SeaStar Medical Adds Fifth Hospital Customer for QUELIMMUNE

January 27, 2025

DENVER, Jan. 27, 2025 (GLOBE NEWSWIRE) -- SeaStar Medical Holding Corporation (Nasdaq: ICU), a commercial-stage therapeutic medical device company developing proprietary solutions to reduce the consequences of hyperinflammation on vital organs, has shipped QUELIMMUNE ™ to a California medical center recognized as a world leader in pediatric research and treatments, increasing commercial customers to five. QUELIMMUNE is the company's Selective Cytopheretic Device (SCD) for treating critically ill children in the intensive care unit (ICU) with acute kidney injury (AKI) and sepsis.

"We are delighted that QUELIMMUNE is now available to treat severely ill children at yet another prominent academic medical center," said Tim Varacek, SeaStar Medical Senior Vice President, Commercial & Business Operations. "We are actively working to secure additional hospital clearances by gaining institutional review board (IRB) approvals for using QUELIMMUNE within their facilities. Currently, we are engaged with more than a dozen new medical centers, with seven of these hospitals advancing into the IRB approval process. Additionally, I'm pleased to report that several of our current customers have reordered QUELIMMUNE for their institutions since the beginning of this year."

"We know of no other commercially available therapy that can modify the inflammatory process once it's triggered to help repair the damage caused by an overactive immune system. It's gratifying to expand access to our potentially lifesaving therapy to more pediatric patients as we make headway in our goal of having more than 20 hospitals utilizing QUELIMMUNE this year," said Eric Schlorff, SeaStar Medical CEO.

QUELIMMUNE is being commercialized following U.S. Food and Drug Administration (FDA) approval for children with AKI and sepsis or septic condition weighing 10 kilograms or more who are being treated in the ICU with renal replacement therapy (RRT). QUELIMMUNE was approved under a Humanitarian Device Exemption (HDE) application, having met the applicable criteria with clinical results showing safety and probable clinical benefit in a limited population of critically ill children with AKI who have few treatment options.

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 COVID-19, sepsis, severe trauma and surgery. AKI can cause hyperinflammation, which is the overproduction or overactivity of inflammatory effector cells and other molecules that can be toxic. Damage resulting from 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 requiring dialysis. Hyperinflammation may also contribute to added healthcare costs, such as prolonged ICU stays and increased reliance on dialysis and mechanical ventilation.

Selective Cytopheretic Device
The Selective Cytopheretic Device (SCD) is a patented cell-directed extracorporeal device that employs immunomodulating technology to selectively target proinflammatory neutrophils and monocytes during continuous renal replacement therapy (CRRT) and reduces the hyperinflammatory milieu including the cytokine storm. Unlike pathogen removal and other blood-purification tools, the SCD is integrated with CRRT hemofiltration systems 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 and eliminate the need for future renal replacement therapy (RRT), including dialysis.

The SCD has been awarded FDA Breakthrough Device Designation in four indications:

- Cardiorenal Syndrome with Left Ventricular Assist Device
- Adult Acute Kidney Injury
- Hepatorenal Syndrome
- Chronic Dialysis

About SeaStar Medical
SeaStar Medical is a commercial-stage therapeutic medical technology company that is redefining how extracorporeal therapies may reduce the consequences of excessive inflammation on vital organs. SeaStar Medical's novel technologies rely on science and innovation to provide life-saving solutions to critically ill patients. The Company is developing and commercializing cell-directed extracorporeal therapies that target the effector cells that drive systemic inflammation, causing direct tissue damage and secreting a range of pro-inflammatory cytokines that initiate and propagate imbalanced immune responses. 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, the ability of the SCD to treat patients with AKI and other diseases; our ability to secure additional hospital clearances to use the SCD; our ability to expand the number of hospitals using QUELIMMUNE; and anticipated cost savings for patients, healthcare providers, and the healthcare system more generally from the adoption of the SCD. 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 access funding under existing agreements; (vi) the risk that third-parties 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 does not intend to update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise.

Contact:

Alliance Advisors IR
Jody Cain
(310) 691-7100
Jcain@allianceadvisors.com

# # #

Source: SeaStar Medical Holding Corporation