Ad hoc announcement pursuant to Art. 53 LR

Newron Further Expands Intellectual Property Portfolio for Evenamide with New EU Composition of Matter Patent

EP4615820 – "Crystalline Forms of Evenamide" is expected to extend asset exclusivity in EU into 2044

- *Evenamide is currently being investigated in Newron's global ENIGMA-TRS Phase III development program, enrolling at least 1,000 schizophrenia patients with topline results expected in Q4-2026*
- *Evenamide is a first-in-class glutamate modulator with a novel mechanism of action for patients who do not respond adequately, or are resistant to, existing antipsychotic therapies*
- *ENIGMA-TRS program aims to establish evenamide as the first approved add-on therapy for treatment resistant schizophrenia (TRS), a patient population with high morbidity and mortality*

Milan, Italy, and Morristown, NJ, USA, January 6, 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 the European Patent Office (EPO) has issued the decision to grant an additional patent covering its lead development compound, evenamide. This composition of matter patent EP4615820 claims crystalline forms of evenamide, processes for their preparation, and their uses. The patent has a scheduled term of 2044.

"This European Patent Office decision is evidence of our comprehensive strategy to continuously strengthen the intellectual property protecting our key assets," stated Elena Barbanti, Newron's Senior Director Intellectual Property (IP).

Stefan Weber, Newron's CEO, added: *"This is an important milestone for Newron and a testament to the outstanding work of our IP team.*

We expect this new patent will extend the exclusivity runway for evenamide, supporting our efforts to maximize its therapeutic and commercial potential. This drug candidate, which is currently progressing through pivotal clinical studies, has the potential to become the first add-on therapy for schizophrenia patients who do not respond adequately, or are resistant to, existing antipsychotic therapies, in our assessment constituting the vast majority of patients suffering from schizophrenia."

Newron has completed the entry into national phases for counterpart patent applications to EP4615820 in all key countries. This new composition of matter patent adds to the current extensive IP protection around evenamide.

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 Pittsburg 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 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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