MedinCell: inclusion of first participants in new Covid-19 prophylaxis clinical trial SAIVE

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The first participants of the SAIVE study have been administered last Friday

SAIVE is a 400-participant, multicenter, randomized, double-blind, placebo-controlled study with an independent Data Monitoring Committee, conducted in the European Union

Interim data are expected mid 2022

SAIVE aims at validating the efficacy in prophylaxis against Covid-19 of administration of Ivermectin in oral daily form

It is part of MedinCell's program to develop a subcutaneous injection that could offer more than 3 months of protection against Covid-19 and its variants

SAIVE follows a Phase 1 clinical study conducted by MedinCell that successfully confirmed the safety of daily, oral Ivermectin administration over a long period of time

"We develop this program in accordance with the highest ethical standards and robust scientific principles, far from polemics, said Joël Richard, Chief Development Officer at MedinCell. *Ivermectin has many modes of action identified and is not only a broad-spectrum antiparasitic agent. There is favorable data published about the prophylactic efficacy of Ivermectin against Covid-19 that must be confirmed by clinical studies conducted in accordance with regulatory authorities' standards. Oral daily administration was chosen to simulate the pharmacokinetic profile, i.e. the circulating drug concentration in the blood, from our long-acting injectable formulation. The data from SAIVE will be analyzed by an independent Data Monitoring Committee and will help inform its future development steps."*

MedinCell's program aims at protecting against Covid-19 with a subcutaneous injection of a long-acting formulation of Ivermectin available in the form of a pre-filled syringe, ready-to-use, with 24-month stability at room temperature. MedinCell's BEPO® technology will allow the formation of a small subcutaneous depot, fully bioresorbable, at the time of injection. It will act as a biodegradable mini pump that releases Ivermectin regularly until it is completely bio resorbed.

A long-acting injectable formulation of Ivermectin could be an additional tool to protect from Covid-19, especially for non-respondents to vaccines, such as immunocompromised people and elderlies, and for those with poor access to vaccines or potential treatments.

A more than 3-month active formulation is ready to enter regulatory development.

The safety of the daily administered Ivermectin dose set at 100 µg/kg was validated during a Phase 1 clinical study conducted by MedinCell *(press release: www.medincell.com/en/2021/04/19/clinical-trial-conducted-by-medincell-confirms-the-safety-of-continuous-administration-of-ivermectin/)*

About the SAIVE study

Study title	SAIVE, A Study to Evaluate the Efficacy and Safety of Ivermectin in COVID-19 Prevention
Description	A multicenter, randomized, double-blind, placebo-controlled trial comparing continuous administration of Ivermectin (in regular, daily, oral form) vs placebo in the prevention of COVID-19 infection as well as symptomatic development, in a close-contact population
Participants	400
Administration	Daily oral Ivermectin or placebo for 4 weeks
Dose	200 µg/kg on Day 1, and then 100 µg/kg/day for Day 2 to Day 28
Primary outcome measure	COVID-19 prophylaxis: proportion of laboratory-confirmed COVID-19 infections between baseline and Day 28

About MedinCell

MedinCell is a pharmaceutical company at premarketing stage 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. Through the controlled and extended release of the active pharmaceutical ingredient, MedinCell makes medical treatments more efficient, particularly thanks to improved compliance, i.e. compliance with medical prescriptions, and to a significant reduction in the quantity of medication required as part of a one-off or chronic treatment. 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 starting from the subcutaneous or local injection of a simple deposit of a few millimeters, fully bioresorbable. MedinCell collaborate with tier one pharmaceuticals companies and foundations to improve Global Health through new therapeutic options. Based in Montpellier, MedinCell currently employs more than 140 people representing over 25 different nationalities.
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