Nuwellis' Distribution Partner, SeaStar Medical, Receives FDA Humanitarian Device Exemption for Pediatric Selective Cytopheretic Device Quelimmune™

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MINNEAPOLIS, Feb. 22, 2024 (GLOBE NEWSWIRE) -- Nuwellis, Inc. (Nasdaq: NUWE), a medical technology company focused on transforming the lives of people with fluid overload, today announced its distribution partner, SeaStar Medical Holding Corporation (Nasdaq: ICU) (SeaStar Medical), has received Humanitarian Device Exemption (HDE) from the U.S. Food and Drug Administration (FDA) for Quelimmune™, its pediatric Selective Cytopheretic Device. Quelimmune provides a new therapy option for children weighing 10 kg or more who have acute kidney injury (AKI) and sepsis or a septic condition requiring continuous kidney replacement therapy (CKRT) in a hospital intensive care unit.

Nuwellis has an exclusive U.S. license and distribution agreement with SeaStar Medical to distribute Quelimmune and will market and distribute the device to nephrologists and intensive care physicians who are trained in pediatric extracorporeal therapy. With FDA HDE in place for Quelimmune, Nuwellis will begin commercial launch activities at targeted medical centers, with further commercial expansion expected later in the first half of 2024.

"Approximately 4,000 pediatric patients are hospitalized with AKI each year in the U.S.[1] and these children are at grave risk when their bodies enter an uncontrolled inflammatory response called a cytokine storm. The unique technology behind Quelimmune has demonstrated a 50% mortality rate reduction in children with potentially deadly hyperinflammation,[2]" said Nestor Jaramillo, Jr., president and chief executive officer of Nuwellis. "The pediatric segment of our business has gained significant traction since the 2020 FDA clearance of our Aquadex device for pediatric patients weighing 20kg or more – growing at a compound annual growth rate (CAGR) of over 30%. The addition of Quelimmune to our current product offering will help save the lives of many pediatric patients and should have a meaningful impact on our revenue trajectory."

"We're proud to receive HDE for Quelimmune, designed to address the limitations of today's therapeutic options for critically ill pediatric patients with cytokine storm-induced hyperinflammation," said Eric Schlorff, chief executive officer of SeaStar Medical. "Through Nuwellis' established relationships within pediatric nephrology and critical care, we look forward to bringing Quelimmune to market quickly to the patients who need it most."

SeaStar Medical's Quelimmune therapy is a patented, cell-directed extracorporeal device for managing cytokine storm-induced hyperinflammation. The therapy precisely targets and neutralizes activated toxic immune cells that drive cytokine storms (an overreaction of the immune system) that can ultimately cause organ damage and failure for critically ill patients. Clinical studies have demonstrated Quelimmune's potential to eliminate dialysis dependency, shorten intensive care unit time, and restore the lives of critically ill pediatric patients. A non-controlled pivotal study funded by the FDA Office of Orphan Products Development demonstrated that those treated with Quelimmune had no device related adverse events, a 50% reduction in mortality rate, and no dialysis required at Day 60.[2,3,4]

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 commercializing the Aquadex SmartFlow® system for ultrafiltration therapy. Nuwellis is headquartered in Minneapolis, with a wholly owned subsidiary in Ireland. For more information visit www.nuwellis.com or visit us on LinkedIn or X.

About SeaStar Medical
SeaStar Medical Holding Corporation is a medical technology company that is redefining how extracorporeal therapies may reduce the consequences of excessive inflammation on vital organs. SeaStar Medical's novel technologies rely on science and innovation to provide life-saving solutions to critically ill patients. SeaStar Medical is developing and commercializing cell-directed extracorporeal therapies that target the effector cells that drive systemic inflammation, causing direct tissue damage and secreting a range of pro-inflammatory cytokines that initiate and propagate imbalanced immune responses. For more information visit https://seastarmedical.com/ or visit us on LinkedIn or X.

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 2024 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 due to new information, future events or otherwise.

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[1] Data on File. America Hospital Directory Database Export January 2020

[2] Goldstein, Stuart L., et al. “Use of the Selective Cytopheretic Device in Critically Ill Children.” Kidney International Reports, vol. 6, no. 3, 18 Dec. 2020, pp. 775–784., https://doi.org/10.1016/j.ekir.2020.12.010.

[3] Tumlin, James A., et al. “A Multi-Center, Randomized, Controlled, Pivotal Study to Assess the Safety and Efficacy of a Selective Cytopheretic Device in Patients with Acute Kidney Injury.” PLOS ONE, vol. 10, no. 8, 2015, https://doi.org/10.1371/journal.pone.0132482.

[4] Yessayan, Lenar T., et al. “Extracorporeal Immunomodulation Treatment and Clinical Outcomes in ICU COVID-19 Patients.” Critical Care Explorations, vol. 4, no. 5, 19 May 2022, https://doi.org/10.1097/cce.0000000000000694.