SeaStar Medical Reaches Milestone of 100th QUELIMMUNE Commercial Device as Shipments Begin to its Third Hospital Customer

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DENVER, Nov. 15, 2024 (GLOBE NEWSWIRE) -- SeaStar Medical Holding Corporation (Nasdaq: ICU), a commercial-stage medical device company developing proprietary solutions to reduce the consequences of hyperinflammation on vital organs, has begun shipping QUELIMMUNE ™ to a third hospital customer. QUELIMMUNE is the Company's Selective Cytopheretic Device (SCD) for treating critically ill children in the intensive care unit (ICU) with acute kidney injury (AKI) and sepsis.

"Within weeks of implementing our direct sales model we have added two commercial customers, underscoring our team's ability to assist hospitals with the Humanitarian Use Device (HUD) requirements and seamlessly fulfill their orders," said Tim Varacek, SeaStar Medical Senior Vice President, Commercial & Business Operations. "We are delighted that QUELIMMUNE is now available to more children who may benefit from our potentially lifesaving therapeutic device as we continue efforts to secure additional hospital clearances. Our recent progress puts us on track for our goal of having QUELIMMUNE commercially available in the ICUs of four to five leading pediatric hospitals by the end of 2024."

"Demand for QUELIMMUNE has been impressive as we've now shipped more than 100 disposable therapeutic devices since our commercial launch in July," said Eric Schlorff, SeaStar Medical CEO. "We are supporting further adoption with data presented at Kidney Week 2024 showing the projected cost savings to hospitals treating these critically ill children, principally driven by the lower expected death rate and shorter length of hospital stay versus standard of care."

QUELIMMUNE

QUELIMMUNE is SeaStar Medicals' Selective Cytopheretic Device (SCD-PED) approved for the treatment of patients weighing 10 kilograms or more with AKI and sepsis or a septic condition on antibiotic therapy and requiring renal replacement therapy (RRT). QUELIMMUNE was granted U.S. Food and Drug Administration (FDA) approval under a Humanitarian Device Exemption (HDE) requiring hospitals to meet HUD requirements for commercial use. QUELIMMUNE is required to gain institutional review board (IRB) approval from each hospital, with IRBs signing off on the protocol for using the device within their facility as well as additional hospital clearances, training of critical care teams on integrating the QUELIMMUNE device into existing hemodialysis equipment and a patient registry.

QUELIMMUNE consists of an SCD-PED cartridge and blood tubing set that are connected in-line to an existing hemodialysis delivery system's extracorporeal continuous renal replacement therapy (CRRT) circuit in a process that takes about 15 minutes. The Company expects that, on average, a full course of treatment for children with AKI will require three to seven days, with the disposable SCD-PED cartridge being replaced every 24 hours.

Acute Kidney Injury (AKI) and Hyperinflammation

AKI is characterized by a sudden and temporary loss of kidney function and can be caused by a variety of conditions such as COVID-19, sepsis, severe trauma and surgery. AKI can cause hyperinflammation, which is the overproduction or overactivity of inflammatory effector cells and other molecules that can be toxic. Damage resulting from hyperinflammation in AKI can progress to other organs, such as the heart or liver, and potentially to multi-organ dysfunction or even failure that could result in worse outcomes, including increased risk of death. Even after resolution, these patients may face chronic kidney disease or end-stage renal disease requiring dialysis, among other complications. Hyperinflammation may also contribute to added healthcare costs, such as prolonged ICU stays and increased reliance on dialysis and mechanical ventilation.

Selective Cytopheretic Device (SCD)

QUELIMMUNE is the brand name of SeaStar Medical's SCD-PED. It was approved in February 2024 under an HDE application, having met the applicable criteria with clinical results showing safety and probable clinical benefit in a limited patient population who have few treatment options. The SCD is a patented cell-directed extracorporeal device that employs immunomodulating technology to selectively target proinflammatory neutrophils and monocytes during CRRT. 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.

SeaStar Medical is conducting the NEUTRALIZE-AKI pivotal trial to evaluate the safety and effectiveness of its SCD in the larger patient population of adults with AKI in the ICU receiving CRRT. The SCD-ADULT device has received FDA Breakthrough Device Designation for this indication, which is awarded to a therapy to treat a serious or life-threatening condition with preliminary clinical evidence indicating it may demonstrate substantial improvement over available therapies on clinically significant endpoints. The

Company is exploring the SCD's application across a range of acute and chronic indications involving dysregulated immune processes where proinflammatory activated neutrophils and monocytes may contribute to disease progression or severity.

About SeaStar Medical

SeaStar Medical is a commercial-stage 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 X.

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 amount and timing of future QUELIMMUNE commercial sales; the ability of SeaStar Medical to add additional new customers, including the ability to make QUELIMMUNE commercially available in the ICUs of four to five leading pediatric hospitals by the end of 2024; the ability of SeaStar Medical to meet the demand for and the revenue recognition on QUELIMMUNE commercial sales; commercial acceptance and availability of QUELIMMUNE; the benefits of QUELIMMUNE to providers and patients, including projected cost savings; the ability of SCD to treat patients with AKI and other diseases, including lower projected death rates and shorter lengths of hospital stays; 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 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 access funding under existing 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 assumes no obligation and does 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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