Newron Pharmaceuticals Announces Planned Pivotal Trial Design for Sarizotan for Patients with Rett Syndrome, a Rare Neurodevelopmental Disease

Recognizes Rett Syndrome Awareness Month*

Provides update on early-stage pipeline prioritization

Milan, Italy – October 28, 2015 – Newron Pharmaceuticals S.p.A. ("Newron"), a research and development company focused on novel central nervous system (CNS) and pain therapies, today announced the study design and details of its planned pivotal trial for sarizotan for the treatment of patients with Rett syndrome, a rare neurodevelopmental disease. October is Rett Syndrome Awareness Month, and Newron is proud to be advancing a potential therapy to make a difference in the lives of these patients. The Company also provided an update on its early-stage pipeline prioritization review.

The planned international pivotal trial with sarizotan is a double-blind, placebo-controlled efficacy study that has been designed based on extensive discussions with regulatory authorities in Europe, the U.S. and Canada as well as consultation with an international group of physicians specializing in Rett syndrome and a leading advocacy group at Rettsyndrome.com.

"Newron is focused on the development of sarizotan to reduce key symptoms of Rett syndrome, such as episodes of apnea, hyperventilation and abnormal heart or brain rhythms, which are a leading cause of death for patients with the disease," said Ravi Anand, M.D., Chief Medical Officer at Newron. "As we prepare to begin this clinical trial, we are encouraged by the views of Rett syndrome experts that our preclinical data suggest that sarizotan could demonstrate improvement in these key symptoms."

"A reduction in respiratory symptoms would be a meaningful benefit for patients and caregivers, improving quality of life and potentially reducing secondary cardio-respiratory complications, thereby extending the lives of girls and women with Rett syndrome," said Daniel Glaze, M.D., neurologist, Professor at Baylor College of Medicine, and Medical Director of the Blue Bird Circle Rett Center and Texas Children's Sleep Center.

The 24-week study is designed to evaluate two fixed-dose groups (5 mg twice daily and 10 mg twice daily) vs. placebo for efficacy (respiratory functioning), safety and pharmacokinetics in initially 90 Rett syndrome patients 13 years of age or older. After 24 weeks, all study patients will be placed on sarizotan and continue in an extension study for up to 48 weeks, with at least 30 patients per group. Respiratory function will be measured using the BioRadio™ system for at-home monitoring. The primary endpoint of the study is a reduction in the number of apnea episodes.

The European Commission and the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation to sarizotan for Rett syndrome earlier this year. If approved by regulatory agencies, sarizotan will be the first product that Newron commercializes on its own.

In addition, Newron has completed its review of the early-stage development programs for sNN0031 and sNN0029 and decided to terminate both development programs. The compounds are delivered into the brain with an investigational drug delivery catheter from a third-party supplier,

who entered into a consent decree with U.S. FDA in April/May 2015, preventing it from commercializing the catheter or engaging in new manufacturing of the catheter until previously identified quality system issues are resolved. This information was highlighted by Newron on 15 September 2015. The issues raised by the FDA relating to the supplier's quality system led Newron to temporarily interrupt any further patient screening activities, surgical implantation of medical device, or randomization of patients to enable Newron to perform a benefit-risk assessment for sNN0029. Our assessment, together with the continuing delays and information relating to the inability of the supplier to manufacture new catheters to replace the current ones that expire on 27 February 2016, has led us to the decision to discontinue the development of both programs.The Company will now inform investigators and help find appropriate solutions for the patients still on treatment. The decision will lead to a restructuring of Newron's operations in Sweden, affecting up to six employees.

About Rett Syndrome

Rett syndrome is a severe neurodevelopmental disorder primarily affecting females, with an estimated prevalence ranging from one in 10,000 to one in 20,000 females. There are no approved treatments available. Rett syndrome is characterised 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 Awareness Month, visit www.rettsyndrome.org

About Sarizotan

Sarizotan, a 5HT1A agonist and D2 agonist/antagonist, has been associated with a 70 to 85 percent reduction of apneas and hyperventilation episodes in preclinical testing with both acute and chronic dosing. Sarizotan has been fully characterised in preclinical studies evaluating its toxicological effects and metabolic profile, without any significant safety concerns. Sarizotan has been well tolerated in previous studies in over 1,500 humans.

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. Marketing authorization in the EU for Xadago® (safinamide) for the treatment of Parkinson's disease was granted by the EU Commission in February 2015, followed by the launch by Zambon in the first key EU country - Germany - in May 2015. The New Drug Application (NDA) has been accepted for review by the FDA, as reported in March 2015. In March 2014, Zambon, Newron's partner, submitted an MAA to Swissmedic. Zambon has the rights to develop and commercialize safinamide globally, excluding Japan and other key Asian territories, where Meiji Seika has the rights to develop and commercialize the compound. Newron's additional projects are based on highly promising treatments for rare disease patients and are at various stages of clinical development. They include sarizotan for patients with Rett syndrome, for which Newron received Orphan Drug Designation in both the US and the EU, ralfinamide for patients with specific rare pain indications, and NW-3509 as potentially the first add-on therapy for the treatment of patients with positive symptoms of schizophrenia. For additional information, please visit http://www.newron.com.

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