



PRESS RELEASE - December 9, 2025 – 2:00 pm CET - Montpellier, France - Euronext: MEDCL

## Medincell's Partner Teva Pharmaceuticals Announces the New Drug Application<sup>1</sup> Submission to U.S. FDA for Olanzapine Extended-Release Injectable Suspension (TEV-'749 / mdc-TJK) for the Once-Monthly Treatment of Schizophrenia in Adults

Olanzapine long-acting injectable (LAI) has the potential to offer the efficacy of olanzapine in a once-monthly, subcutaneous formulation, for a broad patient population<sup>2</sup>

Olanzapine LAI is designed to help support real-world adherence and improved stability, with the goal of addressing a critical treatment gap for people living with schizophrenia<sup>2</sup>

**Teva press release:** <https://ir.tevapharm.com/news-and-events/press-releases/press-release-details/2025/Teva-Pharmaceuticals-Submits-New-Drug-Application-to-FDA-for-Olanzapine-Extended-Release-Injectable-Suspension-TEV-749-for-the-Once-Monthly-Treatment-of-Schizophrenia-in-Adults/default.aspx>

<sup>1</sup> Following a New Drug Application (NDA) submission, the FDA typically takes about 2 months to determine acceptance for review, followed by an additional 8 months for a standard review.

<sup>2</sup> Data on file. Parsippany, NJ: Teva Neuroscience, Inc.

### About Medincell

Medincell is a clinical- and commercial-stage biopharmaceutical licensing company developing long-acting injectable treatments across multiple therapeutic areas. Our innovative treatments are designed to ensure adherence to medical prescriptions, enhance the effectiveness and accessibility of medicines, and reduce their environmental impact.

These treatments combine active pharmaceutical ingredients with our proprietary BEPO<sup>®</sup> technologies, which enables controlled drug delivery at therapeutic levels for several days, weeks, or months following a subcutaneous or local injection of a small, fully bioresorbable deposit.

Risperidone LAI was the first treatment based on BEPO<sup>®</sup> technology to receive FDA approval—initially for schizophrenia in April 2023, and subsequently for Bipolar I Disorder in October 2025. It is marketed in the United States by Teva under the brand name UZEDY<sup>®</sup> (BEPO<sup>®</sup> technology is licensed to Teva as SteadyTeq<sup>™</sup>). Medincell's risperidone LAI was also approved for schizophrenia in Canada and South Korea in 2025.

Our investigational pipeline includes numerous innovative therapeutic candidates in various stages of development, from formulation to Phase 3 clinical trials. We collaborate with leading pharmaceutical companies and foundations to advance global health through new treatment options.

Headquartered in Montpellier, France, Medincell employs over 140 people representing more than 25 nationalities.

**medincell.com**

*UZEDY<sup>®</sup> and SteadyTeq<sup>™</sup> are 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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