FDA Approves Expanded Indication for UZEDY® (risperidone) Extended-Release Injectable Suspension as a Treatment for Adults Living with Bipolar I Disorder

- **FDA approves UZEDY® (risperidone) extended-release injectable suspension for subcutaneous use as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar I disorder in adults.[1]**
- **UZEDY (risperidone) extended-release injectable suspension for subcutaneous use is indicated for use every one or two months for the treatment of schizophrenia in adults.[1]**
- **This approval marks a significant step towards addressing the unmet needs of people living with BD-I and schizophrenia, underscoring Teva's ongoing commitment to drive new advances in neuroscience.[2]**

PARSIPPANY, N.J., TEL AVIV & PARIS, October 10, 2025 - 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 approved UZEDY® (risperidone) as a once-monthly extended-release injectable suspension as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar I disorder (BD-I) in adults. The approval is based on existing clinical data for UZEDY, coupled with Model-Informed Drug Development (MIDD) methodologies that leverage previous findings on the safety and efficacy of risperidone formulations already approved for BD-I.

UZEDY is the first subcutaneous, long-acting formulation of risperidone that utilizes SteadyTeq™, a copolymer technology proprietary to Medincell that controls the steady release of risperidone.[1] Therapeutic blood concentrations are reached within 6-24 hours of a single dose.[1] For the BD-I indication, UZEDY is now approved with three once-monthly dosing options (50 mg, 75 mg and 100 mg).

"Adults living with BD-I experience debilitating manic and depressive symptoms, and today's FDA approval of UZEDY provides a new long-acting formulation of risperidone that may help address existing unmet needs and treatment gaps," said Chris Fox, Executive Vice President, U.S. Commercial at Teva. "This expanded indication for UZEDY builds on its success in adults living with schizophrenia and demonstrates Teva's dedication to developing innovative medicines for complex mental health conditions that place a heavy burden on individuals and their caregivers."

An estimated 1% (or 3,400,000+) of U.S. adults will develop BD-I in their lifetime which is associated with poor long-term outcomes and a substantial increase in mortality compared to the general population from both suicide and cardiovascular disease.[3]

"Bipolar I disorder carries profound implications for a person's life and is linked to suboptimal long-term outcomes, with treatment adherence to daily oral options frequently presenting as a major impediment to effective care," said Craig Chepke, MD, DFAPA, Medical Director, Excel Psychiatric Associates and Scientific Director, HMP Global's Psych Congress events and programs. "The FDA's decision to expand the indication for UZEDY may help those living with BD-I. As a clinician, I am excited to now have a new treatment option for this complex disease."

UZEDY was approved in the U.S. for the treatment of schizophrenia in adults in 2023.[2]

"Long-acting injectables are increasingly recognized as key drivers of innovation in CNS therapeutics," said Christophe Douat, CEO of Medincell. "We're proud that UZEDY is now available to support patients living with bipolar I disorder. This milestone highlights the exceptional regulatory and commercial execution of our partner, Teva."

The data reviewed by the FDA to support UZEDY's approval for the treatment of BD-I includes the Agency's previous findings of safety and efficacy of past risperidone formulations approved for the treatment of BD-I as well as the efficacy, long-term safety and tolerability of UZEDY for the treatment of schizophrenia which was evaluated in two Phase 3 pivotal studies: TV46000-CNS-30072 (the RISE Study – The Risperidone Subcutaneous Extended-Release Study) and TV46000-CNS-30078 (the SHINE Study – Safety in Humans of TV-46000 sc INjection Evaluation).[2]

About Bipolar I Disorder
Bipolar I Disorder (BD-I) is a serious mental health condition defined by episodes of mania—periods of abnormally elevated or irritable mood with increased energy and activity—and often episodes of depression. These episodes can cause significant disruptions in thinking, behavior, and daily functioning. It is challenging to diagnose and is often accompanied by other psychiatric comorbidities. BD-I is associated with poor long-term outcomes and a substantial increase in mortality compared to the general population from both suicide and cardiovascular disease. An estimated 1% or 3,400,000+ of U.S. adults will develop BD-I in their lifetime.[3]

About UZEDY
UZEDY (risperidone) extended-release injectable suspension for subcutaneous use is indicated for the treatment of schizophrenia in adults and as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar I disorder in adults. In clinical trials, UZEDY significantly reduced the risk of schizophrenia relapse.[1,2] UZEDY administers risperidone through copolymer technology under license from Medincell that allows for rapid absorption and sustained release after subcutaneous injection. UZEDY is the only long-acting, subcutaneous formulation of risperidone available in both one- and two-month dosing intervals.[1] For full prescribing information, visit https://www.uzedy.com/globalassets/uzedy/prescribing-information.pdf.

APPROVED USE

UZEDY (risperidone) extended-release injectable suspension is a prescription medicine used in adults

- for the treatment of schizophrenia
- for the maintenance treatment of bipolar I disorder as monotherapy or as adjunctive therapy to lithium or valproate

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about UZEDY?

UZEDY can cause serious side effects, including an increased risk of death in elderly people who are confused, have memory loss, and have lost touch with reality (dementia-related psychosis). UZEDY is not approved for use in patients with dementia-related psychosis.

Do not receive UZEDY if you are allergic to risperidone, paliperidone, or any of its components.

