PRESS RELEASE - May 7, 2025 – 1:00pm CEST - Montpellier, France - Euronext Paris: MEDCL

UZEDY® Continues Strong Momentum in 2025; Olanzapine LAI on Track for FDA Filing in H2 2025

Medincell's partner Teva Pharmaceuticals shared today the following information:

About UZEDY®

- 1-Month and 2-Month subcutaneous risperidone for schizophrenia
- Commercialized in the U.S. since May 2023
- 2024 sales: $117 million,

- **Q1 2025 sales: $39 million, 2.6x increase compared to Q1 2024**
- **Continuous growth of prescription: 2.8x increase compared to Q1 2024**

Medincell receives mid- to high-single digit royalties on all sales and is eligible for $105 million of commercial milestones.

About Olanzapine Long-Acting Injectable (TEV-749 / mdc-TJK)

- 1-Month subcutaneous olanzapine, the most prescribed antipsychotic for schizophrenia in the U.S.
- Pivotal Phase 3 completed in January 2025 with positive Phase 3 efficacy results[1] and no PDSS[2]

- **Preparation for filing and launch on track**
  - **Productive Pre-NDA[3] meeting with FDA held on April 9, 2025**
  - **Safety data to be presented at Psych Congress Elevate, May 28-31, 2025, Las Vegas**
  - **NDA submission planned for H2 2025**

Following an NDA submission, the FDA takes approximately 2 months to determine acceptance for review, followed by an additional 8 months for a standard review, which may lead to approval.

Teva Q1 2025 press release: https://ir.tevapharm.com/news-and-events/press-releases/press-release-details/2025/Teva-Reports-Ninth-Consecutive-Quarter-of-Growth-in-Q1-2025-With-Key-Innovative-Medicines-Growing-40-2025-Profit-Outlook-Improved/default.aspx

Teva Q1 2025 earnings conference call today at 8:00am ET, webcast and replay:
https://events.q4inc.com/attendee/984311609

[1] *Press Release, May 8, 2024: https://www.medincell.com/wp-content/uploads/2024/05/PR_Solaris_08052024_EN_Final.pdf*

[2] *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. Press release, Nov. 6, 2024: https://www.medincell.com/wp-content/uploads/2024/11/PR_MDC_Teva-earnings-Q3_2024_06112024.pdf*

[3] *NDA (New Drug Application): Formal request for approval to market a new pharmaceutical product, containing detailed data on its safety, efficacy, manufacturing, and labeling*

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® and SteadyTeq™ are trademarks of Teva Pharmaceuticals

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