Nuwellis Announces IRB Approval to Begin Its REVERSE-HF Clinical Study

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The REVERSE-HF study will evaluate ultrafiltration therapy for heart failure patients suffering from fluid overload

MINNEAPOLIS, March 15, 2022 (GLOBE NEWSWIRE) -- Nuwellis, Inc. (Nasdaq: NUWE) today announced it has received independent Institutional Review Board (IRB) approval for the trial protocol of the company's REVERSE-HF (Ult **r**afiltration V**e**rsus I**V** Diur**e**tics in Wo**rse**ning **H**eart **F**ailure) clinical study to evaluate the clinical outcomes and economic value of its Aquadex® ultrafiltration therapy in comparison to intravenous diuretics for the treatment of fluid overload in patients with worsening heart failure.

"There are more than 1 million heart failure hospitalizations every year in the U.S., and more than 90 percent of these are due to symptoms associated with fluid overload.[1] Forty percent of these patients are refractory to diuretics, which is the current standard of care," said Nestor Jaramillo, Jr., President and CEO of Nuwellis. "We're eager to gather more clinical evidence about the life-changing benefits of Aquadex for heart failure patients who don't respond well to IV diuretics, which REVERSE-HF is intended to establish."

REVERSE-HF is a multicenter, open-label, randomized controlled trial that will be conducted across the United States. The study will be led by Sean Pinney, M.D., Professor of Medicine and Co-Director of the Heart and Vascular Center at The University of Chicago Medicine, and Maria V. DeVita, M.D., Professor of Medicine at Hofstra School of Medicine/Northwell and Chief of the Division of Nephrology at Lenox Hill Hospital. Enrollment in the trial will begin this year.

"IRB approval of the study protocol marks a key step forward in beginning the REVERSE-HF study," said Megan Cease, Director of Clinical Research and Reimbursement of Nuwellis. "In addition to Drs. Pinney and DeVita, we have top key opinion leaders on the Steering Committee, and they have had a significant impact in the development of the study protocol and treatment guide. They have been wonderful to work with throughout the study design process."

An IRB is a group that operates under FDA regulations and has been formally designated to review and monitor biomedical research involving human subjects. The purpose of IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research. To accomplish this purpose, IRBs use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research.[2]

About Nuwellis

Nuwellis, Inc. (Nasdaq: NUWE) is a medical device company dedicated to transforming the lives of patients suffering from fluid overload through science, collaboration, and innovation. The Company is focused on developing, manufacturing and commercializing the Aquadex SmartFlow® system for ultrafiltration therapy. Nuwellis is headquartered in Minneapolis, with a wholly-owned subsidiary in Ireland.

About the Aquadex SmartFlow® System

The Aquadex SmartFlow system delivers clinically proven therapy using a simple, flexible and predictable method of removing excess fluid from patients suffering from hypervolemia (fluid overload). The Aquadex SmartFlow system is indicated for temporary (up to 8 hours) or extended (longer than 8 hours in patients who require hospitalization) use in adult and pediatric patients weighing 20 kg or more whose fluid overload is unresponsive to medical management, including diuretics. All treatments must be administered by a health care provider, within an outpatient or inpatient clinical setting, under physician prescription, both having received training in extracorporeal therapies.

Forward-Looking Statements

Certain statements in this release may be considered forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including without limitation, statements regarding the new market opportunities and anticipated growth in 2022 and beyond. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Many factors could cause actual future events to differ materially from the forward-looking statements in this release, including, without limitation, those risks associated with our ability to execute on our commercialization strategy, the impact of the COVID-19 pandemic, the possibility that we may be unable to raise sufficient funds necessary for our anticipated operations, our post-market clinical data collection activities, benefits of our products to patients, our expectations with respect to product development and commercialization efforts, our ability to increase market and physician acceptance of our products, potentially competitive product offerings, intellectual property protection, our ability to integrate acquired businesses, our expectations regarding anticipated synergies with and benefits from acquired businesses, and other risks and uncertainties described in our filings with the SEC. Forward-looking statements speak only as of the date when made. Nuwellis does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

[1] Costanzo MR, et al. J Am Coll Cardiol. 2017; 69(19): 2428-45.

[2] https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/institutional-review-boards-irbs-and-protection-human-subjects-clinical-trials

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