MedinCell's Long-Acting Injectable to fight Malaria ready to enter Regulatory Development

MedinCell and the project consortium members, IRD, IRSS and CIRDES, have successfully designed, tested, and confirmed with Unitaid the selection of the lead formulation. Regulatory preclinical activities are starting with the objective of a first clinical trial in 2023.

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MedinCell and the consortium members have conducted an *in vivo* proof of concept on cattle that showed a 3-month mosquitocidal effectiveness of an injectable long-acting formulation of Ivermectin based on the proprietary BEPO® technology.

The investigational product mdc-STM aims at reducing the transmission of the parasite responsible for Malaria, thanks to a killing effect on the vector mosquitoes when they bite treated people.

Malaria remains one of the main health threats worldwide with more than 200 million people infected yearly.

In March 2020, global health agency Unitaid granted MedinCell with a $6.4 million subvention over three years to conduct the formulation and preclinical activities of the program.

mdc-STM benefits from synergies with other MedinCell's programs based on Ivermectin all of them using different formulation and doses fitted to their specific indications.

MedinCell has been collaborating for more than 10 years with IRD, IRSS and CIRDES to conduct *in vivo* studies in Burkina Faso about tackling residual transmission of Malaria. These partners provide theoretical and practical scientific expertise on malaria and vectors, and the essential field infrastructure to support the demonstration of a 3-month active injectable ivermectin formulation against malaria vectors. Administered once to exposed populations at the start of the rainy season, which is the period of highest risk of transmission, the investigational product could have a significant impact on malaria incidence and prevalence in Africa where the burden is the highest.

Malaria remains pandemic in 91 countries representing 50% of the world's population. According to WHO estimates, 228 million people were infected worldwide in 2018, 93% of them in Africa, leading to 405,000 deaths. Children under 5 years are the most vulnerable, accounting for 67% of deaths from malaria.

Ivermectin has a long track record of use as a safe and effective drug to treat several parasitic diseases, such as river blindness. Its safety in continuous dosing over 1-month has been demonstrated by a recent randomized placebo-controlled clinical trial sponsored by MedinCell, in which ivermectin was orally administered daily, to simulate the continuous release of the active substance by a long-acting injection. This study and the expert review recently conducted by Pr. Jacques Descotes about the safety profile of ivermectin supports the progress of MedinCell programs using Ivermectin.

Unitaid aims at expanding access to much-needed drugs and diagnostics. Unitaid has committed to accelerate the impact of long-acting technologies in LMICs by supporting the development of innovative products that could redefine prevention and treatment of infectious diseases like HIV, TB, Malaria and hepatitis C. MedinCell has been the first private company to receive support from Unitaid to help develop and commercialize long-acting medicine.

By supporting MedinCell and the consortium, Unitaid is investing in finding additional solutions to prevent the spread of malaria and in making them more accessible. According to the agreement, the Unitaid-funded Medicines Patent Pool - in charge of licensing agreements for the exploitation of patents for medicines in low- and middle-income countries - will receive a non-exclusive royalty free license to ensure distribution of the final product via public sector in LMICs.

MedinCell will keep potential benefits of marketing rights of the product worldwide and for all potential additional indications where this formulation might have an impact.

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.

www.medincell.com

Contacts

MedinCell
David Heuzé
Head of communication
david.heuze@medincell.com
+33 (0)6 83 25 21 86

NewCap
Louis-Victor Delouvrier
Relations investisseurs
medincell@newcap.eu
+33 (0)1 44 71 94 94

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