Clinical trial conducted by MedinCell confirms the safety of continuous administration of ivermectin

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Clinical trial validates the safety of ivermectin taken daily in oral form, to simulate the continuous release of the active substance by a long-acting injection.

No side effects were observed with the three doses of ivermectin tested up to 100 µg / kg.

MedinCell develops several long-acting injectable formulations of ivermectin, the most advanced aims at preventing infection from Covid-19 and its mutants for several months.

Positive results of the safety study

"All our programs are developed in accordance with the highest ethical standards and on the basis of reliable scientific principles with a view to potential massive deployment. Proving the safety of ivermectin in regular daily administration over a long period was an essential step for our ivermectin programs, in particular mdc-TTG in Covid-19," said Joël Richard, Chief Development Officer at MedinCell.

Ivermectin has already been administered as a once-daily treatment to hundreds of millions of patients worldwide. Its safety as a once-daily treatment has been demonstrated and documented. MedinCell tested ivermectin taken daily in oral form to simulate the continuous release of the active substance by a long-acting injectable. After completion, the study confirms the safety of ivermectin up to a dose of 100 µg / kg / day in continuous administration over 1 month in healthy volunteers. No significant difference was observed between the treated volunteers and the placebo volunteers in the three cohorts studied successively (daily doses of 50 µg / kg, 75 µg / kg and 100 µg / kg respectively).

The pharmacokinetic data of the three cohorts shows a limited peak circulating plasma concentration in the first 12 hours (Cmax between 25-60 ng / mL) and the rapid achievement of a stationary regime and a regular plasma concentration of between approximately 10 and 30 ng / mL for 28 days, depending on the dose administered. These preliminary results are considered positive and live up to Company expectations based on the data in the literature. The dose-response relationship has not yet been established.

After study completion and in regard of the expert review conducted by Professor Jacques Descotes[1] (March 2021), the safety profile of ivermectin supports the progress of MedinCell programs using this molecule, in particular mdc-TTG against Covid-19 and mdc-STM against malaria.

Covid-19: The prophylactic strategy

"Our hypotheses are being confirmed, says Christophe Douat, CEO of MedinCell*: the pandemic continues, and vaccination may not be enough to stop it. The body of clinical data and scientific knowledge supporting the efficacy of ivermectin at a therapeutic dose against Covid-19, in particular as a prophylaxis, continues to grow. In this context, our treatment, based on a widely known molecule, which could be stored at room temperature and which aims to offer protection for several months after a simple injection against Covid-19 and its variants, could become a key tool of the anti-Covid arsenal. Our goal is still to have a product ready in 2022. "*

Currently in regulatory development, the mdc-TTG program aims to offer an injectable treatment in the form of a pre-filled syringe, ready to use, and stable for 24 months at room temperature. MedinCell's BEPO® technology will allow the formation of a small subcutaneous deposit at the time of injection. It will act as a mini pump that releases ivermectin regularly until it disappears completely.

The long-acting formulation of ivermectin in the mdc-TTG program could provide protection against Covid-19 and its mutants for several months after a single injection. It could also be administered to people identified as Covid-19 contact cases to protect them.

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[1] Jacques Descotes, Medical Safety of Ivermectin», March 2021 (www.medincell.com/ivermectin)

About the clinical safety study

Study title	Exploratory phase 1, randomized, double-blind trial assessing the pharmacokinetic profile, safety and tolerability of a regime of continuous daily administration of Ivermectin to healthy volunteers
Participants	3 successive cohorts of 8 healthy volunteers (one cohort per dose)
Administration	Daily dose of Ivermectin or placebo taken orally for 4 weeks by each cohort
Doses tested	Cohort 1: 200 µg/kg (day 1) + 50 µg/kg daily (day 2 to 28)
	Cohort 2: 200 µg/kg (day 1) + 75 µg/kg daily (Day 2 to 28)
	Cohort 3: 200 µg/kg (day 1) + 100 µg/kg daily (day 2 to 28)
Authorization of clinical trials	MHRA (Medicines & Healthcare products Regulatory Agency – United Kingdom)
Study period	September 2020 – March 2021

About MedinCell

MedinCell is a clinical stage pharmaceutical 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. 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. Based in Montpellier, MedinCell currently employs more than 140 people representing over 25 different nationalities.

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