SeaStar Medical Provides Regulatory Update Related to its HDE Application for Pediatric Selective Cytopheretic Device

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DENVER, May 09, 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 that it has received a letter from the Center for Biologics Evaluation and Research (CBER) of the U.S. Food and Drug Administration (FDA) regarding the Company's Humanitarian Device Exemption (HDE) application for its pediatric Selective Cytopheretic Device (SCD), which is designed to treat critically ill children with acute kidney injury (AKI) on continuous kidney replacement therapy (CKRT). In the letter, the FDA indicated that the application is not approvable in its current form but outlined specific guidance as to how the application may be amended and resubmitted successfully.

"We are disappointed by the FDA's decision not to approve our HDE application at this time. After a series of collaborative meetings and correspondence over the past 10 months, and repeatedly being responsive to the Agency's recommendations, this determination is surprising," said Eric Schlorff, SeaStar Medical CEO. "My heart goes out to the critically ill children and their families who could have benefited from immediate access to the SCD. Only about one-half of children in the ICU with AKI requiring CKRT survive, and those who do are at risk of long-term life-threatening conditions, such as chronic kidney disease.

"We believe that each of the current deficiencies cited by the Agency in their letter are readily addressable. However, we intend to initially request FDA's administrative review and submit an appeal if needed. In parallel, we plan to implement other mitigations, where appropriate, and continue working with CBER with the goal of achieving pediatric HDE approval," he added.

The Agency's decision letter on the pediatric HDE does not affect the Company's pivotal clinical trial with the SCD in adults with AKI, which is currently underway.

About the Selective Cytopheretic Device
The Selective Cytopheretic Device (SCD) is a medical device that employs immunomodulating technology to selectively target pro-inflammatory neutrophils and monocytes during CKRT and remove the cytokine storm that causes inflammation, organ failure and possible death in critically ill patients. Unlike pathogen removal and other blood-purification tools, the device works with hemofiltration systems to enable precise fluid and solute balance control to selectively target and transition pro-inflammatory monocytes to reparative and promote activated neutrophils to be less inflammatory. SCD selectively targets the most highly activated proinflammatory neutrophils and monocytes. These cells are then returned back into the body through the blood, and the body is signaled to focus on repair. This unique immunomodulation approach may reverse injury and eliminate the need for CKRT going forward.

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 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, the FDA letter and SeaStar's intent to pursue appeal options and other actions in response to such letter; the ability of SeaStar to address deficiencies raised by the FDA; the ability of SCD to treat pediatric 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 risk that SeaStar may not be able to obtain regulatory approval of its SCD product candidates; (ii) the risk that SeaStar 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, (xiii) the risk that SeaStar Medical is unable to secure or protect its intellectual property, and (xi) 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. (iii) 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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