



## Teva and MedinCell Receive Complete Response Letter for TV-46000/mdc-IRM

PARSIPPANY, N.J., TEL AVIV & PARIS – Teva Pharmaceuticals, a U.S. affiliate of Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA), and MedinCell (Euronext: MEDCL) announced that the U.S. Food and Drug Administration (“FDA”) has issued a Complete Response Letter (CRL) regarding the New Drug Application (NDA) for TV-46000/mdc-IRM (risperidone extended-release injectable suspension for subcutaneous use) for the treatment of schizophrenia.

Teva and MedinCell remain committed to the development of risperidone and to providing patients with access to the product in the U.S., as quickly as possible. Teva is reviewing its next steps based on the letter and will work closely with FDA to address their recommendations.

The application included Phase 3 data from two pivotal studies: TV46000-CNS-30072 (the RISE Study – The Risperidone Subcutaneous Extended-Release Study) and TV46000-CNS-30078 (the SHINE Study – A Study to Test if TV-46000 is Safe for Maintenance Treatment of Schizophrenia). These studies evaluated the efficacy and long-term safety and tolerability of TV-46000 as a treatment for patients with schizophrenia.

### About Teva

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) has been developing and producing medicines to improve people’s lives for more than a century. We are a global leader in generic, biosimilar and specialty medicines with a portfolio consisting of over 3,500 products in nearly every therapeutic area. Around 200 million people around the world take a Teva medicine every day, and are served by one of the largest and most complex supply chains in the pharmaceutical industry. Along with our established presence in generics, we have significant innovative research and operations supporting our growing portfolio of specialty and biopharmaceutical products. Learn more at [www.tevapharm.com](http://www.tevapharm.com).

### About MedinCell

MedinCell is a pharmaceutical company at premarketing stage that develops a portfolio of long-acting injectable products in various therapeutic areas by combining its proprietary BEPO® technology with active ingredients already known and marketed. Through the controlled and extended release of the active pharmaceutical ingredient, MedinCell makes medical treatments more efficient, particularly thanks to improved compliance, i.e. compliance with medical prescriptions, and to a significant reduction in the quantity of medication required as part of a one-off or chronic treatment. The BEPO® technology makes it possible to control and guarantee the regular delivery of a drug at the optimal therapeutic dose for several days, weeks or months starting from the subcutaneous or local injection of a simple deposit of a few millimeters, fully bioresorbable. MedinCell collaborate with tier one pharmaceuticals companies and foundations to improve Global Health through new therapeutic options. Based in Montpellier, MedinCell currently employs more than 140 people representing over 25 different nationalities. [www.medincell.com](http://www.medincell.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 regarding TV-46000/mdc-IRM (risperidone extended-release injectable suspension for subcutaneous use), 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

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operating or financial performance. Important factors that could cause or contribute to such differences include risks relating to our ability to develop TV-46000/mdc-IRM (risperidone extended-release injectable suspension for subcutaneous use); our ability to successfully compete in the marketplace, including our ability to develop and commercialize biopharmaceutical products, competition for our specialty products, including AUSTEDO®, AJOVY® and COPAXONE®; our ability to achieve expected results from investments in our product pipeline, our ability to develop and commercialize additional pharmaceutical products, and the effectiveness of our patents and other measures to protect our intellectual property rights; our substantial indebtedness; our business and operations in general, including uncertainty regarding the COVID-19 pandemic and the governmental and societal responses thereto; our ability to successfully execute and maintain the activities and efforts related to the measures we have taken or may take in response to the COVID-19 pandemic and associated costs therewith; costs and delays resulting from the extensive pharmaceutical regulation to which we are subject or delays in governmental processing time due to travel and work restrictions caused by the COVID-19 pandemic; compliance, regulatory and litigation matters, including failure to comply with complex legal and regulatory environments; other financial and economic risks; and other factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2021, 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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