U.S. Food and Drug Administration (FDA) Accepts Teva's New Drug Application (NDA) for Olanzapine Extended-Release Injectable Suspension (TEV-'749) for the Once-Monthly Treatment of Schizophrenia in Adults

- ***Olanzapine long-acting injectable suspension (TEV-'749) has the potential to offer the efficacy of olanzapine in a once-monthly, subcutaneous formulation*** [1]
- ***If approved, TEV-'749 could help address a significant unmet need in available schizophrenia treatment options by addressing the lack of viable long-acting olanzapine formulations***[1]
- ***Teva is committed to advancing this innovative treatment option and further building on its differentiated LAI franchise and scientific leadership in complex neurological conditions as it drives forward its Pivot to Growth strategy***

PARSIPPANY, N.J. and TEL AVIV, Israel and PARIS, February 20, 2026 - Teva Pharmaceuticals, a U.S. affiliate of Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA), and Medincell (Euronext: MEDCL), announced today that the U.S. Food and Drug Administration (FDA) has accepted its New Drug Application (NDA) for olanzapine extended-release injectable suspension (TEV-'749) for the treatment of schizophrenia in adults. TEV-'749 is designed to improve real-world treatment adherence and help patients maintain long-term stability, with the goal of addressing a critical treatment gap for people living with schizophrenia.

Currently, there is no long-acting olanzapine formulation without an FDA-required Risk Evaluation and Mitigation Strategy (REMS), which mandates administration in a certified healthcare facility and requires a 3-hour post-injection monitoring period. In the Phase 3 SOLARIS trial, TEV-'749 administered as a once-monthly subcutaneous injection demonstrated an efficacy and safety profile consistent with currently available olanzapine formulations and showed no evidence for the need for post-injection monitoring.

"Treatment adherence remains a major challenge and unmet need for people living with schizophrenia, including many 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-monthly treatment," said Eric Hughes, MD, PhD, Executive Vice President, Global R&D and Chief Medical Officer at Teva. "For too long, the lack of a viable long-acting olanzapine formulation has limited the options available to these individuals, and we look forward to working with the FDA on the review of this NDA for TEV-'749 to help address this gap in care."

"Daily olanzapine is one of the most widely prescribed antipsychotics for people living with schizophrenia, and this long-acting formulation may better fit into their lives," said Christophe Douat, CEO of Medincell. "As experience with long-acting injectables continues to grow, they are increasingly recognized as an important treatment option in serious psychiatric conditions. The potential reach of a practical long-acting option is significant."

The NDA for TEV-'749 is based on results from the Phase 3 SOLARIS trial, including Week 56 results studying its efficacy, safety and tolerability in participants aged 18 to 64 living with schizophrenia.[1] The results demonstrated an efficacy and safety profile consistent with currently available olanzapine formulations.[1]

TEV-'749 is an investigational once-monthly subcutaneous LAI of the second-generation atypical antipsychotic olanzapine. It is not approved by any regulatory authority for any use at this time.

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

About Subcutaneous OLAnzapine Extended-Release Injection Study (SOLARIS)

SOLARIS is a multinational, multicenter, randomized, double-blind, parallel-group, placebo-controlled study to evaluate the efficacy, safety and tolerability of olanzapine extended-release injectable suspension for subcutaneous use as a treatment in patients (ages 18-64 years) with schizophrenia.[1] For period one of the study (first 8 weeks), 675 patients were randomized to receive a subcutaneous injection of once-monthly olanzapine LAI (TEV-'749) (low, medium or high dose) or placebo in a 1:1:1:1 ratio.[1] For period two (next 48 weeks), patients who completed period one were randomized and equally allocated to one of the three olanzapine LAI (TEV-'749) treatment groups.[1] The end-of-treatment and follow-up visits were 4 and 8 weeks after administration of the last treatment dose, respectively.[1] The primary objective of the Phase 3 SOLARIS study was to evaluate the efficacy of olanzapine LAI (TEV-'749) in adult patients with schizophrenia.[1] A key secondary objective was to further evaluate the efficacy of olanzapine LAI (TEV-'749) based on additional parameters in adult patients with schizophrenia.[1] A secondary objective of period two of the study was to evaluate the safety and tolerability of olanzapine LAI (TEV-'749) in adult patients with schizophrenia.[1]

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 3.5 million people in the U.S. 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.[5,6,7] 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.[2,3,4,5,6,7]

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.

Cautionary Note Regarding Forward-Looking Statements

This Press Release may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, which are based on management's current beliefs and expectations and are subject to substantial risks and uncertainties, both known and unknown, that could cause our future results, performance or achievements to differ significantly from that expressed or implied by such forward-looking statements. You can identify these forward-looking statements by the use of words such as "should," "expect," "anticipate," "estimate," "target," "may," "project," "guidance," "intend," "plan," "believe" and other words and terms of similar meaning and expression in connection with any discussion of future operating or financial performance. Important factors that could cause or contribute to such differences include risks relating to: our ability to successfully develop olanzapine LAI (TEV-'749) for the treatment of adult patients diagnosed with schizophrenia and to obtain regulatory FDA approval; our ability to successfully compete in the marketplace, including our ability to successfully execute our Pivot to Growth strategy, including to expand our innovative and biosimilar medicines pipeline and profitably commercialize the innovative medicines and biosimilar portfolio, whether organically or through business development; our significant indebtedness; our business and operations in general; compliance, regulatory and litigation matters; other financial and economic risks; and other factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2025, including in the section captioned "Risk Factors." Forward-looking

statements speak only as of the date on which they are made, and we assume no obligation to update or revise any forward-looking statements or other information contained herein, whether as a result of new information, future events or otherwise. You are cautioned not to put undue reliance on these forward-looking statements.

1. Data on file. Parsippany, NJ: Teva Neuroscience, Inc.
2. Substance Abuse and Mental Health Services Administration. Schizophrenia. https://www.samhsa.gov/mental-health/schizophrenia. Accessed February 2026.
3. Velligan DI, Rao S. The Epidemiology and Global Burden of Schizophrenia. J Clin Psychiatry. 2023;84(1):MS21078COM5. https://doi.org/10.4088/JCP.MS21078COM5.
4. Wander C. (2020). Schizophrenia: Opportunities to Improve Outcomes and Reduce Economic Burden Through Managed Care. The Am J Manag Care. 26(3 Suppl), S62–S68. https://doi.org/10.37765/ajmc.2020.43013.
5. Emsley, R., & Kilian, S. (2018). Efficacy and safety profile of paliperidone palmitate injections in the management of patients with schizophrenia: an evidence-based review. Neuropsychiatric Dis. Treat., 14, 205–223.
6. Emsley, R., Chiliza, B., Asmal, L. et al. (2013) The nature of relapse in schizophrenia. BMC Psychiatry 13, 50.
7. Andreasen, N. C., et al. (2013). Relapse duration, treatment intensity, and brain tissue loss in schizophrenia: a prospective longitudinal MRI study. The Am J Psychiatry, 170(6), 609–615.

# # #

Teva Media Inquiries:

TevaCommunicationsNorthAmerica@tevapharm.com

Teva Investor Relations Inquires

TevaIR@Tevapharm.com

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.

Contact: communication@medincell.com

# # #