



Press Release

ABIONYX Pharma Finalizes the Structuring of Its CER- 001 Bioproduction Chain Through a Strategic Partnership with AXPLORA, Marking a Major Milestone Toward Its Potential Commercialization

- **An end-to-end manufacturing process for the purification of recombinant human apoA-I has now been finalized with AXPLORA**
- **A decisive step toward potential first-in-class commercialization**
- **An infrastructure based on the production of a single natural protein, supporting two value creation pathways: regulatory support for market entry in LCAT Deficiency and Phase 2b clinical development in Sepsis**

Toulouse, FRANCE, Fullerton, CA, UNITED STATES, 27 october 2026, 7:00 a.m. CET – ABIONYX Pharma, (FR0012616852 – ABNX – eligible for the PEA PME), a next-generation biopharmaceutical company developing innovative treatments for sepsis and intensive care based on a proprietary apoA-I technology platform, today announced a strategic manufacturing partnership with AXPLORA, a global Contract Development and Manufacturing Organization (CDMO), to apply its specialist purification expertise to recombinant human apoA-I, the key biological component of CER-001, and support the next stages of the program's development.

This new strategic partnership in bioproduction complements the industrial agreements previously entered into with TEXCELL and OLON and marks the completion of the structuring of the CER-001 production chain, from the manufacture of its recombinant protein through to the final stages of biopharmaceutical preparation. Purification activities under this partnership will be carried out at AXPLORA's Pompey site in France, a center of excellence bringing more than 30 years of purification expertise to support the development of CER-001. This milestone is part of the Company's strategy to secure a potential first approval for LCAT Deficiency, while continuing to develop CER-001 for Sepsis, where a Phase 2b clinical trial is in preparation.

A Complete Manufacturing Process for a Complex Biopharmaceutical

CER-001 is an innovative biopharmaceutical based on full-length recombinant human apoA-I, a 243-amino acid protein, assembled with specific phospholipids to form a biomimetic HDL particle designed to enhance the body's immune response by eliminating endotoxins.

Its manufacture requires mastery of a series of demanding technical steps, ranging from the production of the recombinant protein to its purification, followed by its assembly with phospholipids, and the final

pharmaceutical manufacturing operations.

The complexity of this process stems in particular from the need to preserve the structural and functional characteristics of apoA-I while ensuring the quality, homogeneity, and reproducibility of the final product.

To meet this industrial challenge, ABIONYX has gradually built a structured and robust network of specialized partners, bringing together complementary bioproduction expertise of the highest standard:

- **TEXCELL**, an industrial partner already integrated into the CER-001 manufacturing and control system;
- **OLON**, a strategic partner responsible in particular for the production of recombinant human apoA-I, its complexation with phospholipids, and filling and finishing operations;
- **AXPLORA**, a pivotal CDMO partner who brings specialist purification expertise to address the technical challenges of recombinant human apoA-I and support a robust, reproducible manufacturing process.

Thanks to AXPLORA, ABIONYX now has a robust network of partners covering the main stages of the CER-001 production chain. This network forms an industrial foundation to support the next stages of the biopharmaceutical's regulatory and clinical development, subject to the completion of the required validations.

A Single Industrial Pipeline for a Single Molecule Supporting Two Therapeutic Opportunities

ABIONYX's strategy, centered on a single biopharmaceutical derived from a single technological platform based on recombinant human apoA-I, is pursuing two complementary development paths:

- The first concerns LCAT Deficiency, for which ABIONYX is preparing the next regulatory steps toward a potential first market launch,
- The second focuses on Sepsis, a serious condition associated with a dysregulated immune-inflammatory response and organ failure, for which ABIONYX is preparing a Phase 2b clinical trial. This phase—RACERS 2, made possible by the securing of €33 million in funding in June 2026—is the larger-scale follow-up to RACERS 1 (which involved 17 patients and yielded very encouraging clinical results).

The LCAT Deficiency and Sepsis programs differ in their patient populations, clinical requirements, and regulatory pathways, but they are based on the same biologic product. This pooling of expertise and industrial capabilities is a key component of ABIONYX's strategy to prepare for the next stages of CER-001.

A major milestone in ABIONYX's value creation journey

ABIONYX is pursuing a development strategy aimed at translating the scientific advances of its technology platform into clinical, regulatory, industrial, and commercial milestones.

This strategy is based on four complementary pillars:

1. **A scientific rationale** based on the biological role of apoA-I and HDL in inflammatory mechanisms, supported by preclinical, clinical, and genetic studies.
2. **A first potential path to market** in LCAT Deficiency, accompanied by the preparation of the necessary regulatory and industrial elements.
3. **A clinical program in Sepsis**, designed to evaluate the potential of CER-001 in a patient population with a significant unmet medical need.
4. **A structured industrial organization**, bringing together TEXCELL, OLON, and AXPLORA, designed to support the manufacturing of CER-001 and its long-term development.

Cyrille TUPIN, CEO of ABIONYX Pharma, stated:

"We are finalizing the structuring of the entire CER-001 manufacturing chain by effectively and structurally combining the complementary expertise of TEXCELL, OLON, and AXPLORA. Following the securing of our financial resources, the structuring of our production chain and the preparation of our Phase 2b clinical program represent transformative steps in this journey. We are entering an execution phase in which every industrial, regulatory, and clinical milestone reduces the risks associated with the development of CER-001 day by day and secures its long-term value creation potential."

Arul Ramadurai, Chief Commercial Officer of Axplora, commented:

"Strong partnerships start with understanding what a customer needs to achieve and the challenges we need to solve together. Our team at Pompey, in France, brings more than 30 years of purification expertise to help ABIONYX build a reliable manufacturing process for CER-001. Working alongside ABIONYX and its other specialist partners, we are focused on turning that expertise into progress toward a shared goal: bringing a potential new treatment to patients who need better options. This is what Partnership in Motion means to us."

With the completion of its manufacturing chain, ABIONYX has taken another step forward in its journey to make CER-001 a biologic drug eligible for regulatory approval for the treatment of LCAT Deficiency, while continuing its clinical development for Sepsis.

About AXPLORA

AXPLORA is a trusted manufacturing partner for more than 900 of the world's leading pharmaceutical and biotechnology companies. Formed through the merger of PharmaZell, Farmabios, and Novasep CDMO—three industry leaders with decades of experience in pharmaceutical manufacturing—AXPLORA offers high-quality, reliable, and sustainable solutions across the entire pharmaceutical value chain.

With its in-depth expertise in complex chemistry and industrial manufacturing, combined with an agile and exploratory mindset, AXPLORA supports pharmaceutical and biotechnology companies in the development and production of life-changing treatments. PharmaZell and Farmabios are renowned for their expertise in active pharmaceutical ingredients (APIs), highly potent compounds, and regulatory excellence, while Novasep CDMO is a leader in the manufacture of small molecules and antibody-drug conjugates (ADCs), as well as a pioneer in purification technologies.

AXPLORA operates nine API manufacturing sites across Europe and India, offering its partners worldwide multi-site production capacity.

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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