



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



For more information, please contact:

Newron

Stefan Weber – CEO; +39 02 6103 46 26, pr@newron.com

UK/Europe

Simon Conway / Ciara Martin / Natalie Garland-Collins, FTI Consulting; +44 20 3727 1000, SCnewron@fticonsulting.com

Switzerland

Valentin Handschin, IRF; +41 43 244 81 54, handschin@irf-reputation.ch

Germany/Europe

Anne Hennecke / Maximilian Schur, MC Services; +49 211 52925227, newron@mc-services.eu

USA

Paul Sagan, LaVoieHealthScience; +1 617 865 0041, psagan@lavoiehealthscience.com

Important Notices

This document contains forward-looking statements, including (without limitation) about (1) Newron's ability to develop and expand its business, successfully complete development of its current product candidates, the timing of commencement of various clinical trials and receipt of data and current and future collaborations for the development and commercialization of its product candidates, (2) the market for drugs to treat CNS diseases and pain conditions, (3) Newron's financial resources, and (4) assumptions underlying any such statements. In some cases, these statements and assumptions can be identified by the fact that they use words such as "will", "anticipate", "estimate", "expect", "project", "intend", "plan", "believe", "target", and other words and terms of similar meaning. All statements, other than historical facts, contained herein regarding Newron's strategy, goals, plans, future financial position, projected revenues and costs and prospects are forward-looking statements. By their very nature, such statements and assumptions involve inherent risks and uncertainties, both general and specific, and risks exist that predictions, forecasts, projections and other outcomes described, assumed or implied therein will not be achieved. Future events and actual results could differ materially from those set out in, contemplated by or underlying the forward-looking statements due to a number of important factors. These factors include (without limitation) (1) uncertainties in the discovery, development or marketing of products, including without limitation difficulties in enrolling clinical trials, negative results of clinical trials or research projects or unexpected side effects, (2) delay or inability in obtaining regulatory approvals or bringing products to market, (3) future market acceptance of products, (4) loss of or inability to obtain adequate protection for intellectual property rights, (5) inability to raise additional funds, (6) success of existing and entry into future collaborations and licensing agreements, (7) litigation, (8) loss of key executive or other employees, (9) adverse publicity and news coverage, and (10) competition, regulatory, legislative and judicial developments or changes in market and/or overall economic conditions. Newron may not actually achieve the plans, intentions or expectations disclosed in forward-looking statements and assumptions underlying any such statements may prove wrong. Investors should therefore not place undue reliance on them. There can be no assurance that actual results of Newron's research programs, development activities, commercialization plans, collaborations and operations will not differ materially from the expectations set out in such forward-looking statements or underlying assumptions. Newron does not undertake any obligation to publicly update or revise forward-looking statements except as may be required by applicable regulations of the SIX Swiss Exchange or the Dusseldorf Stock Exchange where the shares of Newron are listed. This document does not contain or constitute an offer or invitation to purchase or subscribe for any securities of Newron and no part of it shall form the basis of or be relied upon in connection with any contract or commitment whatsoever.