

The European Medicines Agency Accepts Teva's Marketing Authorization Application for Olanzapine Long-Acting Injectable for the Treatment of Schizophrenia in Adults

The olanzapine long-acting injectable (TEV-'749 / mdc-TJK) is designed to deliver the efficacy of olanzapine in a subcutaneous formulation¹ administered every four weeks.

If approved, TEV-'749 could help fill a significant unmet need in available schizophrenia treatment options by addressing the lack of a viable long-acting olanzapine formulation.

Teva is committed to advancing this innovative treatment option, strengthening its scientific leadership in complex neurological conditions as part of its Pivot to Growth strategy.

TEL AVIV, Israel, and PARIS, France, May 21, 2026 - Teva Pharmaceuticals International GmbH, a subsidiary of Teva Pharmaceutical Industries Ltd. (NYSE: and TASE: TEVA) and Medincell (Euronext: MEDCL), today announced that the European Medicines Agency (EMA) has accepted the Marketing Authorization Application (MAA) for olanzapine long-acting injectable (TEV-'749) for the treatment of schizophrenia in adults. TEV-'749 aims to address treatment adherence in real-world settings and contribute to long-term disease management in people living with schizophrenia.¹

"Treatment adherence remains a challenge for people living with schizophrenia including those who rely on oral forms of Olanzapine. TEV-'749, our investigational subcutaneously delivered olanzapine LAI, has the potential to help provide stability by offering the proven efficacy and safety of olanzapine as a once-every four weeks treatment," said Eric Hughes, MD, PhD, Executive Vice President, and Chief Medical Officer at Teva. *"For too long, treatment options have been limited by the lack of a viable long-acting olanzapine formulation, and we look forward to working with the EMA to help address this gap in care."*

"Daily oral olanzapine is one of the most commonly prescribed antipsychotics in Europe for people living with schizophrenia, and long-acting injectables are already well established in managing serious psychiatric conditions across the region," said Christophe Douat, CEO of Medincell. *"We believe a practical long-acting olanzapine option that fits more naturally into patients' lives can help address a real and persistent need in schizophrenia."*

Schizophrenia affects 0.3 - 1.5% of the population in Europe², yet those living with the condition often face profound challenges of social isolation, unstable employment³, and a life expectancy reduced by 15–20 years⁴.

TEV-'749 is not approved by any regulatory authority worldwide at this time. The submission to the EMA is supported by an extensive clinical development program, including the Phase 3 SOLARIS study. Across clinical development, TEV-'749 demonstrated efficacy, a systemic safety profile, and exposure consistent with oral olanzapine.

TEV-'749 utilizes SteadyTeq™, a copolymer technology proprietary to Medincell that provides a controlled, steady, prolonged release of olanzapine.

¹ Data on file. Parsippany, NJ: Teva Neuroscience, Inc.

² European Brain Council. Rethinking Schizophrenia. 2024. Available at <https://www.braincouncil.eu/projects/rethinking-schizophrenia/#:~:text=Rethinking%20Schizophrenia%20is%20a%20research,that%20of%20the%20general%20population>. Last accessed March 2026

³ Teva What lies beneath: Uncovering the hidden drivers and impact of Stigma in Schizophrenia White Paper 2025. Available at <https://www.tevapharm.com/globalassets/tevapharm-vision-files/teva-white-paper-uncovering-hidden-drivers-and-impact-stigma-in-schizophrenia.pdf> Last accessed March 2026

⁴ Thornicroft G. British Journal of Psychiatry. 2011;199(6):441-442.

