Newron and Myung In Pharm announce license agreement for evenamide in South Korea

- **Myung In Pharm to develop, manufacture and commercialize evenamide in South Korea**
- **Myung In Pharm to contribute 10% of patients to Newron's pivotal Phase III trial for evenamide, and share global development costs**
- **Newron will receive upfront payment, development and regulatory milestones, and royalties on net sales**
- **Newron expects to begin pivotal Phase III trial in H1 2025**

Milan, Italy; Morristown, NJ, USA; and Seoul, Republic of Korea - January 9, 2025 - Newron Pharmaceuticals S.p.A. ("Newron") (SIX: NWRN, XETRA: NP5), a biopharmaceutical company focused on the development of novel therapies for diseases of the central and peripheral nervous system, and Myung In Pharm Co. Ltd. ("Myung In Pharm"), South Korea's leading CNS specialist pharmaceutical company, today announced that they have entered into a license agreement to develop, manufacture and commercialize Newron's innovative modulator of the excessive release of glutamate, evenamide, an add-on therapy for treatment-resistant schizophrenia (TRS) and poorly responding patients with schizophrenia, in South Korea.

Under the terms of the license agreement, Myung In Pharm will contribute 10% of the total patient population to be enrolled into Newron's upcoming pivotal Phase III trial and cover the costs related to this population. Myung In Pharm's involvement leverages its established clinical infrastructure and expertise in the central nervous system (CNS) field. Furthermore, the company will bear a percentage of eligible global development costs and will also be responsible for all regulatory, registration, marketing, and commercialization costs for evenamide in South Korea. In return, Newron will receive an upfront payment, milestone payments for development and regulatory achievements, and royalties on net sales. Further details were not disclosed by the parties.

The Phase III randomized, double-blind, one-year trial is expected to begin in H1 2025 and will compare evenamide to placebo as an add-on treatment in at least 600 patients with TRS. It will be coordinated by Newron, who will oversee the trial design, execution, and data analysis. Myung In Pharm will be responsible for enrolling patients in South Korea through its extensive network of clinical sites, as well as providing support with monitoring and data collection. Newron continues to pursue further development opportunities for evenamide in other territories. On December 13, 2024, Newron and EA Pharma (a subsidiary of Eisai Co., Ltd.) announced a license agreement for evenamide in Japan and other Asian territories.

"We are thrilled to partner with Myung In Pharm in this important clinical trial and to grant them the rights to develop, manufacture and commercialize evenamide in South Korea," said **Stefan Weber, CEO of Newron**. "Their *strong expertise in CNS therapies and their clinical infrastructure will be instrumental in advancing the development of evenamide. This collaboration underscores our shared commitment to transforming the treatment landscape for patients with unmet needs."*

Hang Myung LEE, Chairman of Myung In Pharm, commented: *"Newron's innovative approach aligns with our commitment to improving patient outcomes in the CNS area, and we believe our participation will make a significant contribution to the success of the study. Furthermore, we are honored to have received the license to commercialize evenamide in South Korea. This partnership presents a valuable opportunity for us to bring a new treatment option to patients in South Korea, a key market for Myung In Pharm. We look forward to working closely with the Newron team to bring this promising therapeutic to the forefront of clinical development and expand its impact in South Korea."*

Jefferies International Limited ("Jefferies") acted as the exclusive financial advisor to Newron. Orrick Herrington & Sutcliffe LLP advised as legal counsel to Newron.

Cosmo Group Inc. of USA acted as the advisor to Myung In Pharm.

About schizophrenia
Approximately 25 million people worldwide are affected by schizophrenia, including more than 210,000 in South Korea as reported in 2022 by HIRA (Health Insurance Review & Assessment Service, Government agency). Despite more than 60 different types of atypical and typical antipsychotics used for schizophrenia globally, a considerable number of patients remain severely ill or resistant to treatment. Overall, 30-50% of patients do not respond to the available medications and are defined treatment resistant. In addition to the patients with treatment-resistant schizophrenia (TRS), another 20-30% are described as "poor responders to anti-psychotic medication," even if not meeting the criteria for TRS. New findings indicate that patients with TRS have abnormalities in the glutamatergic system, but not in dopaminergic transmission, so there is a huge unmet medical need for a glutamatergic mechanism of action, efficacious both in TRS patients and in those who are poor responders to the current treatments.

About evenamide
Evenamide is the first new chemical entity that has demonstrated significant benefits in this difficult-to-treat patient population, as seen in the potentially pivotal Phase III study 008A trial, as an add-on treatment to second generation anti-psychotics including clozapine, in 291 poorly responding patients with chronic schizophrenia. The primary endpoint, the Positive and Negative Syndrome Scale (PANSS)[1], and the key secondary endpoint, the Clinical Global Impressions Scale – Severity (CGI-S), were met and showed statistical significance compared to placebo. Importantly, evenamide treatment was associated with statistically significant increase in proportion of patients who experienced "clinically meaningful benefit" on the outcome variables. Evenamide was extremely well tolerated, without any of the usual side effects of available anti-psychotics.

About Newron Pharmaceuticals
Newron (SIX: NWRN, XETRA: NP5) is a biopharmaceutical company focused on the development of novel therapies for patients with diseases of the central and peripheral nervous system. The Company is headquartered in Bresso near Milan, Italy. 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, and is commercialized by Newron's Partner Zambon. Supernus Pharmaceuticals holds the commercialization rights in the USA. Meiji Seika has the rights to develop and commercialize the compound in Japan and other key Asian territories. Newron is also developing evenamide as the potential first add-on therapy for the treatment of patients with symptoms of schizophrenia. For more information, please visit: www.newron.com

About Myung In Pharm
Myung In Pharm is a fully integrated pharmaceutical company established in 1985, based in Seoul, Republic of Korea. The company specializes in the manufacturing, processing, and distribution of pharmaceutical drugs, with a strong focus on central nervous system (CNS) therapies. Ranked number one in South Korea in the CNS field, Myung-In Pharm operates state-of-the-art manufacturing facilities that meet cGMP standards. With a robust network of over 1,200 neurologists and relationships with 98% of domestic neurology hospital departments, Myung In Pharm is dedicated to improving patient care and advancing the field of neuroscience. http://myunginph.co.kr/main/en/

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[1] Positive and Negative Syndrome Scale (PANSS) is widely used in clinical trials of schizophrenia and is considered the "gold standard" for assessment of antipsychotic treatment efficacy (Innvo Clin Neurosci, 2017: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5788255/)

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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.