



MedinCell: mdc-IRM's Phase 3 data to be presented for the first time by Teva at Psych Congress 2021 (Oct. 29-Nov. 1, 2021, San Antonio, USA)

14 original presentations describing improvements in patient-centered outcomes, symptoms over time, as well as patient and healthcare professional preferences and treatment experiences with mdc-IRM will be communicated by MedinCell's partner Teva Pharmaceuticals.

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mdc-IRM [Teva's codename: TV46000], a subcutaneous risperidone injectable suspension for the treatment of patients with schizophrenia, is the most advanced investigational product based on MedinCell's BEPO® technology.

Ongoing New Drug Application review by FDA could lead to mdc-IRM commercialization as early as 2022 by Teva in the U.S., provided marketing authorization. MedinCell is eligible for development milestones, royalties on net sales and future commercial milestones.

“The presentation by Teva of the Pivotal Phase 3 data will provide comprehensive insights into the potential of mdc-IRM for the treatment of schizophrenia, said Christophe Douat, CEO of MedinCell. The findings should confirm the power of our long-acting injectable technology that enables us to develop a growing portfolio of breakthrough innovative treatments.”

TV46000 – Data presentation by Teva at Psych Congress 2021

De Novo

- 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)
- TV-46000, a Long-Acting Subcutaneous Risperidone Injectable, Demonstrated Improved Patient-Centered Outcomes in Patients With Schizophrenia
- TV-46000 Provided Continued Symptom Improvement in Patients With Schizophrenia During the Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Relapse Prevention RISE Study
- Robustness of TV-46000 Efficacy Data from RISE: A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Relapse Prevention Study in Patients With Schizophrenia
- Behavioral-, Metabolic-, Endocrine-, and Cardiovascular-Related Adverse Events in Patients With Schizophrenia Treated With TV-46000
- Efficacy and Safety of TV-46000, Subcutaneous Long-Acting Injectable Risperidone, by Injection Site (Upper Arm, Abdomen): Post Hoc Analysis of the Phase 3 RISE Study
- Contingency Planning and Risk Mitigation Strategies for a Schizophrenia Relapse Prevention Trial During the COVID-19 Pandemic
- Annual Schizophrenia-Related Medical Resource Utilization and Costs Among Patients in the United States Utilizing Atypical Antipsychotic Agents: An Analysis of a Commercial Claims Database
- Treatment Patterns Among Patients in the United States Utilizing Long-Acting Injectable Antipsychotic Agents: An Analysis of a Commercial Claims Database
- Retrospective Analysis of a Commercial Claims Database for Predictors for Initiation of Atypical Long-Acting Injectable Antipsychotic Agents
- Patient Preferences and Treatment Experiences With TV-46000, a Long-Acting Subcutaneous Injectable Risperidone Formulation
- Health Care Professional Preferences and Treatment Experiences With TV-46000, a Long-Acting Injectable Risperidone Formulation
- Determination of Flexible Dose Regimens for TV-46000, a Risperidone Extended Release Suspension for Subcutaneous Injection in Development for the Treatment of Schizophrenia
- Exposure-Response Analysis to Assess the Relationships Between TV 46000 Pharmacokinetic Exposure Parameters, Prevention of Impending Relapse and Adverse Events

Encore

- Network Meta-Analysis of Cohort Studies Involving Oral and Long-Acting Injectable Antipsychotic Agents: Administration Frequency and Incidence Rate of Hospitalization in Schizophrenia
- Association of Oral and Long-Acting Injectable Antipsychotic Administration Frequency With Odds of Hospitalization in Schizophrenia: Network Meta-Analysis of Cohort Studies

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.