Newron to present data and updates on its clinical program evaluating evenamide as an add-on treatment for schizophrenia at the 2025 World Congress of Biological Psychiatry (WCBP)

- *The importance of glutamate release modulation by evenamide used as an add-on therapy for patients with schizophrenia inadequately responding to their second-generation antipsychotics, including clozapine (study 008A) - oral and poster presentation*
- *The key features of a landmark, potentially pivotal, randomized, double-blind, placebo-controlled study designed to demonstrate the short and long-term efficacy and tolerability of evenamide as an add-on treatment to current second-generation antipsychotic(s) in Treatment Resistant Schizophrenia (TRS) (study ENIGMA-TRS 1) - poster presentation*
- *The safety and tolerability of new antipsychotics, demonstrating the relevance of the preclinical mechanism of action - poster presentation*

Milan, Italy, September 5, 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 and give an oral presentation at the upcoming 17th World Congress of Biological Psychiatry (WCBP) taking place September 9-12, 2025, at the Estrel Berlin Hotel & Conference Center, in Berlin, Germany.

The results of Study 008A indicate for the first time that glutamate modulation, in this case through addition of evenamide, is associated with clinically meaningful and statistically significant efficacy. In addition, this trial is the first to demonstrate that the addition of one antipsychotic to another is associated with an improvement in efficacy. Study 008A was an international, randomized, double-blind, placebo-controlled study of evenamide as an add-on to a second-generation antipsychotic (SGA) in patients with symptomatic schizophrenia not responding adequately to their current antipsychotic medication, including clozapine. Evenamide was extremely well tolerated in this study without the occurrence of any typical antipsychotic adverse events and with a minimal dropout rate.

The ENIGMA-TRS 1 (EveNamIde's Glutamate Modulation Ameliorates TRS 1) study's unique design aims to address previous trials' limitations by assessing evenamide's (15 and 30 mg bid) response as an add-on to current SGA medication(s) in patients with TRS, as defined by the TRRIP Working Group Consensus Guidelines, in a blinded, placebo-controlled setting. Patients' eligibility is reviewed by an Independent Eligibility Assessment Committee and SGA plasma concentration measurements are monitored pre- and post-randomization to ensure participants' antipsychotic treatment compliance. This potentially pivotal landmark study plans to enroll more than 600 subjects at around 50 sites in 20 countries and will assess both short-term and long-term efficacy (at week 12, 26 and 52).

The favorable safety and tolerability profile of evenamide will be compared with that of three recently approved antipsychotics. The analysis will focus on the relative risk of each drug compared to placebo in relation to their different modes of action.

Oral and poster presentation
Wednesday, September 10, 2025
1:30 pm – 3:00 pm CEST (oral)
6:15 pm – 7:45 pm CEST (poster)

- **Glutamate Modulation as Adjunctive Therapy in Patients with Schizophrenia Not Adequately Responding to Second-Generation Antipsychotics: Clinical Benefits of Evenamide in a Phase 2/3, International, Randomized, Double-Blind, Placebo-Controlled Trial**

Poster presentation
Thursday, September 11, 2025
6:15 pm – 7:45 pm CEST

- **Evenamide, a Glutamate Release Modulator, as Add-On to Second-Generation Antipsychotics in Treatment-Resistant Schizophrenia: Updates from a Phase 3, Potentially Pivotal, International, Randomized, Double-Blind, Placebo-Controlled Trial**
- **Mechanism of Action of Antipsychotics and their Impact on Tolerability and Safety**

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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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.