



SeaStar Medical Announces FDA Approval of Reduction in Mandatory Enrollment for SAVE Surveillance Registry Evaluating QUELIMMUNE™ Safety for Pediatric AKI

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FDA lowers surveillance requirement to 50 patients from 300 patients in original HDE approval based on assessment of first 21 SAVE Surveillance Registry patients

Compelling efficacy data to date along with completion of registry expected to expand QUELIMMUNE market opportunity

DENVER, Dec. 02, 2025 (GLOBE NEWSWIRE) -- SeaStar Medical Holding Corporation (Nasdaq: ICU), a commercial-stage healthcare company, announced today the Center for Biologics Evaluation and Research (CBER) of the U.S. Food and Drug Administration (FDA) has approved a reduction in the mandatory enrollment size of the [SAVE Surveillance Registry](#) from the originally-required 300 patients to only 50 patients. This new 50-patient registry size will satisfy the post-approval surveillance requirement by the FDA as outlined in the original Humanitarian Device Exemption (HDE) approval and indicates that FDA believes that continued device safety can be successfully shown with fewer patients than originally required.

The SAVE Surveillance Registry is a Post-Approval Study (PAS) that is designed to confirm the safety of the QUELIMMUNE therapy, which was approved in 2024 as a treatment for children with acute kidney injury (AKI) and sepsis or a septic condition. To date, data from 32 pediatric patients have been entered into the SAVE Surveillance Registry.

"We are grateful for this decision by the FDA and believe, once the registry is complete, it will enable us to expand the potential organ-sparing and life-saving benefits of our QUELIMMUNE therapy to more pediatric patients with AKI," stated Eric Schlorff, CEO of SeaStar Medical. "These kids typically have about a 50% survival rate and our data from the first 21 patients in the SAVE Surveillance Registry showed zero device-related adverse events and a clear improvement to 70% survival at 90 days. This decision is a win-win for patients, their families, health care providers, and the overall health care system. We thank the FDA for their rapid evaluation of the required enrollment size of the mandatory surveillance requirements for the registry."

Preliminary results from the [SAVE Surveillance Registry](#) were recently presented at the [5th International Symposium on Acute Kidney Injury in Children](#). The [SAVE Surveillance Registry presentation](#) highlighted the role of [QUELIMMUNE \(Selective Cytopheretic Device for Pediatrics, or SCD-PED\) therapy](#) in the treatment of critically ill pediatric patients with life-threatening Acute Kidney Injury (AKI) and sepsis requiring Renal Replacement Therapy (RRT). Data from the first 21 pediatric patients with AKI and sepsis requiring RRT showed zero device-related adverse events or infections and no reports of immunosuppressive effects by the device. In addition, 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 loss of life compared to historical data, as reported in [Kidney Medicine](#).

"The SAVE Surveillance Registry has provided valuable clinical outcomes data on both the safety and efficacy of our QUELIMMUNE therapy, but it has also slowed the adoption process and potential to treat these pediatric patients due to the complexities of setting up and running a patient registry at these medical institutions," stated Tim Varacek, Senior Vice President, Commercial and Business Operations. "There has been very strong interest in QUELIMMUNE adoption and we are pleased that we can satisfy FDA's registry requirements with far fewer patients than expected, enabling a smoother adoption process and potentially expanding the revenue opportunity to capture a larger portion of the total pediatric AKI market which we estimate to be about \$100 million in the U.S. alone."

The QUELIMMUNE therapy has been adopted by some 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 and has broad applications for treating the destructive hyperinflammation that shuts down organ function and causes loss of life.

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 HDE application that requires medical institutions to also participate in the [SAVE Surveillance 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 studies 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. Recent data presented from the first 21 patients in the SAVE Surveillance Registry mirror the clinical trial results.

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.

About the 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 200 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 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'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 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 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 anticipated adoption of our products; anticipated cost savings for patients, healthcare providers, and the healthcare system more generally from the adoption of the SCD therapy; the total addressable market for pediatric SCD applications; the ability of SeaStar Medical to increase market share and generate sales with respect to the total addressable market for pediatric 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.

Contact:

IR@SEASTARMED.COM