Record Monthly Enrollment Achieved in SeaStar Medical's Pivotal Adult AKI Trial

November 1, 2024

DENVER, Nov. 01, 2024 (GLOBE NEWSWIRE) -- SeaStar Medical Holding Corporation (Nasdaq: ICU), a commercial-stage medical device company developing proprietary solutions to reduce the consequences of hyperinflammation on vital organs, reports setting a new monthly enrollment record with 10 critically ill acute kidney injury (AKI) patients added to the NEUTRALIZE-AKI pivotal trial during the past month, bringing total enrollment to 56. This trial is evaluating the safety and efficacy of the Company's proprietary therapeutic Selective Cytopheretic Device (SCD) in adults with AKI in the intensive care unit (ICU) receiving continuous renal replacement therapy (CRRT).

"The pace of enrollment in our NEUTRALIZE-AKI trial has quickly accelerated, with 14 new subjects enrolled in slightly more than six weeks," said Kevin Chung, MD, Chief Medical Officer of SeaStar Medical. "With three new clinical sites joining our trial in October and more due to be activated by December, we are optimistic that this pace will continue and likely even increase."

"A total of 12 clinical sites are now activated and we are optimistic about enrollment continuing at a rapid pace," said Eric Schlorff, SeaStar Medical CEO. "Last month another prestigious teaching hospital and two premier military medical facilities opened for enrollment, which is in keeping with our strategy of clinical site selection. Critically ill patients with AKI are admitted to all types of facilities, whether top research institutions, community hospitals or government facilities. The range of institutions participating in the NEUTRALIZE-AKI trial demonstrates the ease with which our potentially lifesaving SCD can be incorporated into standard hemofiltration equipment, and helps set the stage for future commercialization. Our goal is to maximize access to the approximate 210,000 patients with AKI in the U.S. each year who may benefit from our device, regardless of where they are treated."

SeaStar Medical's SCD previously received U.S. Food and Drug Administration (FDA) Breakthrough Device Designation for adults with AKI, which is awarded to a therapy to treat a serious or life-threatening condition with preliminary clinical evidence indicating it may demonstrate substantial improvement over available therapies on clinically significant endpoints. In July 2024, the Centers for Medicare & Medicaid Services granted Category B coverage for certain expenses incurred by medical centers when treating Medicare or Medicaid patients enrolled in NEUTRALIZE-AKI.

NEUTRALIZE-AKI Pivotal Trial

The NEUTRALIZE-AKI (**NEUTR**ophil and monocyte de**A**ctivation via Se**L**ective Cytopheretic Device – a random**IZE**d clinical trial in Acute Kidney Injury) is expected to enroll up to 200 adults. The trial's primary endpoint is a composite of 90-day mortality or dialysis dependency of patients treated with SCD in addition to CRRT as the standard of care, compared with the control group receiving only CRRT standard of care. The Company is targeting enrollment of 100 subjects for performing an interim analysis on the trial's 90-day primary endpoint. 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.

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 chronic kidney disease or end-stage renal disease requiring dialysis, among other complications. 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 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 RRT, including dialysis.

The SCD has been awarded U.S. Food and Drug Administration (FDA) Breakthrough Therapy Designation in three indications:

- Cardiorenal Syndrome – Left Ventricular Assist Device (CRS-LVAD)
- Adult Acute Kidney Injury (AKI)
- Hepatorenal Syndrome (HRS)

QUELIMMUNE ™, the SCD-Pediatric device, is being commercialized following FDA approval for children with AKI and sepsis or septic condition weighing 10 kilograms or more who are being treated in the ICU with RRT. QUELIMMUNE was approved in February 2024 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.

About SeaStar Medical

SeaStar Medical is a commercial-stage 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 1955. These forward-looking statements include, without limitation, the ability of SCD to treat patients with AKI and other diseases; anticipated patient enrollment and the expansion of the clinical trial sites; the anticipated Medicare and Medicaid reimbursement by CMS for patients enrolled in clinical trials; 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 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.

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