# Covid-19: MedinCell presents positive first results from the clinical trial aiming at validating the safety of continuous administration of Ivermectin

Euronext: MEDCL • Montpellier - France • December 17, 2020 - 8:00 pm CET

---

Study's first results presented at the international *"Collaborative Workshop – Ivermectin against Covid-19"* held on December 15, 16 and 17 at the initiative of MedinCell

No side effects observed with the first two doses in the study, which includes a total of three doses

A first long-acting injectable formulation is ready to enter regulatory development

---

**Prophylactic strategy**

The objective of the mdc-TTG program is to protect from Covid-19 with a subcutaneous injection of a several months active treatment of Ivermectin, a molecule already widely used in other indications. There is a growing body of hints and related publications showing the activity of Ivermectin on Covid-19.

The prophylactic strategy is similar to the one already used against HIV: "preexposure prophylaxis" (PrEP) has shown its efficacy and also the need for long-acting injectable treatments, as these are the only ones to guarantee the continuity of protection.

The program also aims at providing "postexposure prophylaxis" (PEP) for established close contact with Covid-19.

**Positive preliminary results from the safety study**

The preliminary results of the study are presented at the *"Collaborative Workshop – Ivermectin against Covid-19"* held by MedinCell on December 15, 16 and 17 to foster international collaboration and speed ongoing research activities. Researchers and clinicians from around the world have presented their work on understanding Ivermectin's mode of action against Covid-19 and shared clinical data from its use for therapeutic and prophylactic purposes.

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. The clinical trial underway aims at demonstrating its safety when taken daily in oral form in order to simulate the continuous release of the drug by a long-acting injectable. The results of this study could accelerate the regulatory review of the long-acting injectable formulation developed by MedinCell.

*"There is mounting evidence of Ivermectin's prophylactic effects. That said, we are pursuing our mdc-TTG program in accordance with the highest ethical standards and on the basis of reliable scientific principles. Proving Ivermectin's safety when administered daily over a long period of time is a crucial step in the process towards a potential mass roll-out"*, added Joël Richard, MedinCell's Chief Development Officer.

| | |
|---|---|
| Title of the study | *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* |
| Doses | *3 doses of Ivermectin tested gradually: 50 µg/kg, 75 µg/kg, 100 µg/kg* |
| 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* |
| Authorization of clinical trials | *MHRA (Medicines & Healthcare products Regulatory Agency – United Kingdom)* |

No significant side effects were observed in the first cohorts (daily doses of 50 µg/kg, 75 µ respectively) studied successively. Continuous administration over a 1-month period to healthy volunteers in the first two cohorts of the study confirms Ivermectin's safety up to a dose of 75 µg/kg.

As regards the doses administered to the first two cohorts, the preliminary pharmacokinetic data shows a limited peak circulating plasma concentration in the first 12 hours (Cmax 35-55 ng/mL), the rapid achievement of a stationary regime and a regular plasma concentration of between 10 and 20 ng/mL for 28 days. These preliminary results are highly encouraging and live up to Company expectations based on the data in the literature. The dose-response relationship has not yet been established.

**Formulation candidate ready to commence regulatory development**

mdc-TTG uses MedinCell's BEPO® technology. Three products based on BEPO® technology are already in clinical trials in the United States, the most advanced one at the end of phase 3.

The program aims at providing an injectable treatment in the form of a pre-filled syringe, ready-to-use, with 24-month stability at room temperature. BEPO® technology will allow the formation of a small subcutaneous depot, fully bioresorbable, at the time of injection. It will act as a mini pump that releases Ivermectin regularly until it disappears completely.

Concurently with the clinical trial underway, several injectable formulations have been tested in vivo over the past several months. A preliminary formulation candidate potentially active for one to two months will be ready to enter preliminary preclinical activities of regulatory development in late December. A 3-month active product is also being formulated.

In a favorable scenario, MedinCell could be ready to make submissions for marketing approval in late 2021. Indeed, the validation of the efficacy of Ivermectin by the numerous studies in progress and the persistence of the pandemic could pave the way for mdc-TTG to qualify for a fast-track review by the regulatory authorities, speeding up its clinical development.

**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 130 people representing over 25 different nationalities.

---

**Contacts**

MedinCell
David Heuzé
Communication leader
david.heuze@medincell.com
+33 (0)6 83 25 21 86

NewCap
Mathilde Bohin / Louis-Victor Delouvrier
Investor relations
medincell@newcap.eu
+33 (0)1 44 71 98 53

NewCap
Nicolas Merigeau
Media relations
medincell@newcap.eu
+33 (0)1 44 71 94 98