MedinCell initiates the first clinical trial of its Covid-19 prevention program

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First patient was administered today

The trial aims at validating the safety of continuous administration of Ivermectin in oral form

Simultaneously, several long-acting injectable formulations based on MedinCell's BEPO® technology are being tested *in vivo*

A 1-month active injectable prophylactic treatment should be ready to enter regulatory development before the end of the year

MedinCell may file for market authorization as early as 2021

Universal vaccination remains very hypothetical; this preventive treatment should be essential in all scenarios

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Prophylactic strategy

The objective of the mdc-TTG program is to protect from Covid-19 with a subcutaneous injection of a 1-month active treatment of Ivermectin, a molecule already widely used in other indications. Since the beginning of the pandemic, clues about its potential efficacy against Covid-19 have piled up.

This prevention strategy called "pre-exposure prophylaxis" (PrEP) is similar to the one already used against HIV. People are protected for the duration of treatment. It has demonstrated its efficacy but also the need for long-acting injectable treatments, the only ones to guarantee the continuity of protection.

"We keep focused on developing the third path against Covid-19, prevention, with our BEPO® technology which has already attracted prestigious partners thanks to its large-scale deployment potential", says Christophe Douat, CEO of MedinCell. *"Our program against Covid-19 is a bit like David versus Goliath. But we have already demonstrated the strength of our alliance model, which allows us to collaborate with the best partners."*

A first clinical trial to accelerate the development of the long-acting injectable

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[1].

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.

Ivermectin has already been administered as a single dose to hundreds of millions of patients around the world. Its safety has been demonstrated and documented[2]. The clinical trial initiated today aims at validating its safety when taken regularly in oral form over 4 weeks to simulate the continuous release of the active ingredient by a long-acting injectable.

The current clinical trial will gradually evaluate three increasing doses by daily administration over 4 weeks in three successive cohorts of healthy volunteers. It will serve as a solid foundation for the regulatory development of the long-acting injectable formulation and its potential mass deployment.

"MedinCell develops mdc-TTG in accordance with the highest ethical standards and on the basis of reliable scientific principles. It is essential for us to optimize the clinical development of our product. We must not waste time given the potential impact of the product which could effectively protect tens of millions of people around the world, especially the most vulnerable" explains Joël Richard, Head of Development at MedinCell.

Study title	*A Randomised, Double-Blind, Exploratory Phase I Trial Assessing the Pharmacokinetic Profile, Safety and Tolerability of a Continuous Daily Dosing Regimen of Ivermectin in Healthy Volunteers*
Doses	*3 doses of Ivermectin tested gradually*
Participants	*3 successive cohorts of 8 healthy volunteers (one cohort per dose)*
Administration	*Daily oral Ivermectin or placebo for 4 weeks for each cohort*
Clinical Trial Authorization	*MHRA (Medicines & Healthcare product Regulatory Agency – UK)*

A formulation candidate ready to enter regulatory development before the end of the year

Concurrently with this first clinical trial, the first injectable formulations are currently being tested in vivo. MedinCell expects to have a 1-month active injectable ready to enter the preliminary preclinical stages of regulatory development by the end of 2020. A 3-month active product is also being formulated.

In a favorable scenario, MedinCell will apply for market authorization before the end of 2021. Indeed, the validation of the efficacy of Ivermectin by the numerous studies in progress and the persistence of the pandemic should allow mdc-TTG to benefit from accelerated regulatory pathway for clinical development.

The large-scale production capacities set up as part of the joint venture formed by MedinCell with Corbion, will enable the large-scale supply of the biocompatible polymers required for the production of tens of millions of doses.

In addition, several advanced discussions are underway with public and private partners to fund this program so that it has no impact on MedinCell's cash visibility.

The pandemic continues, Ivermectin confirms its potential

Assumptions that led MedinCell to initiate the mdc-TTG program are being confirmed. The pandemic continues; initiatives and signs of the potential efficacy of Ivermectin against Covid-19 accumulate:

- several potential modes of action are suggested by the scientific community, in particular the one described by Zahir Amoura and Jean-Pierre Changeux[3] which would also explain the protection of smokers, Ivermectin having the same effect as nicotine on the nicotinic receptor, without risk of addiction.
- several studies, observational or clinical, resulted to the publication of favorable data, in particular concerning the potential prophylactic efficacy of Ivermectin. For example, a study by the University of Zagazig about contact cases within families in which a case of Covid-19 was detected[4]. The recently published preliminary results show that 7.4% of the 203 participants who received two doses of Ivermectin 72 hours apart for prevention showed symptoms of Covid-19 infection within two weeks. They were 58.4% to present such symptoms among the 102 subjects of the untreated control group.
- the results of studies sponsored by several prestigious institutes and the ongoing clinical studies - more than 50[5] - aim at proving in the coming months the efficacy of Ivermectin as a curative or prophylactic treatment against Covid-19.

Ivermectin is also already used in several countries to treat patients with the approval of health authorities such as Peru, Bolivia or Australia, where Ivermectin can be prescribed in combination with other drugs.

Finally, many questions remain about the reported vaccines, their real efficacy, their safety, their universality, their duration of action, their acceptance by patients, but also their availability; even if a vaccine becomes available, MedinCell's prevention solution should remain essential.

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
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

[1] Evaluate TV-46000 as Maintenance Treatment in Adult and Adolescent Patients With Schizophrenia (RISE).
https://clinicaltrials.gov/ct2/show/NCT03503318

[2] Quantitative proteomics reveals a broad-spectrum antiviral property of ivermectin, benefiting for COVID-19 treatment. Na Li, Lingfeng Zhao, Xianquan Zhan. July 2020
https://onlinelibrary.wiley.com/doi/10.1002/jcp.30055

[3] A nicotinic hypothesis for Covid-19 with preventive and therapeutic implications. Jean-Pierre Changeux, Zahir Amoura, Felix A Rey, Makoto Miyara. July 2020
https://www.researchgate.net/publication/340847569_A_nicotinic_hypothesis_for_Covid-19_with_preventive_and_therapeutic_implications

[4] Zagazig University Randomized Controlled Ivermectin Study: Prophylactic Ivermectin in COVID-19 Contacts.
Study results available at Clinicaltrials.gov: *https://clinicaltrials.gov/ct2/show/results/NCT04422561*

[5] Ivermectin as a Broad-Spectrum Host-Directed Antiviral: The Real Deal? David A. Jans and Kylie M. Wagsta, Monash University, Sept 2020.
Study available at *https://pubmed.ncbi.nlm.nih.gov/32942671/*