

Teva and Medincell Announce Positive Phase 3 Efficacy Results from SOLARIS Trial Evaluating TEV-‘749 (olanzapine) as a Once-Monthly Subcutaneous Long-Acting Injectable in Adults with Schizophrenia

- The study met its primary endpoint achieving clinically meaningful and statistically significant reductions across all TEV-‘749 dose groups versus placebo in the Positive and Negative Syndrome Scale (PANSS) total score, a widely used assessment tool for schizophrenia symptom severity
- TEV-‘749 was well tolerated, with no incidence of post-injection delirium/sedation syndrome (PDSS) observed to date: additional safety data is being collected as part of the long-term follow-up SOLARIS study
- TEV-‘749 is being developed by Teva as a once-monthly subcutaneous long-acting injection of olanzapine with the use of SteadyTeq™ technology, a copolymer technology proprietary to Medincell

Parsippany, N.J., TEL AVIV & PARIS, May 08, 2024 – Teva Pharmaceuticals, a U.S. affiliate of Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA), and Medincell (Euronext: MEDCL), today announced results from the efficacy portion of the Phase 3 Subcutaneous OLANzapine extended-Release Injection Study (SOLARIS) trial evaluating TEV-‘749 in adult patients with schizophrenia compared to placebo. Results demonstrated that TEV-‘749 met its primary endpoint as measured by a change in the PANSS total score from baseline after 8 weeks compared to placebo. TEV-‘749 utilizes SteadyTeq™, a copolymer technology proprietary to Medincell that provides a controlled steady release of olanzapine, the most prescribed 2nd generation antipsychotic for schizophrenia in the U.S.¹

TEV-‘749 met its primary endpoint across all three dosing groups, with mean difference in change in the Positive and Negative Syndrome Scale (PANSS) total score from baseline to week 8 of -9.71 points, -11.27 points, and -9.71 points versus placebo for the high, medium, and low dose groups, respectively. These differences from placebo were clinically meaningful and statistically significant with adjusted P-values of <0.001 for each comparison. Key secondary endpoints of CGI-S (Clinical Global Impressions – schizophrenia) and PSP (Personal and Social Performance Scale) total score were also statistically significant after adjusting for multiplicity. No cases of PDSS have been reported to date, after administration of approximately 80% of the target injection number.

An estimated 3.5 million people are currently diagnosed with schizophrenia in the U.S. It is a chronic, progressive, and severely debilitating mental disorder that affects how one thinks, feels and behaves. Currently, there is no long-acting olanzapine treatment option available for schizophrenia that does not risk post-injection delirium/sedation syndrome (PDSS). PDSS is characterized by the sudden and unexpected onset of delirium or sedation within the first several hours of receiving treatment and has been associated with the intramuscular injection of long-acting olanzapine.

“These encouraging results from the efficacy portion of our Phase 3 SOLARIS trial demonstrate the potential of TEV-‘749 to be an effective long-acting treatment option for schizophrenia and further show our dedication to advancing innovative science in mental health and beyond,” said Eric Hughes, MD, PhD, Executive Vice President of Global R&D and Chief Medical Officer at Teva. “Schizophrenia can be a devastating disease for both the people struggling with it as well their families. Schizophrenia is often a chronic life-long disease, but by using medication consistently, people can find the treatment help they deserve. This also has the potential to reduce the burden for not only themselves, but their caregivers and loved ones as well.”

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The PANSS is composed of 3 subscales: Positive Scale, Negative Scale, and General Psychopathology Scale. Each subscale is rated with 1 to 7 points ranging from absent to extreme. Each of the 30 items is accompanied by a specific definition as well as detailed anchoring criteria for all seven rating points. These seven points represent increasing levels of psychopathology, as follows: 1- absent 2- minimal 3- mild 4- moderate 5- moderate severe 6- severe 7- extreme; the PANSS overall total score ranges from 30 to 210, with a higher score indicating greater symptom severity. The primary efficacy endpoint was measured by change from baseline to week 8 against the PANSS total score.

