Press Release

Clinical results of the Phase 3 AEGIS-II study of CSL Behring's apoA-I, CSL112:

- **Validation of ABIONYX Pharma's strategic repositioning 4 years ago in severe diseases with short apoA-I treatment, such as sepsis**
- **No safety or tolerability problems in 18,000 patients treated with apoA-I**

Toulouse, FRANCE, Lakeland MI, USA, February 15, 2024, 6:00 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, today acknowledges that the Phase 3 AEGIS-II study evaluating the efficacy and safety of CSL Behring's human-plasma-derived apoA-I, CSL112, compared to placebo in reducing the risk of major adverse cardiovascular events (MACE) in patients following an acute myocardial infarction (AMI), did not meet its primary efficacy endpoint of MACE reduction at 90 days.

In addition, CSL Behring announced that there are no plans for a near-term regulatory filing and added there were no major safety or tolerability concerns with CSL112. With over 18,000 patients treated, the AEGIS-II Trial results stand as a testament to the safety and tolerability of apoA-1-based treatments.

The clinical results of the Phase 3 AEGIS-II Trial of human plasma-derived apolipoprotein A-I, CSL112 in acute myocardial infarction (AMI), strongly supports ABIONYX' decision, made four years ago, to reposition the development of CER-001 out of the treatment of longstanding chronic diseases, such as coronary artery disease, and into acute conditions where the short-term dosing model followed by Abionyx has the potential to make a marked impact. ABIONYX Pharma has meticulously evaluated other diseases where apoA-I is known to have a beneficial or protective effect. Acute sepsis is an example where the beneficial effects of apoA-1 on mortality and other outcomes is supported by a wealth of epidemiological, genetic, animal and human data, including animal and human data with CER-001.

Building on the safety demonstrated during CER-001 Phase 2 and 3 trials with 900 patients in cardiovascular diseases, Abionyx has strategically redirected its focus towards addressing high levels of unmet medical need in acute sepsis, acute renal, inflammatory and ophthalmic diseases. This pivotal decision demonstrates ABIONYX' dedication to innovative treatments where therapy using recombinant apoA-1 can maximize impact on patient outcomes.

About CER-001

CER-001 is a novel engineered recombinant human apoA-I that was designed to mimic the structural and functional biological properties of natural, nascent HDL, also known as pre-β HDL, and has been shown to perform all steps of the Reverse Lipid Transport pathway (RLT), the only natural pathway responsible for lipid elimination.

Administered CER-001 particles increase transient apoA-I and the number of HDL particles and promote the elimination of trapped cholesterol and lipids in tissues in the absence of LCAT enzyme for example, but also the elimination of bacterial lipid endotoxin (LPS) in the case of sepsis. HDL particles are then recognized by the liver, leading to the elimination of these transported lipids via a process called Reverse Lipid Transport (RLT).

About ABIONYX Pharma

ABIONYX Pharma is a next-generation biotech company focused on developing innovative medicines in 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.

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