Newron Pharmaceuticals Announces Initiation of the STARS Study in the United States

Potentially Pivotal Study to Evaluate Sarizotan for the Treatment of Apneas in Rett Syndrome

Milan, Italy and Morristown, N.J., USA – July 21, 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, today announced the initiation of the Sarizotan Treatment of Apneas in Rett Syndrome (STARS) study, a potentially pivotal clinical study to evaluate the efficacy, safety and tolerability of sarizotan in patients with Rett syndrome suffering from respiratory symptoms. The first US study center initiated is the Rush University Medical Center, Chicago, Peter T. Heydemann, MD.

The randomized, double-blind, placebo-controlled STARS Study is expected to enroll 129 patients (three groups of 43) at centers of excellence in the United States, Italy and India. The study protocol was designed following extensive discussions with regulatory authorities in the United States, Europe and Canada. In May of 2016, Newron announced that its Investigational New Drug (IND) application for the evaluation of sarizotan for the treatment of patients with Rett syndrome was approved by the U.S. Food and Drug Administration (FDA).

"This study of sarizotan in the treatment of apneas breaks new ground and has great promise in the search for treatments that may improve the lives of patients with Rett syndrome and their families, said Daniel Glaze, M.D. FAASM, Professor, Pediatrics and Neurology, Baylor College of Medicine, and Medical Director, The Blue Bird Circle Rett Center, Texas Children's Hospital, Houston, Texas, USA, who was deeply involved in the design of the study." Our center and 3 other US centers of excellence have devoted considerable effort in ensuring the study captures the essential features of these patients and we will be working with Newron Pharmaceuticals in ensuring the high quality collection of data on the unique measures being evaluated in this trial".

"The initiation of the STARS study is an exciting milestone in our development program for sarizotan for the treatment of cardinal abnormal respiratory symptoms of Rett syndrome, including episodes of apnea, hyperventilation and breathing dysrhythmia," said Ravi Anand, M.D., Chief Medical Officer at Newron. "Newron looks forward to further collaboration with leading Rett syndrome researchers, experts and advocacy groups to carry out the study and help address patients' alarming and debilitating symptoms that may contribute to morbidity and mortality in the long term."

The primary endpoint for the STARS study is reduction in episodes of clinically significant apneas (>10 sec) during waking time by 20 percent. During this 6-month double blind placebo-controlled study, patients older than 13 years of age will receive treatment with daily doses of 10 and 20 mg of sarizotan, or placebo. The Company expects to have top-line results available for release in 2017.

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**

For more information

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