



## **ABIONYX Pharma announces the successful manufacturing of the first batch of CER-001 with recombinant human ApoA-I using a new innovative and robust industrial bioprocess**

- **Innovative industrial manufacturing based on Good Manufacturing Practices (GMP)**
- **Improved yield and simplification of the biomanufacturing process**
- **Raising the barrier to entry for the patented proprietary manufacturing of CER-001, one of the most advanced biomedicines**

**Toulouse, FRANCE, Lakeland MI, USA, May 10<sup>th</sup>, 2023, 6:30 p.m. CEST - 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, announced the successful GMP (Good Manufacturing Practices) industrial biomanufacturing of a batch of CER-001 using an innovative and robust method.

This success confirms the relevance of the strategy to relocate biomanufacturing to France, which was implemented 4 years ago, not only to contribute to the country's industrial sovereignty in biomedicine, but also to ensure the independence of the Company's development from external constraints. This performance also testifies to the efforts and hard work of ABIONYX's teams who worked to optimize the industrial process, despite raw material inflation, a difficult context and limited financial resources. Finally, this major manufacturing improvement simplifies the process by making it more competitive, which increases the value of the bioproduct and of ABIONYX Pharma, which controls the manufacturing and intellectual property rights.

### **First batch of recombinant human ApoA-I CER-001 produced by an innovative and robust industrial process**

ABIONYX successfully manufactured a GMP-compliant batch of CER-001 using a new innovative and robust industrial process. ABIONYX thus demonstrates that the new production line constitutes an innovative and efficient approach to access the apotherapy market, based on the only human recombinant ApoA-I protein. All the steps of the biomanufacturing process have been revisited, improved and requalified in order to increase the production yield and to serve the targeted markets such as renal diseases, sepsis or ophthalmology.

### **Achievement of a major milestone in the development of the Company's biomedicine**

As a reminder, biomedicines, which are often very complex to produce, play a crucial role in the development of new, highly innovative treatments, as demonstrated by CER-001. Examples of these biomedicines are interferons, coagulation factors, etc. These are large and highly complex molecules.

In contrast to the production of "classic" drugs, a very specific know-how must be implemented during the manufacturing of therapeutic biomolecules due to their high potential sensitivity to changes in environmental conditions such as temperature, the composition of the culture medium, etc. In the case of CER-001, the natural protein ApoA-I is the most important part of the manufacturing process and requires this unique know-how that ABIONYX Pharma is the only company to master to date.

The process was greatly simplified, making it more robust, with a concomitant positive effect on its cost, enabling the filing of a new patent in 2021 to continue to protect and extend its intellectual property.

### **Performance improvement and simplification of the biomanufacturing process**

Since 2005, work on the biomanufacturing of CER-001 has crossed all industrial barriers. Thanks to the innovative process developed, ABIONYX ensures that the industrialization of CER-001 is now possible for production volumes consistent with future needs.

ABIONYX's ApoA-I is the only recombinant protein produced from cells and not an ApoA-I derived from purified plasma or blood. It displays the pleiotropic, anti-inflammatory, vascular integrity restoring and immune system modulating functional properties described for endogenous ApoA-I. This is a unique situation enabling ABIONYX to restore the normal level of ApoA-I to benefit patients with deficiency. ApoA-I deficiency can be due to rare genetic orphan diseases resulting in a severe and chronic deficiency, can be age-related as in ophthalmologic conditions, but can also be due to acute severe inflammatory conditions such as bacterial or viral sepsis, including COVID-19. The known pleiotropic effects of natural ApoA-I enable CER-001 to address a wide range of diseases associated with reduced ApoA-I, and its mechanism of action is independent of endogenous levels of HDL to be effective.

With this successful manufacturing of the first batch, the new manufacturing process was confirmed, advancing apotherapy programs into larger global therapeutic trials to explore new clinical benefits for ApoA-I replacement therapy.

Next financial press release : **Cash position and activity update for Q1 2023, May 17, 2023**

### **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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