Initiation of the Phase 3 study for the second long-acting injectable antipsychotic using MedinCell’s technology (program mdc-TJK)

Euronext: MEDCL • Montpellier - France • January 24, 2023 – 6:00 pm CET

The Phase 3 study conducted in the U.S. will assess the efficacy and safety of the first subcutaneous long-acting Injectable (LAI) formulation of olanzapine for the treatment of patients with schizophrenia.

MedinCell’s partner Teva, who finances and pilots the regulatory development of the product (TEV-44749), has just published details of the study protocol on clinicaltrials.gov (https://clinicaltrials.gov/ct2/show/NCT05693935?term=Teva&recrs=ab&phase=2&draw=2&rank=9).

Enrollment of the first patients is expected in the coming days.

mdc-TJK follows mdc-IRM (LAI risperidone), the first subcutaneous antipsychotic based on MedinCell’s technology currently under regulatory review by the U.S. FDA, with a launch target set for H1 2023.

About MedinCell

MedinCell is a pharmaceutical technology 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.

U.S. FDA approval for the first product using BEPO® technology for patients with schizophrenia is expected in H1 2023.

Two other products are in clinical Phase 3. In addition, several programs should reach the clinic in 2023 and 2024, including two Global Health initiatives in women’s health (contraception) and malaria, supported by the Bill & Melinda Gates Foundation and Unitaid respectively.

Through the controlled and extended release of the active pharmaceutical ingredient, MedinCell makes medical treatments more efficient, particularly thanks to improved compliance, and to a reduction in the quantity of medication required. 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, depending on the product, starting from the subcutaneous or local injection of a simple deposit of a few millimeters, fully bioresorbable.

BEPO® biocompatible polymers, the key components of each MedinCell formulation, are produced and scaled-up at GMP quality level, and already producible at commercial stage through MedinCell’s joint-venture with Corbio (Euronext - CRBN).

MedinCell collaborates with tier one pharmaceuticals companies and foundations to improve Global Health through innovative therapeutic options.

Based in Montpellier, MedinCell is a public company (Euronext, MEDCL), currently employing 150 people from over 30 different nationalities.

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