PRESS RELEASE - September 23rd, 2024 - 8:00 am CEST - Montpellier, France - Euronext: MEDCL

Medincell's Partner Teva Provided Treatment Insights into Switching to UZEDY® from Perseris®

New data presented by Teva at ECNP 2024* demonstrate switching to UZEDY at four weeks after the last dose of once-monthly Perseris® (RBP-7000) provided the most comparable pharmacokinetic (PK) profile based on relevant simulations, with comparable doses identified.

Perseris manufacturer announced in July 2024 the discontinuation of its commercialization.

Teva already presented in June 2024 data informing clinical strategies for switching patients to UZEDY from a once-monthly intramuscular injection of Invega Sustenna® (paliperidone palmitate).**

Richard Malamut, Chief Medical Officer of Medincell said: *"We are delighted to see that our partner is fully committed to supporting healthcare providers in implementing effective switching strategies to UZEDY, which offers several key differentiating features compared to other risperidone or paliperidone palmitate formulations: no loading doses or oral supplementation at initiation, flexible dosing intervals of either one or two months, subcutaneous administration, ready-to-use prefilled syringe."*

About additional results from the Advance study on the utilization of long-acting injectable antipsychotics, which were also reported by Teva at ECNP 2024, Richard Malamut said: "*It is encouraging to see that most of the factors raised by patients with Schizophrenia, their caregivers, and healthcare providers regarding use of a long-acting injectable antipsychotic can be effectively addressed with UZEDY."*

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

In a population pharmacokinetic (PopPK) analysis, simulations were conducted to predict pharmacokinetic (PK) exposures when switching to UZEDY 4-6 weeks after the last injection of once-monthly RBP-7000. The simulation models indicated that switching to UZEDY 4 weeks after the last dose of once-monthly RBP-7000 resulted in comparable PK properties of UZEDY at both the initial exposure and steady state. Comparable doses included UZEDY at 100 mg (once-monthly dosing) or 200 mg (once-every-two-months dosing) to 120 mg of once-monthly RBP-7000.[1]

Any switching strategy should be determined by clinicians on an individual patient basis, considering factors such as patient preference, scheduling convenience and potential tolerability issues or risk of symptom breakthrough.

Additional key data being presented at ECNP 2024 included new quantitative results from the ADVANCE (Attitudes Driving Regional Differences in LAI Antipsychotic Utilization for Schizophrenia Among Healthcare Professionals [HCPs], Patients and Caregivers) surveys, including:

- Among 447 people living with schizophrenia and 375 caregivers, most common patient-reported reasons for accepting an LAI (n=331) were improvement of symptoms/condition with LAIs (68%, n=224), recommendation by their HCP (65%, n=214), and ease of using LAIs versus oral antipsychotics (57%, n=189).[1]
- Patients also reported using LAIs due to fewer side effects versus oral antipsychotics (38%, n=127) and to help prevent hospitalization (20%, n=67).[1]
- Caregivers (n=229) reported that patients accepted LAIs based on ease of use versus oral antipsychotics (78%, n=178), to help prevent hospitalization (62%, n=143), and perception that LAIs would work better for improving condition/symptoms (62%, n=143).[1]
- Among a sample of 791 HCPs from 8 different countries, most HCPs reported that the primary reason for recommending an LAI to a patient was nonadherence to oral medication, with the exception of South Korea where the most common reason was that an LAI would be more efficacious than oral.[1]

The primary reasons cited for not recommending an LAI were patient clinical characteristics and the lack of an available LAI formulation of the patient's current oral treatment, except for China and South Korea, where the primary reasons were LAI cost to patient and LAI product not marketed, respectively.[1]

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

UZEDY is the first product based on Medincell's long-acting injection technology, BEPO® (licensed to Teva under the name SteadyTeq™), that reached commercial stage. US marketing authorization obtained from the U.S. FDA on April 28, 2023, immediately followed by commercial launch by Teva in May 2023.

Medincell may receive up to $105 million in commercial milestones for UZEDY, in addition to royalties on all net sales of both products.

[*] 37th Annual European College of Neuropsychopharmacology (ECNP) Congress - September 21-24, 2024, Milan, Italy. www.ecnp.eu
[**] Medincell's press release, June 3rd, 2024: https://www.medincell.com/wp-content/uploads/2024/06/PR_MDC_Elevate2024_EN_vf.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.

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