

PRESS RELEASE - March 31, 2025 - 7:30pm CEST - Montpellier, France - Euronext: MEDCL

# Medincell's Partner Teva Presented Phase 3 Survey Results Demonstrating Patient and Healthcare Professional Satisfaction with Olanzapine LAI

More than 92% of schizophrenia patients taking Olanzapine LAI in the Phase 3 SOLARIS survey were satisfied or very satisfied with the initiation regimen, dosing schedule and trial medication<sup>1</sup>

Richard Malamut, Chief Medical Officer at Medincell, commented: "Patient and healthcare professional satisfaction with treatment options is critical to successfully managing schizophrenia. In addition to positive efficacy results², the Phase 3 trial of our long-acting injectable formulation of olanzapine has demonstrated promising potential in addressing the significant challenge of PDSS³⁴. Encouraging early clinical feedback further indicates that the key features enabled by our technology - such as a convenient dosing schedule, straightforward initiation regimen, and subcutaneous administration - have been very well received. These advantages could be instrumental in expanding treatment access for more individuals living with schizophrenia."

These survey results were presented by Teva as part of a large set of schizophrenia data at the SIRS 2025, taking place from March 29 to April 2 in Chicago (<u>Teva's press release</u>)

### List schizophrenia data presented by Teva at SIRS 2025

# Olanzapine LAI (mdc-TJK / TEV-'749)

 (De novo) Patient and healthcare professional attitudes and trial experiences with a subcutaneous long-acting injectable olanzapine (TV-44749) for the treatment of schizophrenia

# **UZEDY** (risperidone):

 (De novo) Predictors of response and non-response to treatment for schizophrenia: machine learning analysis of patients treated with TV-46000 or placebo in the RISE study

## Schizophrenia Treatment Landscape:

- (De novo) Healthcare professionals' attitudes toward use of long-acting injectable antipsychotics for schizophrenia treatment differ among settings of care: ADVANCE survey results
- (De novo) The evolving schizophrenia treatment landscape in the United States: A real-world claims analysis of treatment patterns and use of long-acting injectable antipsychotics
- (De novo) Real-world antipsychotic prescription patterns among patients with schizophrenia in Australia: Results from the ARIEL study
- (De novo) Country-specific factors influencing patients' willingness to use a long-acting injectable antipsychotic to treat schizophrenia: patient and caregiver ADVANCE survey results
- (De novo) Patient and caregiver engagement to support the development of clinical trials in adolescents living with schizophrenia

Olanzapine LAI (mdc-TJK / TEV-'749) is an investigational, once-monthly, subcutaneous long-acting injection of the atypical antipsychotic olanzapine for the treatment of schizophrenia. This is the second drug within the partnership with Teva that uses Medincell's co-polymer technology (licensed to Teva under the name SteadyTeq™) to generate a controlled steady release of drug throughout the dosing interval. Teva is currently preparing for regulatory

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<sup>&</sup>lt;sup>1</sup> Data on file. Parsippany, NJ: Teva Neuroscience, Inc.

 $<sup>^2 \</sup> Press \ release, May \ 8, 2024: www.medincell.com/wp-content/uploads/2024/05/PR\_Solaris\_08052024\_EN\_Final.pdf$ 

<sup>&</sup>lt;sup>3</sup> Post-Injection Delirium/Sedation Syndrome (PDSS) is a rare but significant complication associated with existing long-acting injectable formulation of olanzapine. PDSS occurs when a portion of the injected medication unintentionally enters the bloodstream too quickly, causing sudden sedation, confusion, and potentially serious side effects such as respiratory issues. For healthcare providers and patients, PDSS remains a barrier to the widespread use of olanzapine LAI. The requirement for close post-injection monitoring limits the convenience and flexibility of this treatment option. Medincell's olanzapine LAI is designed to eliminate the risk of PDSS, potentially making it a safer and more accessible treatment option.

<sup>&</sup>lt;sup>4</sup> Press release, November 6, 2024; www.medincell.com/wp-content/uploads/2024/11/PR MDC Teva-earnings-Q3 2024 06112024.pdf

submission and launch of Olanzapine LAI, with long-term full safety data expected to be released in Q2 2025 and an NDA submission anticipated in H2 2025. UZEDY<sup>®</sup>, the other drug, was approved by the US FDA in April 2023.

Medincell's partner Teva leads the clinical development and regulatory process and is responsible for commercialization of the long-acting olanzapine. Medincell is entitled to receive royalties on net sales, along with development and commercial milestone payments.

#### **About Medincell**

Medincell is a clinical- and commercial-stage biopharmaceutical licensing company developing long-acting injectable drugs in many therapeutic areas. Our innovative treatments aim to guarantee compliance with medical prescriptions, to improve the effectiveness and accessibility of medicines, and to reduce their environmental footprint. They combine active pharmaceutical ingredients with our proprietary BEPO® technology which controls the delivery of a drug at a therapeutic level for several days, weeks or months from the subcutaneous or local injection of a simple deposit of a few millimeters, entirely bioresorbable. The first treatment based on BEPO® technology, intended for the treatment of schizophrenia, was approved by the FDA in April 2023, and is now distributed in the United States by Teva under the name UZEDY® (BEPO® technology is licensed to Teva under the name SteadyTeq™). We collaborate with leading pharmaceutical companies and foundations to improve global health through new treatment options. Based in Montpellier, Medincell currently employs more than 140 people representing more than 25 different nationalities.

UZEDY<sup>®</sup> and SteadyTeq<sup>™</sup> are trademarks of Teva Pharmaceuticals

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