MedinCell's partner Teva announces successful launch of UZEDY™

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During today’s Q2 earnings call, Richard Francis, President and CEO of Teva, and Eric Hughes, Executive Vice President, Global R&D & Chief Medical Officer, commented the US launch of UZEDY since May 2023 and the olanzapine Long-Acting Injectable (LAI).

About UZEDY

Richard Francis said:
"We are actually right on plan or slightly ahead of our market access strategy targets and we are very happy with the launch."

"The newest member of our innovative family is said risperidone, our long-acting treatment for schizophrenia. Now, to remind everybody, this is a $4 billion market and we've only just launched UZEDY, but we're very pleased with the feedback we're getting from healthcare professionals. And they're confirming that the product profile that we have is unique and advantageous. Now we're seeing this in the fact that our NBRX is 40%, so already we're getting 40% of the risperidone long-acting market. We're also seeing hospitals look to use our free samples and free trial requests, and we're having good discussions with our payers. So once again, I think excitement around UZEDY early days, but initial feedback is very positive."

UZEDY, a long-acting injectable (LAI) risperidone for the treatment of schizophrenia in adults, is the first FDA-approved product based on MedinCell’s BEPO technology. MedinCell is eligible for up to $105m commercial milestones and for royalties on net sales.

About LAI olanzapine (mdc-TJK), initiated in January 2023

Eric Hughes said:
"Our Olanzapine Phase 3 study is actually enrolling very quickly."

"Olanzapine as an oral agent account for 20% of the patients being treated today, but only less than 1% of patients on the long-acting form are being using that product. And that's primarily because of the safety profile."

Richard Francis, said:
"With olanzapine, I've already highlighted the fact that it's a $4 billion market. But if we do manage to bring this to the market with a favorable safety profile, I think we have a real opportunity to have a significant product on our hands here."

mdc-TJK is an investigational long-acting injectable olanzapine also based on BEPO technology. If approved, it could be the first olanzapine LAI with a favorable safety profile offering a valued treatment option as a complement to UZEDY for severe schizophrenia patients. MedinCell is eligible for $12m left out of $17m of development milestones, for up to $105m commercial milestones and for royalties on net sales.

Other programs

Teva and MedinCell also announce the initiation of preliminary formulation activities for a new program in an undisclosed indication, along with the decision to terminate the mdc-ANG program at preclinical stage for strategic reasons.

1 Extracts from the Teva’s Q2 2023 earnings call, August 2, 2023. Full webinar, transcript and presentation are available on ir.tevapharm.com
2 NBRx = new-to-brand prescriptions: new prescriptions, as in the first time a patient is being prescribed a particular drug
3 The only existing LAI of Olanzapine has a FDA black box warning from for PDSS (Post injection Delirium/Sedation Syndrome) that limits its use

About MedinCell

MedinCell is a commercial-stage technology pharmaceutical 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 already known and used active 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.

UZEDY™ and SteadyTeq™ are trademarks of Teva Pharmaceuticals

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This press release contains forward-looking statements, including statements regarding Company’s expectations for (i) the timing, progress and outcome of its clinical trials; (ii) the clinical benefits and competitive positioning of its product candidates; (iii) its ability to obtain regulatory approvals, commence commercial production and achieve market penetration and sales; (iv) its future product portfolio; (v) its future partnering arrangements; (vi) its future capital needs, capital expenditure plans and ability to obtain funding; and (vii) prospective financial matters regarding our business. Although the Company believes that its expectations are based on reasonable assumptions, any statements other than statements of historical facts that may be contained in this press release relating to future events are forward-looking statements and subject to change without notice, factors beyond the Company’s control and the Company’s financial capabilities.

These statements may include, but are not limited to, any statement beginning with, followed by or including words or phrases such as “objective”, “believe”, “anticipate”, “expect”, “foresee”, “aim”, “intend”, “may”, “anticipate”, “estimate”, “plan”, “project”, “will”, “may”, “probably”, “potential”, “should”, “could” and other words and phrases of the same meaning or used in negative form. Forward-looking statements are subject to inherent risks and uncertainties beyond the Company’s control that may, if any, cause actual results, performance, or achievements to differ materially from those anticipated or expressed explicitly or implicitly by such forward-looking statements. A list and description of these risks, contingencies and uncertainties can be found in the documents filed by the Company with the Autorité des Marchés Financiers (the “AMF”) pursuant to its regulatory obligations, including the Company’s registration document, registered with the AMF on September 4, 2018, under number L 18-062 (the “Registration Document”), as well as in the documents and reports to be published subsequently by the Company. In particular, readers’ attention is drawn to the section entitled “Facteurs de Risques” on page 26 of the Registration Document.

Any forward-looking statements made by or on behalf of the Company speak only as of the date they are made. Except as required by law, the Company does not undertake any obligation to publicly update these forward-looking statements or to update the reasons why actual results could differ materially from those anticipated by the forward-looking statements, including in the event that new information becomes available. The Company’s update of one or more forward-looking statements does not imply that the Company will make any further updates to such forward-looking statements or other forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements.

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