Ad hoc announcement pursuant to Art. 53 LR

Newron Strengthens Evenamide Intellectual Property Portfolio

European patent clears opposition period without challenge, providing protection into 2044

Additional formulation patent application could extend protection into 2046

Milan, Italy, and Morristown, NJ, USA, November 23, 2026, 07:00 am CET – 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 its European patent for evenamide has cleared the opposition period without challenge. Newron has also expanded its patent portfolio with additional grants and filings. Evenamide is a first-in-class glutamate modulator in Phase 3 development for treatment-resistant schizophrenia (TRS).

- **European protection into 2044**: Newron's European[1] composition of matter patent EP4615820, "Crystalline Forms of Evenamide", announced in January 2026, has cleared the opposition period without challenge. The patent covers crystalline forms of evenamide, processes for their preparation, and their uses; it extends the asset's exclusivity into 2044.
- **Expanded geographic protection**: Newron has secured that same patent granted in Hong Kong and received an intention to grant from the Eurasian[2] Patent Office. The Company has completed the national phase entry for counterpart patent applications to EP4615820 in key countries, including the USA and China.
- **Additional potential protection into 2046**: Newron has also filed an additional formulation patent application that, if granted, could extend the protection of the evenamide drug product into 2046.

Newron is developing evenamide, a first-in-class glutamate modulator, as a potential first approved add-on therapy for TRS through its global pivotal ENIGMA-TRS Phase 3 program. ENIGMA-TRS 1 has completed enrolment of 618 patients in 19 countries in October 2026, with topline efficacy and safety results from the 12-week primary endpoint assessment expected in Q1 2027. ENIGMA-TRS 2 is currently enrolling at least 400 patients.

"The European patent is an important part of our strategy to protect evenamide as it moves toward potential commercialization," **stated Elena Barbanti, Newron's Senior Director Intellectual Property**. *"Our additional formulation patent application, if granted, could provide another layer of protection for the evenamide drug product into 2046."*

[1] Territories covered by European Patent Convention (EPC): 40 contracting states including all members of the EU, the UK, Switzerland and Turkey
[2] Territories covered by Eurasian Patent Convention (EAPC): eight contracting states

Stefan Weber, Newron's CEO, added: *"This is an important milestone for Newron and a testament to the outstanding work of our IP team. These patent developments support the long-term commercial potential of evenamide as we approach pivotal Phase 3 results in Q1 2027. We believe evenamide has the potential to become the first approved add-on therapy for patients with treatment-resistant schizophrenia."*

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 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. A recent study conducted at University of Pittsburgh suggests that evenamide's efficacy in downregulating the hyperdopaminergic state, social deficits, and memory impairment may result from its ability to attenuate vHipp hyperexcitability (Neuropsychopharmacology; https://doi.org/10.1038/s41386-025-02188-y). Importantly, the benefits seemed to persist for a substantial time after evenamide had been degraded, also suggesting neural plasticity possibly explaining accumulating long-term effects observed in clinical studies 014/015. While the exact causes of TRS are complex and multifactorial, hippocampal dysfunction rooted in impaired neural plasticity is considered a strong contributing factor. 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 ENIGMA-TRS

ENIGMA-TRS 1 is an ongoing, international, 52-week, randomized, double-blind, placebo-controlled Phase 3 study evaluating the efficacy, tolerability, and safety of the 15mg BID and 30mg BID therapeutic doses of evenamide compared to placebo. Patients on second-generation antipsychotics, including clozapine, were required to meet Treatment Response and Resistance Psychosis international consensus criteria for TRS. The study has completed enrollment, with a total of 618 patients enrolled at study centers in 19 countries in Europe, Asia, Latin America, and Canada.
The primary assessment of efficacy and safety of ENIGMA-TRS 1 will be performed 12 weeks after randomization to treatment. Following this initial period, the study will continue to be double-blind and placebo-controlled until the 26- and 52-week time points. The primary efficacy endpoint of the trial will be the change from baseline in the Positive and Negative Syndrome Scale (PANSS) scores at 12 weeks. Newron expects to announce results from the 12-week primary endpoint assessment in Q1 2027.

ENIGMA-TRS 2 is enrolling patients at study centers in Asia and Latin America, with additional sites planned in Europe. The study uses the same screening procedure as ENIGMA-TRS 1. ENIGMA-TRS 2 will include at least 400 patients in a 12-week, randomized, double-blind, placebo-controlled Phase 3 study, designed to evaluate the efficacy, tolerability, and safety of the 15mg BID dose of evenamide compared to placebo. The efficacy and safety analysis will be performed at the 12-week point following successful completion of the study. The FDA clinical hold remains in place at U.S. study centers, where no patients have received evenamide.

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 3 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 and connect with us on LinkedIn.

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