Press Release

ABIONYX Pharma Signs a Strategic Partnership with Lille University Hospital—Burn Treatment Center and Intensive Care Unit—to Explore the Potential of CER-001 in Severe Burn Patients at High Risk for Sepsis

- **Patients with severe burns and those in intensive care and resuscitation: populations at very high risk of sepsis and multi-organ failure, at the heart of the continuum between severe acute inflammation and dysregulation of the host response**
- **A translational research program to better understand the role of apoA-I and endotoxin in the clinical course of critically ill patients, from the disruption of biological barriers to sepsis**
- **Potential for CER-001 as an approach to restoring the physiological functions of apoA-I in populations at high risk of sepsis without specific treatment**

Toulouse, FRANCE, Fullerton, CA, UNITED STATES, 4 November 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 the signing of a strategic partnership with Lille University Hospital, involving the Burn Treatment Center and the Department of Critical Care Medicine - Resuscitation. This partnership aims to develop translational research programs on the role of apoA-I and endotoxin in critically ill patients, in order to better characterize the biological mechanisms linking severe acute inflammation, immune dysregulation, endotoxemia, and sepsis, and to explore the potential of CER-001 in these populations.

This partnership is part of ABIONYX's strategy to expand the scope of CER-001 to new populations at very high risk of sepsis and to deepen our understanding of the biology of apoA-I in severe acute immuno-inflammatory dysregulation.

Patients with severe burns: a clinical model of the continuum between severe acute inflammation and sepsis

Contrary to popular belief, once the initial phase (burn shock, inhalation injuries) has passed, the majority of deaths among patients with severe burns do not result directly from thermal injuries.

The leading cause of mortality then becomes sepsis—organ dysfunction caused by a dysregulated host response to infection, involving both hyperinflammation and immunosuppression—and its progression to multiple organ failure.

In these patients, several mechanisms are simultaneously at play:

- loss of the natural skin barrier;
- major sterile systemic inflammation, preceding any infection;
- translocation of bacterial endotoxins of gastrointestinal origin;
- endothelial dysfunction;
- severe and persistent immunosuppression;
- secondary infections frequently leading to sepsis.

Most of these mechanisms—systemic inflammation, endotoxin load, endothelial dysfunction, and immune dysregulation—are central to the therapeutic approaches developed by ABIONYX around CER-001. They are also accompanied by a marked drop in circulating levels of apoA-I and HDL, observed in severe inflammatory conditions and sepsis, where low levels are associated with a poor prognosis. In patients with severe burns, impairment of the intestinal barrier and dysbiosis can also promote the translocation of bacteria and microbial products—including endotoxins—from the gut microbiota into the circulation. This patient population thus provides a particularly relevant clinical model for studying the sequence and interaction of these phenomena before and during the onset of sepsis.

These mechanisms are found, in various forms, in many intensive care patients, whether due to septic shock or initially non-infectious insults (multiple trauma, major surgery) that in turn expose patients to the risk of sepsis. The Department of Intensive Care Medicine at Lille University Hospital brings to this partnership complementary clinical expertise and access to a broader population of patients with sepsis, allowing for a comparison of data collected from patients with severe burns with those observed in other critical conditions.

A translational program focused on immuno-inflammatory dysregulation and the host response

In particular, the collaboration will enable the study of: the dynamics of apoA-I and functional HDL; endotoxin load; biomarkers of inflammation and innate immunity; markers of endothelial dysfunction; as well as, where relevant, markers of impaired biological barriers and their relationship to the onset of sepsis and organ failure.

The objective will be to better characterize the various biological states experienced by patients following a severe burn—from the initial sterile inflammatory phase to immunosuppression and secondary infections—and to identify the mechanisms and patient profiles that may guide future clinical developments of CER-001. In particular, the program will seek to determine whether impaired barriers, exposure to endotoxins, and decreased apoA-I may contribute to a feedback loop that amplifies the inflammatory response in certain patients.

At the same time, data obtained from the Intensive Care Unit will enable us to study these mechanisms in patients with sepsis from other causes and to determine the extent to which common biological signatures are found across these different populations.

Toward an approach to host restoration in severe immuno-inflammatory dysregulation

Beyond an approach focused on a single indication, ABIONYX aims to deepen its understanding of the biology of apoA-I at the intersection of innate immunity, inflammation, the binding and clearance of microbial lipids (lipopolysaccharide, lipoteichoic acid), and endothelial homeostasis. The goal is to better understand whether various critical insults may converge toward common biological states characterized by a decrease in functional apoA-I, an increase in the microbial load, and dysregulation of the host response.

In critically ill patients, decreased levels of apoA-I and HDL can weaken physiological mechanisms involved in host defense: HDL contributes to the binding, neutralization, and clearance of certain bacterial endotoxins, as well as to the modulation of the inflammatory response and endothelial homeostasis. CER-001, a biomimetic particle consisting of full-length recombinant human apoA-I bound to phospholipids, is being developed as a host-restorative biotherapy: rather than blocking a single inflammatory mediator, it aims to restore the physiological functions of apoA-I that are impaired during severe inflammatory states.

The partnership with Lille University Hospital is intended to generate the translational data needed to refine this approach, test the link between apoA-I, endotoxemia, and immuno-inflammatory dysregulation, and evaluate the potential of CER-001 in critically ill patients, particularly those with severe burns and those in intensive care.

This collaboration thus represents a first step in expanding the scientific scope of CER-001 from sepsis to the broader field of severe acute immuno-inflammatory dysregulation. The identification of common biological signatures could ultimately support a development approach based on the host response and the mechanisms of apoA-I, beyond the sole origin of the initial insult.

"Patients with severe burns and those in intensive care are among those most at risk for sepsis and organ failure, for which there is currently no specific therapeutic solution targeting this dysregulation of the host response. Patients with severe burns fall along a continuum ranging from severe acute inflammation, impairment of biological barriers, exposure to endotoxins, immune dysregulation, and sepsis. "*This strategic partnership with Lille University Hospital should enable us to better understand these mechanisms and, if translational data confirm this, provide a stronger rationale for evaluating CER-001 in this new high-risk population*," said Cyrille Tupin, Chief Executive Officer of ABIONYX Pharma.

"In intensive care, existing severity scores have limited utility in directly guiding day-to-day individual patient care. Predicting a worsening of a patient's condition still relies heavily on clinical assessment and the clinician's experience. Having biomarkers capable of early identification of at-risk patients could change the way we monitor them and adapt their treatment. Studying both intensive care patients and severe burn patients together will allow us to investigate whether some of these markers are common to these two otherwise distinct populations," says Dr. Côme Bureau, Hospital Physician in Intensive Care Medicine at Lille University Hospital.

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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