

MedinCell provides an update on its product portfolio, following the FDA Acceptance of New Drug Application for the product mdc-IRM

Conference held today for shareholders and the financial community:

- Conference in French at 6:00 pm (CEST)
- Conference in English at 7:00 pm (CEST)
- Connection link: <u>invest.medincell.com/conference</u>

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MedinCell and Teva announced yesterday the FDA acceptance of the New Drug Application for mdc-IRM for patients with schizophrenia

This first long-acting injectable treatment based on MedinCell's technology could be commercialized as early as 2022 by Teva in the U.S.

Upcoming portfolio milestones expected:

- mdc-TJK and mdc-ANG: Announcement of next steps by Teva expected by year-end.
- mdc-CWM: Our partner AIC is targeting FDA approval to initiate Phase 3 efficacy studies before the end of 2021. The start of the safety study has been postponed.
- mdc-TTG: MedinCell is awaiting the approval of health authorities in several European countries, including France, to initiate a multi-center, randomized, double-blind, placebo-controlled Phase 2 clinical trial to confirm the prophylactic efficacy of ivermectin in regular, daily, oral form to simulate the continuous release of the active ingredient by a long-acting injectable.

Portfolio of products based on BEPO® technology in regulatory development



mdc-IRM: New Drug Application under review by the FDA

The acceptance by the FDA in the U.S. of the new drug application for mdc-IRM is based on data from two pivotal Phase 3 studies which evaluated the long-term efficacy, safety and tolerability of the product mdc-IRM as a treatment for patients with schizophrenia. Results will be shared by Teva at future scientific conferences and in peer-reviewed publications.

Subject to FDA marketing approval, the product could be commercially launched in 2022 in the U.S. Teva will continue to lead the clinical development and regulatory process and be responsible for commercialization of this candidate treatment, with MedinCell eligible for development milestones, royalties on net sales and future commercial milestones.

"In 2020, the market for long-acting injectable antipsychotics in the U.S. attained \$3.7 billion, with an average annual growth rate of 14% over the past three years," said Christophe Douat, Chairman of MedinCell's Management Board. "Already well established in the U.S. and in the field of the central nervous system, Teva will be a perfect partner to enter this market once mdc-IRM obtains its marketing authorization."

mdc-IRM is the first of three antipsychotic products developed in collaboration with Teva.

Clinical stage products

mdc-IRM Treatment of schizophrenia Partner: Teva Pharmaceuticals	The new drug application is under review by the FDA. The commercial launch in the U.S. could start in 2022.		
mdc-TJK Antipsychotic Partner: Teva Pharmaceuticals	Expected by the end of 2021, the findings of the ongoing analysis of the results of the first-in-human study will drive future developments.		
mdc-CWM Post-operative pain and inflammation	Our partner AIC is targeting FDA approval to initiate Phase 3 efficacy studies before the end of 2021.		
Partner: AIC	At the request of the FDA, the start of the safety study, aimed at completing the long-term safety database for mdc-CWM, has been postponed. It will start after the preliminary results of the first Phase 3 study are obtained. Our partner indicates that this will have no impact on the overall program schedule.		
Next potential candidates for clinical development			
mdc-ANG Antipsychotic Partner: Teva Pharmaceuticals	Ongoing preclinical work could lead to the start of clinical activities before the end of 2021.		
mdc-GRT Organ transplantation MedinCell program	A candidate formulation has been selected based on <i>in vivo</i> studies. The program is in regulatory preclinical development with clinical trials expected to start in the second half of 2022.		
mdc-TTG Covid-19 and variants MedinCell program	MedinCell is awaiting the approval of health authorities in several European countries, including France, to initiate a multi-center, randomized, double-blind, placebo-controlled Phase 2 clinical trial to confirm the prophylactic efficacy of ivermectin in regular, daily, oral form to simulate the continuous release of the active ingredient by a long-acting injectable. The results of this study and the global context of the pandemic will guide and optimize future developments of the long-acting injectable.		
mdc-WWM Contraception Partner: Bill & Melinda Gates Foundation	A candidate formulation has been selected based on <i>in vivo</i> studies. The program is in regulatory preclinical development with clinical trials expected to start in 2023.		
mdc-KPT (animal health) Pain MedinCell program	A candidate formulation has been selected on the basis of <i>in vivo</i> studies. The program is in regulatory development with pivotal studies expected to start in the first half of 2022.		
mdc-STM Malaria Partner: Unitaid	A candidate formulation was selected on the basis of <i>in vivo</i> . The program is in regulatory preclinical development with clinical trials scheduled to begin in 2023.		

Other projects

Several other internal or partnered projects are currently under evaluation or formulation. If successful, they will enrich the company's portfolio.

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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