PRESS RELEASE – February 10, 2025 - 8:00am CET - Montpellier, France - Euronext: MEDCL

Completion of the Pivotal Phase 3 Trial for Olanzapine LAI in Schizophrenia Conducted by Teva Pharmaceuticals

- **Medincell to receive a $5 million development milestone payment from Teva with SOLARIS study completion (last patient last visit)**
- **Richard Malamut, Chief Medical Officer at Medincell comments:** *"Our partner is advancing the clinical development of the olanzapine LAI with plans for regulatory submission in the US. This structured approach highlights a strong commitment to addressing a critical unmet need. As a result of Medincell technology, a long-acting injectable formulation of olanzapine may be widely used by patients with schizophrenia."*

The pivotal clinical phase 3 trial for the olanzapine Long-Acting Injectable (LAI) in schizophrenia (SOLARIS) has been completed, following the final visit of the last patient in the 48 weeks open-label safety period, according to Medincell's partner Teva, who finances and pilots the regulatory development of the product (mdc-TJK / TEV-'749).

In accordance with the partnership agreement, reaching this development milestone triggers a $5 million payment from Teva to Medincell.

Teva and Medincell previously announced that efficacy results from Period 1 of the SOLARIS trial showed that TEV-'749 met its primary endpoint across all three dosing groups of patients with schizophrenia in the study, with statistically significant mean differences in the change in Positive and Negative Syndrome Scale (PANSS[1]) total scores from baseline to week 8 (with P<0.0001 for all groups) for TEV-'749 vs. Placebo. The systemic safety profile of TEV-'749 during Period 1 was consistent with other approved oral formulations of olanzapine with no new safety signals identified.[(2)] Additional findings also demonstrate significant improvement in social functioning and quality of life across multiple validated measures from baseline to week 8[(3)].

Data from the SOLARIS study notably demonstrated that Medincell's subcutaneous delivery technology underlying TEV-'749, resulted in no occurrences of Post-Injection Delirium/Sedation Syndrome (PDSS) events after all injections performed during the SOLARIS clinical program.[(4,5)] Currently, no long-acting olanzapine treatment option is available for the treatment of schizophrenia without restrictions on use due to the risk of PDSS at each injection, which Medincell's technology is designed to help prevent.

SOLARIS study was composed of an 8-week, randomized, double-blind, placebo-controlled trial in patients aged 18-64 years diagnosed with schizophrenia (Period 1) followed by an open-label safety period of up to 48 weeks (Period 2).

Teva is now preparing for regulatory submission and launch, with long-term full safety data expected to be released in Q2 2025 and an NDA submission anticipated in H2 2025.

About mdc-TJK
mdc-TJK (TEV-'749) is an investigational, once-monthly, subcutaneous long-acting injection of the atypical antipsychotic olanzapine for the treatment of schizophrenia.

This is the second drug within the partnership with Teva that uses Medincell's co-polymer technology (licensed to Teva under the name SteadyTeq™) to generate a controlled steady release of drug throughout the dosing interval. UZEDY®, the other drug, was approved by the US FDA in April 2023.

Medincell's partner Teva leads the clinical development and regulatory process and is responsible for commercialization of the long-acting olanzapine. Medincell is entitled to receive royalties on net sales, along with development and commercial milestone payments.

Understanding the pharmaceutical development

- A **Phase 3 clinical trial** is the final stage of testing before regulatory approval. It involves a large group of patients to confirm a drug's effectiveness, monitor side effects, and compare it to standard treatments.

- A **randomized, double-blind, placebo-controlled trial** is a clinical study in which:
  - Participants are randomly assigned (randomization) to different groups.
  - Neither the patients nor the doctors know who is receiving the treatment or the placebo (double-blind).
  - One group receives the tested drug, the other receives a placebo (inactive substance) to compare the effects.

- An **open-label safety period** is a phase of a clinical trial in which all participants receive the active treatment, with no placebo group or blinding. This phase helps collect data on the tolerance and safety of the drug under conditions where its administration is known to both patients and investigators.

- The **Primary Endpoint** is the main outcome of a study that determines if the treatment works (e.g., relapse or symptom reduction, survival rate). It's the key measure for regulatory approval.

- The **Secondary Endpoints** are the additional outcomes of a study that provide extra insights (e.g., additional improvements, quality of life, side effects)

- The **Primary Completion Date** in a clinical trial is the date when the last participant completes the last required measurement for the primary endpoint(s). This marks the end of data collection for the main objectives of the trial, before moving on to final analysis and secondary endpoints.

