



Newron Pharmaceuticals to Present STARS Trial Design at US Rett Syndrome Symposium

Milan, Italy and Morristown, N.J., USA – June 16, 2016 – Newron Pharmaceuticals S.p.A. ("Newron") (SIX: NWRN), a biopharmaceutical company focused on the development of novel therapies for patients with diseases of the central nervous system (CNS) and pain, is scheduled to present the design of the upcoming clinical trial of sarizotan addressing respiratory abnormalities in Rett syndrome (STARS) at the 2016 Rett Syndrome Symposium at the Eaglewood Resort & Spa, Itasca, Illinois, USA, from June 22-24, 2016. The presentation is part of the poster session scheduled for Thursday, June 23, 8:00-10:00 p.m. CT.

"We greatly appreciate the opportunity to present the STARS trial design at this Symposium," said Ravi Anand, M.D., Chief Medical Officer at Newron. "Newron looks forward to continuing to work closely with Rettsyndrome.org, patients, families and caregivers as well as many leading Rett syndrome researchers, experts and other advocacy group leaders to improve the quality of life for patients suffering from this devastating disease."

The 14th Annual Rettsyndrome.org Rett Syndrome Symposium is an international, interdisciplinary meeting focused on new developments in Rett syndrome research. This year's conference includes sessions on Fundamental Science, Translational and Clinical Research and Neuro-Habilitation Research.

The STARS (Sarizotan Treatment of Apneas in Rett Syndrome) trial is planned as a randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety and tolerability of sarizotan in patients with Rett syndrome suffering from respiratory symptoms. It will be conducted at centers of excellence in the United States, with similar centers to be added in other countries. The study protocol was designed following extensive discussions with regulatory authorities in the United States, Europe and Canada. Newron expects to initiate the potentially pivotal STARS trial in the third quarter of this year.

Sarizotan received Orphan Drug Designation for the treatment of Rett syndrome from both the European Commission and the FDA in 2015. It could become the first therapy approved for treatment of Rett Syndrome patients. Newron intends to commercialize sarizotan directly.



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 www.rettsyndrome.org

About Newron Pharmaceuticals

Newron (SIX: NWRN) is a biopharmaceutical company focused on the development of novel therapies for patients with diseases of the central nervous system (CNS) and pain. 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 and Switzerland and is commercialized by Newron's Partner Zambon. US WorldMeds holds the commercialization rights in the US. Meiji Seika has the rights to develop and commercialize the compound in Japan and other key Asian territories. In addition to Xadago® 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 NW-3509 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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