Newron Receives FDA Rare Pediatric Disease Designation for Sarizotan for the Treatment of Rett Syndrome

Milan, Italy and Morristown, NJ, USA, November 19, 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, announced today that the U.S. Food and Drug Administration (FDA) has granted the Rare Pediatric Disease designation for sarizotan, the company's product candidate for the treatment of Rett syndrome, a rare neurodevelopmental disorder primarily affecting females, with no approved treatments currently available.

"The decision of the FDA to designate sarizotan for the treatment of a rare pediatric population, following an earlier decision to grant it an Orphan Drug designation (ODD), highlights the critical need within the Rett community for treatments for this devastating disease," stated Ravi Anand, Newron's Chief Medical Officer. "This designation also represents progress towards qualifying sarizotan for a rare pediatric disease priority review voucher upon potential US marketing approval in the future. We are looking forward to the results of our Sarizotan Treatment of Apneas in Rett Syndrome (STARS) study, a study to evaluate the efficacy, safety and tolerability of sarizotan in patients with Rett syndrome, which we expect within the next few weeks."

The U.S. FDA defines a "rare pediatric disease" as a serious or life-threatening disease primarily affecting individuals age 18 years or younger that impacts fewer than 200,000 individuals in the United States.

The Rare Pediatric Disease designation provides incentives to advance the development of rare disease drugs and biologics. Additionally, the FDA's Rare Pediatric Disease Priority Review Voucher Program states that a sponsor with a Rare Pediatric Disease designation who receives marketing approval for a rare pediatric disease may be eligible for a voucher that can be redeemed to obtain priority review for any subsequent marketing application.

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 https://www.rettsyndrome.org/.

About STARS Study

Newron has successfully completed patient enrollment in the Sarizotan Treatment of Apneas in Rett Syndrome (STARS) study, 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's 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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