



Press release

ABIONYX Pharma Achieves Major Milestone in apoA-I Biomanufacturing with Breakthrough in Synthetic Sphingomyelin Production

Toulouse, FRANCE, Fullerton, CA, USA, March 27, 2026 at 7:00 a.m. CET - ABIONYX Pharma, (FR0012616852 – ABNX – eligible for PEA PME), a next-generation biopharmaceutical company developing innovative therapies in sepsis and critical care based on an exclusive apoA-I technology platform, today announced a significant technological and industrial breakthrough combining high-performance apoA-I bioproduction with exclusive mastery of ultra-pure synthetic sphingomyelin, paving the way for a new class of sepsis therapeutics.

A First-in-Class Scientific and Industrial Breakthrough

As part of its strategy to enable large-scale industrial production of CER-001, ABIONYX Pharma has developed a new manufacturing process allowing:

- A threefold increase in sphingomyelin production yield, one of the two key components of CER-001
- A synthetic component with exceptional purity and structural quality, meeting the most stringent pharmaceutical standards.

All synthesis processes for this component are based on fully proprietary patents, providing ABIONYX Pharma with a major technological and competitive barrier.

A Critical Component Mastered at the Highest Level

Sphingomyelin is a strategic lipid widely recognized for its structural and functional properties. Within the CER-001 biomedicine, it plays a central role:

- It stabilizes the ApoA-I protein in its optimal functional conformation
- It gives CER-001 biological and therapeutic properties fully comparable to natural HDL found in the human body
- It exhibits high intrinsic stability in pure form without added stabilizers—unlike conventional sphingomyelins—strengthening manufacturing robustness and pharmaceutical-grade quality.

Sphingomyelin is also used as a key ingredient in other pharmaceutical applications, including advanced cosmetics, due to its ability to stabilize and protect biological

structures. This may open additional commercial opportunities for ABIONYX Pharma.

The use of 100% synthetic sphingomyelin, replacing traditional sources (egg or bovine), eliminates:

- Any risk of contamination
- Variability in raw materials
- Allergenic risks

With this achievement, the Company overcomes a major technological barrier in the control and production of CER-001.

Strategic Positioning in Sepsis: A High-Unmet-Need Market

ABIONYX Pharma is advancing its platform in sepsis, a global medical emergency characterized by severe systemic dysregulation and a substantial unmet therapeutic need.

The combination of highly purified apoA-I, proprietary synthetic sphingomyelin and optimized formulation technologies positions the company to deliver differentiated therapeutic approaches aimed at restoring essential biological functions in sepsis patients.

A Strong Benefit for the Bioproduction of the Two Validation Batches Prior to Marketing Authorization in LCAT Deficiency

This breakthrough in synthetic sphingomyelin production will also directly benefit the manufacturing of the two validation batches required ahead of Marketing Authorization (MAA) in LCAT deficiency. By ensuring high purity, reproducibility, and secured supply, this innovation significantly de-risks the production process and supports timely execution of these critical batches. These validation lots represent a key milestone for the Company, as they are essential to advancing CER-001 toward regulatory approval.

A Scalable, Best-in-Class Biomanufacturing Platform

This milestone reinforces ABIONYX Pharma's positioning as a leader in advanced biomanufacturing within the biotech sector. The company demonstrates its ability to:

- Manufacture complex, high-value therapeutic proteins at scale
- Control critical lipid components at an unprecedented level of purity
- Integrate these elements into differentiated, functional drug formulations

This achievement validates the industrial scalability of the apoA-I platform, strengthens supply chain security, and supports upcoming clinical and regulatory milestones. It also creates new opportunities for strategic partnerships with global industry players.

About ABIONYX Pharma

ABIONYX Pharma is a next-generation biopharma company pioneering a new therapeutic era in sepsis and critical care through breakthrough biotherapies that address life-threatening conditions with no effective treatments. Leveraging its proprietary apoA-I-based technology platform, ABIONYX Pharma develops innovative biologics and HDL-derived vectors that target the immune and inflammatory dysregulation underlying sepsis and other severe diseases. With a strong scientific foundation and a growing network of global clinical partners, ABIONYX Pharma aims to redefine the standard of care in sepsis and to bring critical care solutions to patients worldwide.

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