Newron to present new analyses from and updates on its clinical program evaluating evenamide as an add-on treatment for schizophrenia at the 38th European College of Neuropsychopharmacology (ECNP) Congress 2025

New post-hoc analyses highlighting the clinical benefit of evenamide for patients with treatment-resistant schizophrenia (TRS) or those inadequately responding to their antipsychotic treatment

Introduction of key features of landmark, potentially pivotal study ENIGMA-TRS 1, designed to demonstrate the short and long-term efficacy of evenamide as an add-on treatment for patients with TRS

Milan, Italy, October 2, 2025 – Newron Pharmaceuticals S.p.A. ("Newron") (SIX: NWRN, XETRA: NP5), a biopharmaceutical company focused on the development of novel therapies for patients with diseases of the central and peripheral nervous system, announced that it will present three posters at the upcoming 38th Congress of the European College of Neuropsychopharmacology taking place in Amsterdam, the Netherlands, from October 11 to 14, 2025.

Results from previous Phase II (study 014/015) and Phase III (study 008A) studies have demonstrated clinically relevant benefits of evenamide. These studies in patients with treatment-resistant schizophrenia (TRS) or in poor responders to antipsychotic medication provided a significant and sustained improvement in TRS patients (up to and including one year) and an improvement in both positive and negative symptoms in poor responders, through evenamide's glutamatergic modulating activity. In addition, evenamide was extremely well tolerated without the occurrence of any typical antipsychotic adverse events and with a minimal dropout rate.

Additional post-hoc analyses from data of these studies further support the unique long-lasting efficacy of evenamide. Over the course of a year, the proportion of responders increased throughout the study with more than 25% of patients achieving remission (i.e. sustained low symptoms level for at least six consecutive months) and more than 50% no longer meeting the protocol criteria for treatment resistance.

Treatment-resistance to antipsychotics is observed in about 30% of patients with schizophrenia, and clozapine, the most potent second-generation antipsychotic and the only approved medication for TRS, is highly underutilized. This is mainly explained by its serious side effects, need for regular monitoring and low tolerability. In contrast, results from previous studies with evenamide suggest that the drug is safe and well tolerated.

Together, these results paved the way for the launch of a potentially pivotal landmark phase III, randomized, one-year double-blind, placebo-controlled study for TRS: the ENIGMA-TRS 1 study (EveNamIde's Glutamate Modulation Ameliorates TRS 1). The study's unique design aims to address previous trials' limitations by assessing the response to evenamide (15 and 30 mg bid) as an add-on to current second-generation antipsychotic (SGA) medication(s) in patients with TRS.

Poster presentations

PS01-0225 – Saturday, October 11, 2025
12:00 pm – 1:25 pm CEST
Evenamide Phase 3 Program: Study 023 (ENIGMA-TRS 1) evaluates the efficacy of add-on glutamate modulation in patients with documented treatment-resistant schizophrenia

EP08-0712 – Monday, October 13, 2025
8:00 am – 8:30 am CEST
Success in the mechanism-based development of evenamide for patients with inadequate response or treatment-resistant schizophrenia

PS04-3209 – Tuesday, October 14, 2025
12:35 pm – 2:00 pm CEST
Glutamate modulation by evenamide produces statistically significant and clinically relevant improvement in patients with treatment-resistant schizophrenia

About treatment-resistant schizophrenia (TRS)
A significant proportion of patients with schizophrenia show virtually no beneficial response to antipsychotics (APs) despite adequate treatment, leading to a diagnosis of treatment-resistant schizophrenia (TRS). TRS is defined as no, or inadequate, symptomatic relief despite treatment with therapeutic doses of two APs from two different chemical classes for an adequate period. About 15% of patients develop TRS from illness onset, and about one-third of patients overall. Increasing evidence supports abnormalities in glutamate neurotransmission in TRS, not targeted by current APs, along with normal dopaminergic synthesis, to explain the lack of benefit of most typical and atypical antipsychotics.

About evenamide
Evenamide, an orally available new chemical entity, specifically blocks voltage-gated sodium channels (VGSCs) and is devoid of biological activity at >130 other CNS targets. It normalizes glutamate release induced by aberrant sodium channel activity (veratridine-stimulated), without affecting basal glutamate levels, due to inhibition of VGSCs. Combinations of ineffective doses of evenamide and other APs, including clozapine, were associated with benefit in animal models of psychosis, suggesting synergies in mechanisms that may provide benefit in patients who are poor responders to current APs, including clozapine.

About Newron Pharmaceuticals
Newron (SIX: NWRN, XETRA: NP5) is a biopharmaceutical company focused on developing novel therapies for patients with diseases of the central and peripheral nervous system.
Headquartered in Bresso, near Milan, Italy, Newron is advancing its lead compound, evenamide, a first-in-class glutamate modulator, which has the potential to be the first add-on therapy for treatment-resistant schizophrenia (TRS) and for poorly responding patients with schizophrenia. Evenamide is currently in Phase III development and clinical trial results to date demonstrate the benefits of this drug candidate in the TRS patient population, with significant improvements across key efficacy measures increasing over time, as well as a favourable safety profile, which is uncommon for available antipsychotic medications.
Newron has signed development and commercialization agreements for evenamide with EA Pharma (a subsidiary of Eisai) for Japan and other Asian territories, as well as Myung In Pharm for South Korea.
Newron has a proven track record in bringing CNS therapies to market. Its Parkinson's disease treatment, Xadago® (safinamide), is approved in over 20 markets, including the USA, UK, EU, Switzerland, and Japan, and commercialized in partnerships with Zambon and Meiji Seika.

For more information, please visit: www.newron.com

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