



Restoring Fluid Balance. Transforming Care.

Nuwellis Announces First Pediatric Patient Treated in a Commercial Setting with SeaStar Medical's QUELIMMUNE™ Therapy at Cincinnati Children's

July 26, 2024

MINNEAPOLIS, July 26, 2024 (GLOBE NEWSWIRE) -- [Nuwellis, Inc.](#) (Nasdaq: NUWE), a medical technology company dedicated to transforming the lives of patients suffering from fluid overload, today announced that the first patient has been treated with the newly launched QUELIMMUNE™ therapy in a commercial setting at Cincinnati Children's. QUELIMMUNE, manufactured for SeaStar Medical (Nasdaq: ICU) and exclusively licensed and distributed in U.S. pediatric hospitals by Nuwellis, is a novel therapy designed to treat pediatric patients (weighing 10 kg or more) suffering from acute kidney injury (AKI) with sepsis or a septic condition and requiring kidney replacement therapy (KRT).

[Dr. Stuart Goldstein](#), Director of the Center for Acute Care Nephrology at Cincinnati Children's, and Principal Investigator of the multi-center studies that led to FDA clearance of QUELIMMUNE, oversaw the administration of QUELIMMUNE to the first patient. Dr. Goldstein expressed his enthusiasm about the potential of this therapy: "We are excited to offer QUELIMMUNE to our critically ill pediatric patients. The ability to mitigate the devastating effects of a cytokine storm caused by acute kidney injury and sepsis holds significant promise for improving patient outcomes. This therapy represents an advancement in our efforts to provide the best care possible to these vulnerable patients."

Nestor Jaramillo, President and CEO of Nuwellis, shared his thoughts on this milestone: "We are thrilled to introduce QUELIMMUNE to critically ill pediatric patients in need. This marks a significant step forward in Nuwellis' mission to execute our pediatric business development strategy. By partnering with SeaStar Medical, we are committed to bringing this groundbreaking therapy to U.S. healthcare providers, offering new hope to children suffering from severe immune system reactions."

Approximately 4,000 pediatric patients are hospitalized with AKI each year in the U.S.¹ QUELIMMUNE is designed to address the underlying immune dysregulation in pediatric patients, aiming to reduce the incidence and severity of cytokine storms. This therapy represents a significant advancement in the management of AKI and sepsis, offering a novel approach to improving patient outcomes.

About QUELIMMUNE

QUELIMMUNE is a patented cell-directed extracorporeal device that employs immunomodulating technology to selectively target proinflammatory neutrophils and monocytes during KRT and reduces the hyperinflammatory milieu including the cytokine storm that causes inflammation, organ failure and possible death in critically ill patients. Unlike pathogen removal and other blood-purification tools, the device is integrated with KRT hemofiltration systems to selectively target and transition proinflammatory monocytes to a reparative state and promote activated neutrophils to be less inflammatory. QUELIMMUNE selectively targets the most highly activated proinflammatory neutrophils and monocytes. These cells are then returned back into the body through the blood, and the body is signaled to lower its inflammatory environment and focus on repair. This unique immunomodulation approach may promote long-term organ recovery and eliminate the need for future KRT, including dialysis.

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 commercial-stage 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



Source: Nuwellis, Inc.