



Press Release

ABIONYX Pharma and OLON Enter into Strategic Manufacturing Partnership to Prepare CER-001 biologic for Regulatory Approval and Commercial Supply

- **CER-001: a distinctive manufacturing challenge to produce a full-length recombinant human apoA-I, a 243-amino-acid protein to form a biomimetic HDL particle**
- **A strategic partnership including 2 validation batches for the LCAT regulatory pathway and the commercial production of CER-001 in sepsis**
- **The partnership with OLON establishes an integrated manufacturing framework designed to support CER-001 from regulatory validation through potential commercial supply**

Toulouse, FRANCE, Fullerton, CA, UNITED STATES, October 7, 2026, 7:00 a.m. CEST – ABIONYX Pharma, (FR0012616852 – ABNX – eligible for the PEA PME), a next-generation biopharmaceutical company developing innovative therapies for sepsis and critical care based on a proprietary apoA-I technology platform, today announced a strategic manufacturing partnership with OLON, a global CDMO, to support the next stage of development and commercialization of CER-001.

Preparing CER-001 for the transition from development to market

The collaboration will initially focus on the production of two validation batches of CER-001, a key manufacturing milestone in ABIONYX's regulatory strategy for LCAT deficiency. It is also intended to establish the industrial capabilities required for future commercial supply, subject to regulatory approval.

Manufacturing activities under the partnership will be carried out across two OLON sites in France. The Company will be involved at two critical stages of the process: the upstream cell-culture production of recombinant human apoA-I and, following purification, the complexation of apoA-I with phospholipids to form CER-001, followed by Fill & Finish.

The partnership therefore extends beyond the production of the validation batches. ABIONYX and OLON are putting in place a manufacturing framework designed to support CER-001 through potential market entry and subsequent commercial scale-up.

CER-001: a distinctive manufacturing challenge

Unlike approaches based on short apoA-I-derived peptides, CER-001 incorporates full-length recombinant human apoA-I, a 243-amino-acid protein, which is subsequently assembled with specific phospholipids to form a biomimetic HDL particle.

Producing the protein is only one part of the process. Manufacturing CER-001 also requires the reproducible assembly of apoA-I and phospholipids into a homogeneous and stable biological particle with the required pharmaceutical characteristics.

This complexity is closely linked to the design of CER-001. By retaining full-length apoA-I within an HDL-like particle, CER-001 is designed to reproduce key structural and functional properties of naturally occurring nascent HDL and to enable biological activity throughout the circulation.

ABIONYX has built considerable manufacturing experience around CER-001 over the course of its development. The process, together with the Company's intellectual property and accumulated manufacturing know-how, represents an important part of the asset's differentiation and creates a meaningful technological barrier to replication.

The partnership with OLON is intended to translate that experience into a robust, reproducible and scalable manufacturing process suitable for potential commercial supply.

A partnership designed beyond validation

The immediate objective of the collaboration is the successful manufacture of the two validation batches. The longer-term objective is to ensure that, if CER-001 receives regulatory approval, the manufacturing infrastructure and capabilities required to supply the market are already in place.

With this partnership, ABIONYX is moving beyond manufacturing CER-001 solely for clinical development and beginning to establish the infrastructure required for potential commercialization. The two validation batches provide the immediate milestone. The more important strategic objective is what comes next: a scalable manufacturing platform capable of supporting CER-001 from a potential first market entry in LCAT deficiency to a substantially broader opportunity in sepsis.

Cyrille TUPIN, Chief Executive Officer of ABIONYX Pharma, commented:

"CER-001 is a demanding biologic to manufacture. We produce the full-length, 243-amino-acid human apoA-I protein and then assemble it with specific phospholipids into a biomimetic HDL particle. Building a reliable and scalable process around that complexity has taken years of development and know-how. Thanks to OLON, we are now putting that manufacturing capability in place for the next stage of CER-001: first through our regulatory strategy in LCAT deficiency and, in parallel, through Phase 2b development in sepsis."

Andrea Conforto, M&S VP CDMO Biotech OLON, commented:

"Our work with ABIONYX brings together several areas of OLON's biomanufacturing expertise, from the upstream production of a full-length recombinant protein, the complexation of apoA-I with phospholipids and Fill & Finish. The validation batches represent an important first milestone, but the manufacturing strategy has been designed from the outset with the longer-term requirements of CER-001 in mind. The program reflects our ability to manage complex biologics manufacturing processes and to support innovative products as they progress from clinical development towards potential commercial supply."

One manufacturing platform supporting two development paths

The investment in manufacturing also supports ABIONYX's broader strategy for CER-001. In LCAT deficiency, an ultra-rare genetic disease, ABIONYX is pursuing a regulatory pathway intended to provide CER-001 with a potential first route to market. The two validation batches to be produced as part of the OLON program are an important step in preparing the manufacturing package supporting that strategy. At the same time, ABIONYX is advancing CER-001 into Phase 2b development in sepsis, where the Company is evaluating the potential of the same full-length apoA-I biologic in a much larger patient population with significant unmet medical need.

The two programs are different in scale and development pathway, but they share the same underlying product and manufacturing platform. This allows the industrial capabilities being established for LCAT deficiency to support the longer-term development of CER-001, including in sepsis.

For ABIONYX, the strategy is therefore straightforward: use the rare-disease pathway to pursue a potential first market entry for CER-001 while developing the same proprietary biologic in sepsis, where the potential patient population is substantially larger.

About OLON

OLON is an Italian company specializing in the development and production of active pharmaceutical ingredients (APIs), combining expertise in chemical synthesis and biological processes. Headquartered in Rodano (Milan, Italy), OLON operates 14 manufacturing sites and 14 R&D centers worldwide, with over 2,800 employees. With decades of experience, the company provides end-to-end support, from early development to commercial manufacturing, while maintaining a strong commitment to innovation, sustainability, and quality.

About ABIONYX Pharma

ABIONYX Pharma is a next-generation biopharmaceutical company focused on sepsis and critical care, developing breakthrough biotherapies for serious diseases for which there are no effective treatments. Through its proprietary apoA-I-based technology platform, ABIONYX Pharma designs innovative biopharmaceuticals and next-generation HDL vectors that target the immune-inflammatory dysregulation at the core of sepsis and other severe diseases. Driven by recognized scientific expertise, a differentiated pipeline, and an expanding global clinical network, ABIONYX Pharma aims to redefine therapeutic standards for sepsis and become a key player in intensive care.

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