



SeaStar Medical Announces Newly Published QUELIMMUNE Health Economic Study Projecting Significantly Reduced Health Care Costs in the Treatment of Pediatric AKI due to Estimated Shorter Hospital Stays and Increased Survival

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Study shows approximately 18% savings per hospitalization

DENVER, Sept. 02, 2025 (GLOBE NEWSWIRE) -- SeaStar Medical Holding Corporation (Nasdaq: ICU), a commercial-stage healthcare company focused on transforming treatments for critically ill patients facing organ failure and potential loss of life announced today the publication of a health economic analysis estimating significant cost savings with the use of the QUELIMMUNE therapy in pediatric patients with Acute Kidney Injury (AKI) in the ICU setting. The analysis, as presented in the [Journal of Medical Economics](#) (IJME) estimates a cost savings of \$69,146 per hospitalization when the QUELIMMUNE therapy is administered compared to modeled hospitalization costs with standard continuous renal replacement therapy (CRRT). These projected savings are estimated to offset the cost of the QUELIMMUNE therapy with a potential for institutions to incur no out-of-pocket costs for 6 days (median duration) of treatment of pediatric AKI.

"Data from the QUELIMMUNE clinical studies showed organ sparing and life-saving benefits for critically ill pediatric patients with AKI requiring CRRT," stated Kevin Chung, MD, Chief Medical Officer of SeaStar Medical and co-author of the publication. "Our analysis shows that the QUELIMMUNE therapy may "pay for itself" with the projected savings."

Dr. Chung continued, "Many of the most highly regarded children's medical centers have already adopted the QUELIMMUNE therapy, including, most recently, a prominent pediatric hospital in Philadelphia. We believe that this added economic benefit will support broader adoption of QUELIMMUNE therapy with a clear understanding of its beneficial implications in patient care."

Highlights from the IJME publication include:

- A historical matched analysis of pediatric patients receiving CRRT without QUELIMMUNE from the Prospective Pediatric CRRT (ppCRRT) Registry found significantly better survival with QUELIMMUNE versus CRRT alone (adjusted odds ratio 13.4; P=0.01). Bayesian analysis indicated a 98% probability of higher survival odds with the QUELIMMUNE therapy, with a predicted risk difference of 22.4%. There are no other approved selective therapies in the US for pediatric patients with AKI due to sepsis on CRRT. These data were also previously published in 2024 in [Kidney Medicine](#).
- Given the encouraging survival rates among critically ill children treated with the QUELIMMUNE therapy, the objective of the health economic study was to determine its financial impact to a health care system from an inpatient perspective by combining publicly available hospitalization cost data with non-cost clinical metrics derived from prior QUELIMMUNE studies and estimating the effect of the QUELIMMUNE therapy on inpatient hospital costs among a pediatric population receiving CRRT.
- Analysis of matched patient data sets to patients in the QUELIMMUNE studies (N=22) were derived from two pediatric patient registries: the Kid's Inpatient Database (KID) Registry (N=106) and the ppCRRT Registry (N=210).
- Modeled hospitalization costs from the KID and ppCRRT cohorts were \$457,092 and \$389,451 respectively, versus a lower estimated cost of \$320,304 for pediatric patients treated with the QUELIMMUNE therapy for a median of 6 days. Compared to the ppCRRT Registry cohort, the QUELIMMUNE therapy yields an estimated savings of \$69,146 per hospitalization. The cost reduction is driven by two key metrics: reduced hospital length of stay of approximately 3 days and improved survival.

QUELIMMUNE was approved by the US Food and Drug Administration (FDA) in 2024 under a Humanitarian Device Exemption for pediatric patients with AKI due to sepsis or a septic condition on antibiotic therapy and requiring Renal Replacement Therapy (RRT). Clinical data from the FDA application, subsequently published in [Kidney Medicine](#), showed a 77% survival rate in patients treated with QUELIMMUNE versus standard of care, representing a potential ~50% reduction in loss of life compared to historical data in this patient population. No dialysis was required for survivors at Day 60 after QUELIMMUNE treatment.

