SeaStar Medical Updates Subject Enrollment in its Pivotal Trial with the Selective Cytopheretic Device in Adults with Acute Kidney Injury

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DENVER, Dec. 28, 2023 (GLOBE NEWSWIRE) -- SeaStar Medical Holding Corporation (Nasdaq: ICU), a medical device company developing proprietary solutions to reduce the consequences of hyperinflammation on vital organs, announces enrollment of 12 subjects in the NEUTRALIZE-AKI pivotal clinical trial evaluating the safety and efficacy of its patented, first-in-class, cell-directed Selective Cytopheretic Device (SCD) extracorporeal therapy in critically ill adults with acute kidney injury (AKI) requiring continuous kidney replacement therapy (CKRT).

“Over the past six weeks we have enrolled five subjects in this clinical trial while also continuing progress in activating additional clinical sites,” said Kevin Chung, MD, Chief Medical Officer of SeaStar Medical. “We are grateful to the dedicated investigators and their research staff who are working diligently to help validate the efficacy and safety of the SCD in this vulnerable population.”

“We look forward to providing periodic updates on patient enrollment and site activations as this important trial progresses,” said Eric Schlorff, CEO of SeaStar Medical. “We believe the more than 200,000 U.S. adult patients each year with AKI who require CKRT deserve a better treatment option. To that end, we are committed to advancing our pivotal clinical trial with the goal of saving lives and improving quality of life by eliminating dialysis dependency through renal recovery.”

SeaStar Medical expects to receive U.S. Food & Drug Administration (FDA) approval for its SCD Pediatric (SCD-PED) under a Humanitarian Device Exemption (HDE) for use in children weighing 10 kilograms or more with AKI and sepsis or a septic condition requiring continuous CKRT anytime within the next 30 to 45 days and to commence commercialization of the SCD-PED in Q1 2024.

About the NEUTRALIZE-AKI Pivotal Trial
The 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) pivotal trial is expected to enroll up to 200 patients. The trial’s primary endpoint is a composite of 90-day mortality or dialysis dependency of patients treated with SCD in addition to CKRT as the standard of care, compared with the control group receiving only CKRT 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 SCD therapy in AKI patients with sepsis and acute respiratory distress syndrome. More information is available here.

About Hyperinflammation
Hyperinflammation is the overproduction or overactivity of inflammatory cells that can lead to damage of vital organs. It occurs when the body overproduces inflammatory effector cells and other molecules that can be toxic, damaging to vital organs and result in multi-organ failure and even death. This is known as the cytokine storm. Unlike pathogen removal and other blood-purification tools, the SCD selectively targets the most highly activated proinflammatory neutrophils and monocytes. The Company has observed that these most highly activated immune cells are turned off in a low calcium environment. The SCD therapy mimics nature by creating a unique micro-environment, attracting these highly activated effector cells and neutralizing them in such an environment. These cells are then returned back into the body through the blood, and the body is signaled to focus on repair.

About SeaStar Medical
SeaStar Medical is a 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 https://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 ability of SCD to treat patients with AKI and other diseases; the expected regulatory approval process and timeline for commercialization; and anticipated enrollment progress. 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 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, including the equity line of credit and forward purchase 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 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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