



SeaStar Medical to Present Early SAVE Registry Data of QUELIMMUNE in Pediatric Acute Kidney Injury at the 5th International Symposium on Acute Kidney Injury in Children

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DENVER, Sept. 23, 2025 (GLOBE NEWSWIRE) -- SeaStar Medical Holding Corporation (Nasdaq: ICU), a commercial-stage healthcare company, announced today that preliminary results from the [SAVE Surveillance Registry](#) will be presented by SeaStar Medical and its research collaborators at the [5th International Symposium on Acute Kidney Injury in Children](#). The SAVE Registry presentation will highlight the role of [QUELIMMUNE \(Selective Cytopheretic Device for Pediatrics, or SCD-PED\) therapy](#) in the treatment of critically ill pediatric patients with life-threatening Acute Kidney Injury (AKI) and sepsis requiring Renal Replacement Therapy (RRT). Safety data will also be presented.

A second accepted abstract will also be presented and include details of the SAVE Registry study design. It will be presented concurrent with the SAVE Registry data on Saturday, September 27, 2025, 6:20 – 8:00 pm Eastern Time. The presentations are as follows:

- Early Post-Approval Real-World Clinical Experience of the Selective Cytopheretic Device (SCD) in Pediatric Acute Kidney Injury (AKI)
- Study Design of the SAVE Registry: Selective Cytopheretic Device for Pediatric Surveillance Registry

The SAVE Surveillance Registry is a Real-World Evidence (RWE) surveillance program that is designed to confirm safety and efficacy of the QUELIMMUNE therapy. Medical institutions employing the QUELIMMUNE therapy will continue to collect RWE for up to the first 300 patients treated with QUELIMMUNE. Specific outcomes data will include 90-day survival and dialysis dependency along with safety data with plans to compare to an existing control group of patients with similar severity of illness. SeaStar Medical believes that initial results from the SAVE Surveillance Registry will support broader adoption of the QUELIMMUNE therapy, inform payer discussions, and complement the company's ongoing effort to recruit patients into its adult NEUTRALIZE-AKI pivotal trial.

About Acute Kidney Injury (AKI) and Hyperinflammation

AKI is characterized by a sudden and temporary loss of kidney function and can be caused by a variety of conditions such as sepsis, severe trauma, surgery and COVID-19. AKI can cause destructive hyperinflammation, which is the overproduction or overactivity of inflammatory effector cells and other molecules that can be toxic. Damage resulting from this destructive hyperinflammation in AKI can progress to other organs, such as the heart or liver, and potentially to multi-organ dysfunction or even failure that could result in worse outcomes, including increased risk of death. Even after resolution, these patients may face complications including chronic kidney disease or end-stage renal disease (ESRD) requiring dialysis. Extreme hyperinflammation may also contribute to added healthcare costs, such as prolonged ICU stays and increased reliance on dialysis and mechanical ventilation.

About QUELIMMUNE

The [QUELIMMUNE™ therapy](#) is being commercialized for children with AKI and sepsis or septic condition weighing 10 kilograms or more who are on antibiotics and being treated in the ICU with Renal Replacement Therapy (RRT). It was approved in February 2024 under a Humanitarian Device Exemption application that requires medical institutions to also participate in the [SAVE Surveillance Registry](#) and complete Institutional Review Board approvals prior to adoption and use of the QUELIMMUNE therapy. This prolongs the adoption timeline by medical institutions, but provides important data on the use of QUELIMMUNE in the "real-world" setting.

Data from two clinical studies of the QUELIMMUNE therapy, published in [Kidney Medicine](#), showed a 77% survival rate in patient treated with QUELIMMUNE versus standard of care, representing an approximate 50% reduction in loss of life compared to historical data in this patient population. No dialysis was required for survivors and 87.5% of survivors had normal kidney function at Day 60 after ICU discharge.

In January 2025, SeaStar Medical was awarded the 2025 Corporate Innovator Award by the National Kidney Foundation for its significant contribution to improving the lives of pediatric patients with AKI based on the approval and introduction of the QUELIMMUNE therapy.

About the SeaStar Medical Selective Cytopheretic Device Therapy

The Selective Cytopheretic Device (SCD) therapy is designed as a disease-modifying device that neutralizes over-active immune cells and stops the cytokine storm that yields destructive hyperinflammation and creates a cascade of events that wreak havoc in the patient's body. The SCD therapy has broad applications in multiple acute and chronic kidney and cardiovascular diseases, representing patients who today have no FDA-approved options for treating their disease. Unlike pathogen removal and other blood-purification tools, the SCD therapy is integrated with an existing CRRT hemofiltration system to selectively target and transition proinflammatory monocytes to a reparative state and promote activated neutrophils to be less inflammatory. This unique immunomodulation approach may promote long-term organ recovery, eliminate the need for future RRT, including dialysis, and prevent loss of life.

About SeaStar Medical

SeaStar Medical is a commercial-stage healthcare company focused on transforming treatments for critically ill patients facing organ failure and potential loss of life. SeaStar's first commercial product, [QUELIMMUNE \(SCD-PED\)](#), was approved in 2024 by the U.S. Food and Drug Administration (FDA). It is the only FDA approved product for the ultra-rare condition of life-threatening acute kidney injury (AKI) due to sepsis or a septic condition in critically ill pediatric patients. SeaStar's Selective Cytopheretic Device (SCD) therapy has been awarded Breakthrough Device Designation for six therapeutic indications by the FDA, enabling the potential for a speedier pathway to approval and preferable reimbursement dynamics at commercial launch. The company is currently conducting a pivotal trial of its SCD therapy in adult patients with AKI requiring continuous renal replacement therapy (CRRT), a life-threatening condition with no effective treatment options that impacts over 200,000 adults in the U.S. annually.

For more information, visit www.seastarmedical.com or visit us on [LinkedIn](#) or [X](#).

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