



SeaStar Medical Ships First QUELIMMUNE Product Order to U.S. Distribution Partner

July 12, 2024

DENVER, July 12, 2024 (GLOBE NEWSWIRE) -- [SeaStar Medical Holding Corporation](#) (Nasdaq: ICU) (SeaStar Medical) reports the initial commercial sale of QUELIMMUNE™-Pediatric to its U.S. license and distribution partner, Nuwellis, Inc. QUELIMMUNE is SeaStar Medical's Selective Cytopheretic Device-Pediatric (SCD-PED), a patented cell-directed extracorporeal therapy that selectively targets the most highly activated neutrophils and monocytes responsible for hyperactive immune response. QUELIMMUNE is approved by the U.S. Food and Drug Administration (FDA) as a Humanitarian Use Device (HUD) under a Humanitarian Device Exemption (HDE) to treat pediatric acute kidney injury (AKI) in patients weighing 10 kilograms or greater with sepsis or a septic condition requiring kidney replacement therapy (KRT).

"It's highly gratifying to ship our first commercial QUELIMMUNE product order to Nuwellis for these patients," said Eric Schlorff, CEO of SeaStar Medical. "QUELIMMUNE is a best-in-class therapy that across two pediatric clinical studies has been shown to have a probable benefit of reducing mortality and decreasing dialysis dependency in these severely ill children. We expect prestigious pediatric hospitals to meet the HDE requirements this quarter, with a more robust commercial rollout in the fourth quarter of 2024."

QUELIMMUNE consists of a SCD-PED cartridge and blood tubing set that are connected in-line to an existing hemodialysis delivery system's extracorporeal continuous KRT 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 of treatment with the disposable SCD-PED cartridge being replaced every 24 hours.

Each year in the U.S., approximately 4,000 children with AKI require continuous KRT, with a mortality rate of approximately 50%. Many of those who survive experience long-term complications that can include chronic kidney disease and a lifetime of dialysis. Pooled analysis from two non-controlled studies, one of which was funded by the FDA office of Orphan Products Development, showed that children with AKI weighing 10 kilograms or more requiring continuous KRT treated with QUELIMMUNE had a 77% survival rate with no dialysis dependency at 60 days, and had no device-related serious adverse events or device-related infections.

SeaStar Medical is actively enrolling patients in the pivotal adult NEUTRALIZE-AKI clinical trial. The adult AKI population is 50 times greater than the pediatric population, which the Company believes represents a multibillion-dollar market opportunity.

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 (SCD)

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

About Nuwellis

Nuwellis, Inc. (Nasdaq: NUWE) 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 <http://www.nuwellis.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 1995. These forward-looking statements include, without limitation, SeaStar Medical’s expectations with respect to the amount and timing of future QUELIMMUNE commercial sales; commercial acceptance of QUELIMMUNE; the ability of SCD to treat patients with AKI and other diseases; 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 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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Source: SeaStar Medical Holding Corporation