



## SeaStar Medical Reports Statistically Significant Survival Findings from Post-Approval QUELIMMUNE® SAVE Registry Analysis in Pediatric Sepsis-Associated AKI

October 22, 2026

*New late-breaking data presented today at ASN Kidney Week 2026*

*QUELIMMUNE (SCD-PED) treatment group demonstrates statistically significant higher survival in the primary analysis at Day 60, Day 90, and at hospital discharge versus comparator cohort*

*No device-related adverse events (AEs) occurred in patients treated with QUELIMMUNE*

DENVER, Oct. 22, 2026 (GLOBE NEWSWIRE) -- SeaStar Medical Holding Corporation (Nasdaq: ICU), a commercial-stage healthcare company focused on transformational treatments for critically ill patients facing organ failure and potential loss of life, announced today new positive data from the late-breaking presentation at ASN Kidney Week 2026 in Denver, Colorado.

The late-breaking poster, titled “*Improved Outcomes in Pediatric Sepsis-Associated (SA) AKI: Comparison of the Selective Cytopheretic Device for Pediatrics (SCD-PED) Surveillance Registry (SAVE) with a Historical Cohort*,” compared survival in QUELIMMUNE (SCD-PED)-treated critically ill pediatric patients from its post-approval SAVE registry and one non-registry patient with life-threatening acute kidney injury (AKI) and sepsis requiring CRRT (QUELIMMUNE SCD-PED cohort) with clinically aligned cohorts from Kids’ Inpatient Database (KID), the largest publicly available, all-payer pediatric inpatient care database in the United States representing broad clinical complexity. To assess the robustness of the findings, the authors used a multi-pronged analytic approach that included both Bayesian and frequentist methods across primary, landmark, and time-to-event analyses. Key results are reported. A separate safety analysis of QUELIMMUNE (SCD-PED)-treated patients was also presented.

### Summary of Key Highlights:

- **Day 90 Survival:** The primary exposure-defined analysis at Day 90 resulted in a statistically significant increase in survival of the QUELIMMUNE (SCD-PED) cohort achieving 65.1% survival compared to 47.4% for the KID cohort ( $P = 0.043$ ), representing more than double the odds of survival for QUELIMMUNE (SCD-PED)-treated patients (odds ratio [OR] 2.07; 95% confidence interval, [CI] 1.04-4.11). The Bayesian probability of higher survival in QUELIMMUNE (SCD-PED) patients was 98.2%. A second landmark sensitivity analysis favored the QUELIMMUNE (SCD-PED) cohort achieving 63.8% Day 90 survival, an increase of 15.1 percentage points over the KID cohort survival of 48.7% ( $P = 0.074$ ), representing 86% higher estimated odds of survival (OR 1.86; 95% CI, 0.96-3.60). The Bayesian probability of higher survival in the QUELIMMUNE (SCD-PED) landmark cohort was 96.8%.
- **In-Hospital Survival:** Survival to hospital discharge was significantly higher with the QUELIMMUNE (SCD-PED) cohort compared to KID in the primary analysis ( $P = 0.04$ ). Bayesian analyses were directionally consistent, with 98.5% and 97.3% posterior probabilities of higher QUELIMMUNE (SCD-PED) survival in the primary and landmark analyses, respectively.
- **Mortality:** All four Day 90 mortality models favored the QUELIMMUNE (SCD-PED) cohort showing 34% to 40% reduction in estimated hazard of mortality (Hazard Ratio range, 0.60-0.66) compared with combined KID. While frequentist models did not reach statistical significance, both Bayesian time-to-death models exceeded the 95% probability threshold, providing supportive evidence of a lower mortality hazard with QUELIMMUNE therapy.
- **Renal Replacement Therapy (RRT) Independence:** 20 of the 24 survivors (83%) in the QUELIMMUNE (SCD-PED) cohort who did not require RRT at baseline were independent of RRT at 90 days.
- **Adverse Events (AEs):** No device-related AEs occurred in patients treated with the QUELIMMUNE (SCD-PED) therapy from SAVE registry patients. All new bloodstream infections (12% overall and 6% during treatment) within 28 days of SCD-PED initiation were adjudicated by an independent data and safety monitoring board to be unrelated to QUELIMMUNE therapy.

“These real-world, post-approval data show a significant association with higher survival and a consistent safety profile in the QUELIMMUNE (SCD-PED)-treated patients with sepsis-associated AKI requiring CRRT with a broad range of clinical complexities,” said Stuart Goldstein, MD, Director, Center for Acute Care Nephrology at Cincinnati Children’s and a member of the SeaStar Medical Scientific Advisory Board.\* “The consistency of the survival signal across analyses support continued and further exploration of these and additional data that is forthcoming from new patients. Given the urgency of this rare and life-threatening condition combined with no device-related adverse events, I believe there is a clear observed potential benefit from the SCD-PED

therapy with a favorable safety profile.”

“Selection as a late-breaker at ASN Kidney Week reflects the urgent need for better options for critically ill children with sepsis-associated AKI,” said Kevin Chung, MD, Chief Medical Officer of SeaStar Medical. “These real-world findings are consistent with our previous clinical results and the association with higher survival held across every analytic approach we applied. Sharing them with the nephrology community at its premier meeting is an important step toward making QUELIMMUNE therapy available to every child who may benefit.”

