Press Release

ABIONYX Pharma Reaches Another Key Milestone in the Industrialization of CER-001 by Entering into a Strategic Partnership with TEXCELL (ABL Diagnostics) for the Viral Safety and Clearance of Biologics

- **Preparation of validation batches for the CER-001 bioproduction process based on viral safety studies**

- **A key step in the industrial and regulatory dossier toward a future market launch for the treatment of LCAT**

Toulouse, FRANCE, Fullerton, UNITED-STATES, September 10, 2026, 6:00 pm CEST – **ABIONYX Pharma (FR0012616852 - ABNX - PEA PME eligible)**, a next-generation biopharmaceutical company developing innovative therapies for sepsis and critical care based on a proprietary apoA-I-based technology platform, announces the establishment of a strategic partnership with TEXCELL, a division of ABL Diagnostics, for the viral safety and clearance testing of its biopharmaceutical development.

This collaboration marks a key milestone in the industrial and regulatory preparation of CER-001. It forms part of the manufacturing process validation batches designed to document process control, reproducibility, and safety. This work is necessary for the next stages of CER-001's development, particularly for LCAT deficiency.

Viral safety: a critical step in the validation of a biologic drug

As a biologic product, CER-001 is subject to specific quality and safety requirements that must be documented throughout its development. Viral clearance studies are specifically designed to demonstrate that ABIONYX Pharma's innovative manufacturing process incorporates steps capable of effectively removing or inactivating potential viral contaminants.

ABIONYX Pharma selected TEXCELL for its global expertise in this field and its experience in supporting the development of biologic drugs. As part of ABL Diagnostics, TEXCELL now benefits from a unique combination of expertise in viral safety, molecular diagnostics, microbiology, virology and sequencing, further strengthening the capabilities of its viral clearance platform to support ABIONYX Pharma through one of the most critical stages of its program.

Continued Industrialization of CER-001 in France

The collaboration with TEXCELL forms part of a broader industrial program initiated by ABIONYX Pharma for CER-001 in France. The objective is to demonstrate that the manufacturing process is fully controlled, reproducible, documented and compliant with the regulatory requirements applicable to biologic drugs.
In this context, the production of process validation batches represents a pivotal step. These batches are intended to demonstrate that the manufacturing process can consistently and under controlled conditions reproduce a bioproduct that meets predefined quality specifications.
TEXCELL's viral safety studies will confirm the industrial process parameters required for the production of the two validation batches requested by regulatory authorities.

This key milestone will enable ABIONYX Pharma to advance three essential aspects of the industrialization of CER-001 in parallel :

- the quality and safety of CER-001;
- the preparation of its industrial and regulatory environment; and
- the establishment of the industrial conditions required for the future market launch of CER-001.

These studies will be conducted on TEXCELL's viral safety and clearance platforms, recognized for their scientific excellence and compliance with international regulatory standards. They will contribute to documenting the overall robustness of ABIONYX Pharma's innovative manufacturing process against the criteria expected for biologics intended for major global markets, particularly the U.S. market.

Industrial and regulatory preparation of CER-001 for the next phases leading to its future market launch for the treatment of LCAT deficiency

Through this strategic partnership in France, ABIONYX Pharma is securing its industrial autonomy while continuing to progressively establish all the expertise required for the biomanufacturing of CER-001.
The Company intends to advance, in a coordinated manner, the key pillars required for the commercialization of the biologic drug: clinical development, biomanufacturing, analytical control, quality and regulatory preparation. The conduct of viral safety studies with TEXCELL marks another key milestone in this journey and contributes to preparing CER-001 for the next phases toward a future market launch in LCAT deficiency.

Cyrille Tupin, Chief Executive Officer of ABIONYX Pharma, stated: "Our partnership with TEXCELL represents a significant step forward in the industrialization of CER-001. We have selected an internationally recognized platform with expertise in viral safety and biosafety to support us through a strategic phase of our development. This collaboration strengthens our industrial and regulatory dossier and contributes to preparing the next stages of CER-001's development for the treatment of LCAT deficiency."

Chalom Sayada, Chief Executive Officer of TEXCELL – ABL Diagnostics, added: "We are proud to support ABIONYX Pharma at this important stage in the development of CER-001. Viral safety and clearance studies are an essential component of biologic drug development. Through the combined expertise of TEXCELL and ABL Diagnostics, we are providing ABIONYX Pharma with an internationally recognized scientific platform that meets the highest regulatory standards and is capable of supporting innovative biopharmaceutical companies through the most advanced stages of their development."

About ABIONYX Pharma

ABIONYX Pharma is a next-generation biopharmaceutical company focused on sepsis and critical care, developing breakthrough biotherapies for serious conditions for which there are no effective treatments. Through its proprietary apoA-I-based technology platform, ABIONYX Pharma designs innovative biologics and next-generation HDL carriers 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.

About ABL Diagnostics

ABL Diagnostics (Euronext B: ABLD – ISIN: FR001400AHX6) is an international company specializing in innovative molecular biology tests and comprehensive solutions for its customers:

- Molecular detection via polymerase chain reaction (PCR) with UltraGene®;
- Genotyping via DNA sequencing with DeepChek®;
- Virology, biosafety, viral safety, and biopharmaceutical development services through TEXCELL.

ABL Diagnostics markets its entire product line globally through its own sales team and a network of exclusive distributors operating on every continent.

Following the acquisition of TEXCELL's business, ABL Diagnostics has expanded its operations in the life sciences sector by integrating expertise and services dedicated to virology, biosafety testing, viral safety, and biopharmaceutical development. TEXCELL's technology platforms are scientifically validated and meet the international scientific, quality, and regulatory standards required to support biologic product development programs for major global markets, including the United States.

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