



## **Newron completes enrollment of explanatory safety and efficacy study with evenamide in schizophrenia patients**

*Final study data intended to support the initiation of Newron's planned phase III pivotal trial program for evenamide*

**Milan, Italy and Morristown, NJ, USA, January 21, 2021** - [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, today announced the completion of enrollment for its explanatory study 008 with evenamide in patients with schizophrenia.

Results from the four-week, randomized, double-blind placebo-controlled study are expected in March 2021. Explanatory study 008 is designed to evaluate the safety, tolerability, EEG effects, and preliminary efficacy of two fixed doses of evenamide (7.5 mg and 15 mg BID) in outpatients with chronic schizophrenia receiving treatment with one of the leading second-generation atypical antipsychotics. Enrollment to the study has been completed with 138 patients randomized to treatment with placebo, 7.5 mg BID, or 15 mg BID of evenamide at study centers in the United States and India.

The US Food and Drug Administration (FDA) requested that Newron complete additional short-term explanatory studies in rats and humans to address concerns from a study of evenamide in rats, and CNS events observed following high-dose administration of evenamide in dogs.

The data from study 008 will be a key component in the package of information to be submitted to the FDA to support the approval of the initiation of Newron's planned phase III pivotal trial program for evenamide. Preclinical results confirming absence of toxicity have already been submitted to the FDA to support this package.

The proposed phase III clinical trial program with evenamide targets patients with schizophrenia experiencing worsening of psychosis on atypical antipsychotics, and treatment-resistant patients not responding to clozapine. Clozapine is the only antipsychotic approved worldwide for treatment-resistant schizophrenia.

Newron is currently evaluating potential options for partnering/co-developing the further development of evenamide.

### **About evenamide**

Evenamide has the potential to be first add-on therapy for the treatment of patients with positive symptoms of schizophrenia. The compound is an orally available New Chemical Entity that specifically targets voltage-gated sodium channels for the treatment of schizophrenia. Evenamide originates from Newron's ion channel program and has a unique mechanism of action: glutamate modulation and voltage-gated sodium channel blockade. Evenamide modulates sustained repetitive firing, without inducing impairment of normal neuronal excitability. It normalizes glutamate release induced by aberrant sodium channel activity. In a Phase IIa clinical study, Newron demonstrated evenamide's evidence of efficacy in significantly improving symptoms of psychosis compared with placebo when added to two of the most commonly prescribed atypical antipsychotics in patients with chronic schizophrenia. The study also indicated that evenamide is devoid of an effect on any of the over 130 neurotransmitters, enzymes, or transporters targeted by most antipsychotics.



### **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 USA, Australia, Canada, Brazil, Colombia, 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 positive symptoms of schizophrenia. For more information, please visit: [www.newron.com](http://www.newron.com)

### **For more information**

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