### Statistical Design and Analyses:

The observational external-control exploratory study compared all known eligible QUELIMMUNE (SCD-PED)-treated pediatric patients (SAVE Registry patients plus one non-registry patient) with available outcome data through completion of the pre-specified SAVE enrollment target of 50 patients versus clinically aligned patients from the 2019 and 2022 Healthcare Cost and Utilization Project Kids' Inpatient Databases (KID). KID is the largest publicly available all-payer pediatric inpatient care database in the United States, containing unweighted data from over three million pediatric discharges per data year, representing a broad range of patients, comorbidities, and complexities, including extracorporeal membrane oxygenation (ECMO), thus provided the broadest available pediatric comparator population. Both cohorts included critically ill pediatric patients with life-threatening AKI and sepsis requiring CRRT with high clinical complexities, such as malignancy, immunocompromised status and transplant. Greater than 95% required invasive mechanical ventilation, vasopressor use, and/or management for shock in both groups. Advanced life support therapy, such as ECMO, was administered in 33% to 34% of patients in the SAVE cohort and 28% to 29% of patients in the KID cohort.

The primary exposure-defined analysis compared the QUELIMMUNE (SCD-PED) cohort patients who received greater than one day of QUELIMMUNE therapy (N=43) versus clinically aligned patients in the KID cohort (N=196).

The landmark sensitivity analysis compared the QUELIMMUNE (SCD-PED) cohort patients who were alive one day post-initiation of QUELIMMUNE therapy (N=47) versus patients from the KID cohort who survived beyond one calendar day of CRRT initiation (N=191).

Safety outcomes for the QUELIMMUNE (SCD-PED) cohort included new bloodstream infections and Day 90 renal replacement therapy (RRT)-free status among survivors not RRT-dependent at baseline.

Data Source: The authors acknowledge the source of the data as the Kids' Inpatient Database (KID), Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality. Interpretations and conclusions from these data are those of the authors and do not constitute the findings, policies, or recommendations of the U.S. Government, the U.S. Department of Health and Human Services, or AHRQ.

The poster with all results as of the presentation will be available on the Healthcare Professional section of the [SeaStar Medical website](#). Please note data from the original posted abstract was updated and the poster presentation of data is the official data source. Final study results and interpretations are expected to be reported in a peer-reviewed manuscript.

### About QUELIMMUNE

The [QUELIMMUNE® \(SCD-PED\) therapy](#) is being commercialized for children with AKI and sepsis or septic condition weighing 10 kilograms or more and aged ≤22 years who are on antibiotics and being treated in the ICU with RRT. It was approved in February 2024 under a Humanitarian Device Exemption application.

Data from two clinical trials 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 February 2026, data published in the prestigious, peer-reviewed journal, [Pediatric Nephrology](#), highlighted the early experience from the QUELIMMUNE [SAVE Registry](#), a post-approval surveillance registry, evaluating the role of the QUELIMMUNE therapy in the treatment of critically ill pediatric patients with life-threatening Acute Kidney Injury (AKI) and sepsis requiring renal replacement therapy. The publication reported observations from the first 21 pediatric patients with AKI and sepsis requiring renal replacement therapy. Data showed no device-related adverse events or infections and no reports of immunosuppressive effects by the device. In addition, preliminary outcomes analyses show a 76% survival rate at Day 28 and Day 60, and a 71% survival rate at Day 90. These findings are broadly consistent with the survival observations reported in the registration studies reported in [Kidney Medicine](#).

The patented technology behind QUELIMMUNE is known as the Selective Cytopheretic Device (SCD) therapy and could have broad applications for treating the destructive hyperinflammation that shuts down organ function and causes loss of life.

QUELIMMUNE was approved by FDA under a Humanitarian Device Exemption based on safety and probable benefit. The effectiveness of this device for this use has not been demonstrated. Adverse reactions observed in clinical studies include hypotension, hypothermia, tachycardia, hyperglycemia, and thrombocytopenia. Additional risks may include blood loss or extracorporeal circuit complications. QUELIMMUNE must be used with citrate anticoagulation.

For complete risk information, please see: <https://seastarmedical.com/quelimmune>

### **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 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 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 339 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 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 severe infections or other septic conditions, severe trauma, surgery, and organ failures. 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 SeaStar Medical**

SeaStar Medical is a commercial-stage healthcare company focused on transformational treatments for critically ill patients facing organ failure and potential loss of life. SeaStar Medical'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 requiring renal replacement therapy (RRT) in critically ill pediatric patients. SeaStar Medical'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 the NEUTRALIZE-AKI pivotal clinical trial of its SCD therapy in adult patients with AKI requiring continuous renal replacement therapy, 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](http://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 the potential benefit from the SCD-PED therapy with a favorable observed safety profile; anticipated improved survival in real-world critical care practice; anticipated adoption of our products; 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.

Contact:

[IR@SEASTARMED.COM](mailto:IR@SEASTARMED.COM)

QUELIMMUNE is a registered trademark of SeaStar Medical Holding Corporation.

\*As a member of the SeaStar Medical Scientific Advisory Board, Dr. Goldstein has received financial compensation for his service in this capacity.