SeaStar Medical Announces Publication in Pediatric Nephrology of Positive Real-World Experience for QUELIMMUNE™ (SCD-PED) Therapy in Pediatric Acute Kidney Injury (AKI)

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Strong survival data extending to 90 days

Real-world experience shows results consistent with clinical trial data

Favorable safety profile – no device-related adverse events

DENVER, Feb. 09, 2026 (GLOBE NEWSWIRE) -- SeaStar Medical Holding Corporation (Nasdaq: ICU), a commercial-stage healthcare company, announced today the publication of early post-approval clinical experience from the use of the QUELIMMUNE (Selective Cytopheretic Device for Pediatrics, or SCD-PED) therapy in the prestigious, peer-reviewed journal *Pediatric Nephrology*.

The publication, co-authored by leading experts including Stuart Goldstein, Kelli Krallman, Meredith Harris, Rajit Basu, David Askenazi, Shina Menon, Matt Zinter, Steven Gorga, and H. David Humes, highlights early experience from the 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.

Observations from the first 21 pediatric patients with AKI and sepsis requiring renal replacement therapy 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 new data are on track to validate a 50% reduction in patient mortality at 60 days compared to historical data, similar to what was observed in the registration study reported in *Kidney Medicine*.

Additional analyses included survival of patients requiring extracorporeal membrane oxygenation (ECMO) and independence from renal replacement therapy for pediatric patients without a history of end-stage renal disease or a recent kidney transplant. The evaluation of five patients concomitantly treated with the QUELIMMUNE therapy and ECMO showed a 60% survival rate at Day 90. Among pediatric patient survivors without a history of end-stage renal disease or a recent kidney transplant, 75% (9 of 12) and 83% (10 of 12) were dialysis free at Day 28 and Day 90, respectively.

“These real-world experiences of the QUELIMMUNE therapy are compelling for a number of reasons,” stated Stuart Goldstein, MD, Director, Center for Acute Care Nephrology at Cincinnati Children’s and a member of the SeaStar Medical Scientific Advisory Board.* “First, they mirror the results from the two registrational trials that enabled FDA approval of the therapy in critically ill patients with AKI and sepsis requiring renal replacement therapy, further demonstrating the reproducibility of the therapeutic benefit. Second, the complexity of the patient population with respect to their comorbidities show a much broader array of use compared to the narrower patient selection in the registrational trials. And finally, with no device-related serious adverse events to date, I believe there is a clear potential benefit from the QUELIMMUNE therapy with minimal downside risk to patient safety. For these reasons, we have had the QUELIMMUNE therapy available since FDA approval for our patients who present with such life-threatening conditions.”

“*Pediatric Nephrology* is widely considered a key resource for clinicians and researchers dealing with childhood kidney disease, and we are delighted that these data have undergone the scrutiny of their peer-review process and will now be available widely,” stated Kevin Chung, MD, Chief Medical Officer of SeaStar Medical. “We are passionate about giving these critically ill kids a chance. This broad exposure of the data is a welcome step in our goal to make QUELIMMUNE available to every child that may benefit from this therapy.”

The SAVE Registry is a Post-Approval Study that is designed to collect additional safety and other clinical effectiveness data of the QUELIMMUNE therapy in the treatment of pediatric patients with AKI and sepsis requiring renal replacement therapy. FDA initially required the enrollment of 300 patients in the SAVE Registry. After submission of data to the FDA from the first 21 patients and discussion between SeaStar Medical and the Agency, FDA reduced its mandated target from 300 to 50 patients. Medical institutions employing the QUELIMMUNE therapy will continue to collect data for up to the first 50 patients treated with QUELIMMUNE. Specific outcomes data will include 28-day safety, and 90-day survival and dialysis dependency with plans to compare the SAVE Registry data to an existing control group of patients with similar illness severity. SeaStar Medical believes that initial real-world experience from the SAVE Registry will support broader adoption of the QUELIMMUNE therapy and complement the company’s ongoing effort to recruit patients into its adult NEUTRALIZE-AKI pivotal trial.

The QUELIMMUNE therapy has been adopted by nationally recognized children's medical centers in the United States. Participants in the SAVE Registry are listed on ClinicalTrials.gov and include the following top-rated children's medical centers: Children's of Alabama, Lucille Packard Children's Hospital Stanford, UCSF Benioff Children's, Children's Hospital of Atlanta – Arthur M. Blank, Children's Hospital of Atlanta – Scottish Rite, Lurie Children's Hospital of Chicago, Cincinnati Children's Medical Center, CS Mott Children's Hospital, Cleveland Clinic Children's Hospital, Children's Hospital of Philadelphia, Children's Medical Center Dallas, Cook Children's Hospital, and Texas Children's Hospital.

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 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 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 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.

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

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 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 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 1955. These forward-looking statements include, without limitation, SeaStar Medical's expectations with respect to the anticipated adoption our products; anticipated cost savings for patients, healthcare providers, and the healthcare system more generally from the adoption of the SCD therapy; the reduction in loss of life; the potential results of

the SAVE Registry study; 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.

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

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