



The apoA-I company

Press Release

ABIONYX Pharma has completed a successful pre-IND meeting with the FDA for CER-001 Phase 2b/3 Clinical Trial for Patients with Sepsis

- **Based on encouraging Phase 2a data and a productive pre-IND Type B meeting with U.S. Food and Drug Administration (FDA), ABIONYX Pharma intends to file an Investigational New Drug application (IND) in the coming months which will include a Phase 2b/3 clinical trial for CER-001 in Sepsis**

Toulouse, FRANCE, Lakeland, USA, June 13th, 2024, 7:00 pm CEST - ABIONYX Pharma, (FR0012616852 - ABNX - eligible for PEA PME), a new generation biotech company dedicated to the discovery and development of innovative therapies based on the world's only natural recombinant apoA-I, today announced that the company has completed a pre-IND (Investigational New Drug Application, IND) meeting with the US Food and Drug Administration and has received feedback to support an IND filing for its candidate drug. This is an important validation of the quality of the project and a significant step towards an application to include American study centers in future clinical trials. ABIONYX Pharma intends to file an IND application to the US authority in the coming months.

Our latest phase 2a clinical study with CER-001, was published by BMC Medicine, in a translational research paper that included important *in-vitro* data, proof of concept in a pig model of sepsis and a four-arm controlled study in patients with sepsis. All sets of data showed statistically significant effects on parameters such as endotoxin levels, key inflammatory cytokines such as IL-6 and TNF- α and endothelial markers of inflammation such as sVCAM-1, sICAM-1 and MCP-1.

"The positive pre-IND meeting with the FDA reflects the quality and strength of the combined preclinical and clinical generated so far during the development of CER-001. We appreciate the FDA's guidance as we prepare to advance our novel therapy into phase 2b/3", said Dr. Rob Scott, Head of R&D and CMO at ABIONYX Pharma. "The successful completion of this pre-IND engagement is an important milestone that provides much regulatory clarity for the future path forward for CER-001. Based on the wealth of scientific evidence for the role of apoA-I in sepsis produced by us and others, including compelling genetic validation, we believe our recombinant apoA-I has potential to change the outcomes for patients with sepsis. We are now eager to move ahead in the future clinical development phases".

About Sepsis

Sepsis is defined as life-threatening organ dysfunction caused by a dysregulated host response to infection. Sepsis affects an estimated 49 million people worldwide each year, including more than 20 million children under age 5, and 1.7 million people in the U.S alone. It is a leading cause of mortality worldwide and causes more than 350,000 deaths per year in the U.S., which makes it the third leading cause of overall mortality and the leading cause of in-hospital death. Sepsis causes more deaths than chronic lower respiratory diseases, stroke, Alzheimer’s disease, diabetes, or accidental death. Sepsis is also the most expensive in-hospital condition in the U.S., costing an estimated \$62 billion each year, counting just acute in-hospital care and skilled nursing costs. There are no approved treatments that specifically target sepsis and current management relies on anti-microbial therapy and supportive care. Without any approved therapies for sepsis, the global sepsis market size is still estimated to reach \$7 billion in 2030 and grow at a compound annual growth rate of 5.6% between 2024 to 2030.

About CER-001

CER-001 is an engineered pre-β HDL particle which contains recombinant human apolipoprotein A-I (apoA-I), complexed with phospholipids. Pre-β HDL particles have been shown to be highly effective scavengers of bacterial endotoxins, thereby inactivating lipopolysaccharide (LPS) for removal by the liver.

About ABIONYX Pharma

ABIONYX Pharma is a next-generation biotech company focused on developing innovative medicines for diseases where there is no effective or existing treatment, even the rarest ones. The company expedites the development of novel therapeutics through an extensive expertise in lipid science and a differentiated apoA-I-based technology platform. ABIONYX Pharma is committed to radically improving treatment outcomes in Sepsis and critical care.

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