Newron Reports Top-Line Results from its STARS Study Evaluating Sarizotan in Patients with Rett Syndrome

Pivotal trial did not meet primary or secondary efficacy variables

Newron will prioritize its Phase III development program of Evenamide in schizophrenia and evaluate additional pipeline candidates

Milan, Italy and Morristown, NJ, USA, May 4, 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, announced today that top-line results from its STARS clinical study evaluating sarizotan in patients with Rett syndrome did not demonstrate evidence of efficacy on the primary or secondary efficacy variables. Consequentially, Newron has decided to terminate this development program.

The STARS (Sarizotan for the Treatment of Apneas in Rett Syndrome) clinical study qualified and enrolled 129 Rett syndrome patients in 14 centres throughout the US, Europe, Asia and Australia for the six-month clinical trial. Patients received treatment with daily doses of 10 mg and 20 mg of sarizotan, or placebo. The primary endpoint of the STARS study was a percentage reduction in episodes of apnea during waking time compared with placebo. Newron plans to work with the Rett research community and families to share learnings from the STARS clinical study as well as from the Rett Syndrome International Burden of Illness Survey, to further advance scientific and medical understanding of this disease.

Ravi Anand, M.D., Chief Medical Officer of Newron, commented: "We are very disappointed that the top-line results in the STARS study did not meet the study endpoints. The results of this well designed and executed study, based on highly promising data from a genetic model of Rett syndrome in mice, indicate the difficulties inherent in translating effects in animal models to human clinical studies. We are currently awaiting results of additional explanatory analyses and will continue to analyse the full data set from the study to understand more about the results."

Stefan Weber, Newron's Chief Executive Officer, said: "We sincerely want to thank the patients, caregivers and their families who participated in this landmark study. This was an extremely challenging study and the enthusiasm of the patients and caregivers indicates their need to find a treatment for this serious, underserved disease. Each participant has the gratitude of the study investigators, Newron's employees, advisors and vendors who have worked diligently on this study over the last five years."

"Newron continues to develop its pipeline and evaluate additional candidates, consistent with its long-term strategy of developing novel therapies for patients with diseases of the central and peripheral nervous system. In the near term, we look forward to progressing our Phase III clinical program evaluating Evenamide in schizophrenia."

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.

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 currently holds the commercialization rights in the USA and has entered into a definitive agreement to sell its Xadago rights, along with other CNS assets, to Supernus Pharmaceuticals. Meiji Seika has the rights to develop and commercialize the compound in Japan and other key Asian territories. 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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