



PRESS RELEASE

Positive Meeting between Combioxin and EMA's Innovation Task Force on CAL02 Clinical Development Plan

November 12, 2019, Geneva - Combioxin SA met today with the Innovation Task Force (ITF) of the European Medicines Agency (EMA) to review clinical development plans for CAL02.

EMA's ITF members and experts provided today their opinion on the clinical development plan for CAL02, an innovative medicine treating and preventing complications associated with severe and resistant infections. Critical questions pertaining to the next clinical trials with this emerging therapy were answered.

"Today was another important day for Combioxin", said Dr. Samareh Azeredo da Silveira Lajaunias, Director at Combioxin. "On this World Pneumonia Day, we are grateful to the EMA's ITF for a fruitful meeting bringing all the clarifications sought to advance, full-speed, with CAL02 in severe pneumonia patients."

About CAL02

CAL02 provides a totally new and eagerly awaited solution for patients and doctors around the world. This simple and highly efficient drug has the potential to transform standard of care for millions of individuals with severe infections.

CAL02 is a disruptive medicine addressing the severity and complications of infections. It consists of liposomes engineered to catch and neutralize virulence effectors produced by pathogens most commonly responsible for severe infections such as severe pneumonia. CAL02 is a broad-spectrum drug which can be administered irrespective of the antibiotics prescribed for the patients. The first-in-human clinical results with CAL02 in severe pneumonia patients were published in May 2019 in *The Lancet Infectious Diseases*, which ranked this study "a medical breakthrough".

CAL02 and the Fight against Antimicrobial Resistance

CAL02 is at the forefront of the fight against the dramatic rise of bacterial resistance. CAL02 does not give rise to resistance and is active regardless of any existing resistance to antibiotics. Moreover, CAL02 directly treats resistant infections by depriving bacteria of tools they use to survive and multiply, and by acting as a shield for the immune system which can thereby better combat the infection on its own.

CAL02 and Pneumonia

Despite best antibiotic treatments, pneumonia is still the first cause of infectious mortality in the world. The World Health Organization estimates that pneumonia affects 450 million people every year worldwide, 20% of whom require hospitalization. Besides the suffering and high mortality rates, which have not decreased during the past decades, severe pneumonia also represents a high economic burden due to prolonged hospitalization.

About the European Medicines Agency's Innovation Task Force

The EMA's ITF provides support for medical innovations in the European Union, with a particular focus on emerging and innovative therapies and technologies. This multidisciplinary group provides an interactive platform to proactively discuss the scientific, legal and regulatory aspects of the development of such therapies.

About Combioxin

Combioxin SA is a Swiss-based clinical-stage biotechnology company founded in 2015. The company is committed to the development of disruptive treatments for severe infections.

Contact details

Combioxin SA, 8 rue de la Rôtisserie, 1204 Geneva, Switzerland
info@combioxin.com