. (Nasdaq: HJLI, HJLIW), a company specializing in medical devices that restore cardiac and vascular health, announced today that it has received regulatory approval from INVIMA, the Colombian equivalent of the U.S. Food and Drug Administration, for its first-in-human trial for the VenoValve®. INVIMA is the final regulatory approval needed to begin the first-in-human study in Bogota, Colombia.

Hancock Jaffe will now make arrangements to export the VenoValves into Columbia and begin screening and enrolling patients for the study. The company will next provide an update once initial patient enrollment is completed and dates are set for the first implantations.

“The first quarter of 2019 will be monumental for our company as we begin the VenoValve study in Bogota, and the CoreoGraft study at the Texas Heart Institute,” said Robert Berman, Hancock Jaffe’s CEO. “The knowledge gained from in-human testing of the VenoValve will be invaluable for the continued development of the product and will provide us with the feedback to make any necessary product modifications before approaching the FDA regarding our U.S. pivotal trial.”

The first-in-human Colombian study will initially include 5 to 10 patients who suffer from severe chronic venous insufficiency (CVI), a condition that occurs when the valves in the veins of deep venous system of the leg are injured or destroyed, causing blood to pool in the lower extremities. Severe CVI includes swelling, debilitating pain, and skin ulcerations that become ongoing, open wounds. The VenoValve is a potential treatment and cure for severe CVI, a condition that effects approximately 4.5 million people in the U.S. and tens of millions of additional patients worldwide. There are currently no FDA approved treatments for deep venous CVI.

About Hancock Jaffe Laboratories, Inc.

HJLI specializes in developing and manufacturing bioprosthetic medical devices to establish improved standards of care for treating cardiac and vascular diseases. HJLI currently has three product candidates: the porcine tissue based VenoValveÒ, which is intended to be surgically implanted in the deep venous system of the leg to treat Chronic Venue Insufficiency; the CoreoGraftÒ, a bovine tissue based off the shelf conduit intended to be used for coronary artery bypass surgery, and a porcine tissue based heart valve, which based upon its relatively small size and increased output, is an ideal candidate for pediatric aortic/mitral valve replacement.

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, the performance of the new board members described herein) 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.

HJLI Press Contacts:

Amy Carmer
Tel: 949-261-2900
Email: ACarmer@HancockJaffe.com

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