Press release

ABIONYX Announces Final Patient Enrollment in Phase 2a Clinical Trial with CER-001, Bio-HDL for the Treatment of Patients with Sepsis at High Risk of Developing Acute Kidney Injury

- **Top line results by late fall 2022**
- **A potentially modifying effect on the progression of the inflammatory cascade in sepsis**

Toulouse, FRANCE, Lakeland, ETATS-UNIS, October 4th 2022, 6.00pm CEST – **ABIONYX Pharma, (FR0012616852 – ABNX – eligible PEA PME)**, a next-generation biotech company dedicated to the discovery and development of innovative therapies, announces that the last patient has been enrolled in the Phase 2a clinical trial evaluating CER-001, Bio-HDL, as a potential treatment for patients with sepsis at high risk of developing acute kidney injury.

Professor Loreto Gesualdo, Full Professor, Head of Nephrology, Dialysis and Transplantation Unit, University of Bari Aldo Moro, Italy, said: *"Following the positive interim results already obtained in the RACERS clinical trial, a **RA**ndomized study comparing short-term infusions of **CER**-001 at different doses to prevent acute kidney injury induced by **S**epsis, we have finally been able to complete patient enrollment. We are more determined than ever to contribute to the development of real treatment options for sepsis, and to fight against the mortality that strikes this patient population, more than 250,000 deaths being recorded each year in Europe and the United States."*

RACERS is a randomized, open-label, placebo-controlled, parallel-group, Phase 2a study evaluating the safety and efficacy of CER-001 administered intravenously to critically ill patients with sepsis who are at high risk of acute kidney injury (AKI) based on their Sequential Organ Failure Assessment (SOFA) score. A total of 20 patients were randomized to receive CER-001 or placebo over 6 days. The primary endpoint of the study was the onset and severity of acute renal failure according to KDIGO criteria, as well as the safety and tolerability of the dosing regimens, to select the optimal dose of CER-001. Additional efficacy parameters included changes from baseline levels of endotoxin and key inflammatory biomarkers.

The clinical study is being conducted in partnership with the University of Bari.

The company reconfirms that the final topline results will be reported by the end of fall 2022**.**

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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