MedinCell's partner Teva today announced refiling for approval of mdc-IRM and confirmed planned launch in the U.S. in H1 2023

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MedinCell's partner, Teva, today announced that it recently completed the re-submission to a New Drug Application to the U.S. FDA for mdc-IRM, a risperidone subcutaneous Long-Acting Injectable (LAI) for the maintenance treatment of schizophrenia using MedinCell's proprietary technology.

Following a complete response letter from the FDA in mid-April, Teva worked quickly to align on a path forward and to conduct a complete quality check of all clinical data.

Teva now expects review and approval to take up to six months post resubmission. Teva is confident that it will achieve FDA approval and launch mdc-IRM under the brand name UZEDY™ in the first half of 2023. Teva continues to be committed to working closely with the Agency to bring this new and important risperidone subcutaneous LAI product to the schizophrenia patients who need it.

Initiation of Phase 3 activities for a second LAI antipsychotic using the same LAI technology was notified to MedinCell by Teva in September 2022. It will assess the efficacy and safety of potentially the first subcutaneous LAI formulation of olanzapine for the treatment of patients with schizophrenia.

For each product, MedinCell is potentially eligible for development and commercial milestones (up to $122 million), and royalties on net sales.

About MedinCell

MedinCell is a pharmaceutical company at premarketing stage 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. MedinCell collaborate with tier one pharmaceuticals companies and foundations to improve Global Health through new therapeutic options. Based in Montpellier, MedinCell currently employs more than 150 people representing over 30 different nationalities.
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control that may, if any, cause actual results, performance, or achievements to differ materially from those anticipated or expressed explicitly or implicitly by such forward-looking statements. A list and description of these risks, contingencies and uncertainties can be found in the documents filed by the Company with the Autorité des Marchés Financiers (the "AMF") pursuant to its regulatory obligations, including the Company's registration document, registered with the AMF on September 4, 2018, under number I. 18-062 (the "Registration Document"), as well as in the documents and reports to be published subsequently by the Company. In particular, readers' attention is drawn to the section entitled "Facteurs de Risques" on page 26 of the Registration Document.

Any forward-looking statements made by or on behalf of the Company speak only as of the date they are made. Except as required by law, the Company does not undertake any obligation to publicly update these forward-looking statements or to update the reasons why actual results could differ materially from those anticipated by the forward-looking statements, including in the event that new information becomes available. The Company's update of one or more forward-looking statements does not imply that the Company will make any further updates to such forward-looking statements or other forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements.

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