SeaStar Medical Reports DSMB Recommendation to Continue the NEUTRALIZE-AKI Pivotal Trial in Adult Acute Kidney Injury

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Independent DSMB reports zero device-related safety issues
Supports potential clinical benefit
Trial sample size re-estimated to strengthen statistical power

DENVER, Sept. 24, 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 that the independent Data Safety Monitoring Review Board (DSMB) has recommended the continuation of the NEUTRALIZE-AKI pivotal trial of the Selective Cytopheretic Device (SCD) therapy in adult patients with acute kidney injury (AKI) requiring continuous renal replacement therapy (CRRT).

The interim analysis by the independent DSMB evaluated the safety and potential clinical benefit of the first 100 patients enrolled in the NEUTRALIZE-AKI pivotal clinical trial. The DSMB reported:

- No device-related safety concerns, with zero device-related adverse events. This is consistent with the previously published safety profile of the SCD therapy as well as the preliminary results from the QUELIMMUNE SAVE pediatric registry.
- A signal of potential clinical benefit in the treatment group across key study outcome measures.

To ensure the study is adequately powered to validate the potential clinical efficacy signal, the DSMB recommended increasing the total enrollment from 200 to 339 patients, consistent with the trial's statistical analysis plan. To date, 137 patients have been enrolled, representing significant progress toward this target. SeaStar Medical is taking proactive steps to accelerate enrollment to meet the new target. It estimates patient enrollment will be complete near the end of 2026, based on the current enrollment rate of clinical trial sites and the addition of several new sites in the NEUTRALIZE-AKI trial.

"We are encouraged by the DSMB's recommendation, which reinforces the overall safety profile of our SCD therapy and suggests a potential clinical benefit, which we are observing in the commercial setting with QUELIMMUNE in the pediatric population" said Kevin Chung, MD, Chief Medical Officer of SeaStar Medical. "Sample size re-estimations are well established practices in pivotal trials, and while an upward re-estimation will extend the trial timeline, we are optimistic it will strengthen the statistical power and provide critical care teams with greater confidence in the results."

"Patients continue to face a high risk of death or long-term organ failure due to lack of a disease-modifying therapy, despite availability of CRRT for severe AKI," said Eric Schlorff, CEO of SeaStar Medical. "The DSMB's recommendation reinforces our confidence in advancing the NEUTRALIZE-AKI trial and our mission to deliver a first-in-class therapy that can change outcomes for these critically ill patients."

Mr. Schlorff added, "We intend to continue to drive shareholder value through successful execution of our QUELIMMUNE commercial efforts and the completion of the NEUTRALIZE-AKI trial and the potential filing and approval of the SCD therapy in adult AKI. We have been prudently managing our financial resources and will continue to monitor our options to secure future sources of capital, as needed, to support the achievement of our future milestones."

The NEUTRALIZE-AKI (NEUTRophil and monocyte deActivation via SeLective Cytopheretic Device – a randomIZEd clinical trial in Acute Kidney Injury) is an event driven study. 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.

SeaStar Medical's SCD therapy has been approved by the US Food and Drug Administration for use in life-threatening AKI due to sepsis or a septic condition in critically ill pediatric patients. It was approved in 2024 and is sold under the brand name QUELIMMUNE™. It has been adopted by nationally-recognized children's medical centers throughout the United States. SeaStar Medical recently announced positive preliminary results from the SAVE Surveillance Registry which is assessing the use of the QUELIMMUNE therapy in the commercial setting. Based on the data collected from the first 20 pediatric patients in the SAVE Surveillance Registry, there were no device related safety events with the QUELIMMUNE therapy and 75% of patients survived through 28 days. These data are on track to validate or potentially exceed a 50% reduction in loss of life compared to historical data, as reported in Kidney Medicine.

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 the SeaStar Medical Selective Cytopheretic Device 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.

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 anticipated patient benefits from our products including the reduction in loss of life; the potential results of the Save Surveillance Registry study; the expected regulatory approval process and timeline for our products; 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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