MedinCell's partner Teva provides Guidance for UZEDY in 2024 and an Update on the treatment-candidate of Olanzapine Long-Acting Injectable (LAI)

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- Guidance for 2024 UZEDY Teva’s revenue: ~ $80 million
- Olanzapine LAI ongoing Phase 3: 675 patients (recruitment completed), 62% of the targeted 3,600 injections performed, no PDSS (Post injection Delirium/Sedation Syndrome) observed

About UZEDY

During the Q4 2023 earnings call held today by Teva Pharmaceutical Industries Ltd., President and CEO Richard Francis stated that he expects a strong uptake and significant growth for UZEDY in 2024. He notably provided the annual revenue guidance for UZEDY, projecting approximately $80 million for 2024.

This revenue projection is aligned with MedinCell’s forecasted earnings from UZEDY, as the company receives royalties on sales and may earn up to $105 million in commercial milestones.

UZEDY is the first product based on MedinCell’s long-acting injection technology, BEPO, to reach commercial stage

- US marketing authorization obtained from the U.S. FDA on April 28, 2023
- Commercial launch by Teva in May 2023
- MedinCell has already received first royalties of €0.6 million, calculated on Teva’s net sales from mid-May to end of September 2023

About Olanzapine LAI (mdc-TJK)

Eric Hughes, Executive Vice President, Global R&D & Chief Medical Officer, announced during the call that 62% of the targeted 3,600 injections have already been performed as part of the ongoing Phase 3 clinical trial and that no PDSS has been observed. Full clinical package on efficiency and safety is expected in the second half of 2024.

mdc-TJK is an investigational once-monthly subcutaneous long-acting injection of the atypical antipsychotic olanzapine for the treatment of schizophrenia. It has the potential to be the first long-acting Olanzapine with a favorable safety profile as other LAIs of Olanzapine have a FDA black box warning for PDSS that limits their use.

Teva is fully responsible to lead the development and commercialization of olanzapine LAI globally.

MedinCell may receive up to $117 million in development and commercial milestones over the coming years for mdc-TJK, and is eligible for royalties on all net sales.

Christophe Douat, CEO of MedinCell, says: “The guidance on UZEDY is very positive. Teva’s ambition reaffirms its confidence in its potential. Olanzapine LAI Phase 3, potential First-in-Class product, is progressing impressively and is ahead of schedule with a major milestone this year. Both illustrate the ability of MedinCell technology to do breakthrough products. Based on these news, we confirm our objective to achieve operational profitability as soon as possible and to generate additional revenue with new partnerships to extend our cash visibility until this horizon.”

About MedinCell

MedinCell is a clinical- and commercial-stage biopharmaceutical 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.

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”, “anticipates”, “estimate”, “plan”, “project”, “will”, “may”, “probably”, “potential”, “should”, “could” and other words and phrases of the same meaning or used in negative form.

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