About Schizophrenia

Schizophrenia is a chronic, progressive and severely debilitating mental disorder that affects how one thinks, feels and acts.² Patients experience an array of symptoms, which may include delusions, hallucinations, disorganized speech or behavior and impaired cognitive ability.^{2,3,4} Approximately 1% of the world's population will develop schizophrenia in their lifetime, and 0.3 - 1.5% of the population in Europe are currently diagnosed with the condition.^{3,4} Although schizophrenia can occur at any age, the average age of onset tends to be in the late teens to the early 20s for men, and the late 20s to early 30s for women.⁴ The long-term course of schizophrenia is marked by episodes of partial or full remission broken by relapses that often occur in the context of psychiatric emergency and require hospitalization.⁴ Approximately 80% of patients experience multiple relapses over the first five years of treatment, and each relapse carries a biological risk of loss of function, treatment refractoriness, and changes in brain morphology. Patients are often unaware of their illness and its consequences, contributing to treatment nonadherence, high discontinuation rates, and ultimately, significant direct and indirect healthcare costs from subsequent relapses and hospitalizations.^{2,3,4}

About Teva

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) is transforming into a leading innovative biopharmaceutical company, enabled by a world-class generics business. For over 120 years, Teva's commitment to bettering health has never wavered. From innovating in the fields of neuroscience and immunology to providing complex generic medicines, biosimilars and pharmacy brands worldwide, Teva is dedicated to addressing patients' needs, now and in the future. At Teva, We Are All In For Better Health. To learn more about how, visit www.tevapharm.com.

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® / BEPO® Star 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 depot.

Risperidone LAI was the first treatment based on BEPO® 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®. Medincell's risperidone LAI was also approved for schizophrenia in Canada and South Korea in 2025.

A New Drug Application (NDA) for Olanzapine LAI as a once-monthly treatment for schizophrenia in adults was submitted to the U.S. FDA in December 2025 by Medincell's partner, Teva. U.S. FDA accepts Teva's New NDA for Olanzapine LAI on February 20, 2026.

Medincell's 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® is a trademark of Teva Pharmaceuticals. Medincell's BEPO® technology is licensed to Teva as SteadyTeq™, a trademark of Teva Pharmaceuticals.

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This press release contains forward-looking statements, including statements regarding Company's expectations for (i) the timing, progress and outcome of its clinical trials; (ii) the clinical benefits and competitive positioning of its product candidates; (iii) its ability to obtain regulatory approvals, commence commercial production and achieve market penetration and sales; (iv)

its future product portfolio; (v) its future partnering arrangements; (vi) its future capital needs, capital expenditure plans and ability to obtain funding; and (vii) prospective financial matters regarding our business. Although the Company believes that its expectations are based on reasonable assumptions, any statements other than statements of historical facts that may be contained in this press release relating to future events are forward-looking statements and subject to change without notice, factors beyond the Company's control and the Company's financial capabilities.

These statements may include, but are not limited to, any statement beginning with, followed by or including words or phrases such as "objective", "believe", "anticipate", "expect", "foresee", "aim", "intend", "may", "anticipate", "estimate", "plan", "project", "will", "may", "probably", "potential", "should", "could" and other words and phrases of the same meaning or used in negative form. Forward-looking statements are subject to inherent risks and uncertainties beyond the Company's control that may, if any, cause actual results, performance, or achievements to differ materially from those anticipated or expressed explicitly or implicitly by such forward-looking statements. A list and description of these risks, contingencies and uncertainties can be found in the documents filed by the Company with the Autorité des Marchés Financiers (the "AMF") pursuant to its regulatory obligations, including the Company's universal registration document, filed with the AMF on July 29, 2025, under number D. 25-0580 (the "Universal Registration Document"), as well as in the documents and reports to be published subsequently by the Company. In particular, readers' attention is drawn to the section entitled "Facteurs de Risques" on page 30 *et seq.* 26 of the Registration Document.

Any forward-looking statements made by or on behalf of the Company speak only as of the date they are made. Except as required by law, the Company does not undertake any obligation to publicly update these forward-looking statements or to update the reasons why actual results could differ materially from those anticipated by the forward-looking statements, including in the event that new information becomes available. The Company's update of one or more forward-looking statements does not imply that the Company will make any further updates to such forward-looking statements or other forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements.

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