

December 13, 2024

EA Pharma Co., Ltd.  
Newron Pharmaceuticals S.p.A.

## **EA Pharma and Newron announce license agreement for evenamide in Japan and other Asian territories**

- **EA Pharma will pay 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**

EA Pharma Co., Ltd. (Head Office, Chuo-ku, Tokyo, Japan; President, Hidenori Yabune; “EA Pharma”) and Newron Pharmaceuticals S.p.A. (Head Office, Bresso, Italy; CEO, Stefan Weber; “Newron”) 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<sup>1</sup>.

Under the terms of the license agreement, in exchange for full rights in the licensed territories, EA will pay up to a maximum total of €117 million to Newron, 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.

“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

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<sup>1</sup> 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

schizophrenia,” said Hidenori Yabune, President of EA Pharma. “We believe that the field of psychiatry is closely related to the gastrointestinal field, in which we have strong expertise, from the perspectives of the gut-brain connection and comorbid symptoms. By focusing on both the gastrointestinal and psychiatric fields, we aim to create synergies and make further contributions to patients. We are committed to delivering evenamide to patients as quickly as possible and plan to begin clinical trials in Japan.”

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.”

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## More Information

### 1. About schizophrenia

Schizophrenia, which approximately 1% of the Japanese population is affected by, consists of positive symptoms (such as hallucinations and delusions), negative symptoms (such as reduced emotions and avolition), and cognitive impairment (such as memory and decision-making difficulties), and those symptoms may cause difficulty in everyday life and social activities<sup>2</sup>. Current antipsychotics mainly function through the dopamine and/or serotonin pathways, and those antipsychotics are known to show side effects (such as extrapyramidal symptoms, weight gain, and prolactin elevation). Among those patients treated with current antipsychotics, a considerable number of patients become treatment-resistant or poor responsive. Therefore, there is a demand for a drug which can address all those points.

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<sup>2</sup> National Center of Neurology and Psychiatry (NCNP) (<https://www.ncnp.go.jp/en/>)

## **2. 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 antipsychotics, in 291 poorly responding patients with chronic schizophrenia. The primary endpoint, the Positive and Negative Syndrome Scale (PANSS)<sup>3</sup>, 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 antipsychotics.

## **3. 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/>

## **4. 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](http://www.newron.com)

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<sup>3</sup> 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/>)