Ad hoc announcement pursuant to Art. 53 SIX Listing Rules

Newron Initiates First Potentially Pivotal Study with Evenamide in Patients with Schizophrenia

Evenamide has the potential to be the first add-on therapy for patients with positive symptoms of schizophrenia

Four-week, double-blind, placebo-controlled study to evaluate safety and efficacy of therapeutic dose (30mg BID)

Minimum of 200 patients to be enrolled at study centers in Europe, Asia and Latin America

Evenamide's glutamatergic inhibition mechanism of action offers an innovative therapeutic option to patients not benefitting from current antipsychotic treatments

Milan, Italy and Morristown, NJ, USA, September 6, 2021, 07:00 am CEST – 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 initiation of Study 008A, the first potentially pivotal study with evenamide in patients with schizophrenia.

Study 008A, a four-week, randomized, double-blind placebo-controlled international study, is designed to evaluate the efficacy, tolerability, and safety (including effects on the electroencephalogram (EEG)) of the 30mg BID therapeutic dose of evenamide in patients with chronic schizophrenia, currently being treated with a second-generation antipsychotic. Newron plans to randomize at least 200 patients in study centers in Europe, Asia and Latin America. Results from the study are expected by Q4 2022.

This study is part of Newron's Phase III evenamide clinical trial program that targets patients with schizophrenia experiencing worsening of psychosis on therapeutic doses of atypical antipsychotics, as well as treatment-resistant patients.

Ravi Anand, MD, Newron's CMO, commented: "Evenamide has been shown to be safe in studies treating more than 300 healthy volunteers and patients at doses of up to 60mg. Study 008A will now evaluate the efficacy, tolerability and safety of the therapeutic dose of 30mg BID. If successful, Newron believes the study would qualify as the first adequate and well-controlled (pivotal) study with evenamide in patients with schizophrenia who are inadequate responders to antipsychotics. Evenamide would currently be the first add-on therapy approved for the treatment of patients with positive symptoms of schizophrenia, and its unique glutamatergic inhibition mechanism of action offers a truly innovative therapeutic option to those patients who are not benefitting from their current antipsychotics."

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. Additional studies in about 200 healthy volunteers and patients with schizophrenia have met the objective of safety on all variables.

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, Brazil, Colombia, 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 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**

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