AUROBAC STARTS CLINICAL DEVELOPMENT OF ITS FIRST-IN-CLASS SEPTIC SHOCK DRUG ATX101

Lyon (France), August 19, 2025

AUROBAC THERAPEUTICS, a pharmaceutical company dedicated to tackling urgent unmet medical needs in the treatment of bacterial infections and their consequences in acute hospital settings, today announced the approval of its Clinical Trial Application (CTA) and the successful dosing of the first healthy volunteers in its Phase 1 clinical trial evaluating its sepsis drug candidate, ATX101 (NCT07107802).

ATX101 is a first-in-class treatment, addressing shock, organ failure and mortality in sepsis, a life-threatening condition for which current treatments are limited and often insufficient. AUROBAC is developing ATX101 under a collaboration and license agreement with Boehringer Ingelheim.

"The initiation of our first clinical trial with ATX101 marks a significant milestone for AUROBAC and reflects our continued progress in developing novel solutions to combat life-threatening conditions such as sepsis and septic shock", said Dr. Johan Frieling, Chief Medical Officer of AUROBAC THERAPEUTICS. *"ATX101 represents a unique host-targeted approach to address the pathophysiological mechanisms of sepsis and septic shock, offering the potential for a life-saving intervention where current therapies fall short".*

The study is a randomized, double-blinded, placebo-controlled, single-center, single ascending dose (SAD) trial designed to evaluate the safety, tolerability, and pharmacokinetics (PK) of administered ATX101 in healthy participants. It is being conducted at a clinical research facility in Europe, with topline results expected early 2026.

About the Burden of Sepsis & ATX101:

Sepsis is a severe and potentially fatal condition caused by a dysregulated host response to infection, resulting in widespread inflammation, endothelial dysfunction, and increased vascular permeability. These changes can lead to hypotension (shock), multi-organ failure, and death. In 2017 alone, sepsis affected 49 million people globally and accounted for 11 million deaths – approximately 20% of global mortality.

Despite advances in supportive care, mortality in sepsis remains unacceptably high, particularly in cases progressing to septic shock. Current treatments, including fluid resuscitation and antibiotics, are essential but insufficient in tackling some of the key underlying pathophysiological mechanisms that drive organ failure.

ATX101 is a novel, host-targeted therapy developed to address this critical gap. By targeting the host's dysregulated response to infection rather than the pathogen itself, ATX101 potentially improves survival and reduces complications in patients with sepsis and septic shock.

About AUROBAC THERAPEUTICS:

AUROBAC THERAPEUTICS is a biopharmaceutical company established in 2022 through a strategic partnership between three global leaders in life sciences innovation: Boehringer Ingelheim, Evotec and bioMérieux. AUROBAC is dedicated to tackling urgent and unmet medical needs in the treatment of bacterial infections and their consequences in acute hospital settings, with a strong focus on the escalating threat of antimicrobial resistance (AMR).

The company is advancing a robust and diversified pipeline, headlined by ATX101, a first-in-class host-targeted therapy in development for the treatment of sepsis and septic shock. In parallel, AUROBAC is building a proprietary drug discovery engine aimed at identifying novel antimicrobial agents. This innovative platform spans a broad range of therapeutic modalities—including peptides, medicinal chemistry approaches, biologics, and natural products—and aims to accelerate the development of novel treatments for acute respiratory infections, such as Hospital-Acquired Pneumonia (HAP) and Ventilator-Associated Pneumonia (VAP) caused by Gram-negative pathogens.

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