



The apoA-I companY

Press Release

World Sepsis Day September 13, 2023

ABIONYX Pharma confirms its commitment to sepsis, a global public health issue

- Sepsis, the world's 3rd leading cause of death, is exacerbated by the spread of bacterial infections due to global warming and an aging population
- No effective treatment specific to sepsis is available to date
- ABIONYX's innovative approach restores apoA-1 protein levels in the human body to eliminate endotoxins, enabling patients to fight sepsis more effectively
- Positive clinical results from the Phase 2a RACERS study for the treatment of sepsis will be detailed in a scientific paper to be published by the end of 2023

Toulouse, FRANCE, Lakeland MI, USA, September 12, 2023, 8:00 p.m. CEST - ABIONYX Pharma, (FR0012616852 - ABNX - PEA PME eligible), a new generation biotech company dedicated to the discovery and development of innovative therapies based on the world's only natural recombinant apoA-1, reports on its commitment and strategic analysis for the development of its innovative breakthrough treatment on World Sepsis Day.

Sepsis, the world's 3rd leading cause of death, is exacerbated by the spread of bacterial infections due to global warming and an aging population

Sepsis is already the 3rd leading cause of death worldwide. Added to this are a number of factors that are likely to exacerbate the spread of sepsis in the years to come. It is widely recognized that bacterial infections will increase as a result of global warming. 2023 saw the accelerated development of potentially deadly bacteria which proliferate in the world's oceans as a result of warmer waters due to climate change, according to a study published in the journal Scientific Reports on March 23, 2023.

Current climatic trends are increasing the spread of drug-resistant infectious diseases. Intensive antimicrobial use worldwide is exacerbating this pattern of resistance. Combined with the aging of the world's population, which naturally weakens the human immune system, resistance to antibiotics an important adjunctive treatment for sepsis - will lead to an increase in sepsis cases worldwide. All in all, the number of fatal cases is set to double over the next fifty years, with nearly 14 million deaths a year in 2019 (The Lancet study, 2022).

No effective sepsis treatment option available to date

For over twenty years, and despite considerable progress in understanding the pathophysiology associated with sepsis, no new therapies specific to this disease have emerged. Patients with sepsis are generally admitted to intensive care units, where they receive antibiotics and life-support. However, with increasing antibiotic resistance (or AMR for AntiMicrobial Resistance), which renders one or more antibiotics ineffective against a bacterial infection, the phenomenon can lead to sepsis becoming untreatable.

A new approach, through the restoration of apoA-1 protein levels in the human body, to eliminate inflammation-causing endotoxins and enable patients to fight sepsis

ABIONYX Pharma is developing a new approach to the treatment of sepsis that goes beyond previous approaches. In fact, the Company is developing and producing a biological drug consisting of a recombinant replica of one of the most abundant natural proteins in human plasma, apoA-1. This protein enables the elimination of endotoxins, components of bacterial walls, which are responsible for the toxic effects triggered by severe bacterial infections.

In fact, when apoA-1 levels fall in the human body in fragile or weakened patients, the immune system is less able to naturally eliminate the endotoxins present following a bacterial infection. ABIONYX Pharma, the only biotech capable of developing and producing recombinant apoA-1, proposes to supplement and restore the human body's apoA-1 levels according to the patient's specific needs, so that endotoxins present in the body can be eliminated, allowing antibiotics to play their full role in destroying infected bacteria.

Positive clinical results in the 2a RACERS study for the treatment of sepsis, which will be detailed in a scientific paper to be published by the end of 2023

ABIONYX Pharma is developing a phospholipid-complexed recombinant apoA-1 called CER-001. The efficacy of this recombinant apoA-1 was demonstrated in a Phase 2a clinical trial, called RACERS, in septic patients at high risk of developing acute kidney injury.

The clinical results of RACERS, a study led by Professor Loreto Gesualdo and his research team from the Department of Nephrology at the University of Bari, Italy, demonstrate for the first time in a human trial that restoration of normal apoA-1 levels by CER-001 infusion induces a rapid and sustained reduction in endotoxin levels, as well as a consequent reduction in the inflammatory cascade caused by sepsis, compared with standard reference treatment alone. The reduction in the number of days spent in the intensive care unit for patients treated with the CER-001 biologic, and the improvement in thirty-day survival, will be detailed in figures in a publication in a scientific journal to be published by the end of 2023.

About sepsis/septicemia

Sepsis is the Anglo-Saxon and international term used to characterize a generalized inflammatory response associated with severe infection. The term septicemia, coined in 1837 by French physician Pierre Piorry from the Greek words "Σήψις" (sêptikós), putrefaction, and "αίμα" (haîma), blood, refers to the presence of bacteria (or even fungi or viruses) in the blood. Sepsis mainly affects already-weakened individuals, newborns and the elderly, but can also affect people with no prior ailment. Worldwide, an estimated 11 million people die each year from sepsis. Future projections suggest a doubling in the number of cases over the next fifty years, particularly as the population ages.

About RACERS

RACERS is a clinical trial named RACERS (a RAnomized study comparing short-term CER-001 infusions at different doses to prevent Sepsis-induced acute kidney injury) with CER-001 in septic patients at high risk of developing acute kidney injury.

Following the positive signals observed in the Temporary Authorization for Named Use (ATUn) in an ultra-rare kidney disease, the study assessed the role of CER-001, a novel, in preventing Acute Kidney Injury (AKI) in septic patients. The core component of the program is the launch of a 30-day Phase 2a clinical dose-finding trial with the Company's lead product candidate, CER-001, in the prevention of AKI in septic patients. Researchers have demonstrated that in humans, reconstituted HDLs have a scavenger role in reducing circulating endotoxin, as well as major anti-inflammatory and endothelial activity. These important effects were also demonstrated with CER-001 in a rigorous preclinical model of sepsis-induced AKI developed in collaboration with an Italian Veterinarian Hospital (Surgical Section, Chief: Prof. Antonio Crovace). Several other AKI/sepsis models showed that HDL is a critical factor in modifying the disease.

This clinical study, designed in concert with expert Italian nephrologists (Nephrology, Dialysis and Transplantation Unit, Chief: Prof. Loreto Gesualdo) and intensivists (Anesthesiology and Resuscitation Unit, Chief: Prof. Salvatore Grasso), was a randomized, open labelled, placebo-controlled, parallel-group study evaluating the safety and efficacy of intravenously administered CER-001 in patients with sepsis at high risk for AKI based on their endotoxin levels and Sequential Organ Failure Assessment (SOFA score). A total of 20 patients were randomized to receive 8 doses of CER-001 over 6 days on top of standard of care, or standard of care alone. The primary endpoint of the study was the onset and severity of AKI according to KDIGO criteria as well as safety and tolerability of the dosage regimens in order to select the optimal dose of CER-001.

The clinical study was partnered with the University of Bari.

About ABIONYX Pharma

ABIONYX Pharma is a new generation biotech company that aims to contribute to health through innovative therapies in indications where there is no effective or existing treatment, even the rarest ones. Thanks to its partners in research, medicine, biopharmaceuticals and shareholding, the company innovates on a daily basis to propose drugs for the treatment of renal and ophthalmological diseases, or new HDL vectors used for targeted drug delivery.

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