SeaStar Medical to Initiate a Pilot Study of Selective Cytopheretic Device in COVID-19 patients with Acute Respiratory Distress Syndrome and Acute Kidney Injury

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DENVER, April 28, 2020 /PRNewswire/ -- SeaStar Medical, a medical device company focused on delivering novel immunomodulating medical device solutions to improve organ function, today announced it has received approval of their Investigational Device Exemption (IDE) supplement from the U.S. Food and Drug Administration (FDA) to initiate a feasibility, compassionate use study. The immunomodulating medical device, the Selective Cytopheretic Device (SCD), will focus on positive COVID-19 patients with acute respiratory distress syndrome (ARDS) or Acute Kidney Injury (AKI). The IDE supplement approval recognizes there is sufficient safety and efficacy data to permit clinicians to use the SCD to treat patients with COVID-19.

New evidence shows that many COVID-19 patients with ARDS are also developing AKI and require renal replacement therapy. An estimated 40 percent to 60 percent of COVID-19 patients in intensive care units (ICU) are experiencing kidney failure and may require dialysis. While some patients have pre-existing and underlying conditions that impact the kidneys, AKI is also often experienced by patients with no previous kidney illness. This is due to the excessive release of cytokines, small proinflammatory proteins released by cells to fight infection or injury. Overproduction of these proteins is known as the cytokine storm or cytokine distress syndrome and can cause excessive inflammation which can be toxic and lead to multi-organ failure. The study will evaluate the use of immunomodulating devices to reduce and repair kidney injury.

SeaStar's SCD next-generation immunomodulating device selectively targets proinflammatory neutrophils and monocytes during continuous renal replacement therapy (CRRT) to ameliorate and remove the cytokine storm that causes inflammation, organ failure and possible death in critically ill patients. The device works with hemofiltration systems to enable precise fluid and solute balance control to selectively target and transition proinflammatory monocytes to reparative and reduce activated neutrophils. This unique immunomodulation approach may reverse injury and eliminate the need for CRRT going forward.

"We believe the SCD is the first immunomodulating device in renal care that can quell the storm and normalize the immune system to help repair kidney injury and prevent organ failure. We have observed preliminary evidence of what the SCD can do for patients," said Eric Schlorff, CEO of SeaStar Medical. "We are working closely with leading medical centers and regulators to expedite this study to help COVID-19 patients and expect to share the results later this year."

Previous SCD clinical trial data has observed reduced mortality and zero dialysis dependency at day 60, normally in the range of 25 percent, in adult patients with AKI requiring CRRT.

In addition, a Phase II clinical trial to assess the safety and efficacy of the SCD in pediatric patients with acute kidney injury and multi-organ failure is underway. This unique study was funded by the FDA to help study the SCD for this rare condition in children where few therapeutic options are researched or available. Results of the pediatric study are expected later this year.

About the SCD (SCD-005) Study

The SCD pilot study will assess the clinical activity, safety and tolerability of SCD among patients who have ARDS prior to CRRT and/or AKI with CRRT. The study will target 35 adult subjects in up to 10 U.S. institutions. Key objectives of the study include reducing mortality rates and dialysis dependency and increasing ventilation free survival. Achieving these endpoints may lead to a reduction in ICU and hospitalization days.

The trial will be conducted in collaboration with EmpiriStat, a contract research and clinical trial management organization based in Kitty Hawk, N.C. EmpiriStat's rigorous methodologies and experience will be a significant factor in the rapid analysis dissemination of the clinical data.

About Acute Kidney Injury (AKI)

AKI is a sudden episode of kidney failure or kidney damage that can occur within a few hours or days. AKI causes a build-up of waste products in the blood and makes it harder for the kidneys to maintain the right balance of fluid in the body. Each year, approximately 1.7 million people die from acute kidney injury. Approximately 25 percent of AKI survivors develop chronic kidney disease, requiring lifetime dialysis. AKI can also affect other organs such as the brain, heart and lungs, leading to multi-organ failure.

About ARDS

ARDS is a respiratory failure that occurs when fluid builds up in the lungs. The fluid keeps lungs from filling with enough air,

depriving organs of the oxygen they need to function. This leads to multi-organ failure and fatality. ARDS typically occurs in people who are already critically ill or are hospitalized with other conditions. ARDS impacts an estimated 130,000 people per year. This does not include the increase anticipated this year with the prevalence of ARDS in COVID-19 patients.

About SeaStar Medical

Denver-based SeaStar Medical is a privately held medical device company that has redefined how extracorporeal therapies may reduce the consequences of excessive inflammation on vital organs through novel solutions and services. SeaStar's focus is on removing pro-inflammatory mediators, known as cytokines, or transforming key immune system messengers from pro inflammatory to reparative physiology. SeaStar's next generation technologies rely on science and innovation to build upon existing purification technologies to provide life-saving solutions to critically ill patients.

SeaStar's proprietary CLR 2.0 hemofilter has FDA 510(k) clearance for acute kidney injury, congestive heart failure and pulmonary edema. Many of the COVID-19 patients experience pulmonary edema as well as acute kidney injury, where the CLR 2.0 could help patients. CLR 2.0 has a CE Mark approval indicating it meets European market standard and ISO 13485:2016 certification of its quality management systems. For more information visit seastarmedical.com.

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