



MedinCell announces positive results for the SAIVE clinical study in prevention of Covid-19 infection in a contact-based population

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The study conducted in 399 participants met its primary efficacy endpoint with a reduction of 72% of COVID-19 infection in the group treated with daily oral administration of ivermectin compared to the placebo group

Ivermectin administered for 28 days demonstrated acceptable safety and tolerability without any unexpected safety signals

The SAIVE study was conducted to support mdc-TTG program, whose objective is to provide prevention of Covid-19 infection for weeks or months with a single injection of a long-acting formulation of ivermectin based on MedinCell's proprietary technology, BEPO®

Note: this publication is not a recommendation to use ivermectin against Covid-19.

The SAIVE Trial (NCT 05305560) is a Phase 2, multicenter, randomized, double-blind, placebo-controlled, parallel-group clinical study, evaluating the safety and efficacy of ivermectin tablets taken orally for 28 days, under the oversight of a U.S. based independent Data Monitoring Committee. The study was conducted in Bulgaria between March and November 2022.

All participants were unvaccinated adults and had been exposed to the virus within 5 days of screening after documented close contact with a person who had a PCR-confirmed SARS-CoV-2 infection.

Participants randomized to ivermectin group showed a highly statistically significant reduction (72%) of laboratory-confirmed infections between baseline and Day 28 (30/200) versus placebo (105/199), the study's primary endpoint, with $p < 0,0001$.

No safety signals related to daily intake of ivermectin, 200 microgram/kg on Day 1 then 100 microgram/kg daily from Day 2 to Day 28 were identified during the study.

The company plans to share the final analysis of the study in a peer-reviewed publication at a later date.

"The SAIVE study provides encouraging data demonstrating efficacy and safety of ivermectin in prevention of Covid-19 infection in a post-exposure situation. It supports the development of a long-acting injectable, said Christophe Douat, CEO of MedinCell. Such a long-acting injectable would provide a complementary tool against Covid-19. Several candidate formulations of ivermectin are ready for clinical batch manufacturing to start regulatory preclinical and clinical development. We will be reviewing the strategy for this asset based on this top line result and the upcoming comprehensive analysis of the study."

About MedinCell

MedinCell is a pharmaceutical technology company that develops a portfolio of long-acting injectable products in various therapeutic areas by combining its proprietary BEPO® technology with active ingredients already known and marketed.

U.S. FDA approval for the first product using BEPO® technology for patients with schizophrenia is expected in H1 2023.

Two other products are in clinical Phase 3. In addition, several programs should reach the clinic in 2023 and 2024, including two Global Health initiatives in woman health (contraception) and malaria, supported by the Bill & Melinda Gates Foundation and Unitaid respectively.

Through the controlled and extended release of the active pharmaceutical ingredient, MedinCell makes medical treatments more efficient, particularly thanks to improved compliance, and to a reduction in the quantity of medication required. The BEPO® technology makes it possible to control and guarantee the regular delivery of a drug at the optimal therapeutic dose for several days, weeks or months, depending on the product, starting from the subcutaneous or local injection of a simple deposit of a few millimeters, fully bioresorbable.

BEPO® biocompatible polymers, the key components of each MedinCell formulation, are produced and scaled-up at GMP quality level, and already producible at commercial stage through MedinCell's joint-venture with Corbion (Euronext - CRBN).

MedinCell collaborates with tier one pharmaceuticals companies and foundations to improve Global Health through innovative therapeutic options.

Based in Montpellier, MedinCell is a public company (Euronext, MEDCL), currently employing 150 people from over 30 different nationalities.

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