Combioxin

PRESS RELEASE

Combioxin SA announces that it has received positive feedback from FDA on its pre-investigational new drug application (PIND) for use of CAL02 in COVID-19 patients at high risk of secondary bacterial infections.

Geneva, Switzerland, 04 May 2020 - **Combioxin SA**, a clinical-stage biotechnology company dedicated to the development of first-in-class life-saving drugs for severe infections, announced today that the U.S. Food and Drug Administration (FDA) has favorably reviewed the company's PIND application for CAL02. The review was conducted within the framework of the Coronavirus Treatment Acceleration Program (CTAP), FDA's expedited process for possible therapies to treat COVID-19 patients as quickly as possible.

The COVID-19 pandemic is exerting tremendous pressure on intensive care units (ICUs). Secondary bacterial infections are observed in a substantial number of critically ill COVID-19 patients and represent a leading cause of death. Co-infections also extend further the duration of intensive care management. In the majority of these cases, co-infected ICU patients suffer from increasingly severe and potentially fatal complications, which occur whether bacteria are eventually cleared by antibiotics or not. Based on guidelines for the management of viral pneumonia with respiratory failure, critically ill COVID-19 patients receive early administration of empirical antibiotics to prevent and treat suspected or confirmed secondary bacterial pneumonia, which inevitably amplifies the risk of increased resistance to commonly-used antibiotics.

"We are extremely satisfied with the positive feedback provided by the FDA for the clinical development of CAL02 in COVID-19 patients. Without any required additional pre-clinical work, we plan to assess CAL02 versus placebo in its ability to prevent and treat secondary bacterial infection complications", said **Dr. Toni Perez**, Combioxin's Chief Medical Officer.

"Our objective is to improve the recovery of critically ill COVID-19 patients and save their lives. The positive feedback from the FDA is meaningful encouragement towards the development of CAL02 for this goal", said **Dr. Samareh Azeredo da Silveira Lajaunias**, co-founder and General manager of Combioxin. "Based on our preliminary results with enveloped viruses, this trial will also offer a chance to assess the anti-viral potential of CAL02 and we are working around the clock to accelerate our program in this new setting."

About CAL02:

CAL02 is a broad spectrum, non-antibiotic drug that acts as a universal trap for bacterial virulence effectors (toxins) which are responsible for infection-related complications, sepsis, septic shock and death. CAL02 consists of liposomes engineered to clear away the virulence effectors produced by the most relevant bacteria seen in severe pneumonia. CAL02 is poised to play a key role in the fight against anti-microbial resistance, since it works even in case of multi-drug-resistant (MDR) infection, its action is complementary to that of antibiotics and it does not give rise to drug resistance.

Clinical results to date underscore the potential of CAL02 to transform the standard of care and to dramatically reduce the time and the cost of care for millions of critically ill patients. CAL02 was recently studied in severe pneumococcal pneumonia patients and was shown to be safe and well-tolerated. Importantly, CAL02 treatment led to a faster resolution of organ dysfunction, a faster normalization of the hyper-inflammatory response (including a decrease in interleukin-6), a shorter duration of invasive mechanical ventilation, and a dramatic reduction of ICU length of stay (*Laterre et al. The Lancet Infectious Diseases 2019*).

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.

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