Phase 1 data of mdc-TJK investigational long-acting injectable of olanzapine for schizophrenia patients, exhibited favorable characteristics of an extended-release profile

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mdc-TJK has the potential to be the first long-acting injectable of olanzapine with a favorable safety profile

MedinCell's partner, Teva Pharmaceuticals, highlighted mdc-TJK as one of their three promising late-stage assets poised to accelerate growth during their Investor Day on May 18, 2023 (replay and presentation available here)[1]

mdc-TJK is the second product developed by Teva based on BEPO® (licensed under the name SteadyTeq™ to Teva), MedinCell's long-acting injectable technology, which has a proven safety profile as established with UZEDY™ (FDA approved on April 28, 2023)

As announced on May 4, 2023, MedinCell's partner Teva Pharmaceuticals communicated an original presentation describing pharmacokinetic characteristics of an investigational long-acting subcutaneous formulation of olanzapine (mdc-TJK) at the 2023 Schizophrenia Investigational Research Society (SIRS) on Friday, May 12.

Data came from a 127-participant phase 1 clinical study evaluating, among other things, the pharmacokinetics of single ascending doses of mdc-TJK in healthy volunteers and single and multiple once-monthly doses in patients with schizophrenia or schizoaffective disorder.

mdc-TJK exhibited favorable characteristics of an extended-release profile:

- Reaching clinically relevant therapeutic olanzapine plasma concentrations (≥ 10 ng/mL) within a 1 to 2 day and maintaining them during the 28-day dosing interval
- At steady-state conditions over a 28 dosing interval, the systemic exposure of mdc-TJK at doses 318, 425 and 531 mg were comparable to oral daily corresponding doses 10 mg, 15 mg, and 20 mg respectively
- No burst or uncontrolled rise in olanzapine plasma concentrations following mdc-TJK subcutaneous administration was observed

The results of this study supported dose selection of mdc-TJK in the ongoing Phase 3.

The phase 3 study is designed to establish both efficacy and safety, including to identify PDSS (*post-injection delirium/sedation syndrome)* event occurrence. Both MedinCell and Teva believe that BEPO® technology and subcutaneous administration will allow olanzapine LAI to have a favorable safety profile.

Richard Malamut MD, CMO of MedinCell, comments: *"We are hopeful that the safety profile of mdc-TJK will be favorable compared to other long-acting injections available for olanzapine. With the long-acting product already available, patients have to be monitored for 3 hours after injection because of risk of PDSS. An improved long-acting injectable of olanzapine could answer a significant unmet medical need."*

"We are very excited to see both UZEDY™ and *mdc-TJK highlighted as having the potential to drive long-term growth of Teva at their recent investor day presentation."*, adds Christophe Douat, CEO of MedinCell.

mdc-TJK is the second antipsychotic (following approval of UZEDY™) based on MedinCell's BEPO® technology. MedinCell is eligible for development milestones, royalties on net sales, and future commercial milestones.

[1] *https://ir.tevapharm.com/Events-and-Presentations/events-and-presentations/event-details/2023/Teva-Pharmaceutical-Industries-2023-Investor-Day--2023-QP7tTiob5U/default.aspx*

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About MedinCell

MedinCell is an innovative pharmaceutical company, from development to market, with a portfolio of long-acting injectable products in various therapeutic areas by combining its proprietary BEPO® technology (licensed to Teva under the name SteadyTeq™) 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 collaborates with tier one pharmaceuticals companies and foundations to improve Global Health through new therapeutic options. Based in Montpellier, MedinCell currently employs more than 140 people representing over 25 different nationalities.
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