Clinical Trial for Groundbreaking Device to Treat Septic Shock set to Begin

Conditional Investigational Device Exemption Granted by the FDA for Seraph 100
Seraph 100 used under FDA EUA to treat COVID-19

MARTINEZ, Calif. – ExThera Medical's Seraph® 100 Microbind® Affinity Blood Filter (Seraph 100), a blood purification device with many potential applications including the treatment of sepsis, will be studied in an upcoming randomized control trial. The endpoint of the trial is to determine the Seraph's effectiveness against a variety of bloodstream infections that can lead to sepsis**.** The Seraph 100 is the first blood purification device to be shown to reduce both bacterial and viral loads in the bloodstream and has been used on more than 300 US and EU patients with COVID-19 since April 2020. The device has been in use under an Emergency Use Authorization since that time and has been shown to dramatically reduce mortality in severe COVID-19 cases.

ExThera Medical, the manufacturer of the Seraph 100 has obtained conditional approval from the US FDA to conduct the multicenter study on the treatment of critically ill patients with potentially fatal pathogen-associated shock (PURIFY-RCT), a form of septic shock. The trial – the first US Randomized Control Trial to test this class of sepsis treatments – is part of the PURIFY program conducted in partnership with the Henry Jackson Foundation (HJF) for the Advancement of Military Medicine and Uniformed Services University of the Health Sciences (USUHS). The device has previously been tested successfully in partnership with the Department of Defense and the Defense Advanced Research Projects Agency (DARPA).

The study will evaluate the safety and efficacy of Seraph 100 blood purification therapy in critically ill patients with pathogen-associated shock across health centers in the United States. Approximately 15 US sites have been recruited, including both community and military hospitals.

"We are 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 that this new trial will help lead to the expansion of approved indications for Seraph 100 in the United States in life-threatening bloodstream infections beyond COVID-19."

"The innovations behind the Seraph 100 has brought a transformational treatment approach to the battle against severe COVID-19 cases in the United States. We are confident we can take the device beyond that narrow indication," **said Lakhmir Chawla, MD, Scientific Advisory Board Chair at ExThera Medical.** "The data behind the Seraph 100 is promising and we look forward to the opportunity to prove that the device can be effective in saving the lives of many more patients suffering from a wide variety of bloodstream infections."

The new study comes on the heels of preliminary observational data from PURIFY-OBS – the multicenter observational study of SERAPH 100 – showing very significant improvement in survival rates among critically-ill COVID-19 patients treated with the Seraph 100. The filter is currently available in the United States for the treatment of COVID-19 and in 'CE Mark countries' for the reduction of bloodborne pathogens during bloodstream infections.

ExThera Medical recently announced a European distribution partnership with Fresenius Medical Care, the world's leading provider of products and services for individuals with renal diseases. Click here for more information.

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.

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

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