Ad hoc announcement pursuant to Art. 53 LR
Newron and EA Pharma (a subsidiary of Eisai Co., Ltd.) announce license agreement for evenamide in Japan and other Asian territories

- **Newron will receive up to a maximum of €117 million from an upfront payment, development milestones and commercialization milestones, and up to double-digit tiered royalties on net sales**
- **Evenamide is a unique modulator of the excessive release of glutamate in treatment resistant schizophrenia (TRS) and poorly responding patients with schizophrenia**
- **Newron expects to begin a pivotal Phase III trial in H1 2025 for evenamide as an add-on therapy to any current anti-psychotic in TRS patients**
- **Newron continues to pursue further development opportunities for evenamide in other territories**

Milan, Italy, Morristown, NJ, USA, and Tokyo, Japan, December 13, 2024, 7 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, and EA Pharma Co., Ltd. (Head Office, Chuo-ku, Tokyo, Japan; President, Hidenori Yabune; "EA Pharma"), a subsidiary of Eisai Co., Ltd., 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, in Japan and other designated Asian territories[1].

Under the terms of the license agreement, in exchange for full rights in the licensed territories, Newron will receive up to a maximum total of €117 million from EA Pharma, including an upfront payment of €44 million, financial contributions to its upcoming Phase III one-year study to be performed outside of the licensed territories, regulatory and commercialization milestones, and tiered royalties up to a double-digit percentage of net sales for evenamide.

The execution of this agreement, especially the upfront payment of €44 million, is expected to materially impact Newron's 2024 financial statements.

Stefan Weber, CEO of Newron, commented: *"This partnering agreement for evenamide is a key milestone in our goal to offer a truly innovative, evidence-based alternative to patients suffering from schizophrenia, those who are responding poorly to their treatments, or who have become treatment resistant to currently available medications. We are thrilled to work with the EA Pharma team and to have the opportunity to advance evenamide through a Phase III study and towards regulatory submission in Japan and other Asian territories by one of Japan's leading pharmaceutical companies. Newron will now focus on the initiation of our Phase III one-year study in TRS and expect to start that study outside of the licensed territories in H1 2025. We are also pursuing further development opportunities for evenamide in other territories."*

"EA is thrilled to acquire the license for evenamide in Japan and other Asian territories. Evenamide has a new mechanism of action involving glutamate regulation and is the first in the world with this mechanism of action to demonstrate therapeutic efficacy in clinical trials. It is the result of many years of outstanding research by the Newron team. We believe evenamide has the potential to be transformational for patients suffering from schizophrenia." **said Hidenori Yabune, President of EA Pharma.**

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1 *Brunei Darussalam, the Kingdom of Cambodia, the Republic of Indonesia, the Lao People's Democratic Republic, Malaysia, the Union of Myanmar, the Republic of the Philippines, the Republic of Singapore, the Kingdom of Thailand, the Socialist Republic of Vietnam*

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

About schizophrenia
Approximately 25 million people worldwide are affected by schizophrenia. 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)[2], 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.

Evenamide development milestones
During Q1 2024, Newron reported final one-year results from study 014/015, a Phase II open label trial evaluating evenamide as an add-on therapy to a single antipsychotic in treatment-resistant patients. The data demonstrated that evenamide as an add-on treatment for patients with TRS was associated with sustained, clinically significant benefits that increased throughout the one-year course of treatment, with more than 70% of patients experiencing a clinically important reduction in disease severity.

Overall, data from study 014 has demonstrated that evenamide was safe and well-tolerated at all doses, with 97% of patients completing six weeks of treatment. The incidence of treatment-emergent adverse events was very low, and more than 90% of the completers chose to continue with evenamide treatment into the long-term extension study (study 015).

In Q2 2024, the Company announced two sets of data from study 008A, a potentially pivotal four-week randomized, double-blind and placebo-controlled study of evenamide as an add-on therapy in patients with chronic schizophrenia demonstrating inadequate benefit to their current second-generation antipsychotic. Topline data announced in April confirmed evenamide's favorable safety and tolerability profile, followed by compelling data from additional analyses reported in May.

The study met the primary endpoint (improvement of the Positive and Negative Syndrome Scale (PANSS) Total Score), and there was no increase in EPS, weight gain, blood glucose, metabolic syndrome, sexual dysfunction or gastro-intestinal side effects, CNS or cardiac effects, or laboratory abnormalities. The study also met the secondary endpoint (improvement of the Clinical Global Impression of Severity (CGI-S)), with a high rate of study completion (96%). No new or specific concerns were raised in the study; only 25% of the patients in the study experienced at least one adverse event (evenamide 25% versus placebo 25.8%).

The totality of these results validated evenamide as the first glutamate modulator to demonstrate efficacy in inadequately responding patients with schizophrenia in a placebo-controlled study.

Newron is expected to initiate a Phase III randomized, double-blind, one-year trial in H1 2025 that will compare evenamide to placebo as add-on treatment in at least 600 patients with treatment-resistant schizophrenia (TRS). The primary efficacy endpoint will be change from baseline in the Positive and Negative Syndrome Scale (PANSS) scores at 12 weeks. Following this initial period, subjects will continue on their assigned treatment until week 52, for demonstration of long-term

2 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/)

efficacy and safety and tolerability of evenamide. Newron continues to pursue further development opportunities for evenamide in other territories.

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 EA Pharma
EA Pharma Co., Ltd. is a subsidiary of Eisai Co., Ltd. It was established in April 2016 by integration of the gastrointestinal business unit with more than 60 year's history of the Eisai Group and the gastrointestinal business unit of the Ajinomoto Group having amino acid as its business core. EA Pharma Co., Ltd., is a specialty pharmaceutical company with a full value chain covering R&D, production & logistics and sales & marketing. For further information on EA Pharma Co., Ltd., please visit https://www.eapharma.co.jp/

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