“These data reinforce the potential of TEV-‘749 as a subcutaneous long-acting injectable by using a proven molecule with an established long-acting delivery system,” said Christoph Correll, MD, Professor of Psychiatry at the Zucker School of Medicine, Hempstead, NY and SOLARIS study co-ordinating investigator. “Most patients with schizophrenia will experience one or more relapses throughout their treatment journeys, so I very much welcome the development of new and innovative long-acting treatment options that may better fit into their lives.”

“The positive news from the phase III SOLARIS trial continues to encourage ongoing innovation in treatment options for those living with schizophrenia. We are thrilled to be part of this journey with Teva through a strong partnership that allows us to leverage our pioneering long-acting technology for the benefit of patients,” said Christophe Douat, CEO of MedinCell.

Additional efficacy and safety findings from the Phase 3 SOLARIS study are planned for presentation at a medical meeting later this year.

The long-term safety of TEV-‘749 and incidence of PDSS are also being evaluated in the SOLARIS open-label study (period 2) with safety data topline readout expected in the second half of 2024.

TEV-‘749 is an investigational once-monthly subcutaneous long-acting injection of the 2nd generation antipsychotic olanzapine and is not approved by any regulatory authority for any use and its safety and efficacy are not established.

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 18-65 years) with schizophrenia. For period one of the study (first 8 weeks), 675 patients were randomized to receive a subcutaneous injection of once-monthly TEV-‘749 (low, medium or high dose) or placebo in a 1:1:1:1 ratio. For period two, which will last for up to 48 weeks, patients who completed period one were randomized and equally allocated to one of the three TEV-‘749 treatment groups. The end-of-treatment and follow-up visits will be at 4 and 8 weeks after administration of the last treatment dose, respectively. The primary objective of the Phase 3 SOLARIS study was to evaluate the efficacy of TEV-‘749 in adult patients with schizophrenia. A key secondary objective was to further evaluate the efficacy of TEV-‘749 based on additional parameters in adult patients with schizophrenia. A secondary objective that is still ongoing through period two of the study is to evaluate the safety and tolerability of TEV-‘749 in adult patients with schizophrenia.

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.^{3,4,5,6,7}

About Teva

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) is a global pharmaceutical leader with a category-defying portfolio, harnessing our generics expertise and stepping up innovation to continue the momentum behind the discovery, delivery, and expanded development of modern medicine. For over 120 years, Teva's commitment to bettering health has never wavered. Today, the company's global network of capabilities enables its ~37,000 employees across 58 markets to push the boundaries of scientific innovation and deliver quality medicines to help improve health outcomes of millions of patients every day. To learn more about how Teva is all in for better health, visit www.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. www.medincell.com

Note: TEV-'749 is referenced as mdc-TJK in Medincell's documentation and corporate website.

Cautionary Note Regarding Forward-Looking Statements

This press release contains 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 adults with schizophrenia; our ability to achieve successful results from the efficacy portion of the Phase 3 trial for olanzapine LAI (TEV-'749); our ability to achieve successful results from the safety portion of the Phase 3 trial for olanzapine LAI (TEV-'749); our ability to successfully compete in the marketplace, including our ability to develop and commercialize additional pharmaceutical products; 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, and to sustain and focus our portfolio of generic medicines; the effectiveness of our patents and other measures to protect our intellectual property rights; and other factors discussed in our Quarterly Report on Form 10-Q for the first quarter of 2024, and in our Annual Report on Form 10-K for the year ended December 31, 2023, 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.

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¹ NPA TRx - MAT Jan 2024; schizophrenia factors sourced from 2022 Analytics Link (IQVIA)

² Substance Abuse and Mental Health Services Administration. Schizophrenia. <https://www.samhsa.gov/mental-health/schizophrenia>. Accessed November 2023.

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 American journal of managed 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 disease and treatment*, 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 American journal of psychiatry*, 170(6), 609–615.