



FDA Grants SeaStar Medical Breakthrough Device Designation for its SCD Therapy for the Treatment of Hyperinflammation in Adult Patients with Sepsis or a Septic Condition

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Potentially accelerates development, assessment, and review for approval by FDA

Sepsis impacts about 1.7 million U.S. adults annually and contributes to nearly one in three in-hospital deaths

DENVER, Oct. 07, 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 that the U.S. Food and Drug Administration (FDA) has granted SeaStar Medical Breakthrough Device Designation for its Selective Cytopheretic Device (SCD) therapy for the treatment of hyperinflammation in adult patients with sepsis or a septic condition. The Breakthrough Device Designation is a regulatory pathway designed to provide for accelerated development, assessment, and review for FDA approval of medical devices and potentially more effective treatments of life-threatening or irreversibly debilitating diseases or conditions. This marks the seventh Breakthrough Device Designation for the SCD therapy thus far across a range of indications.

"This new Breakthrough Device Designation for our SCD therapy continues to exemplify the importance and critical need for an innovative therapy that can effectively treat the hyperinflammation that destroys organs and takes far too many lives each year," stated Eric Schlorff, CEO of SeaStar Medical. "Our protocol for the ongoing NEUTRALIZE-AKI pivotal clinical trial includes pre-specified statistical analysis of the subset of patients with sepsis or septic like condition, and as such, we expect to have important data to present to the FDA for this indication in the near term. We will move as quickly as possible to submit the relevant data to the FDA and discuss ways to help these patients who today have few options for effectively treating sepsis."

Sepsis is a medical emergency caused by an overreaction of the immune system to an infection. It often results in an uncontrolled "cytokine storm" that drives widespread immune activation and endothelial injury. In severe cases, this culminates in septic shock, organ dysfunction, and ultimately death. Today, there are no FDA approved therapies to address the dysregulated inflammatory host response in sepsis.

In the U.S. alone, sepsis impacts an estimated 1.7 million adults annually and contributes to nearly one in three in-hospital deaths. For the patients who survive the acute phase of illness, up to 70% experience post-sepsis syndrome, a debilitating condition characterized by persistent immune dysregulation, cognitive decline, and physical impairments that severely degrade health-related quality of life. This combination of high acute mortality and enduring chronic morbidity makes sepsis one of the main drivers of cost in the U.S. Healthcare System.

"Sepsis remains one of the most challenging conditions we face in critical care, in large part because treating the infection does not necessarily stop the dysregulated immune response that drives organ injury," said Kevin Chung, MD, Chief Medical Officer of SeaStar Medical. "The SCD therapy is designed to selectively modulate that response without broadly suppressing the immune system. This Breakthrough Device Designation underscores the significant unmet need in the treatment of sepsis, and we look forward to working with the FDA to advance this therapy for critically ill patients."

Dr. Chung continued, "This is now the seventh indication for which the SCD has received Breakthrough Device Designation. Each reflects the FDA's determination that the applicable criteria have been met, including a reasonable expectation that the technology could provide more effective treatment for a life-threatening or irreversibly debilitating condition. We believe the breadth of these designations reinforces the disease-agnostic potential of the SCD platform to address dysregulated inflammation across multiple serious conditions, and we are committed to generating the clinical evidence needed to advance these indications."

SeaStar Medical also recognizes Col. (Ret.) Ian Stewart, MD, USAF, a talented nephrologist and physician-scientist, who made important contributions to this FDA submission while serving as a [Skillbridge](#) Fellow with SeaStar Medical through the [Hiring Our Heroes](#) program. SeaStar Medical is proud to have supported this program and grateful for the expertise Dr. Stewart brought to the team.

SeaStar Medical's seven Breakthrough Device Designations, including its first designation for a pediatric indication, have been granted by CBER for treatment of the following conditions:

- Immunomodulatory dysregulation in adult patients with acute kidney injury (AKI);
- Systemic inflammatory response in adult cardiac surgery;

- Systemic inflammatory response in pediatric cardiac surgery to prevent post-operative adverse complications and outcomes;
- Acute on chronic systolic heart failure and worsening renal function due to cardiorenal syndrome awaiting LVAD implantation;
- Chronic systemic inflammation in end-stage renal disease (ESRD) requiring chronic dialysis;
- Adult patients with Hepatorenal Syndrome (HRS);
- Hyperinflammation in adult patients with sepsis or a septic condition.

About the FDA's Breakthrough Device Designation

FDA grants Breakthrough Device Designation when a device has the potential to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions. It must also represent one or more of the following: a) a breakthrough technology, b) a therapeutic treatment where no approved or cleared alternatives exist, c) offer significant advantages over existing approved or cleared alternative, and/or d) the device availability is in the best interest of patients. The Breakthrough Device Designation is designed to provide timely access to medical devices to speed up development, assessment, and review for FDA approval.

About QUELIMMUNE

The [QUELIMMUNE® \(SCD-PED\) therapy](#) is being commercialized for children with AKI and sepsis or a septic condition weighing 10 kilograms or more who are on antibiotics and being treated in the ICU with RRT.

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. 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 an observed 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](#).

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.

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 continuous RRT 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 continuous RRT, 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 continuous RRT. 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 continuous RRT as the standard of care, compared with the control group receiving only continuous RRT 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 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 total addressable market for the SCD applications; the ability of SeaStar Medical to gain market share and generate; the amount and timing of future QUELIMMUNE commercial sales; commercial acceptance of QUELIMMUNE; 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.