Newron updates on STARS study FDA interaction

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

Topline results from pivotal study on track for Q2 2020

Milan, Italy and Morristown, NJ, USA - March 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, announces that it has received the final minutes from a meeting with the U.S. Food and Drug Administration (FDA) held on February 5, 2020. In the meeting, the parties discussed the Company's statistical analysis plan (SAP), submitted to the FDA in September 2019, and the FDA's recommendations. The clinical database for the STARS study remains locked and blinded.

Ravi Anand, MD, Chief Medical Officer of Newron, stated: "We are pleased to report that Newron and the FDA have agreed on the SAP, the primary and key secondary efficacy measures, and the statistical analyses to be performed for efficacy. We are now finalizing the SAP and will submit it to the FDA in the coming weeks. Following the agency's review and approval of the plan, the contract research organization involved in the study will be able to complete its programming work and then move ahead towards unblinding of the results. We expect to be able to share the topline results of this important study with the global Rett community and the markets in Q2 2020."

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. The primary endpoint of the STARS study is the percentage reduction in these episodes of apnea during waking time compared with placebo.

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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