SeaStar Medical Announces Completion of FDA Enrollment Requirement for SAVE Surveillance Registry Evaluating QUELIMMUNE Safety for Pediatric AKI

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Completion of enrollment marks a key milestone toward satisfying FDA post-approval requirements

DENVER, March 05, 2026 (GLOBE NEWSWIRE) -- SeaStar Medical Holding Corporation (Nasdaq: ICU), a commercial-stage healthcare company, announced today that it has completed the required enrollment in the SAVE Registry, a Post-Approval Study (PAS) required by the FDA that is designed to confirm the safety of the QUELIMMUNE™ therapy as a treatment for children with acute kidney injury (AKI) due to sepsis or a septic condition requiring renal replacement therapy (RRT). The registry has successfully enrolled 50 patients, and the company will be reporting the 28-day safety results from the SAVE Registry to the FDA upon completion of its analysis of the data.

“The early results from the SAVE Registry, as published recently in the prestigious, peer-reviewed journal *Pediatric Nephrology*, have provided valuable clinical outcomes data on both the safety and probable benefit of our QUELIMMUNE therapy,” stated Eric Schlorff, CEO of SeaStar Medical. “We look forward to evaluating the safety data from the full cohort of 50 patients and submitting that to the FDA in the coming months.”

“We also look forward to the further expansion of our customer base to children’s hospitals where the complexities of setting up and running a patient registry has hindered faster adoption of the QUELIMMUNE therapy,” stated Tim Varacek, Senior Vice President of Business and Commercial Operations. “There continues to be very strong interest in QUELIMMUNE adoption, and we are pleased that we have met the FDA’s registry enrollment requirements.”

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.

The patented technology behind QUELIMMUNE is known as the Selective Cytopheretic Device (SCD) therapy and has potential 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 infection. 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 (age ≤22 years) with AKI due to sepsis or a septic condition weighing 10 kilograms or more who are on antibiotics and being treated with Renal Replacement Therapy (RRT). It was approved in February 2024 under a HDE application that required 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 has prolonged the adoption timeline by medical institutions, but provides important data on the use of QUELIMMUNE™ in the “real-world” setting. 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.

Data from two clinical studies of the QUELIMMUNE therapy, published in Kidney Medicine, showed a 77% survival rate in patients 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 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 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 potential broad applications in multiple acute and chronic kidney and cardiovascular diseases, representing patients who today have few or 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 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 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 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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