FDA Confirms SeaStar Medical Has Fulfilled the Post-Approval Study Requirements for QUELIMMUNE® for the Treatment of Sepsis-Associated Acute Kidney Injury (AKI) in Pediatric Patients

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DENVER, Nov. 03, 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 the Center for Biologics Evaluation and Research (CBER) of the U.S. Food and Drug Administration (FDA) has determined that the QUELIMMUNE Pediatric SAVE Surveillance Registry (SAVE Registry) has fulfilled the post-approval study requirements as outlined in the original Humanitarian Device Exemption (HDE) approval of QUELIMMUNE.

“We are grateful for this decision by FDA and believe it will enable us to expand the potential life-saving benefits of our QUELIMMUNE therapy to more critically ill children with life-threatening AKI,” stated Eric Schlorff, CEO of SeaStar Medical. “These kids typically have about a 50% survival rate with traditional supportive care alone, and we believe this decision will be a win-win for patients, their families, health care providers, and the overall health care system.”

Results from the SAVE Registry were recently presented at a late-breaking presentation at ASN Kidney Week 2026. The presentation highlighted the clinically meaningful and statistically significant improved survival of the QUELIMMUNE therapy in the treatment of critically ill pediatric patients with life-threatening AKI and sepsis requiring renal replacement therapy (RRT). Data from the SAVE Registry patients showed no device-related adverse events.

This late-breaking presentation at ASN Kidney Week 2026 reported a clinically meaningful and statistically significant improvement in 90-day survival of 65.1% for the QUELIMMUNE (SCD-PED) patients (N=43) versus only 47.5% (P = 0.043) for patients from clinically aligned cohorts from the Kids’ Inpatient Database (KID) (N=196). Statistically significant increases for both in-hospital and 60-day survival were also seen in the primary analysis for patients treated with QUELIMMUNE (SCD-PED) compared to the KID cohorts. KID is the largest publicly available, all-payer pediatric inpatient care database in the United States representing a broad range of diagnoses, procedures, and clinical severity. The ASN Kidney Week 2026 late-breaking poster presentation is available on the Healthcare Professional section of the SeaStar Medical website.

“It is hard to describe how sick these children really are. Many are fighting sepsis and multi-organ failure at the same time,” stated Kevin Chung, MD, Chief Medical Officer of SeaStar Medical. “The SAVE Registry gives us crucial real-world evidence on both safety and probable benefits in these patients, and we are grateful to the pediatric teams and families who made it possible. We remain committed to collecting data wherever feasible, so that we keep learning how best to use QUELIMMUNE for the children who need it most.”

FDA’s decision now enables hospitals to employ the QUELIMMUNE therapy without the research infrastructure that the SAVE Registry demanded, which will expand access to critically ill pediatric patients with sepsis-associated AKI on RRT at medical centers that previously could not participate. SeaStar Medical will continue to voluntarily enroll patients in the SAVE Registry at medical centers that choose to take part to continue to build on the real-world evidence for the use of QUELIMMUNE.

The QUELIMMUNE therapy has been adopted by many of the highest rated children’s medical centers in the United States. The patented technology behind QUELIMMUNE is known as the Selective Cytopheretic Device (SCD) therapy that has broad potential applications for the treatment of destructive hyperinflammation that shuts down organ function and causes loss of life.

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.

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 RRT, 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.

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 benefits from the SCD therapy; anticipated improved survival in real-world critical care practice; anticipated adoption of SeaStar's 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.

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QUELIMMUNE is a registered trademark of SeaStar Medical Holding Corporation.