SeaStar Medical Announces Details of the Selective Cytopheretic Device Pivotal Study in Critically ill Adults with Acute Kidney Injury

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The NEUTRALIZE-AKI study will evaluate safety and efficacy of the SCD 's ability to target and neutralize the highly activated proinflammatory neutrophils and monocytes that drive hyperinflammation

DENVER, Feb. 15, 2023 (GLOBE NEWSWIRE) -- SeaStar Medical (Nasdaq: ICU), a medical device company developing proprietary solutions to reduce the consequences of hyperinflammation on vital organs, announces details of its pivotal NEUTRALIZE-AKI study evaluating the safety and efficacy of its Selective Cytopheretic Device (SCD) in adults with acute kidney injury (AKI) requiring continuous kidney replacement therapy (CKRT). The recently approved study will be initiated in March and is expected to enroll up to 200 patients at up to 30 U.S. clinical trial sites.

This randomized, controlled study, called NEUTRALIZE-AKI (**NEUTR**ophil and monocyte de**A**ctivation via se**L**ective cytopheret**I**c device - a randomi**ZE**d clinical trial in **A**cute **K**idney **I**njury), will evaluate the safety and efficacy of the SCD to quell the hyperinflammatory process and cytokine storm by targeting and neutralizing activated effector cells in critically ill adults with AKI requiring CKRT, a condition with a high mortality rate.

The study's primary endpoint is a composite of 90-day mortality or dialysis dependency among patients treated with SCD in addition to CKRT standard of care, compared with the control group receiving CKRT standard of care alone. Secondary endpoints include mortality at Day 28, 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 subgroups to explore the effectiveness of SCD therapy in AKI patients with sepsis and acute respiratory distress syndrome (ARDS).

"We are eager to begin this study that addresses life-threatening hyperinflammation in the setting of critical illness. An estimated six million American adults and children are diagnosed with AKI each year, and more than 200,000 require CKRT as part of their care," said Kevin Chung, MD, Chief Medical Officer of SeaStar Medical. "We believe the SCD holds potential to change practice by improving outcomes in all ICU patients with this unmet medical need caused by highly activated neutrophils and monocytes."

The SCD is a patented, cell-directed extracorporeal therapy that selectively targets the most highly activated proinflammatory neutrophils and monocytes to stop the cytokine storm that can cause organ failure and death. SCD therapy is currently delivered through continuous CKRT to target and neutralize proinflammatory neutrophils and monocytes, allowing the body to return to homeostasis. The SCD received FDA Breakthrough Device Designation in 2022.

The SCD has demonstrated success in critically ill patients with AKI requiring CKRT in previous clinical studies. In the Company's SCD 005 pilot study evaluating the safety and feasibility of the SCD in COVID-19 patients with AKI and/or ARDS, patients experienced reductions in activated neutrophils and monocytes, which led to a reduction in proinflammatory cytokines and improved clinical outcomes. Based on the per-protocol minimum of 96 hours of SCD treatment, Day 60 mortality of treated patients was significantly lower at 31% compared with the control population treated under standard of care at 81%. All patients in the study were treated in the ICU and received CKRT as the SCD delivery vehicle.

In four additional non-COVID AKI studies in adults and children, patients treated with the SCD showed Day 60 reductions in mortality of up to 50% and no dialysis dependency, compared with 15% to 25% dialysis dependency in historical controls.

About SeaStar Medical, Inc.
SeaStar Medical is a medical technology company focusing on 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 extracorporeal therapies that target the effector cells that drive systemic inflammation, causing direct tissue damage and secreting a range of proinflammatory cytokines that initiate and propagate imbalanced immune responses. For more information visit www.seastarmedical.com or visit us on LinkedIn or Twitter.

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 timing of regulatory approval of its products, the expected timing on enrollment, generation of study results, submission of PMA and other corporate milestones, the ability of SCD to treat patients with AKI, and the potential benefits of SCD to treat other diseases. 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 inability to recognize the anticipated benefits of the business combination with LMAO, which may be affected by, among other things, competition and the ability of the post-combination company to grow and manage growth profitability and retain its key employees, (ii) costs related to the business combination, (iii) the outcome of any legal proceedings that may be instituted against SeaStar Medical following the business combination, (iv) the ability to maintain the listing of its securities on NASDAQ, (v) the ability to implement business plans, forecasts, and other expectations after the completion of the business combination, and identify and realize additional opportunities, (vi) the risk of downturns and the possibility of rapid change in the highly competitive industry in which SeaStar Medical operates, (vii) 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, (viii) the risk that SeaStar Medical may never achieve or sustain profitability; (ix) the risk that SeaStar Medical may need to raise additional capital to execute its business plan, which may not be available on acceptable terms or at all; (x) the risk that third-parties suppliers and manufacturers are not able to fully and timely meet their obligations, (xi) the risk of product liability or regulatory lawsuits or proceedings relating to SeaStar Medical's products and services, (xii) the risk that SeaStar Medical is unable to secure or protect its intellectual property, and (xiii) other risks and uncertainties indicated from time to time in SeaStar Medical's registration statement on Form S-4, as amended (File No. 333-264993), 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 assume 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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