SeaStar Medical is currently conducting the NEUTRALIZE-AKI pivotal trial to evaluate the safety and efficacy of the SCD therapy in 200 patients with AKI in the ICU receiving CRRT. It has received FDA Breakthrough Device Designation for this indication and five others, including:

- Systemic inflammatory response in adult cardiac surgery
- Systemic inflammatory response in pediatric cardiac surgery to prevent post-operative adverse complications and outcomes
- Adult cardiorenal syndrome awaiting left ventricular assist device (LVAD) implantation
- End-stage renal disease (ESRD) requiring chronic dialysis

- Adult hepatorenal syndrome (HRS)

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 \(SCD-PED\) therapy](#) is SeaStar Medical's first commercial product based on its patented Selective Cytopheretic Device (SCD) technology. The QUELIMMUNE™ therapy is being commercialized for children (age 22 or younger) with AKI and sepsis or a 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 obtain Institutional Review Board approval 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 a potential ~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 April 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 NEUTRALIZE-AKI Pivotal Trial

The [NEUTRALIZE-AKI](#) (NEUTrophil and monocyte deActivation via SeLective Cytopheretic Device – a randomIZEd clinical trial in Acute Kidney Injury) pivotal trial is evaluating the safety and efficacy of the SCD therapy in 200 adults with AKI in the ICU receiving CRRT. The trial's primary endpoint is a composite of 90-day mortality or dialysis dependency of patients treated with the SCD therapy in addition to CRRT as the standard of care, compared with the control group receiving only CRRT standard of care. Secondary endpoints include mortality at 28 days, ICU-free days in the first 28 days, major adverse kidney events at Day 90 and dialysis dependency at one year. The study will also include subgroup analyses to explore the effectiveness of the SCD therapy in AKI patients with sepsis and acute respiratory distress syndrome.

About the SeaStar Medical Selective Cytopheretic Device (SCD) Therapy

The 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 is designed for 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 continuous renal replacement therapy (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 CRRT, 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. The [QUELIMMUNE \(SCD-PED\)](#) therapy is SeaStar Medical's first commercial product based on its patented Selective Cytopheretic Device (SCD) technology. It was approved in 2024 by the U.S. Food and Drug Administration (FDA). QUELIMMUNE 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 US annually.

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

Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, without limitation, SeaStar Medical’s expectations with respect to anticipated patient enrollment and the expansion of the clinical trial sites; the total addressable market for adult SCD applications; the ability of SeaStar Medical to gain market share and generate sales with respect to the total addressable market for adult SCD applications; the ability of SCD to treat patients with AKI and other diseases; the expected regulatory approval process and timeline for commercialization; and the ability of SeaStar Medical to meet the expected timeline. Words such as “believe,” “project,” “expect,” “anticipate,” “estimate,” “intend,” “strategy,” “future,” “opportunity,” “plan,” “may,” “should,” “will,” “would,” “will be,” “will continue,” “will likely result,” and similar expressions are intended to identify such forward-looking statements. 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 significant risks and uncertainties that could cause the actual results to differ materially from the expected results. Most of these factors are outside SeaStar Medical’s control and are difficult to predict. Factors that may cause actual future events to differ materially from the expected results include, but are not limited to: (i) the risk that SeaStar Medical may not be able to obtain regulatory approval of its SCD product candidates; (ii) the risk that SeaStar Medical may not be able to raise sufficient capital to fund its operations, including current or future clinical trials; (iii) the risk that SeaStar Medical and its current and future collaborators are unable to successfully develop and commercialize its products or services, or experience significant delays in doing so, including failure to achieve approval of its products by applicable federal and state regulators, (iv) the risk that SeaStar Medical may never achieve or sustain profitability; (v) the risk that SeaStar Medical may not be able to secure additional financing on acceptable terms; (vi) the risk that third-party suppliers and manufacturers are not able to fully and timely meet their obligations, (vii) the risk of product liability or regulatory lawsuits or proceedings relating to SeaStar Medical’s products and services, (viii) the risk that SeaStar Medical is unable to secure or protect its intellectual property, and (ix) other risks and uncertainties indicated from time to time in SeaStar Medical’s Annual Report on Form 10-K, including those under the “Risk Factors” section therein and in SeaStar Medical’s other filings with the SEC. The foregoing list of factors is not exhaustive. Forward-looking statements speak only as of the date they are made. Readers are cautioned not to put undue reliance on forward-looking statements, and SeaStar Medical assumes no obligation and do not intend to update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise.

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Source: SeaStar Medical