# Newron Pharmaceuticals provides clinical and business update

- *All evenamide pre-clinical studies requested by FDA completed and first clinical safety study initiated; on track to initiate evenamide Phase III program in 2021*
- *In advanced evaluation of opportunities to broaden pipeline of treatments for central and peripheral nervous system diseases*
- *International conference call for investors and analysts today at 3:00 PM CET/ 9:00 AM ET*

**Milan, Italy and Morristown, NJ, USA, August 11, 2020 -** 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 provided a clinical and business update.

**Evenamide**

"Newron has made considerable progress with our lead clinical program, evenamide, potentially the first add-on therapy for the treatment of patients with symptoms of schizophrenia," said Stefan Weber, Newron's Chief Executive Officer. "Earlier this year we reached agreement with the U.S. Food and Drug Administration (FDA) on the design and conduct of evenamide explanatory studies to address potential safety issues they had raised. I am pleased to announce that we have now successfully completed the preclinical part of these studies and no toxicity issues were reported. Newron has now initiated the first clinical safety study (008)."

Explanatory study 008 is a four-week, randomized, double-blind placebo controlled study designed to evaluate the safety, tolerability, EEG effects and preliminary efficacy of two fixed doses of evenamide (7.5 mg and 15 mg BID) in outpatients suffering from chronic schizophrenia receiving treatment with one of the leading second generation atypical antipsychotics. Newron intends to recruit approximately 120 patients into the study at study centers in the United States and India. As anticipated, the initiation of the study was delayed due to the limitations imposed by COVID-19. Nevertheless, enrollment is progressing well and investigators have already enrolled over 40 patients into the study. Contingent on COVID-19 restrictions not further constraining enrollment, results from the study are currently expected in Q1 2021 and, if positive, will form part of the package to prepare for the planned Phase III program with evenamide.

Ravi Anand, Newron's Chief Medical Officer, added: "Enrollment to study 008 is proceeding rapidly despite the first site being initiated only a few weeks ago. Results from the study supporting good tolerability of evenamide in patients will be submitted to the FDA, once we have the data and as soon as feasible thereafter. Together with the preclinical results confirming absence of toxicity that have been submitted to the FDA already, the extensive explanatory study package should deliver robust, convincing clinical data to proceed with the next, pivotal phase of clinical development. We remain confident that the Phase III studies with evenamide will be initiated in Q2 2021. Study 008 is also designed to provide further evidence of efficacy for evenamide as an add-on therapy in patients suffering from chronic schizophrenia who are worsening on another second-generation antipsychotic. Evenamide, by its complementary and unique mechanism of action, involving modulation of abnormal glutamate release, is expected to enhance the efficacy of their current treatment."

In May 2019, the FDA requested that Newron complete additional short-term explanatory studies in rats and human subjects to address concerns on findings from a recently completed study of evenamide in rats, as well as CNS events observed following high dose administration of evenamide in dogs.

Subject to the successful completion of these studies, Newron has agreement with the FDA that it may commence its proposed Phase III clinical trial program with evenamide for patients with schizophrenia experiencing worsening of psychosis on atypical antipsychotics, and for treatment-resistant patients not responding to clozapine. Clozapine is the only antipsychotic approved worldwide for treatment-resistant schizophrenia.

Newron is currently evaluating potential options for partnering/co-developing the further development of evenamide.

**Pipeline**
In addition, Newron is in advanced evaluation of a select number of opportunities to broaden its pipeline of novel therapies for patients with diseases of the central and peripheral nervous system. The market will be updated upon successful completion of any of the ongoing discussions.

**Xadago®/safinamide**
The Company reports that progress has been made in discussions with Newron's partner Zambon relating to the performance of a potentially pivotal efficacy study to evaluate the effects of Xadago®/safinamide in patients with Parkinson's disease levodopa-induced dyskinesia (PD LID). The study would be performed in the US, Europe and Asia/Australia. Zambon has acknowledged Newron's experience in the development of Xadago in patients with Parkinson's disease and agreed that Newron should be the party responsible for conducting the study, Zambon will remain associated with the study. Once discussions should be successfully completed, Newron will submit the final study design to the key regulatory authorities for approval and start preparations towards initiation of the study.

**Financials**
Newron´s total available funds including the EIB loan funds not yet drawn, complemented by its royalty income and Italian R&D tax credits, will cover the pursuit of Newron's development programs and operations, as currently contemplated, well into 2022.

**Conference call**
Newron management will hold an international conference call today, **August 11, 2020, 3:00 PM CET, 9:00 AM ET** to provide an update and to answer questions.

**Dial-in details to the media/analyst/investor conference call:**
• Switzerland/Europe: +41 (0)58 310 50 00
• United Kingdom: +44 (0)207 107 0613
• United States: +1 (1)631 570 5613

**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.

**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 USA, Australia, Canada, Brazil, Colombia, the United Arab Emirates and Japan, and is commercialized by Newron's Partner Zambon. US WorldMeds currently holds the commercialization rights in the USA and has entered into a definitive agreement to sell its Xadago rights, along with other CNS assets, to Supernus Pharmaceuticals. 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 positive symptoms of schizophrenia. For more information, please visit: **www.newron.com**

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