**PRESS RELEASE** - November 4, 2024 - 08:00am CET - Montpellier, France - Euronext Paris: MEDCL

# Medincell's partner Teva Unveils New Phase 3 Positive Results for Olanzapine LAI, and Presents Real-World Data on UZEDY® at Psych Congress 2024[1]

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**TEV-'749 / mdc-TJK - Investigational Olanzapine Long-Acting Injectable**

- **Teva presented positive data from the initial period of the Phase 3 SOLARIS trial evaluating Olanzapine LAI in adult patients diagnosed with schizophrenia.**
- **Findings demonstrate significant improvement in social functioning and quality of life across multiple validated measures from baseline to week 8.**
- **Data show that Medincell subcutaneous delivery technology underlying olanzapine LAI resulted in no occurrence of Post-Injection Delirium/Sedation Syndrome (PDSS) events to date.**
- **Richard Malamut, Chief Medical Officer of Medincell, said:** *"These new data are quite impactful as improvements in social functioning and quality of life would represent a substantial benefit for people living with schizophrenia and their families. This is an important addition to the positive efficacy results for the primary endpoint of the phase 3 study that were announced last May. Teva also confirmed that there are still no cases of PDSS observed. This is crucial because the risk of PDSS, along with the associated post-injection monitoring requirement, has been a major barrier to the use of the approved intramuscular olanzapine LAI product."*

**UZEDY® - Risperidone Long-Acting Injectable**

- **Real-world analyses of UZEDY reveal high adherence rates and utilization in adults with schizophrenia who have barriers to treatment.**
- **Christophe Douat, CEO of Medincell, commented:** *"Data presented on UZEDY usage highlights the significant social vulnerability faced by many individuals with schizophrenia, emphasizing the need for innovative and effective treatments like our risperidone LAI and investigational olanzapine LAI to address this critical societal challenge."*

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**Extract below from Teva's press release - November 1st, 2024:** read here the complete press release

## About Olanzapine LAI Phase 3 SOLARIS

SOLARIS study Period 1 is an 8-week, randomized, double-blind, placebo-controlled trial in patients aged 18-64 years diagnosed with schizophrenia, followed by an open-label safety period of up to 48 weeks (Period 2). In the study, TEV-'749 significantly improved social functioning and quality of life by week 8 across all three doses evaluated compared to placebo in a hospitalized population. The results showed:

- The mean difference in change in the Personal and Social Performance Scale, a standard measure of social functioning, from baseline to week 8 was superior with TEV-'749 318mg (4.63), 425mg (3.15), and 531mg (4.93) versus placebo (all P<0.05). The mean difference in change to week 4 was statistically significant for TEV-'749 318mg (P<0.05) and numerically greater for all other TEV-'749 doses versus placebo.[2]
- Treatment with TEV-'749 significantly improved Schizophrenia Quality of Life Scores, with greater mean difference in change from baseline to week 8 observed at the 318mg (-3.99), 425mg (-5.39), and 531mg (-5.65) doses versus placebo (all P<0.05).[2]
- Changes from baseline to week 8 in EuroQoL-5 Dimensions-3 Levels (exploratory endpoint), another quality-of-life measure, were numerically higher at week 8 with TEV-'749 at the 425mg dose versus placebo.[2,3]

As previously announced, efficacy results from the SOLARIS trial showed that by week 8, TEV-'749 met its primary endpoint across all three dosing groups, with statistically significant mean differences in the change in Positive and Negative Syndrome Scale (PANSS) total scores from baseline to week 8 (all P<0.0001). The systemic safety profile

of TEV-'749 was consistent with other approved oral formulations of olanzapine, with no new safety signals identified and no PDSS events reported to date.

**About UZEDY real-world analyses**

The results provide insight into real-world treatment patterns with UZEDY since its approval for the treatment of schizophrenia in adults by the U.S. Food and Drug Administration in April 2023.

Analyses of U.S. claims data from adults living with schizophrenia who received treatment with UZEDY (n=715) examined social determinants of health (SDOH) as well as patterns of adherence. Results reveal high adherence rates in adults living with schizophrenia who have unmet social needs.

- 41% of patients were covered by Medicaid, 8% had Medicare, and 40% had dual coverage.[2]
- Of those patients with available data on SDOH (n=189), over half had low educational attainment, lived in poverty, had experienced food insecurity, and/or had limited access to healthcare. A large minority (44% ; n=83/189) were additionally affected by housing instability.[2]
- 69% were adherent (defined as proportion of days covered greater than or equal to 80%).[2]
- A lines of therapy analysis found that use of UZEDY as a first-line treatment option was at 12%, however patients prescribed UZEDY had most commonly received oral second-generation antipsychotics as their initial therapy.[2]

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**UZEDY®** (1-month and 2-month subcutaneous risperidone for treatment of schizophrenia), is the first product based on Medincell's long-acting injection technology, BEPO®, that reached commercial stage. US marketing authorization was obtained from the U.S. FDA on April 28, 2023, immediately followed by commercial launch by Teva in May 2023.

**TEV-'749 / mdc-TJK** is an investigational once-monthly subcutaneous long-acting injection of the atypical antipsychotic olanzapine for treatment of schizophrenia. It has the potential to be the first long-acting Olanzapine with a favorable safety profile as other LAIs of olanzapine have been associated with a FDA black box warning for PDSS that limits their use.

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

[1] Psych Congress 2024, October 29-November 2, 2024, in Boston, MA (USA): www.hmpglobalevents.com/psych-congress
[2] Data on file. Parsippany, NJ: Teva Neuroscience, Inc.
[3] EuroQol-5 Dimensions-3 Levels (EQ-5D-3L) is a standardized tool for measuring health-related quality of life. It assesses the impact of a disease or treatment on a person's quality of life across five dimensions: mobility (problems with movement), self-care (ability to wash and dress oneself), usual activities (daily tasks, work, leisure), pain/discomfort, and anxiety/depression.

**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.



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