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Amarex Client Now Enrolling Patients for a Blood Filtration Device Study Treating COVID-19 Patients Experiencing Septic Shock

Germantown, MD, USA (June 02, 2020) – In April, Amarex Clinical Research, LLC, an NSF International company, achieved rapid, supplemental Investigation Device Exemption (IDE) approval from the U.S. FDA, on behalf of its client, to treat COVID-19 patients experiencing septic shock under an already underway Phase III clinical trial of a blood filtration device.

Enrollment of COVID-19 patients into this trial was initiated immediately at study centers already conducting this trial with non-COVID-19 positive sepsis patients.

Dr. Kazem Kazempour, Amarex President and CEO, stated, “There is evidence from previous research that the use of this treatment in septic shock patients decreases ventilator dependency due to improved lung function. We are hopeful that with the approval of this IDE, that we can reduce the mortality rate of this pandemic.”

Amarex also helped their client to prepare, submit and achieve compassionate use approval for this device and several COVID-19 patients in the U.S. have already received treatment.

About Amarex Clinical Research, LLC, an NSF International company

Amarex Clinical Research, LLC, an NSF International company, is a global, full service Contract Research Organization (CRO), whose leadership team has significant expertise conducting biomedical research, and whose combined experience includes the design and conduct of several hundred clinical research projects in many therapeutic indications. Amarex provides comprehensive services in Project Management (Phase I-IV, BE/BA, PK/PD), Regulatory Affairs (FDA Applications and meetings, Applications to International Health Authorities, GxP Compliance Audits), Clinical Operations, Adaptive Study Designs, Statistical Analysis, Data Management, Medical Monitoring, Safety and Pharmacovigilance, and General Consulting. Amarex can take your product through the entire approval process, from creating the regulatory approval strategy, to conducting trials, to writing the marketing approval application. Join our growing list of clients with approved products. Amarex provides high quality and cost efficient services. For more information visit www.amarexcro.com.

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