



Press Release

**ABIONYX Pharma presents preclinical results  
for CER-001 in Brain Fog,  
at the 1<sup>st</sup> International Scientific Congress  
on Brain-Kidney Interaction  
in Naples on November 23-24, 2023**

- **CER-001 treatment attenuated systemic inflammation, downregulated Indoleamine-2,3-dioxygenase (IDO1) thereby reducing neuroactive metabolites and waste accumulation**
- **Preclinical data support the concept that the use of CER-001 may have the potential to enhance renal and cognitive function**

**Toulouse, FRANCE, Lakeland MI, USA, November 23, 2023, 7:30 p.m. CET – 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-I, announces the presentation of new preclinical data for CER-001 in the treatment of brain dysfunction associated with acute kidney injury at the 1<sup>st</sup> International Congress on brain-kidney interaction: from physiology to clinics, to be held from November 23 to 24, 2023 in Naples, Italy.

This lecture presentation follows the presentation of preclinical results on the effects of CER-001 in brain dysfunction induced by acute kidney injury, which were the subject of a dedicated poster at the 2023 Annual Meeting of the American Society of Nephrology (ASN) held from November 2 to 5, 2023, as part of Kidney Week.

To date there are no appropriate preventive or therapeutic solutions to treat brain dysfunction related to kidney injury consecutive or concomitant with sepsis.

A preclinical study has been sponsored by ABIONYX Pharma to assess the effects of recombinant apoA-I phospholipid complexes in reducing the inflammatory process and preventing sepsis-induced acute renal failure and brain dysfunction.

In both CER-001 dose groups (20 mg/kg and 2x20 mg/kg), blood samples showed a significant reduction in Indoleamine-2,3-dioxygenase enzyme activity, measured as the kynurenine/tryptophan ratio ( $p < 0.05$ ) and quinolinic acid levels ( $p < 0.005$ ) compared with the untreated control group. In addition, a significant decrease in systemic and brain interleukin-6 (IL-6) levels was observed after CER-001 treatment.

Taken together, these data indicate that CER-001 treatment can reduce the inflammatory response, retention of residual substances and neuroactive compounds, thereby potentially improving renal and cognitive function in sepsis-induced acute renal failure. These results pave the way for future clinical trials in potential additional indications, such as neuropsychiatric lupus or, more importantly long Covid.

**Prof. Loreto Gesualdo, Head of the Unit of Nephrology, Dialysis and Transplantation at the University of Bari Aldo Moro in Italy, and principal investigator of the RACERS study, comments:** *"Following our exclusive presentation of robust data in sepsis at the ASN in early November, the results obtained in Brain Fog demonstrate the broad spectrum of efficacy of CER-001, one of the world's most advanced biologics. The unique properties conferred by recombinant apoA-I lipoprotein complexes appear to potentially reduce kidney and brain disorders in patients suffering from sepsis. Taken together, these data support the clinical development of CER-001 in potential new indications affecting the gut-kidney-brain axis"*.

**Session:** oral presentation, 3:30 pm, November 24, 2023

Lecture title: ***Gut-Brain-Kidney: the stunning interplay***

#### About Brain Fog

Brain fog is a set of symptoms describing a decline in the quality of mental functioning. Numerous previous studies suggest that partial convalescence following sepsis-induced acute renal failure can have long-term consequences predisposing to chronic dysfunction and accelerated neurocognitive decline in patients. There is a close relationship between kidney damage and cerebral dysfunction, even after the effects of acute sepsis-induced renal failure have subsided, leading to severe wakefulness.

#### 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.

#### Contacts:

##### **NewCap**

Investor relations  
Nicolas Fossiez  
Louis-Victor Delouvrier  
abionyx@newcap.eu  
+33 (0)1 44 71 98 53

##### **NewCap**

Media relations  
Arthur Rouillé  
abionyx@newcap.eu  
+33 (0)1 44 71 00 15