Treatment for Critically Ill COVID Patients Begins 1st Randomized Clinical Trial

Study to Investigate ExThera Medical Seraph® 100 Microbind® Affinity Blood Filter's Ability to Reduce ICU Length of Stay and Mortality Rate

MARTINEZ, Calif. – Physicians across the country are using ExThera Medical's Seraph® 100 Microbind® Affinity Blood Filter (Seraph 100) under emergency use authorization from the U.S. Food and Drug Administration to treat critically ill COVID patients resulting in statistically significant improvements in 63% survival rate among patients whose blood was filtered with the Seraph 100.

The first multicenter randomized controlled trial of the Seraph 100, which has successfully treated hundreds of COVID patients, will be studying the treatment's ability to reduce ICU length of stay, hospital duration and mortality in patients suffering from septic shock..

"The initial findings in our observational study for COVID patients have been very promising. This feasibility study will get us another step closer to helping assess whether or not this therapy has a role in the care of all septic patients, not just COVID," said **Col. Kevin K. Chung, MD, a leading critical care physician and PURIFY investigator.**

The study will evaluate the safety and efficacy of pathogen-removing extracorporeal blood purification therapy in critically ill patients with pathogen associated shock utilizing ExThera's Seraph 100. This trial is sponsored by the Henry M. Jackson Foundation for the Advancement of Military Medicine and is in collaboration with the Uniformed Services University (USU) of the Health Sciences. Interventional multicenter randomized controlled trials are rare in extracorporeal therapies and require robust signals of efficacy improvement as demonstrated in this case by the PURIFY OBS study.

"ExThera is proud to be saving lives during the COVID-19 pandemic under our FDA Emergency Use Authorization," said **ExThera Medical CEO Robert Ward**. "We are confident the this new trial will further the expansion of Seraph 100 use in the United States, not only in the treatment of COVID-19 patients, but also in sepsis caused by other viral, bacterial and fungal bloodstream infections."

Enrollment is slated to begin this Fall.

"The more we are able to study the Seraph 100 in a clinical setting will only help us reach more patients fighting COVID-19, which continues to be a concern across the United States," said **ExThera Medical Scientific Advisory Chair Lakhmir Chawla, MD**.

The study's primary outcome measures include the following:

1. Efficacy: ICU-free days in the first 28 days
    a. Alive and not in the ICU in the first 28 days from the time of randomization
2. Safety: Adverse Events
    a. SAEs and >/= grade 3 AEs per CTCAE v5 evaluated from enrollment until the end of hospitalization

The study's secondary outcome measures include the following: mortality evaluated in-hospital and at 28 days; ventilator free days in the first 28 days; vasopressor-free days in the first 28 days; kidney replacement therapy-free days in the first 28 days; hospital stay duration; and survival, 90 days after enrollment.

As this study will also serve as the investigational device exemption (IDE) research needed for Seraph 100's FDA approval, the first 10 patients enrolled will study additional parameters demonstrating avoidance of antibiotic adsorption as has been demonstrated in the past.

###

About ExThera Medical Corporation

ExThera Medical Corporation develops and commercializes extracorporeal blood filtration devices, including the Seraph® 100 Microbind® Affinity Blood Filter for removing a broad range of harmful substances from the bloodstream of patients. Seraph can be used in hospitals, clinics, or field hospitals to address infections caused by battlefield wounds or pandemics. ExThera Medical's extracorporeal products have demonstrated life-saving capabilities in a wide range of critically ill patients suffering from severe infections. With a growing body of outcome and health economic evidence from independent clinical studies, participation in the DARPA Dialysis-Like Therapeutics program, and from successful clinical use in the US and EU, the company is well positioned to serve healthcare professionals and patients alike. The Seraph 100 is CE marked and commercially available in the EU, and has FDA Emergency Use Authorization (EUA) for treatment of COVID-19 in the USA.

For more information visit the company's website at www.extheramedical.com

About Seraph 100

As a patient's blood flows through the Seraph 100 filter, it passes over beads with receptors that mimic the receptors on human cells that pathogens target when they invade the body. Harmful substances quickly captured and adsorbed onto the surface of the beads and are thereby removed from the bloodstream. Seraph targets the pathogens that cause the infection, while it also binds and removes harmful substances generated by the pathogen and by the body's response to the infection. Seraph's adsorption media (the beads) constitute a flexible platform that uses immobilized (chemically bonded) heparin for its well-established blood compatibility and its unique ability to bind bacteria, viruses, fungi, and important sepsis mediators reported to contribute to organ failure during sepsis. The 'antithrombogenic' heparin media can be combined with other ExThera-proprietary media to tailor the capability of future Seraph products for the treatment of specific diseases, or to further broaden Seraph's capability.

For more news stories on the Seraph 100 click here: https://www.extheramedical.com/news

Disclaimer

All information contained in this news release derives from plausible reliable sources, which, however, have not been independently examined. There is no warranty, confirmation or guarantee, and no responsibility or liability is taken concerning correctness or completeness. As far as it is allowed by the relevant law, no liability whatsoever is taken on for any direct or indirect loss caused by the deployment of this news release or its contents. This communication includes forward-looking statements regarding events, trends and business prospects that may affect our future operating results and financial position. Such statements are subject to risks and uncertainties that could cause our actual results and financial position to differ materially. The investment and/or the revenues that arise from it can rise or fall. A total loss is possible. Persons who are in possession of this news release are requested to obtain information concerning possible legal limitations and to observe them accordingly. We assume no responsibility to update or revise any forward-looking statements contained in this news release to reflect events, trends, or circumstances after the date of this news release.