



Restoring Fluid Balance. Transforming Care.

## Nuwellis Marks First Commercial Sale of QUELIMMUNE™ Therapy to Cincinnati Children's

July 17, 2024

MINNEAPOLIS, July 17, 2024 (GLOBE NEWSWIRE) -- [Nuwellis, Inc.](https://www.nuwellis.com) (Nasdaq: NUWE), a medical technology company dedicated to transforming the lives of patients suffering from fluid overload, is proud to announce its first commercial sale of QUELIMMUNE™, a novel therapy developed by SeaStar Medical Holding Corporation for pediatric patients suffering from an uncontrolled inflammatory response triggered by their immune systems, to Cincinnati Children's. We believe this milestone marks a significant advancement in pediatric critical care and underscores Nuwellis' commitment to revolutionizing pediatric patient outcomes.

QUELIMMUNE, or Selective Cytopheretic Device for pediatrics, represents a transformative solution for pediatric patients suffering from acute kidney injury (AKI) due to sepsis or a septic condition on antibiotic therapy and requiring kidney replacement therapy (KRT). Early clinical data suggest a 77% survival rate for patients treated with this new therapy<sup>1</sup>. Through Nuwellis' exclusive U.S. license and distribution agreement with SeaStar Medical (Nasdaq: ICU), the developer of QUELIMMUNE, this therapy is now accessible under a Humanitarian Device Exemption (HDE) from the Food and Drug Administration (FDA) to medical institutions like Cincinnati Children's, giving nephrologists and intensive care physicians a novel option to address the needs of these critically ill pediatric patients.

Dr. Stuart Goldstein, Director of the Center for Acute Care Nephrology at Cincinnati Children's Hospital, and Principal Investigator of the multi-center studies that led to FDA clearance of QUELIMMUNE, expressed his enthusiasm for the introduction of QUELIMMUNE as standard of care: "We are excited to integrate QUELIMMUNE into our arsenal of therapies for critically ill children with sepsis and AKI requiring CKRT. This innovative treatment offers new hope for this population that had not seen improvement in outcomes for the last 20 years."

Nestor Jaramillo, President and CEO of Nuwellis, emphasized the company's dedication to advancing pediatric healthcare through strategic collaborations and innovative solutions: "The first commercial sale of QUELIMMUNE marks a significant achievement in our pediatric business development strategy. We are excited to collaborate with SeaStar Medical to deliver this life-saving therapy to critically ill patients, reinforcing Nuwellis' commitment to driving positive change in pediatric critical care."

### 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](https://www.nuwellis.com) or visit us on [LinkedIn](#) or [X](#).

### About SeaStar Medical

[SeaStar Medical Holding Corporation](https://www.seastarmedical.com) 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. Goldstein, Stuart L., et al. Use of the Selective Cytopheretic Device to Support Critically Ill Children Requiring Continuous Renal Replacement Therapy: A Probable Benefit-Risk Assessment. medRxiv, 2023.08.22.23294378; doi: <https://doi.org/10.1101/2023.08.22.23294378>



Source: Nuwellis, Inc.