

## Medincell's partner Teva provides update on pivotal clinical Phase 3 of investigational Olanzapine Long-Acting Injectable (LAI) and UZEDY® commercial progress

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### Olanzapine LAI (mdc-TJK)

- No PDSS\* observed after completion of c.95% of the targeted injections for submission
- Full phase 3 safety results on track for H2 2024
- Positive phase 3 efficacy results have already been announced in May 2024 ([read the full PR](#))

### UZEDY®

- Reaffirming revenue guidance for 2024: c.\$80 million
  - Exploring an additional indication for UZEDY® for the treatment of Bipolar I Disorder in adults
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**About Olanzapine LAI** Teva Pharmaceuticals, a U.S. affiliate of Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA), announced during its Q2 2024 earnings call held today that c.95% of the targeted injections for submission have been performed as of today ([presentation available here](#)). Teva also confirmed that the full submission safety results are expected to be available in H2 24.

Olanzapine LAI is an investigational once-monthly subcutaneous long-acting injection of the atypical antipsychotic olanzapine. 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.

Christophe Douat, CEO of Medincell, commented: *"Just eighteen months after the launch of Phase 3 of Olanzapine LAI, we already have positive efficacy results, and the full submission safety database is expected to be available before the end of year. For the first time, a long-acting injectable formulation of olanzapine may be widely used thanks to an unprecedented favorable safety profile made possible by Medincell technology."*

**About UZEDY® (1-month and 2-month subcutaneous risperidone for treatment of schizophrenia)**, Teva reaffirmed revenue guidance of \$80 million for 2024, first full year of commercialization, in line with Medincell's forecasts. Medincell partner also announced that it is exploring an additional indication for UZEDY® for the treatment of Bipolar I Disorder in adults.

UZEDY® is the first product based on Medincell's long-acting injection technology, BEPO®, that reached commercial stage.

- US marketing authorization obtained from the U.S. FDA on April 28, 2023, immediately followed by commercial launch by Teva in May 2023
- €1.7 million of royalties already received by Medincell, calculated on Teva's net sales from mid-May 2023 to end of March 2024

**About both partnered programs**, Teva is fully responsible for leading the development and commercialization. Medincell may receive up to \$117 million in development and commercial milestones for mdc-TJK and up to \$105 million in commercial milestones for UZEDY® over the coming years, in addition to royalties on all net sales of both products.

\*PDSS = Post injection Delirium/Sedation Syndrome

## About Medincell

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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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> (BEPO<sup>®</sup> technology is licensed to Teva under the name SteadyTeq<sup>™</sup>). 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 registered trademarks of Teva Pharmaceuticals.*

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A list and description of such risks, hazards and uncertainties can be found in the documents filed by the Company with the Autorité des Marchés Financiers (AMF) pursuant to its regulatory obligations, including in the Company's document de base, registered with the AMF on September 4, 2018 under number I. 18-062, as well as in documents and reports to be published subsequently by the Company. Furthermore, these forward-looking statements only apply as of the date of this press release. Readers are cautioned not to place undue reliance on these forward-looking statements. Except as required by law, the Company undertakes no obligation to publicly update these forward-looking statements, nor to update the reasons why actual results may differ materially from those anticipated in the forward-looking statements, even if new information becomes available. The Company's updating of one or more forward-looking statements does not imply that it will or will not update these or any other forward-looking statements.

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