Newron to present at the 31st European Congress of Psychiatry

Presentation will include full data from the six-month interim timepoint from the cohort of the first 100 patients randomized in study 014/015, a Phase II trial evaluating evenamide as add-on therapy for patients with treatment-resistant schizophrenia

Milan, Italy, March 17, 2023, 7am 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), announced that it will present two e-posters at the 31st European Congress of Psychiatry, taking place on 25-28 March 2023, at the Palais des Congrès of Paris - Place de la Porte Mailot in Paris, France.

New data suggestive of clinically important response in TRS patients

The first poster will present full results from the cohort of the first 100 patients completing six months/endpoint of treatment with evenamide in study 014/015, an international, randomized, open label, rater-blinded study of evenamide as an add-on to an antipsychotic (excluding clozapine) in patients with moderate to severe treatment-resistant schizophrenia (TRS) not responding to their current antipsychotic medication. Encouraging top-line, six-month results from this cohort of patients were announced in January 2023, and top-line one-year results were announced in February 2023.

The second poster will detail the characterization of "Responder" in TRS patients based on data from this study.

Both posters will be presented during the "Schizophrenia and other psychotic disorders 10" session at 12:30pm CET on 28 March 2023 at e-poster area station 12. Full poster titles are below:

> Poster 1: "Evenamide, as an add-on to antipsychotics, benefits patients with treatment resistant schizophrenia: 6-month interim results from the first 100 patients in an ongoing international randomized study";
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> Poster 2: "Characterization of "Responder" in patients with Treatment-Resistant Schizophrenia (TRS) treated with a new antipsychotic added to their current antipsychotic monotherapy".

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, explaining the lack of benefit of most typical and atypical APs.

About study 014/015
Study 014 is 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 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 is 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, are 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

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