SeaStar Medical Provides Regulatory Update Regarding Selective Cytopheretic Device Use in Pediatric Acute Kidney Injury Under a Humanitarian Device Exemption

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Com pany to finalize labeling with FDA Approv able Letter expected within a month

DENVER, Oct. 03, 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 receipt of a correspondence from the U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) indicating that the Agency considers the Selective Cytopheretic Device (SCD) Pediatric (SCD-PED) to be approvable under a Humanitarian Device Exemption (HDE) 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).

The correspondence further indicates that an Approvable Letter, which is a standard part of CBER's approval process, is expected to be issued within a month. The Approvable Letter will outline conditions, including language for safety, probable benefit and labeling for intended use, which will be required for formal marketing approval.

"The correspondence provides a clear path forward in making this much needed therapy accessible to critically ill children suffering with AKI and sepsis," said Eric Schlorff, SeaStar Medical CEO. "Only about half of the children in the ICU with AKI requiring CKRT survive and those who do are at increased risk of long-term conditions such as chronic kidney disease. We understand the agency's appropriate caution in these medically fragile septic patients whose care requires significant resources, and we appreciate the agency's willingness to work collaboratively with SeaStar Medical and our advisors to review the HDE application, as well as its recognition of SCD as a therapy with probable benefit for these children. This is an important milestone for SeaStar Medical, and we intend to follow the regulatory path laid out by the FDA to commercialize SCD for this indication by the end of 2023."

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. In the HDE regulatory approval process of SCD-PED for children with AKI and sepsis, the FDA considered clinical results showing safety and probable clinical benefit to these patients who have few treatment options. 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. The Company believes the SCD could become the new standard of care for AKI patients requiring CKRT in the ICU and could also have significant benefit in additional indications where dysregulated immune processes are involved.

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.

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 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, SeaStar Medical's expectations with respect to the regulatory approval process for HDE; the anticipated timing for commercialization of SCD; and the benefits of SCD to treat acute kidney injury (AKI) and 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 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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