



Ad hoc announcement pursuant to Art. 53 LR

Newron completes enrollment of schizophrenia patients in potentially pivotal study 008A with Evenamide

290 patients participate at study centers in Europe, Asia and Latin America

Results from the study are expected in March 2024

Milan, Italy, December 29, 2023, 07:00 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, today announced the completion of patient enrollment in study 008A, its potentially pivotal study with evenamide in patients suffering from schizophrenia.

Study 008A is a four-week, randomized, double-blind and placebo-controlled study assessing the efficacy, tolerability, and safety of evenamide (30 mg bid) in patients with chronic schizophrenia currently being treated with a second-generation antipsychotic, but who demonstrate an inadequate response to that treatment. A total of 290 patients were enrolled at study centers in Europe, Asia and Latin America. Results from the potentially pivotal study are expected in March 2024. If positive, study 008A would be the first well-controlled study to demonstrate the clinical utility of evenamide in schizophrenia patients who show an inadequate response to treatment with atypical antipsychotics.

About evenamide

Evenamide, an orally available new chemical entity, specifically blocks voltage-gated sodium channels (VGSCs) and is devoid of biological activity at >130 other CNS targets. It normalizes glutamate release induced by aberrant sodium channel activity (veratridine-stimulated), without affecting basal glutamate levels, due to inhibition of VGSCs. Combinations of ineffective doses of evenamide and other APs, including clozapine, were associated with benefit in animal models of psychosis, suggesting synergies in mechanisms that may provide benefit in patients who are poor responders to current APs, including clozapine.



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

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