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DENVER, CO (April 8, 2025) – SeaStar Medical Holding Corporation (Nasdaq: ICU), a commercial-stage healthcare company focused on transforming treatments for critically ill patients facing organ failure and potential loss of life, announced today that the U.S. Food and Drug Administration (FDA) has granted SeaStar Medical two new Breakthrough Device Designations for its Selective Cytopheretic Device (SCD) therapy. The two new Breakthrough Device Designations are indicated for the treatment of systemic inflammatory response in 1) adult patients undergoing cardiac surgery and 2) pediatric patients undergoing cardiac surgery towards prevention of post-operative adverse complications and outcomes. Approximately 15 percent of the estimated 300,000 adults that undergo cardiac surgery each year are considered high risk and, we believe, could benefit most from the SCD therapy to prevent post-surgical complications. Of the 40,000 pediatric patients that undergo congenital heart surgery each year, we believe that approximately one third might benefit from SCD therapy.

“These two new Breakthrough Device Designations bring our total to six, underscoring the importance and critical need for a therapy that can effectively treat hyperinflammation that destroys organs and takes far too many lives each year,” stated Eric Schlorff, SeaStar Medical CEO. “These new indications add to our growing pipeline of product candidates and extend further our total market opportunity. With our first commercial product, QUELIMMUNE, in the initial launch phase and the PMA filing in 2026 that would follow a successful NEUTRALIZE-AKI trial, we believe we are executing on our strategic commercial plans to effectively address severely underserved markets with our first-in-class SCD therapy.

Kevin Chung, MD, Chief Medical Officer of SeaStar, stated, “Cardiopulmonary bypass (CPB) during heart surgery has long been associated with hyperinflammation with downstream clinical complications that impact multiple organs such as the kidneys, heart, brain, and lungs, among others. It is most unfortunate for someone to undergo lifesaving surgery, only to succumb to the consequences of uncontrolled inflammation. We believe the SCD therapy can optimize conditions to allow for a successful recovery after this type of surgery.”

SeaStar Medical is currently commercializing its first SCD therapy, QUELIMMUNE, under a Humanitarian Device Exemption for the treatment of critically ill pediatric patients with acute kidney injury (AKI) due to sepsis or a septic condition. It plans to expand its proprietary SCD therapy into the broader adult patient population. The company is conducting a pivotal clinical trial, NEUTRALIZE-AKI, in adult patients with AKI and is also conducting an investigational study in patients with cardiorenal syndrome awaiting left ventricular assist device (LVAD) implantation. Both indications have been granted Breakthrough Device Designation by FDA.

The Breakthrough Device Designation is designed to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions and provides timely access to medical devices by speeding up development, assessment, and review for FDA approval. The designation is rare. According to the FDA, just over 1000 Breakthrough Device Designations were granted by the FDA and only 12 Breakthrough Device Designations were granted by the Center for Biologic Evaluation and Research (CBER) between 2015 and September 2024. SeaStar Medical’s six Breakthrough Device Designations, including its first designation for a pediatric indication, were granted by CBER between April 2022 and March 2025 and include treatment of the following conditions:

- Adult AKI

- Systemic inflammatory response in adult cardiac surgery
- Systemic inflammatory response in pediatric cardiac surgery to prevent post-operative adverse complications and outcomes
- Adult cardiorenal syndrome awaiting LVAD implantation
- End-stage renal disease (ESRD) requiring chronic dialysis
- Adult hepatorenal Syndrome (HRS)

About the FDA's Breakthrough Device Designation

FDA grants Breakthrough Device Designation when a device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions. It must also represent one or more of the following: a) a breakthrough technology, b) a therapeutic treatment where no approved or cleared alternatives exist, c) offer significant advantages over existing approved or cleared alternative, and/or d) the device availability is in the best interest of patients. The Breakthrough Device Designation is designed to provide timely access to medical devices to speed up development, assessment, and review for FDA approval.

About the SeaStar Medical Selective Cytopheretic Device Therapy

The Selective Cytopheretic Device (SCD) is a patented cell-directed extracorporeal device that employs immunomodulating technology to selectively target proinflammatory neutrophils and monocytes during continuous renal replacement therapy (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.

About SeaStar Medical

SeaStar Medical is a commercial-stage healthcare company focused on transforming treatments for critically ill patients facing organ failure and potential loss of life. SeaStar's first commercial product, QUELIMMUNE (SCD-PED), was approved in 2024 by the U.S. Food and Drug Administration (FDA). It is the only FDA approved product for the ultra-rare condition of life-threatening acute kidney injury (AKI) due to sepsis or a septic condition in critically ill pediatric patients. SeaStar Medical's Selective Cytopheretic Device (SCD) therapy has been awarded Breakthrough Device Designation for six therapeutic indications by the FDA, enabling the potential for a speedier pathway to approval and preferable reimbursement dynamics at commercial launch. The company is currently conducting a pivotal trial of its SCD therapy in adult patients with AKI requiring continuous renal replacement therapy, a life-threatening condition with no effective treatment options that impacts over 200,000 adults in the U.S. annually.

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 anticipated patient benefits from our products; the expected regulatory approval process and timeline for our products; 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 secure additional financing on acceptable terms; (vi) the risk that third-party 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 do not intend to update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise.

For more information visit www.seastarmedical.com or visit us on LinkedIn or X.

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