FDA Issues Approvable Letter for SeaStar Medical's Selective Cytopheretic Device for Pediatric Patients

October 30, 2023

DENVER, Oct. 30, 2023 (GLOBE NEWSWIRE) -- SeaStar Medical Holding Corporation (Nasdaq: ICU), a medical device company developing proprietary solutions to reduce the consequences of dysregulated immune responses including hyperinflammation on vital organs, announces that the U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) has issued an Approvable Letter for the company's proprietary Selective Cytopheretic Device Pediatric (SCD-PED) for use in children weighing 10 kilograms or more with acute kidney injury (AKI) and sepsis or a septic condition requiring continuous kidney replacement therapy (CKRT) in the hospital intensive care unit (ICU). As announced in early October 2023, SeaStar Medical expected the FDA to issue this approvable letter within a month of such announcement.

The issuance by the FDA of an Approvable Letter is a standard step in the approval process of a Humanitarian Device Exemption (HDE) application. The Approvable Letter indicates that SeaStar Medical's HDE application substantially meets the requirements for an Approval Order and outlines remaining administrative steps that must be finalized before the HDE can be active for commercialization. For the SCD-PED, these include revisions to product labeling and minor modifications to the post-approval study plan. SeaStar Medical intends to work diligently with the FDA to complete these action items in the coming weeks and expects to commence commercialization of the SCD by the end of 2023 or the first quarter of 2024.

"Receipt of this Approvable Letter is a major accomplishment indicating that the FDA supports our application and acknowledges the potential of our device to save lives and eliminate dialysis dependency in critically ill children with AKI and sepsis," said Kevin Chung, MD, Chief Medical Officer of SeaStar Medical. "We intend to work closely with the FDA to complete the final steps outlined in the Letter and anticipate the much-needed availability of the product in pediatric intensive care units by early next year."

"We are well on our way to commercializing SeaStar Medical's Selective Cytopheretic Device (SCD) in the first of what we believe will be multiple high-value indications where dysregulated inflammation plays a role," said Eric Schlorff, SeaStar Medical Chief Executive Officer. "Our pivotal trial in critically ill adults with AKI is progressing well with the goal of the SCD becoming the standard of care for AKI in the ICU. In addition to adult AKI, we have recently received Breakthrough Device Designations for the SCD in both cardiorenal syndrome and hepatorenal syndrome, which should expedite the clinical development and regulatory review of the SCD for use in these indications."

The SCD is a patented, cell-directed, extracorporeal device designed to be used as an adjunct therapy that selectively targets and transitions pro-inflammatory monocytes to promote reparative processes and reduce the acute inflammatory and damaging effects of activated neutrophils. Pooled analysis from two non-controlled studies, SCD-PED-01 (funded by the FDA Office of Orphan Products Development) and SCD-PED-02 showed that pediatric patients ≥10kg with AKI requiring CKRT treated with the SCD had no device-related serious adverse events or infections, a 77% reduction in mortality rate, and no dialysis dependency at Day 60. The SCD-PED-01 (weight range ≥15 kg) and PED-02 (weight range ≥10 kg) studies demonstrated 75% and 83% reductions in mortality, respectively.

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 can result in multi-organ failure and even death. This is known as the cytokine storm.

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 disrupt 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 pro-inflammatory 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, 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 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 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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