Press release

ABIONYX Pharma successfully manufactures a second batch of recombinant human ApoA-I CER-001 using a new, innovative and robust industrial bioprocess

- **Demonstrated success for the industrial biomanufacturing of CER-001, one of the most advanced biomedicines**
- **Confirmation of improved yield and simplification of the biomanufacturing process**
- **Positioning on the biomanufacturing trajectory requiring 3 consecutive batches for Marketing Authorization**

Toulouse, FRANCE, Lakeland MI, USA, July 26th, 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, announces the successful completion of a second batch for the GMP (Good Manufacturing Practice) industrial biomanufacturing of CER-001 using an innovative and robust method.

Demonstrated success for the industrial biomanufacturing of CER-001, one of the most advanced biomedicines

ABIONYX has successfully manufactured a second batch of CER-001 under GMP conditions, using a novel and robust industrial process. This confirms that ABIONYX's new production line, based on an innovative and efficient approach, is ready to enter the Apotherapy market, based on the only natural recombinant ApoA-I protein. All stages of the biomanufacturing process are designed to increase production yields, enabling ABIONYX Pharma to serve its target markets in kidney disease, sepsis and ophthalmology.

Confirmation of improved yield and simplification of the biomanufacturing process

This second batch confirms the improved yield and simplification of the biomanufacturing process defined and followed for industrialization. This batch confirms that all industrial barriers have been crossed to ensure the generation of production volumes consistent with future needs.

Positioning on the biomanufacturing trajectory requiring 3 consecutive batches for marketing approval

Before applying for marketing approval, based on the success of clinical trials conducted to assess the efficacy and safety of the biomedicine, at least 3 consecutive batches using the intended commercial process must be manufactured in accordance with Good Manufacturing Practices (GMP) in order to

obtain regulatory approval. Biomedicines manufactured in compliance with GMP guarantee the quality, safety and reliability of the bioproduct in order to meet regulatory requirements.

Finally, to obtain regulatory approval, the biotech must also provide data on the long-term stability of the biomedicine. This involves carrying out stability tests on 3 consecutive batches to determine the product's shelf life.

In fact, thanks to the successful production of this second batch, the new manufacturing process has been reconfirmed, positioning us on a biomanufacturing trajectory that will require the completion of 3 consecutive GMP pilot batches at the yield level of CER-001's future commercial operation.

Next press release: **Cash and business update, Q2 2022, 17 August 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.

Contacts

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

NewCap
Media relations
Arthur Rouillé
abionyx@newcap.eu
+33 (0)1 44 71 94 98