Nuwellis Announces Peer Reviewed Data Demonstrating 71% Survival with Kidney Replacement Therapy Using a Modified Aquadex in Low-Birth-Weight Preterm Neonates

November 3, 2022

Findings Demonstrate Encouraging Results for Pediatrics with Kidney Failure Treated with Kidney Replacement Therapy

MINNEAPOLIS, Nov. 03, 2022 (GLOBE NEWSWIRE) -- Nuwellis, Inc. (NasdaqCM: NUWE), a medical technology company focused on transforming the lives of people with fluid overload, today announced the publication of promising clinical data supporting the use of kidney replacement therapy with ultrafiltration to treat preterm, low weight neonates with end-stage kidney disease in *Pediatrics*.

The investigator-led, retrospective study examined seven preterm neonates with end-stage kidney disease who were successfully managed using an innovative approach to kidney replacement therapy using a physician modified Aquadex SmartFlow ultrafiltration system, which is cleared by the U.S. Food and Drug Administration only for use in adults and pediatric patients weighing 20 kg (44 lbs.) or more. Five of the seven newborns (71%) survived to hospital discharge.

Managing neonates with kidney failure can be challenging, as dialysis and other therapies used to treat kidney failure are typically designed for adults or larger pediatric patients. These challenges are especially pronounced in preterm neonates. Interventions are sometimes not available for these small patients, who are typically transitioned to palliative care, or a medical caregiving approach aimed at optimizing quality of life and mitigating suffering among neonates with serious, complex, and often terminal illnesses. However, many of these patients are otherwise healthy and would be considered survivable if kidney replacement therapy were available.[1]

“Physicians continue to express the urgent need for neonatal fluid management therapies designed to support small children and infants,” said Nestor Jaramillo, Jr., President and CEO of Nuwellis. “We remain committed to developing safe innovations and bringing them to market as quickly as possible to address this critical unmet need. This patient population continues to be an important and fast-growing segment of our business.”

Nuwellis, which did not sponsor the study that is the subject of the publication, is currently developing a new, fully integrated pediatric continuous renal replacement therapy (CRRT) device designed to provide care for small babies and children under 20 kg. This device is funded in part by a $1.7 million grant from the National Institutes of Health (NIH). Nuwellis has partnered with Minneapolis-based research and development firm Koronis Biomedical Technologies Corporation (KBT), the grant recipient, to design and develop a custom pediatric product that will enable clinicians to better care for babies with limited kidney function.

About Nuwellis

Nuwellis, Inc. (Nasdaq: NUWE) is a medical technology 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, MN, with a wholly owned subsidiary in Ireland.

About the Aquadex SmartFlow® System

The Aquadex SmartFlow system delivers clinically superior therapy using a simple, flexible and smart 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 are 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] Sutherland SM, Davis AS, Powell D, Tanaka J, Woo M, Josephs S, Wong CJ. Kidney Replacement Therapy in Low Birth Weight Preterm Newborns. Pediatrics. 2022 Sep 1;150(3):e2022056570. doi: 10.1542/peds.2022-056570. PMID: 35945293.

CONTACTS

INVESTORS:

Lynn Blake
Chief Financial Officer, Nuwellis, Inc.
ir@nuwellis.com

Vivian Cervantes
Gilmartin Group
Vivian.Cervantes@gilmartinir.com

MEDIA:
Sarah Lundberg
Health+Commerce
sarahlundberg@healthandcommerce.com

Source: Nuwellis, Inc.