Covid-19: MedinCell publishes an extensive Ivermectin Safety Expert Analysis

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No safety concern is anticipated that would prevent health authorities from assessing the use of Ivermectin against Covid-19 as a new indication

The expert review written by a prominent toxicologist is an assessment of ivermectin medical safety profile

It is based on an extensive analysis of over 350 articles plus clearly identified and accessible web sources

The analysis will be submitted shortly by the author for peer review to an internationally acknowledged journal

MedinCell is making this review available immediately at www.medincell.com/ivermectin

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"Publications over the last few months show a significant body of clinical data and scientific knowledge supporting the efficacy of ivermectin at therapeutic dose against Covid-19, for both curative and prophylactic purpose", says Christophe Douat, CEO of MedinCell.

"Safety is also critical to decide on the approval and use of a drug. An exhaustive analysis of existing ivermectin medical safety scientific literature was missing. MedinCell mandated its international toxicology expert to conduct this analysis to contribute to the global momentum to assess the use of ivermectin to fight the Covid-19 pandemic."

"The conclusion of the expert analysis is clear: no safety concern is anticipated that would prevent health authorities from assessing the use of Ivermectin against Covid-19 as a new indication."

The analysis has been performed by Pr. Jacques Descotes*, MD, PharmD, PhD, Professor Emeritus, Claude Bernard University of Lyon (France), a world-known toxicologist with a 40-year track as an independent consultant for the pharmaceutical industry as well as an advisor to regulatory bodies worldwide.

"Ivermectin has been administered orally to hundreds of millions of people throughout the world in the past three decades. The assessment of reported adverse events temporally associated with ivermectin exposure shows that ivermectin-induced adverse effects have so far been infrequent and usually mild to moderate", declares Pr. Jacques Descotes.

"It is noteworthy that no deaths have seemingly ever been reported after an accidental or suicidal overdose of ivermectin. No greater toxicity of ivermectin has been substantiated in elderly people despite repeated assertions that an ageing blood-brain barrier might lead to increased ivermectin toxicity level. The positive clinical experience accumulated with ivermectin administration led many medical experts to break away from early adamant contra-indications in pregnant women. Finally, several national pharmacovigilance networks around the world released information and opinions to ascertain ivermectin safety in human subjects. So far, there are no critical safety limitations to ivermectin prescription in current indications."

"I also want to point out that no severe adverse event has been reported in dozens of completed or ongoing studies involving thousands of participants worldwide to evaluate the efficacy of ivermectin against COVID-19."

* Declaration of interest: Jacques Descotes holds shares in MedinCell SA but has no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or conflict with the subject matter.

This press release is not a recommendation for off label use of Ivermectin.

About MedinCell and Ivermectin against Covid-19

This expert review has been completed in parallel to the program launched by Medincell in March 2020 aiming at protecting from Covid-19 infection and its variants for several months with ivermectin.

MedinCell is developing a Long-Acting Injectable of ivermectin based on its BEPO® technology in the form of a pre-filled syringe, ready-to-use, with 24-month stability at room temperature. It 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.

A first formulation candidate has entered preclinical activities of regulatory development in January.

As part of this program, MedinCell is currently completing a clinical trial aiming at demonstrating the safety of ivermectin when taken daily in oral form in order to simulate the continuous release of the drug by a long-acting injectable. After positive interim data published in December, full results will be made available in the coming weeks. They will support the regulatory review of the long-acting injectable formulation developed by MedinCell.

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.

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