# SeaStar Medical Submits Investigational Device Exemption (IDE) Application to FDA to Study a Novel Therapy to Reduce Hyperinflammation in Adult Acute Kidney Injury Patients

January 9, 2023

*Building upon demonstrated clinical success, the pivotal study will evaluate the Selective Cytopheretic Device in adults with AKI requiring CKR T*

**DENVER, Jan. 09, 2023 (GLOBE NEWSWIRE) --** SeaStar Medical (Nasdaq: ICU), a medical technology company developing proprietary solutions to reduce the consequences of hyperinflammation on vital organs, has submitted an investigational device exemption (IDE) application to the U.S. Food and Drug Administration (FDA) requesting approval to initiate a pivotal study to evaluate the effectiveness of the Company's Selective Cytopheretic Device (SCD) in reducing hyperinflammation in adults with acute kidney injury (AKI) requiring continuous kidney replacement therapy (CKRT).

The randomized, controlled study is expected to enroll 200 subjects, with a primary endpoint of a composite of 90-day mortality and dialysis dependency of SCD patients compared to the control group. Details of the study design will be provided upon IDE approval by the FDA. The study is anticipated to begin in the first quarter of 2023 with interim results expected in the fourth quarter of 2023 and topline results and submission for Pre-market Approval (PMA) in the third quarter of 2024.

"We are pleased to take this important step in our journey towards creating the new standard of care in reducing harmful hyperinflammation. The FDA has demonstrated continued support in the SCD in granting breakthrough therapy status in adults and a substantive review of a Humanitarian Device Exemption (HDE) for pediatric AKI patients," said Eric Schlorff, Chief Executive Officer of SeaStar Medical. "Now we aim to prove efficacy and attractive health care economics when the therapy is used to treat adults with AKI."

The SCD, the company's innovative platform therapy, is a patented cell-directed extracorporeal therapy that selectively targets the most activated pro-inflammatory neutrophils and monocytes to stop the cytokine storm that causes organ failure and possible death in critically ill patients. The therapy currently is delivered through continuous CKRT to target and neutralize pro-inflammatory neutrophils and monocytes allowing the body to return to homeostasis. The SCD received Breakthrough Device Designation by the FDA in May 2022.

Approximately 6 million cases of adult AKI are diagnosed annually in the U.S. The SCD has demonstrated success in critically ill adult patients with AKI requiring CKRT, a condition with a high mortality rate. In the Company's previously completed pilot SCD 005 clinical study evaluating the safety and feasibility of the SCD in COVID-19 patients with AKI and/or acute respiratory distress syndrome (ARDS), patients experienced reductions in activated neutrophils and monocytes, which led to reduction in proinflammatory cytokines and improved clinical outcomes. Based on the per-protocol minimum of four days of therapy, the mortality of treated patients was significantly lower (41%) than the contemporaneous control population that was treated under the current standard of care (81%). All patients received CKRT as the delivery vehicle for the therapy.

"Filing of this IDE represents the rigorous first step toward our goal of delivering this life-saving therapy to the hands of the adult nephrology and critical care community and we look forward to the FDA's feedback and to launching the study," said Kevin Chung, MD, Chief Medical Officer of SeaStar Medical. "We have been in active discussions with numerous leading U.S. institutions who have expressed interest in participating in the study. We are eager to get enrollment initiated as soon as possible."

In July 2022, SeaStar Medical announced it has submitted its application to the FDA for Humanitarian Device Exemption (HDE) for use of the Selective Cytopheretic Device (SCD) for critically ill children with AKI. The HDE application submission to the FDA was based on findings from SeaStar Medical's Pilot Study (NCT02820350) of pediatric patients with AKI which demonstrated that the SCD was safe for use in pediatric patients. The Company expects the FDA to complete its substantiative review of the HDE in the first quarter of 2023, with a commercial launch in the second quarter of 2023.

**About SeaStar Medical, Inc.**

SeaStar Medical is a medical technology company focusing on 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 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**.

**SeaStar Medical 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 timing of regulatory approval of its products and other corporate milestones, the ability of SCD to treat 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 inability to recognize the anticipated benefits of the business combination with LMAO, which may be affected by, among other things, competition and the ability of the post-combination company to grow and manage growth profitability and retain its key employees, (ii) costs related to the business combination, (iii) the outcome of any legal proceedings that may be instituted against SeaStar Medical following the business combination, (iv) the ability to maintain the listing of its securities on NASDAQ, (v) the ability to implement business plans, forecasts, and other expectations after the completion of the business combination, and identify and realize additional opportunities, (vi) the risk of downturns and the possibility of rapid change in the highly competitive industry in which SeaStar Medical operates, (vii) 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, (viii) the risk that SeaStar Medical may never achieve or sustain profitability; (ix) the risk that SeaStar Medical may need to raise additional capital to execute its business plan, which may not be available on acceptable terms or at all; (x) the risk that third-parties suppliers and manufacturers are not able to fully and timely meet their obligations, (xi) the risk of product liability or regulatory lawsuits or proceedings relating to SeaStar Medical's products and services, (xii) the risk that SeaStar Medical is unable to secure or protect its intellectual property, and (xiii) other risks and uncertainties indicated from time to time in SeaStar Medical's registration statement on Form S-4, as amended (File No. 333-264993), 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.

Media:
PSC Consulting
Patty Caballero
(973) 348-5055
**patty@pscconsulting.net**

Investors:
LHA Investor Relations
Jody Cain
(310) 691-7100
**Jcain@lhai.com**

# # #

Source: SeaStar Medical Holding Corporation