Press Release

ABIONYX Pharma announces a named patient Temporary Authorization for Use (ATUn) for CER-001 in France

Toulouse, FRANCE, Lakeland MI, UNITED-STATES, January 8th, 2020, 8:00 am 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 announced that the French Drug Safety Agency (Agence Nationale de Sécurité du Médicament or ANSM), granted a named patient Temporary Authorization for Use ("ATU nominative") for CER-001 in an untreated, ultra-rare renal disease. As part of its strategy to focus on existing assets and given the current availability of CER-001 vials, ABIONYX Pharma has committed to supply the product free of charge over a period of three months.

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, are subject to obtainment of a named patient Temporary Authorization for Use from the ANSM. The current data do not allow presumption of a favourable benefit-risk ratio for the use of CER-001 in the context of this named patient Temporary Authorization for Use.

In particular, a named patient Temporary Authorization for Use 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 on the market, with no possibility to include a patient in an ongoing clinical trial

- The ATUn 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 dedicated to the discovery and development of innovative therapies for patients. The biotech assets inherited from CERENIS Therapeutics constitute a rich portfolio of valuable programs for the treatment of cardiovascular diseases and associated metabolic diseases such as NAFLD and NASH as well as a HDL targeted drug delivery platform in oncology, more specifically in immuno-oncology and chemotherapy.

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