Press release

ABIONYX Announces First Patient Enrolled in Phase 2a Clinical Study with CER-001, the Bio-HDL for the Treatment of septic patients at high risk of developing Acute Kidney Injury

- **Evaluation of the clinical activity by dosage level of CER-001 in the prevention of Acute Kidney Injury in ICU patients with septicemia**
- **A potentially modifying effect on the progression of the inflammatory cascade in sepsis**

Toulouse, FRANCE, June 8 2021, 7.30am CEST – **ABIONYX Pharma** (**FR0012616852 - ABNX - PEA PME eligible)**, a new generation biotech company dedicated to the discovery and development of innovative therapies for patients, today announces that the first patient has been enrolled in a Phase 2a clinical study evaluating CER-001, the Bio-HDL, as a potential treatment for septic patients at high risk of developing acute kidney injury.

"After positive clinical results in an ultra-rare kidney disease, we believe that CER-001 could have a scavenger role in reducing circulating endotoxin, as well as inflammation and endothelial damage. Several other AKI/sepsis models showed that HDL is a critical factor in modifying the disease," said Professor Loreto Gesualdo, full Professor, Head of the Nephrology, Dialysis and Transplantation unit, University of Bari Aldo Moro, Italy. "*Following the promising results obtained in our preclinical LPS-induced sepsis model, we are now starting patient enrollment in **RACERS** (a **RA**ndomized study comparing short-term **CER**-001 infusions at different doses to prevent **S**epsis-induced acute kidney injury). We are strongly committed to improve therapeutic options and mortality in sepsis patients"*

RACERS is a randomized Phase 2a, open labelled, placebo-controlled, parallel-group study evaluating the safety and efficacy of intravenously administered CER-001 in ICU patients with sepsis at high risk for AKI based on their Sequential Organ Failure Assessment (SOFA score). A total of 20 patients will be randomized to receive 8 doses of CER-001 or placebo over 6 days. The primary endpoint of the study will be 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 is partnered with the University of Bari and the Consorzio per Valutazioni Biologiche e Farmacologiche (CBVF) and is already fully funded.

About ABIONYX Pharma

ABIONYX Pharma is a new generation biotech company dedicated to the discovery and development of innovative therapies for patients. The biotech develops a Bio-HDL, a bioproduct that mimics the natural HDL for the treatment of kidney diseases and the delivery of targeted drugs.

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