UZEDY may cause serious side effects, including:

- **Stroke in elderly people (cerebrovascular problems) that can lead to death.**
- **Neuroleptic Malignant Syndrome (NMS). NMS is a rare but very serious problem that can lead to death. Seek medical attention right away** if you have any of these symptoms: high fever, severe muscle stiffness, confusion, sweating, irregular heartbeat, fast heart rate, or changes in your blood pressure.
- **Uncontrolled facial or body movements (tardive dyskinesia)** that may not go away, even if you stop receiving UZEDY. Tardive dyskinesia may also start after you stop receiving UZEDY.

- **Problems with your metabolism** that may include high blood sugar (hyperglycemia), diabetes mellitus, changes in the fat levels in your blood (dyslipidemia), and weight gain. Extremely high blood sugar can lead to coma or death. If you have diabetes or are at risk for diabetes (e.g., obesity, family history of diabetes), your healthcare provider should check your blood sugar before you start and during treatment with UZEDY. Call your healthcare provider if you have symptoms of high blood sugar including: feeling very thirsty, hungry, sick to your stomach, weak or tired, or confused; needing to urinate more than usual; or your breath smells fruity.
- **High levels of prolactin in your blood.** UZEDY may cause a rise in the blood levels of a hormone called prolactin that may cause side effects including missed menstrual periods, decreased fertility in women, leakage of milk from the breasts, development of breasts in men, or problems with erection.
- **Decreased blood pressure (orthostatic hypotension).** You may feel lightheaded or faint when you rise too quickly from a sitting or lying position.
- **Falls.** Antipsychotic medicines like UZEDY may cause drowsiness or dizziness when you are standing, which could increase your risk for falls and related injuries.
- **Low white blood cell count.**
- **Problems thinking clearly and moving your body.** Do not drive, operate machinery, or do other dangerous activities until you know how UZEDY affects you.
- **Seizures (convulsions).**
- **Difficulty swallowing that can cause food or liquid to get into your lungs.**
- **Prolonged or painful erection lasting more than 4 hours.** Call your healthcare provider or go to your nearest emergency room right away if you have an erection that lasts more than 4 hours.
- **Problems with control of your body temperature (too high or too low). Avoid getting overheated or dehydrated.**

The most common side effects of risperidone in patients with

- **Schizophrenia** included slow movements, stiffness, shaking, restlessness, abnormal muscle contractions or movements, drowsiness, dizziness, anxiety, blurred vision, nausea, vomiting, indigestion, diarrhea, increased saliva, constipation, dry mouth, increased appetite, weight gain, tiredness, rash, and common cold symptoms

- **Bipolar disorder** were weight increased (5% in monotherapy trial) and slow movements, stiffness, shaking (≥10% in adjunctive therapy trial).

- **Injection site reactions** including a lump or itching were reported with UZEDY.

  These are not all the possible side effects of UZEDY. Tell your healthcare provider if you have any side effect that bothers you or that does not go away. For more information, ask your healthcare provider or pharmacist.

Do not drink alcohol during treatment with UZEDY.

Before receiving UZEDY, tell your healthcare provider about all your medical conditions, including if you:

- have had Neuroleptic Malignant Syndrome.
- have or have had uncontrolled movements of your tongue, face, mouth, or jaw (tardive dyskinesia).
- have diabetes or have a family history of diabetes.
- have had dizziness or fainting or are being treated for high blood pressure.
- have had a low white blood cell count.
- have or have had seizures or epilepsy.
- are pregnant or plan to become pregnant during treatment with UZEDY. It is not known if UZEDY will harm your unborn baby. Use of UZEDY during the third trimester of pregnancy may cause side effects in the newborn infant, including agitation, abnormal muscle tone, tremor, drowsiness, difficulty feeding, and difficulty breathing. Seek medical attention if you notice these signs. If you become pregnant during treatment with UZEDY, talk to your healthcare provider about registering with the National Pregnancy Registry for Atypical Antipsychotics, or call 1-866-961-2388 or visit http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/.
- are breastfeeding or plan to breastfeed. If you are receiving UZEDY and are breastfeeding, monitor your infant for sleepiness, inadequate weight gain, jitteriness, tremors, and abnormal muscle movements. Seek medical care if you notice these signs.
- have or have had kidney or liver problems.

Tell your healthcare provider about all the medicines you take or plan to take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. UZEDY and other medicines may affect each other.

You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, **or call** 1-800-FDA-1088.

For more information about UZEDY, see the full Prescribing Information including Boxed WARNING, or talk to your healthcare provider.

About Teva
Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) is a leading innovative biopharmaceutical company, enabled by a world-class generics business. For over 120 years, Teva's commitment 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 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 and

commercialize UZEDY (risperidone) extended-release injectable suspension as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar I disorder (BD-I) in adults; 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 other factors discussed in our Quarterly Report on Form 10-Q for the second quarter of 2025 and in our Annual Report on Form 10-K for the year ended December 31, 2024, including in the section captioned "Risk Factors" and "Forward Looking Statements." 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.

References

1. UZEDY® (risperidone) extended-release injectable suspension, for subcutaneous injection Current Prescribing Information. Parsippany, NJ. Teva Neuroscience, Inc.
2. Data on file. Parsippany, NJ: Teva Neuroscience, Inc.
3. Merikangas KR, Akiskal HS, Angst J, et al. Lifetime and 12-Month Prevalence of Bipolar Spectrum Disorder in the National Comorbidity Survey Replication. Arch Gen Psychiatry. 2007;64(5):543–552. doi:10.1001/archpsyc.64.5.543

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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.

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