Newron Pharmaceuticals to Request Type A FDA Meeting Prior to Unblinding of STARS Clinical Trial Data

Meeting expected to occur within thirty days of FDA's receipt of the meeting request and meeting package

STARS (Sarizotan Treatment of Apneas in Rett Syndrome) clinical study to evaluate the effect of sarizotan in patients with Rett syndrome

STARS Extension Study underway with over 80% of patients receiving medication

Milan, Italy and Morristown, NJ, USA - December 9, 2019 - 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, announces that it has received a communication from the U.S. Food and Drug Administration (FDA) suggesting that Newron discuss the company's proposed statistical plan, submitted to the FDA in September 2019, in a Type A meeting prior to unblinding the STARS clinical trial data results.

The clinical database for Newron's STARS study has been locked and will remain blinded. Newron is initiating procedures for the Type A meeting with the FDA and will provide an update to the markets as soon as possible. Ravi Anand, MD, Chief Medical Officer of Newron, stated: "We look forward to meeting with the Agency to discuss their suggestions for the STARS study statistical plan and are eager to share the final results of the study with the global Rett community and markets, once the plan has been agreed with the FDA."

The type A meeting is expected to occur within thirty days of FDA's receipt of the meeting request and meeting package. Newron will provide an update on the timing of the final unblinding and report of results of the STARS study for sarizotan after receipt of the FDA's final meeting minutes, which typically become available within thirty days after the type A meeting.

On November 19, 2019, the FDA granted the Rare Pediatric Disease designation for sarizotan, Newron's product candidate for the treatment of Rett syndrome, a rare neurodevelopmental disorder primarily affecting females, with no approved treatments currently available.

About Rett Syndrome

Rett syndrome is a severe neurodevelopmental disorder primarily affecting females, with an estimated prevalence of one in 10,000 females. There are no approved treatments available. Rett syndrome is characterized by a loss of acquired fine and gross motor skills and the development of neurological, cognitive and autonomic dysfunction, which leads to loss of ability to conduct daily life activities, walk or communicate. Rett syndrome also is associated with a reduced life expectancy. Approximately 25 percent of the deaths in patients with Rett syndrome are possibly related to multiple cardio-respiratory dysrhythmias that result from brain stem immaturity and autonomic failure. More than 95 percent of these patients have a random mutation in the MeCP2 gene. Episodes of apnea, hyperventilation and disordered breathing are found in approximately 70 percent of patients with Rett syndrome at some stage of their life. For more information on Rett syndrome, visit http://www.rettsyndrome.org

About Sarizotan
Sarizotan, a new chemical entity licensed from Merck KGaA, is a highly selective compound for specific serotonin or dopamine receptors that modulates the activity of these neurotransmitters in the brain. As Sarizotan was originally developed in another indication, the compound was licensed with an extensive safety and tolerability data package. Sarizotan is being evaluated as a treatment for Rett syndrome, a debilitating genetic disorder with no specific treatment options, targeting respiratory disturbances. In preclinical evaluation studies, the full agonist at the serotonergic 5HT1A receptor has demonstrated dramatic improvement of respiration in a number of genetic mouse models of Rett.

About the STARS study
Newron Pharmaceutical's Sarizotan Treatment of Apneas in Rett Syndrome (STARS) is a clinical study to evaluate the efficacy, safety and tolerability of sarizotan in patients with Rett syndrome suffering from respiratory symptoms. Among the core symptoms of Rett, breathing disturbances may affect the whole person body; they can have a marked effect on biochemistry, influence emotions, circulation and digestive function as well as musculoskeletal structures in the respiratory process.

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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Important Notices (update based on results)

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