EA Pharma Co., Ltd.
News Release

January 7, 2026
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EA Pharma Announces Initiation of Phase III Clinical Trial of EA8001, a Novel Treatment for Schizophrenia, in Japan

EA Pharma Co., Ltd. (Head Office, Chuo-ku, Tokyo, Japan; President, Hidenori Yabune; “EA Pharma”) announced today that Phase III clinical trial of EA8001 (non -proprietary name: evenamide), a novel excessive glutamate release modulator, is now ready to begin in Japan (hereinafter the “Trial”).

EA Pharma initiates the Trial after review by the institutional review board of the clinical site and other related procedures. This Trial is a multicenter randomized double-blind placebo-controlled clinical trial in patients with treatment-resistant schizophrenia who show poor or inadequate response to at least two different types of antipsychotics, evaluating the efficacy, safety and tolerability of EA8001 as an add-on treatment. EA Pharma is striving to quickly contribute to addressing the needs of, and increasing the benefits provided to, patients with schizophrenia, their families and healthcare providers.

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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 [1]. 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.

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 [2], as an add-on treatment to second generation anti-psychotics, in 291 poorly responding patients with chronic schizophrenia. The primary endpoint, the Positive and Negative Syndrome Scale (PANSS) [3], 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[4].

* Against placebo in the two categories: at least 20% improvement in PANSS, and Score 2 or below in Clinical Global Impression Scale – Corrections (CGI-C)

3. About Alliance between EA Pharma and Newron Pharmaceuticals S.p.A.

EA Pharma obtained the right to develop, manufacture and commercialize evenamide in Japan and other key Asian territories [5] under the license agreement with Newron Pharmaceuticals S.p.A. as of December 2024.

For more details, please see https://www.eapharma.co.jp/en/investors/news/2024/1213

4. About EA Pharma Co., Ltd.

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/en/

5. Newron Pharmaceuticals S.p.A.

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 ENIGMA-TRS Phase III development program. Newron has signed development and commercialization agreements for evenamide with EA Pharma 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: https://www.newron.com/

[1] National Center of Neurology and Psychiatry（https://www.ncnp.go.jp/en/）
[2] A “pivotal phase III trial” is a key clinical trial to collect definitive evidence of efficacy and safety in primary endpoints that can support a regulatory approval. Usually, data collected from multiple confirmatory trials (pivotal trials) are required for a regulatory approval in many countries.
[3] 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/)
[4] Efficacy and safety of evenamide, a glutamate modulator, added to a second-generation antipsychotic in inadequately/poorly responding patients with chronic schizophrenia: Results from a randomized, double-blind, placebo-controlled, phase 3, international clinical trial. (Neuropharmacology. 2025: https://pubmed.ncbi.nlm.nih.gov/39708914/)
[5] Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand, Vietnam