Combioxin receives Clinical Trial Authorization to initiate a first-in-man study with CAL02 in patients with severe pneumococcal pneumonia

GENEVA, SWITZERLAND, 12 January 2016 – Combioxin SA is pleased to announce that it has received approval from the French National Agency for Medicines and Health Products Safety (ANSM) and the Belgian Federal Agency for Medicines and Health Products (FAMHP) to commence a randomised, multicentre, double-blind, placebo-controlled first-in-man clinical study for the treatment of severely-ill patients with pneumococcal pneumonia with CAL02.

The study shall aim at assessing safety, tolerability, efficacy and pharmacodynamics of two effective doses of the novel anti-virulence drug. The clinical trial application was submitted and approved via a Voluntary Harmonisation Procedure involving UK, France and Belgium.

CAL02 is a novel broad-spectrum non-antibiotic drug designed to capture bacterial toxins. Severe pneumococcal pneumonia accounts for 20% to 30% of intensive-care units' patients, with a mortality rate that can exceed 30% despite best currently available therapy. Pre-clinical studies have shown that CAL02 increases antibiotics' efficacy to fully rescue infected mice from deadly bacteraemia and pneumonia infections.

"This represents a significant milestone for the company. We are looking forward to our collaboration with critical care specialists and to exciting developments for the company this year", says Frédéric Lajaunias, director at Combioxin.

Antonio Perez, Chief Medical Officer, declared today "At the edge of the "post-antibiotic era" with the unstoppable progression of resistance to antimicrobials we are looking forward to confirming the potential benefit of CAL02 for the treatment of patients with severe infections".

ABOUT CAL02

CAL02 is a broad-spectrum anti-virulence therapeutic agent targeting bacterial toxins for the treatment of severe infections, including those caused by antibiotic-resistant strains. CAL02 acts in combination to antibiotics and also indirectly affects bacterial survival by depriving bacteria from the tools they use to feed and multiply, and by protecting the immune system, which can then appropriately combat the infection. Its use as monotherapy or even as prophylaxis is therefore also foreseeable. The technology was in-licenced from the University of Bern, Switzerland, at *in vitro* stage and *in vivo* proof-of-concept results led to a highly visited article in *Nature Biotechnology*.

ABOUT COMBIOXIN

Combioxin SA, an affiliate of LASCCO SA founded in 2015, is a Swiss-based biotechnology company dedicated to the development of anti-infective drugs. For more information, please visit http://www.lascco.com.

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