Ad hoc announcement pursuant to Art. 53 LR

Newron presents encouraging interim results for evenamide in patients with Treatment-Resistant Schizophrenia (TRS) at the 33rd CINP Hybrid World Congress of Neuropsychopharmacology

Interim results show improved symptoms of psychosis in patients with chronic TRS

Study 014 represents first international trial of a New Chemical Entity (NCE) antipsychotic as an add-on in TRS, with treatment implications for TRS patients

Newron to host an investor, analyst and media conference call today at 3 pm CET/ 9 am ET

Milan, Italy, June 7, 2022, 7 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 (CNS), today announced encouraging interim results from the first 100 patients in its world-first, international, six-week, open-label, randomized, rater-blinded, multi-centre study of evenamide as an add-on to an antipsychotic in patients with moderate to severe treatment-resistant schizophrenia (TRS) who were not responding to current antipsychotic medication.

The results presented at the 33rd Collegium Internationale Neuro-Psychopharmacologicum (CINP) Hybrid World Congress of Neuropsychopharmacology, in Taipei, Taiwan, show that the addition of evenamide (7.5/15/30mg bid) improved symptoms of psychosis in patients with chronic TRS, reflected by an approximately 12% reduction in the PANSS score, CGI-S improvement of 0.7, and CGI-C ratings indicating 77% of patients responded to the treatment. The first 100 patients were mostly treated with the 7.5 and 15 mg bid doses, as patients were initially randomized to treatment with these doses; an Independent Safety Monitoring Board reviewed the safety data from the first 50 patients completing the trial prior to allowing randomization to the 30 mg bid dose.

Ravi Anand, M.D., Newron's Chief Medical Officer, stated: "We are excited to present the interim results of this study, which demonstrate the potential of evenamide as an add-on therapy to antipsychotics in patients with treatment resistant schizophrenia. The data presented today confirm evenamide's potential to improve symptoms of psychosis in patients who, despite treatment with various antipsychotics, continue to experience severe symptoms of psychosis and functional disabilities. These patients represent about one third of the overall schizophrenia population and thus a significant unmet medical need. Evenamide acts through selective attenuation of an abnormal release of glutamate and synergizing with the background antipsychotic activity. The outcome of this study may change the treatment of future TRS patients when confirmed in a larger, placebo-controlled study."

Newron expects to initiate a potentially pivotal, multinational, randomized, placebo-controlled study in patients with treatment resistant schizophrenia in the first quarter of 2023, as part of its ongoing Phase II/III development plan for evenamide.

Study 014 design
This six-week, randomized, rater-blinded study is being conducted at multiple sites in three countries. The study will include approximately 180 patients with TRS on a stable, therapeutic dose of a single antipsychotic other than clozapine. The primary objective of the study is to evaluate the safety and tolerability of evenamide given orally at three fixed doses (7.5, 15 and 30 mg bid). The assessment of preliminary efficacy, based on changes from baseline in the Positive and Negative Syndrome Scale (PANSS), Clinical Global Impression - Change from baseline (CGI-C), Severity of illness (CGI-S), and Strauss-Carpenter Level of Functioning (LOF) scale, is a secondary objective.

Patients were moderately to severely ill (CGI-S of 4 to 6), with a baseline PANSS total score ≥70 and <90 and predominant positive symptoms (score of 4 or more on at least 2 core symptoms, along with a total score of at least 20 on these 4 core items plus 3 other positive symptoms), along with functional deficits (GAF ≤50). Efficacy and safety assessments were conducted at one to two-week intervals. Patients participating in the study are continuing to receive treatment with evenamide in long-term extension study 015 to determine the long-term benefits of glutamate release inhibition.

Conference call
Newron's CEO Stefan Weber and CMO Ravi Anand will host a conference call today, June 7, at 3 pm CET/ 9 am ET.

The call can be accessed via the following dial-in numbers:

Switzerland/Europe:	+41 (0) 58 310 5000
United Kingdom:	+44 (0) 207 107 0613
United States:	+1 (1) 631 570 5613

The presentation for this conference call as well as the abstracts/videos presented at the 33rd CINP World Congress of Neuropsychopharmacology, covering the interim results of study 014, the safety profile of evenamide and the study design of the upcoming, potentially pivotal study with evenamide in TRS, can be downloaded as of today, June 7, at 7 am CET, on Newron's website. (https://www.newron.com/investors/reports-and-presentation/year/2022#reports,-presentations-&-webcasts).

About treatment-resistant schizophrenia
About one third of patients with schizophrenia, of which about 15% from illness onset, show virtually no beneficial response to antipsychotics (APs), despite adequate treatment. They are diagnosed as having treatment-resistant schizophrenia (TRS), operationally defined as no, or inadequate, symptomatic relief despite treatment with therapeutic doses of two antipsychotics from two different chemical classes for an adequate period. Increasing evidence supports abnormalities in glutamate neurotransmission in TRS, not targeted by current APs, along with normal dopaminergic synthesis, to explain the lack of benefit of most typical and atypical antipsychotics.

About evenamide
Evenamide has the potential to be the first add-on therapy for the treatment of patients with schizophrenia. The compound is an orally available New Chemical Entity that specifically targets voltage-gated sodium channels. 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. Studies in more than 400 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, 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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Important Notices

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