FDA Grants Humanitarian Device Exemption Approval to SeaStar Medical's Selective Cytopheretic Device for Pediatric Acute Kidney Injury

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SCD-PED (Pediatric) is the first FDA-approved product in the Company's Quelimmune ™ product family

DENVER, Feb. 22, 2024 (GLOBE NEWSWIRE) -- SeaStar Medical Holding Corporation (Nasdaq: ICU), a medical device company developing proprietary solutions to reduce the consequences of hyperinflammation on vital organs, announces that the U.S. Food and Drug Administration (FDA) has granted a Humanitarian Device Exemption (HDE) Approval Order to the Selective Cytopheretic Device (SCD) Pediatric (SCD-PED) for use in children weighing 10 kilograms or more with acute kidney injury (AKI) due to sepsis or a septic condition requiring kidney replacement therapy (KRT). This is the first product in the Company's newly branded Quelimmune product family, and the Quelimmune pediatric device can now be commercially marketed as a Humanitarian Use Device (HUD).

"This first regulatory approval is a major accomplishment for our company and, most importantly, it provides critically ill children with AKI access to a much-needed new therapy," said Eric Schlorff, SeaStar Medical CEO. "Only about one-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. In clinical studies, Quelimmune for pediatric AKI has been shown to reduce mortality rates and dialysis dependency in clinical studies.

"We appreciate the FDA's willingness to work collaboratively with SeaStar Medical and our advisors to grant HDE approval to Quelimmune for pediatric use," Mr. Schlorff added. "We believe the HDE for children weighing as little as 10 kilograms – or roughly 22 pounds – acknowledges the proven life-saving capabilities of our device and addresses a critical unmet need for patients. We are working to make Quelimmune therapy the new standard of care for AKI requiring CKRT in the ICU and to demonstrate its benefit in the many indications where hyperinflammation and dysregulated inflammatory processes are involved."

The initial commercial launch of Quelimmune for pediatric AKI is expected in the coming weeks by SeaStar Medical's U.S. license and distribution partner Nuwellis, with a full commercial program to follow. Nuwellis has established strong relationships with pediatric nephrology and intensive care key opinion leaders across the U.S.

"The unique technology behind Quelimmune has demonstrated great promise in making a positive impact on children with potentially deadly hyperinflammation," said Nestor Jaramillo, Jr., Nuwellis President and CEO. "The pediatric segment of our business has gained significant traction over the past several years, and we are excited to add the Quelimmune pediatric device to our product offering."

The FDA granted HDE approval to the Quelimmune pediatric device for AKI based upon clinical results showing safety and probable clinical benefit to critically ill children with AKI 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 Quelimmune pediatric device had no device-related serious adverse events or device-related 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. These data were recently published in the journal *Kidney Medicine*. SeaStar Medical is currently focused on its NEUTRALIZE-AKI pivotal clinical trial to evaluate Quelimmune therapy in the larger adult AKI population, while exploring other applications for this device.

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 Quelimmune
Quelimmune is a patented cell-directed extracorporeal device that employs immunomodulating technology to selectively target proinflammatory neutrophils and monocytes during CKRT and reduces the hyperinflammatory milieu including 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 is integrated with CKRT hemofiltration systems to selectively target and transition proinflammatory monocytes to a reparative state and promote activated neutrophils to be less inflammatory. Quelimmune 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 lower its inflammatory environment and focus on repair. This unique immunomodulation approach may promote long-term organ recovery and eliminate the need for future KRT, including dialysis.

About Nuwellis
Nuwellis, Inc. is a medical technology company dedicated to transforming the lives of patients suffering from fluid overload through science, collaboration, and innovation. The company is focused on commercializing the Aquadex SmartFlow® system for ultrafiltration therapy. Nuwellis is headquartered in Minneapolis, with a wholly owned subsidiary in Ireland. For more information, visit www.nuwellis.com or visit us on LinkedIn or X.

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 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 commercialization effort of Quelimmune, the SCD's ability to treat hyperinflammation, and the expected results of clinical trials. 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.

Contact:

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

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