Newron announces initiation of new clinical trial with Evenamide in patients with schizophrenia, following approval of plan by FDA

Milan, Italy and Morristown, NJ, USA, January 9, 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, announced today that it has reached agreement with the U.S. Food and Drug Administration (FDA) on the design and conduct of explanatory studies with Evenamide required to address previously announced potential safety issues raised by the FDA. Newron is developing Evenamide as the potential first add-on therapy for the treatment of patients with positive symptoms of schizophrenia.

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. Newron met with the FDA on August 28, 2019, to discuss the issues, the proposed plans for these studies and the eventual start of the Phase III program with Evenamide. The FDA approved the plan proposed by Newron as well as the protocol for a first, four-week explanatory study in patients with schizophrenia, which is expected to start enrolling patients in the next few days. Newron expects initial results from the additional studies in rats and humans in Q3 2020.

Subject to the successful completion of these studies, Newron intends to 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 the antipsychotic drug clozapine.

"We are pleased to announce not only the FDA's concurrence with the plan for these additional short-term studies with Evenamide, but also their approval of the first clinical protocol that will start enrolment in the next few days," said Ravi Anand, Newron's Chief Medical Officer. "The initiation of these studies in humans represents progress in addressing the issues raised by the FDA in May 2019. We expect to submit initial results to the FDA in Q3 2020, and the results from the next study in patients in Q4 2020. The acceptance of these results from studies in humans together with the results of the additional toxicology studies should allow us to start the Phase III clinical program in schizophrenia patients shortly thereafter."

About Evenamide

Evenamide has the potential to be first add-on therapy for the treatment of patients with positive symptoms of schizophrenia. Evenamide is an orally available New Chemical Entity that specifically targets voltage-gated sodium channels for the treatment of schizophrenia. The compound 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 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. In addition to Xadago®/safinamide for Parkinson's disease, Newron has a strong pipeline of promising treatments for rare disease patients at various stages of clinical development, including sarizotan for patients with Rett syndrome and ralfinamide for patients with specific rare pain indications. 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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