Press release

ABIONYX Pharma announces that the French Drug Safety Agency (Agence Nationale de Sécurité du Médicament or ANSM) has granted a Compassionate Access Authorization for the bio-HDL (CER-001) in COVID-19 disease

Toulouse, FRANCE, January 3rd , 2021, 6.00pm CET – **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 French Drug Safety Agency (Agence Nationale de Sécurité du Médicament or ANSM), granted a Compassionate Access Authorization for the bio-HDL (CER-001) in COVID-19 disease.

COVID-19 is associated with respiratory symptoms characterized by acute lung injury, rapidly progressing to acute respiratory distress syndrome. The pulmonary dysfunction is rapidly accompanied by a major "cytokine storm" during which inflammatory cytokines are released abundantly into the bloodstream leading to host tissue damage.

Decreased levels of total cholesterol, LDL and HDL have been observed in patients with COVID-19 infections. Patients with low HDL at hospital admission had an increased risk of developing severe disease compared with patients with high HDL. With recovery from COVID-19 infections, serum lipid levels return to pre-infection levels.

These lipid abnormalities could be modified by pharmacological agents that increase plasma ApoA-I and HDL levels, but more importantly increase the number of functional HDL particles.

Thus, CER-001, a recombinant bio-HDL, may have the potential to improve the clinical outcome of patients with COVID-19. The current data do not allow us to presume a favourable benefit-risk ratio for the use of CER-001 in the context of this authorization.

In France, the use of proprietary drugs that do not yet benefit from a market authorization (AMM) and that are not the subject of a clinical trial, may be obtained with a Compassionate Access Authorization from the ANSM.

The patient Temporary Authorizations for Use (ATU) have become Compassionate Access Authorizations (AAC); the terms and criteria for access to these treatments have not been changed overall by the reform for patients or healthcare professionals; on the other hand, pharma and biotech companies must apply for early access if they are considering clinical and commercial development in a given indication.

In particular, a Compassionate Access Authorization is granted by the ANSM under the following conditions:

- The product is meant to treat, prevent or diagnose a severe or rare disease,
- There is no appropriate treatment available, with no possibility to include a patient in an ongoing clinical trial,
- The ACC is delivered at the request and under the sole responsibility of the prescribing physician, when the drug is likely to benefit to the patient.

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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