



PRESS RELEASE

Positive Topline Results from First-in-Man Trial with CAL02 in the Treatment of Severe Pneumonia

17 April 2018 – Swiss-based anti-infective company Combioxin SA has announced positive results from the first clinical trial of its novel antibacterial agent CAL02. This novel broad-spectrum liposomal anti-toxin drug was shown to be safe and well tolerated at all dose levels. Consistent and promising efficacy trends were also obtained.

CAL02 captures and neutralizes the toxins released from a wide range of bacteria associated with severe infections – an action which is synergistic with antibiotic treatment. It is these toxins which are responsible for the development of severe and fatal complications. CAL02 is a first-in-class non-antibiotic liposomal drug which is active against both Gram-positive and Gram-negative bacteria, including those which are multi-drug resistant. It acts regardless of the resistance profile of the target pathogen and does not elicit the emergence of resistance.

The randomized, multicenter, double-blind, placebo-controlled First-in-Man (FIM) study, led by Dr. Bruno François, University Hospital of Limoges, France and Prof. Pierre-François Laterre, St. Luc University Hospital, Belgium, compared CAL02 plus standard antibiotic therapy with placebo plus standard antibiotic therapy in adult patients admitted to intensive care units (ICUs) due to severe community-acquired pneumococcal pneumonia. Two different doses of CAL02 were compared, namely a low and a high dose. A total of 19 patients were enrolled at six ICUs in France and Belgium.

CAL02 was shown to be safe and well tolerated, with no difference in adverse events and serious adverse events between CAL02 and placebo.

Consistent superiority in efficacy trends was observed across different clinical parameters.

“Although the primary aim of this small study was to demonstrate the safety of CAL02, which it did, we were delighted to observe that it also demonstrated promising positive results which were relatively unexpected given the sample size”, commented Dr. François.

“Assuming that these results can be replicated in the larger studies which we are now planning, CAL02 has the potential to save many lives around the world as a first-line treatment for severe infection” added Prof. Laterre.

Professor Steven Opal, Brown University, USA, also added: “For years we have attended to critically ill patients who appear toxemic with bacteremic pneumococcal pneumonia resulting in a very high mortality within the first few days in ICU. Combioxin’s anti-toxin agent might prove to be a unique defense strategy.”

“We are very excited about this potential breakthrough treatment for severe infection” concluded Jeffrey B. Jump, chairman of Combioxin. “CAL02 could potentially become standard of care to help severely-infected patients and may also be a game changer in the fight against antibiotic resistance.”

Full results from the CAL02 FIM study will be published during the third quarter of 2018.

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About Combioxin

Combioxin SA, founded in 2015, is a Swiss-based biotechnology company dedicated to the development of anti-infective drugs. For more information, please visit www.combioxin.com or email info@combioxin.com.

Media Enquiries:

Please contact Richard Kenyon

+44 7831 569940

richardkenyon44@hotmail.com