



Phase 3 data of mdc-IRM, first product based on MedinCell's technology, shows significant improvements in patients with schizophrenia:

- **Prolonged time to impending relapse**
- **Decreased risk of relapse**
- **Increased chance of clinical stability**

Developed in collaboration with Teva Pharmaceuticals, mdc-IRM, a risperidone extended-release injectable suspension for the treatment of patients with schizophrenia (Teva codename: TV-46000), is the most advanced investigational product based on MedinCell's BEPO® technology. Ongoing New Drug Application review by FDA could lead to commercialization as early as 2022 in the U.S. by Teva, provided marketing authorization. MedinCell is eligible for development and commercial milestones (\$122 million), and royalties on net sales.

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MedinCell are delighted to present the key outcomes of the pivotal mdc-IRM findings to shareholders and the broader financial community during conferences scheduled on Tuesday, November 2:

- **Conference in French at 6:30 pm (CET)**
 - **Conference in English at 7:30 pm (CET)**
 - **Connection link: invest.medincell.com/conference**
 - **Replay will be available on invest.medincell.com**
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MedinCell's partner, Teva Pharmaceuticals, announced results from the pivotal Phase 3 **Risperidone Subcutaneous Extended-release (RISE)** study comparing TV-46000 once monthly (q1m) and TV-46000 once every two months (q2m) with placebo (1:1:1) in patients with schizophrenia who underwent stabilization on oral risperidone. Results showed treatment with TV-46000 (overall, q1m or q2m) significantly prolonged time to relapse, decreased proportions of patients with impending relapse at week 24 and demonstrated significant increase in proportions maintaining stability. The safety profile of TV-46000 is favourable, with no new safety signals versus existing data for both oral and other long-acting formulations of risperidone. These findings, amongst others, were presented during the poster session at the 2021 Psych Congress Annual Meeting taking place Oct. 29 - Nov. 1, 2021 in San Antonio, TX.

“Supported by the unveiling of this pivotal data by our partner, mdc-IRM demonstrates significant potential in reducing the risk of relapse and in stabilizing clinical symptoms, both of which are key to improving the management of this burdensome disease,” said Christophe Douat, CEO of MedinCell. *“These findings further strengthen our belief that our long-acting technology could positively impact the adoption of long-acting injectables, and notably for mdc-IRM, patients with first-episode psychosis and early-stage schizophrenia.”*

Schizophrenia is a chronic and severe mental disorder¹ characterized by distortions in thinking, perception, emotions, language, sense of self and behavior.² Twenty million people worldwide are affected by schizophrenia¹, often living with considerable disability.² Currently, about 70% of people living with schizophrenia are not receiving appropriate care³ despite the treatability of the illness.²

Efficacy and Safety of Subcutaneous Risperidone Injectable (TV-46000) in Patients With Schizophrenia: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Relapse Prevention Study (RISE Study)

The Phase 3 RISE was a multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy of risperidone extended-release injectable suspension for subcutaneous use as a treatment in patients (ages 13-65 years) with schizophrenia. 544 patients were randomized to receive a subcutaneous injection of TV-46000 once monthly (q1m), once every two months (q2m), or placebo in a 1:1:1 ratio (stage 2). The study was designed to compare

¹ GBD 2017 Disease and Injury Incidence and Prevalence Collaborators. Global, regional, and national incidence, prevalence, and years lived with disability for 354 diseases and injuries for 195 countries and territories, 1990–2017: a systematic analysis for the Global Burden of Disease Study 2017. [published correction appears in *Lancet*. 2019 Jun 22;393(10910):e44]. *Lancet*. 2018;392(10159): 1789–1858.

² World Health Organization. Schizophrenia. www.who.int/news-room/fact-sheets/detail/schizophrenia. Accessed on October 4, 2021.

³ Lora A, et al. Service availability and utilization and treatment gap for schizophrenic disorders: a survey in 50 low- and middle-income countries. *Bulletin of the World Health Organization*. 90 (1), 47–54B. World Health Organization. <http://dx.doi.org/10.2471/BLT.11.089284>

TV-46000 q1m and TV-46000 q2m with placebo in patients with schizophrenia who underwent stabilization on oral risperidone (stage 1). The primary endpoint was time to impending relapse and secondary endpoints included proportions of patients with impending relapse at week 24 and proportions of patients who maintained stability at week 24. No new safety signals were identified with TV-46000 versus accumulated safety data of oral risperidone and other long-acting risperidone formulations.

Out of 1267 patients screened, 863 were enrolled and 544 were randomized. Time to impending relapse significantly favored TV-46000 (hazard ratio [95% CI]; overall: 0.283 [0.184, 0.435], $P < .0001$; q1m: 0.200 [0.109, 0.367], $P < .0001$; q2m: 0.375 [0.227, 0.618], $P < .0001$) versus placebo. TV-46000 also prolonged time to relapse by 3.5, 5.0 and 2.7 times, respectively, versus placebo. Proportions of patients with impending relapse at week 24 were significantly lower for TV 46000 (overall: 9%; q1m: 7%; q2m: 11%) versus placebo (28%; $P < .0001$, $P < .0001$, $P = .0001$, respectively). Proportions of patients maintaining stability were significantly higher (83%, 87%, 80% vs 61%; $P < .0001$, $P < .0001$, $P = .0001$, respectively). The safety profile of TV-46000, as observed in this study, is consistent with other formulations of risperidone. The most common adverse reactions ($\geq 5\%$ and greater than placebo) were nasopharyngitis, increased weight, and extrapyramidal disorder.

About MedinCell

MedinCell is a clinical stage pharmaceutical company 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. Based in Montpellier, MedinCell currently employs more than 140 people representing over 25 different nationalities.

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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 the development, approval and commercialization of 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, 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 its impact on our business, financial condition, operations, cash flows, and liquidity and on the economy in general, 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, 2020, 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.