Newron to present at the 34th CINP World Congress of Neuropsychopharmacology and the 2023 Congress of the Schizophrenia International Research Society (SIRS)

Further data from study 014/015 of evenamide in treatment-resistant schizophrenia (TRS) confirms potentially relevant role of glutamatergic release modification when added to TRS patients not responding to marketed antipsychotics

International TRS advisory committee will contribute to design of potentially pivotal, multinational, randomized, placebo-controlled trial with evenamide in patients with TRS

A total of six posters will be presented at the upcoming conferences, including:

- *Results from all 161 patients at the 6-week primary endpoint of Study 014*
- *Full data from the one-year interim timepoint from the cohort of the first 100 patients in study 014/015*
- *Evidence for sustained multidimensional benefits in patients with TRS by combining evenamide's glutamate release modification with dopamine/serotonin inhibition of current antipsychotics*
- *Characteristics of early and late responders in patients with treatment-resistant schizophrenia*

Milan, Italy, May 3, 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 six posters in various presentation formats at the upcoming 34th CINP World Congress of Neuropsychopharmacology, taking place 7-10 May 2023 at the Fairmont The Queen Elizabeth hotel in Montreal, Québec, Canada, and the 2023 Congress of the Schizophrenia International Research Society (SIRS) taking place 11-15 May 2023 at The Westin Harbour Castle in Toronto, Ontario, Canada.

The posters and presentations will feature first-time disclosures of additional results from 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 TRS not responding to their current antipsychotic medication.

These results offer further analyses of the multidimensional efficacy of glutamate release modification in patients with TRS and the characteristics of early and late responders in patients with TRS, thus deepening the understanding of the potential long-term benefits an innovative add-on therapy that modifies glutamate release could offer to TRS patients.

Presentations at the CINP, Montreal: (all times EDT)

Monday, May 8, 2023

- 12:15 - 1.15 pm

  "Evenamide Added On To Antipsychotics In Patients With TRS Is Associated With Significant Efficacy: Results From A Pilot, 6-week, Phase 2 Study"
  Brief Oral Abstract
  Session 2
  Foyer Theatre

- 05:30 - 06.20 pm

  "Characteristics Of Early And Late Responders To Evenamide Add-on In TRS Patients Not Responding To An Antipsychotic: Results From A Phase 2 Study"
  Printed Poster, Q&A, Digital slides
  Moderated Featured Poster Session: FP01
  Foyer Theatre

Tuesday, May 9, 2023

- 10:15 - 10:45 am

  "Significant and Clinically Important Efficacy of Evenamide Add-on to an Antipsychotic in TRS Patients Treated for 1-year in a Phase 2 Study"
  Printed Poster, Digital slides
  Poster Session Number: P2
  Level 2, Foyer

Presentations at the SIRS, Toronto: (all times EDT)

Friday, May 12, 2023

- 11:00 - 11:20 am

  "Addition of evenamide, a Glutamate Release inhibitor, to Patients with Treatment Resistant Schizophrenia Already on an Antipsychotic is Effective and Associated with Long-Term efficacy: Results of a Phase 2 Study"
  Pharmaceutical Pipeline Presentation, Q&A & Poster
  Harbour B room

- 12:00 – 2:00 pm

“Evenamide, as an Add-On to antipsychotics, Benefits Patients with Treatment-Resistant schizophrenia: 1-Year Interim Results from the First 100 Patients in an Ongoing International Randomized Study”
Poster
Metropolitan Centre / East room

Saturday, May 13, 2023

- 12:30 – 2:30 pm

“Evenamide, a New Chemical entity, Benefits Patients with Treatment-Resistant Schizophrenia when Used as an Add-On to antipsychotics: Final Results from a Phase II, international, Randomized Study”
Poster
Metropolitan Centre / East room

These two renowned international congresses represent essential forums of scientific dialogue for key opinion leaders. For this reason, Newron will host an advisory committee meeting with clinical experts on treatment-resistant schizophrenia, insights of which will contribute to the design of a potentially pivotal, multinational, randomized, placebo-controlled trial with evenamide in patients with TRS.

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 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

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