Newron to present at the 2026 Annual Congress of the Schizophrenia International Research Society (SIRS)

Presentations explore the role of glutamatergic modulation in treatment-resistant schizophrenia (TRS) across preclinical and clinical research

Milan, Italy, and Morristown, NJ, USA, March 20, 2026 – 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, today announced that it will take part in a workshop and present three posters at the upcoming SIRS 2026 Annual Congress taking place March 25-29, 2026, at the exhibition and congress area Firenze Fiera in Florence, Italy.

Workshop
Wednesday, March 25, 2026
3:30-5:30 PM CET – Room: Auditorium

- **Modulation of Glutamate in Patients With TRS: Results From Trials With Evenamide** (within the workshop "U*se of Biomarkers in Evaluating Novel Treatments for Patients with Schizophrenia")*

Posters
Thursday, March 26, 2026
12:00-2:00 PM CET - Room: Cavaniglia

- **T10: Novel Findings from a Neurodevelopmental Animal Model of Schizophrenia Support Long-Term Clinical Benefits of Evenamide in Treatment-Resistant Schizophrenia**

Friday, March 27, 2026
12:00-2:00 PM CET - Room: Cavaniglia

- **F7: Novel Add-On Glutamate Modulation with Evenamide in Treatment-Resistant Schizophrenia: Updates from the Phase III, Potentially Pivotal, ENIGMA-TRS Program**

Saturday, March 28, 2026
12:00-2:00 PM CET - Room: Cavaniglia

- **S10: Unique Benefits of Evenamide on Social Functioning and Life Engagement in Patients with Treatment-Resistant Schizophrenia or Inadequate Response to Second-Generation Antipsychotics**

About ENIGMA-TRS

The ENIGMA-TRS pivotal Phase III program consists of ENIGMA-TRS 1 and ENIGMA-TRS 2. ENIGMA-TRS 1, initiated in August 2025, is an international, one-year, double-blind, placebo-controlled study in at least 600 patients to evaluate the efficacy, tolerability, and safety of evenamide 15 mg and 30 mg twice daily as an add-on therapy to current antipsychotics, including clozapine, compared to placebo. ENIGMA-TRS 2, initiated in December 2025, is a Phase III, international, 12-week, randomized, double-blind, placebo-controlled trial evaluating the efficacy, safety, and tolerability of evenamide 15 mg twice daily as an add-on therapy to current antipsychotics, including clozapine, compared to placebo, in patients suffering from TRS. ENIGMA-TRS 2 will enroll at least 400 patients.

About evenamide

Evenamide is a novel, orally available new chemical entity with a unique mechanism of action distinct from all currently marketed antipsychotics. It acts by selectively blocking voltage-gated sodium channels (VGSCs) and exhibits no biological activity at more than 130 other central nervous system (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 subtherapeutic doses of evenamide and other APs, including clozapine, were associated with benefit in animal models of psychosis, suggesting synergies in mechanisms that may provide meaningful benefits for patients who do not adequately respond to current APs, including those on clozapine. Importantly, the benefits seemed to persist for a substantial time after evenamide had been degraded, explaining the long-term effects seen in clinical studies. Through its novel glutamatergic modulation, evenamide represents a first-in-class approach aimed at addressing the unmet needs of patients with schizophrenia who are resistant to existing treatments.

About treatment-resistant schizophrenia (TRS)

A significant proportion of patients with schizophrenia show virtually little to no beneficial response to currently available antipsychotic (AP) treatments, leading to a diagnosis of treatment-resistant schizophrenia (TRS). TRS is defined as no or inadequate symptom relief despite treatment with therapeutic doses of two APs from two different chemical classes for an adequate period. It is estimated that approximately 15% of patients develop TRS from the onset of illness, and about one-third to 50% of patients with schizophrenia overall. Emerging scientific evidence supports abnormalities in glutamate neurotransmission in TRS, not targeted by current APs, along with normal dopaminergic synthesis, to explain the lack of clinical benefit of most typical and atypical antipsychotics, which act primarily on dopamine receptors. These insights underline the need for novel therapeutic approaches that target the underlying glutamatergic dysfunction in schizophrenia, offering hope for patients who currently have limited or no effective treatment options.

About Newron Pharmaceuticals

Newron (SIX: NWRN, XETRA: NP5) is a biopharmaceutical company focused on the development of innovative therapies for patients with diseases of the central and peripheral nervous system. Headquartered in Bresso near Milan, Italy, the Company has a strong track record of advancing neuroscience-based treatments from discovery to market. Newron's lead compound, evenamide, is a first-in-class glutamate modulator and 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 developed in the global pivotal ENIGMA-TRS Phase III development program. Clinical trial results to date demonstrate the benefits of this drug candidate in the TRS as well as poorly responding patient population, with significant improvements across key efficacy measures increasing over time, as well as a favorable 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's first marketed product, Xadago®/safinamide has received marketing authorization for the treatment of Parkinson's disease in the European Union, Switzerland, the UK, the USA, Australia, Canada, Latin America, Israel, the United Arab Emirates, Japan and South Korea. The product is commercialized by Newron's partner Zambon, with Supernus Pharmaceuticals holding marketing rights in the U.S., and Meiji Seika responsible for development and commercialization in Japan and other key Asian territories. For more information, please visit: www.newron.com

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