Newron to present three posters on its clinical program evaluating evenamide in the treatment of schizophrenia at the 36th European College of Neuropsychopharmacology Congress

Poster presentations will include the full results from all 161 patients randomized in study 014 at the six-month time point from extension study 015, a Phase II trial evaluating evenamide as an add-on therapy for patients with treatment-resistant schizophrenia (TRS)

The company will also present the design a potentially pivotal, randomized, double-blind, placebo-controlled study to demonstrate the efficacy and tolerability of evenamide as an add-on treatment in TRS

An international advisory committee of TRS experts to review new results from studies 014/015

Milan, Italy, October 04, 2023 – 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, announced that it will present three posters at the upcoming 36th European College of Neuropsychopharmacology (ECNP) Congress taking place October 7-10, 2023, at the Centre Convencions Internacional de Barcelona (CCIB) in Barcelona, Spain.

Full results from all 161 patients who were randomized in study 014 and who completed six months of participation in study 015 will be presented. Study 015 is an international, randomized, open-label, rater-blinded, phase II extension study of evenamide as an add-on therapy to an antipsychotic (excluding clozapine) in patients with moderate to severe TRS, not responding to their current antipsychotic medication. Newron presented the data from all 161 patients at the six-week time point and data from the first 100 patients randomized in study 014 who completed one-year of participation in these studies at the 34th CINP World Congress of Neuropsychopharmacology and at the 2023 SIRS Annual Congress in May 2023.

The design of a potentially pivotal, international, randomized, double-blind, placebo-controlled, Phase III study aims to demonstrate the efficacy and tolerability of two doses (15 and 30 mg bid) of evenamide as an add-on treatment in TRS patients not benefiting from their current antipsychotic treatment will also be presented at the ECNP.

Posters to be presented at the ECNP Congress:
Monday, October 9, 2023
12:35-14:00 CEST

- **"Evenamide as add-on treatment for treatment-resistant schizophrenia patients not benefiting from antipsychotics: design of an international potentially pivotal clinical trial"**
    - Presentation number: P.0709

- **"Evenamide, add-on to antipsychotics, benefits patients with treatment-resistant schizophrenia: final dose-wise results from a Pilot, Phase II, multinational, randomized study"**
    - Presentation number: P.0710

- **"Evenamide, as an add-on to antipsychotics, benefits patients with treatment resistant schizophrenia: 6-month results from an ongoing international randomised study"**
    - Presentation number: P.0793

About treatment-resistant schizophrenia (TRS)
A significant proportion of patients with schizophrenia show virtually no beneficial response to antipsychotics (APs) despite adequate treatment, leading to a diagnosis of treatment-resistant schizophrenia (TRS). TRS is defined as no, or inadequate, symptomatic relief despite treatment with therapeutic doses of two APs from two different chemical classes for an adequate period. About 15% of patients develop TRS from illness onset, and about one-third of patients overall. 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 study 014/015
Study 014 was a six-week, randomized, rater-blinded study being conducted at multiple sites in three countries (India, Italy and Sri Lanka). Study 014 has completed the enrollment of 161 patients with TRS on a stable, therapeutic dose of a single antipsychotic other than clozapine. The primary objective of the study was 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 was based on changes from baseline in the Positive and Negative Syndrome Scale (PANSS). Changes from baseline in Clinical Global Impression of Change (CGI-C), Severity of Illness (CGI-S), and Strauss-Carpenter Level of Functioning (LOF) scale, were secondary objectives. Study 015 is the extension study to determine the long-term benefits of glutamate release inhibition. Seventy-seven (77) of the first 100 patients completed the 1-year of

treatment with evenamide, 16 discontinued the study early, two due to adverse events (one patient due to fever, vomiting, and nausea, the other due to somnolence, reduced concentration and increased sweating), the other 14 due to withdrawal of consent or lost to follow up.

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

For more information, please contact:

Newron
Stefan Weber – CEO
+39 02 6103 46 26
pr@newron.com

UK/Europe
Simon Conway / Ciara Martin / Natalie Garland-Collins, FTI Consulting
+44 20 3727 1000
SCnewron@fticonsulting.com

Switzerland
Valentin Handschin, IRF
+41 43 244 81 54
handschin@irf-reputation.ch

Germany/Europe
Anne Hennecke / Caroline Bergmann, MC Services
+49 211 52925222
newron@mc-services.eu

USA
Paul Sagan, LaVoieHealthScience
+1 617 374 8800, Ext. 112
psagan@lavoiehealthscience.com