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Medincell's Partner Teva Presented New Efficacy, Safety, and Tolerability Data from Pivotal Phase 3 of Olanzapine LAI for Adult Patients Diagnosed with Schizophrenia

Teva presented at ECNP 2024* new positive efficacy, safety, and tolerability results for Phase 3 SOLARIS trial evaluating Olanzapine LAI (TV-'749 / mdc-TJK) in adult patients diagnosed with schizophrenia.

Richard Malamut, Chief Medical Officer of Medincell, said: ***"In addition to publishing the positive efficacy results for the primary and secondary endpoints of the SOLARIS study, the data presented by Teva unveiled the three doses evaluated, which align with the three doses of oral olanzapine currently available for the treatment of patients with schizophrenia. This alignment is very important as it should simplify the work for physicians when switching their patients from oral olanzapine to our LAI formulation. All three doses demonstrate systemic safety profile consistent with other approved olanzapine formulations, with no new safety signals identified. Most notably, no PDSS has been observed to date. This is crucial because the risk of PDSS, along with the associated post-injection monitoring requirement, has been a major barrier to the use of the approved intramuscular olanzapine LAI."***

Extract below from Teva's press release - September 21, 2024: read here the complete press release

Period 1 of the SOLARIS study is an 8-week, randomized, double-blind, placebo-controlled trial in patients aged 18-64 years diagnosed with schizophrenia, followed by an open-label safety period of up to 48 weeks (Period 2). Efficacy results from Period 1 of the SOLARIS study show that by week 8:

- TEV-'749 met its primary endpoint across all three dosing groups, with statistically significant mean differences in the change in Positive and Negative Syndrome Scale (PANSS) total scores from baseline to week 8 of -9.71 points, -11.25 points, and -9.69 points versus placebo for the high (531 mg, corresponding to 20 mg/day of oral olanzapine), medium (425 mg, corresponding to 15 mg/day of oral olanzapine), and low (318 mg, corresponding to 10 mg/day of oral olanzapine) dose groups, respectively (all P<0.0001).[1]
- TEV-'749 treatment significantly improved Clinical Global Impression-Severity (CGI-S) scale scores across all three dosing groups, with reductions of -0.47 points (high), -0.61 points (medium), and -0.53 points (low) versus placebo from baseline to week 8 (all P<0.0001).[1]
- TEV-'749 treatment significantly improved Personal and Social Performance (PSP) scale scores across all three dosing groups, with increases of 4.93 points (high), 3.15 points (medium), and 4.63 points (low) versus placebo from baseline to week 8 (all P<0.02).[1]

The systemic safety profile of TEV-'749 was consistent with other approved formulations of olanzapine, with no new safety signals identified. Additional safety and tolerability results from Period 1 (917 active injections) through week 8 of the SOLARIS study show that:

- There were no reported cases of PDSS.[1]
- Treatment-emergent adverse events that occurred more often in patients receiving TEV-'749 versus placebo included weight increase (35% [173/500] versus 8% [13/167]), injection site induration (13% [64/500] vs. 2% [4/167]), injection site pain (10% [50/500] versus 4% [7/167]) and injection site erythema (10% [48/500] versus 1% [1/167]).[1]
- Serious adverse events and discontinuations due to adverse events were reported in 1% (7/500) and 3% (16/500) of patients treated with TEV-'749, respectively, and in 2% (3/167) and 3% (5/167) of patients treated with placebo, respectively.[1]

Also presented at ECNP 2024, results from the Phase 1 study of TEV-'749 show similar safety and tolerability results, including no reports of PDSS events. Additionally, a presented pre-clinical study suggests that the subcutaneous route of administration and formulation characteristics of TEV-'749 appear to greatly reduce the hypothesized risk of PDSS occurrence for patients receiving the treatment.

The long-term safety of TEV-'749 and incidence of PDSS are also being evaluated in the SOLARIS open-label study (Period 2), with safety data topline readout expected in the first half of 2025.

[1] Data on file. Parsippany, NJ: Teva Neuroscience, Inc.

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

Teva is fully responsible for leading the development and commercialization of Olanzapine LAI. Medincell may receive up to $117 million in development and commercial milestones for mdc-TJK, in addition to royalties on all net sales.

* 37th Annual European College of Neuropsychopharmacology (ECNP) Congress - September 21-24, 2024, Milan, Italy. www.ecnp.eu

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.

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