- The **Study Completion Date** is the date when the last participant completes the last required measurement for the entire study, including both primary and secondary endpoints as well as any long-term follow-up assessments. It marks the official end of the clinical trial.

- A **Database Lock (DB Lock)** occurs after primary and study completion date of a clinical trial. All collected data are cleaned and verified, and no further changes can be made. It ensures that the dataset is final and ready for statistical analysis.

- A **Statistical analysis** is performed after the primary completion date and the study completion date and after database lock. It is the process of evaluating clinical trial data to determine if the treatment is effective and/or safe. It involves applying statistical methods to compare results between the treatment and control groups. It aims at supporting regulatory submission and providing evidence for healthcare decisions and commercialization.

- **Statistically significant** means that the results of a study are unlikely to have occurred by chance alone. It indicates that the observed effect or difference is real and not due to random variation in the data. In statistical testing, a result is considered statistically significant if the p-value (probability of obtaining the observed results under the assumption that there is no real effect) is below a pre-defined threshold, usually 0.05 (or 5%). This means there is less than a 5% chance that the results occurred by random chance.

- A **NDA (New Drug Application)** is the formal process in the US of submitting clinical trial data, analyses, and supporting documents to health authorities (FDA) for review and approval of a new drug or therapy. The submission is not automatically public unless the company chooses to disclose it.

- The **FDA Filing Review** occurs within 60 days of NDA submission to check if the application is complete. If accepted, the FDA assigns a PDUFA date; if not, the application is returned for revisions.

- **PDUFA** (Prescription Drug User Fee Act) sets the FDA's deadline for review: 10 months for standard review and 6 months for priority review. Companies may choose to share or not share their PDUFA date publicly.

- The **Full Review** starts after the filing review period and lasts approximately 8 months, during which the FDA evaluates efficacy, safety, and manufacturing data. The FDA issues its final decision on the PDUFA date.

- After review, the FDA may issue:
  - **Approval,** the drug can be marketed and listed on the Drugs@FDA database.
  - **Approval with Conditions,** additional safety monitoring or post-marketing studies are required.
  - **Complete Response Letter (CRL),** the NDA is rejected due to deficiencies that must be fixed before potential resubmission.

- **Labeling** is the official FDA-approved information about how to use the drug, including what it treats, dosage instructions, and possible side effects.

- A **Labeling Extension** happens when the label is updated, such as adding a new use, dosage, or safety warning. These updates require additional studies and FDA approval.

[1] The PANSS is composed of 3 subscales: Positive Scale, Negative Scale, and General Psychopathology Scale. Each subscale is rated with 1 to 7 points ranging from absent to extreme. Each of the 30 items is accompanied by a specific definition as well as detailed anchoring criteria for all seven rating points. These seven points represent increasing levels of psychopathology, as follows: 1- absent 2- minimal 3- mild 4- moderate 5- moderate severe 6- severe 7- extreme; the PANSS overall total score ranges from 30 to 210, with a higher score indicating greater symptom severity. The primary efficacy endpoint was measured by change from baseline to week 8 against the PANSS total score.

[2] Press release, May 8, 2024: www.medincell.com/wp-content/uploads/2024/05/PR_Solaris_08052024_EN_Final.pdf

[3] Press release, November 4, 2024: www.medincell.com/wp-content/uploads/2024/11/PR_MDC_Psych-Congress-2024_eng.pdf

[4] Post-Injection Delirium/Sedation Syndrome (PDSS) is a rare but significant complication associated with existing long-acting injectable formulation of olanzapine. PDSS occurs when a portion of the injected medication unintentionally enters the bloodstream too quickly, causing sudden sedation, confusion, and potentially serious side effects such as respiratory issues. For healthcare providers and patients, PDSS remains a barrier to the widespread use of olanzapine LAI. The requirement for close post-injection monitoring limits the convenience and flexibility of this treatment option. Medincell's olanzapine LAI is designed to eliminate the risk of PDSS, potentially making it a safer and more accessible treatment option.

[5] Press release, November 6, 2024: www.medincell.com/wp-content/uploads/2024/11/PR_MDC_Teva-earnings-Q3_2024_06112024.pdf

About Medincell

Medincell is a clinical- and commercial-stage biopharmaceutical licensing 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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