Newron Announces IND Approval for Sarizotan for Treatment of Rett Syndrome

Potentially Pivotal STARS (Sarizotan Treatment of Apneas in Rett Syndrome) Trial is First for Rett's

Milan, Italy and Morristown, N.J., USA – May 17, 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, announced today 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). Newron expects to initiate the potentially pivotal STARS (Sarizotan Treatment of Apneas in Rett Syndrome) in the third quarter of this year.

STARS is a randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety and tolerability of sarizotan in patients with Rett syndrome with respiratory symptoms. It will be conducted at centers of excellence in the United States, with similar centers to be added in other countries. The study protocol was designed following extensive discussions with regulatory authorities in the United States, Europe and Canada.

"The FDA approval of the STARS trial is a major step in the development of sarizotan for the treatment of cardinal abnormal respiratory symptoms of Rett syndrome, such as episodes of apnea, hyperventilation and breathing dysrhythmia, that are not only alarming and incapacitating for the patient, but also may contribute to morbidity and mortality long-term", said Ravi Anand, M.D., Chief Medical Officer at Newron. "Newron greatly appreciates the many leading Rett syndrome researchers, experts and advocacy group leaders who provided us with significant input on the trial design for STARS, which is the first pivotal study to be performed in patients with Rett syndrome."

Patients with Rett syndrome experience respiratory symptoms, such as episodes of apnea and hyperventilation, whose onset is as early as 3 years of age and that may persist for 10-15 years. These apneic episodes may occur as frequently as 10-60 times / hour during waking time. Regulatory endorsement of the study endpoints represents a growing recognition of the importance and contribution of respiratory symptoms.

Sarizotan has shown consistent, dramatic and statistically significant reduction in apneic episodes in genetic knock-out murine models of Rett's syndrome that exhibit the characteristic phenotypic features of the disease. These effects were achieved with plasma levels of sarizotan that approximate those that will be achieved at the doses evaluated in the STARS study.

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 commercialise Sarizotan directly.

About Rett Syndrome

Rett syndrome is a severe neurodevelopmental disorder primarily affecting females, with an estimated prevalence ranging from one in 10,000 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, 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

Media	Investors and Analysts
Newron Stefan Weber – CEO Phone: +39 02 6103 46 26 E-mail: pr@newron.com	**Newron** Stefan Weber – CEO Phone: +39 02 6103 46 26 E-mail: pr@newron.com
UK/Europe Julia Phillips FTI Consulting Phone: +44 (0)20 3727 1000	**UK/Europe** Julia Phillips FTI Consulting Phone: +44 (0)20 3727 1000
Switzerland Martin Meier-Pfister IRF Communications Phone: +41 43 244 81 40	**Switzerland** Martin Meier-Pfister IRF CommunicationsPhone: +41 43 244 81 40
Germany Anne Hennecke MC Services AG Phone: +49 211 52925222 anne.hennecke@mc-services.eu	**Germany** Anne Hennecke MC Services AG Phone: +49 211 52925222 anne.hennecke@mc-services.eu

USA Alison Chen LaVoieHealthScience Phone: +1 617 374 8800, Ext. 104 achen@lavoiehealthscience.com	**USA** Beth Kurth LaVoieHealthScience Phone: +1 617 374 8800, Ext. 109 bkurth@lavoiehealthscience.com

Important Notices

This document contains forward-looking statements, including (without limitation) about (1) Newron's ability to develop and expand its business, successfully complete development of its current product candidates and current and future collaborations for the development and commercialisation of its product candidates and reduce costs (including staff costs), (2) the market for drugs to treat CNS diseases and pain conditions, (3) Newron's anticipated future revenues, capital expenditures and financial resources, and (4) assumptions underlying any such statements. In some cases these statements and assumptions can be identified by the fact that they use words such as "will", "anticipate", "estimate", "expect", "project", "intend", "plan", "believe", "target", and other words and terms of similar meaning. All statements, other than historical facts, contained herein regarding Newron's strategy, goals, plans, future financial position, projected revenues and costs and prospects are forward-looking statements. By their very nature, such statements and assumptions involve inherent risks and uncertainties, both general and specific, and risks exist that predictions, forecasts, projections and other outcomes described, assumed or implied therein will not be achieved. Future events and actual results could differ materially from those set out in, contemplated by or underlying the forward-looking statements due to a number of important factors. These factors include (without limitation) (1) uncertainties in the discovery, development or marketing of products, including without limitation negative results of clinical trials or research projects or unexpected side effects, (2) delay or inability in obtaining regulatory approvals or bringing products to market, (3) future market acceptance of products, (4) loss of or inability to obtain adequate protection for intellectual property rights, (5) inability to raise additional funds, (6) success of existing and entry into future collaborations and licensing agreements, (7) litigation, (8) loss of key executive or other employees, (9) adverse publicity and news coverage, and (10) competition, regulatory, legislative and judicial developments or changes in market and/or overall economic conditions. Newron may not actually achieve the plans, intentions or expectations disclosed in forward-looking statements and assumptions underlying any such statements may prove wrong. Investors should therefore not place undue reliance on them. There can be no assurance that actual results of Newron's research programmes, development activities, commercialisation plans, collaborations and operations will not differ materially from the expectations set out in such forward-looking statements or underlying assumptions.Newron does not undertake any obligation to publicly up-date or revise forward looking statements except as may be required by applicable regulations of the SIX Swiss Exchange where the shares of Newron are listed.This document does not contain or constitute an offer or invitation to purchase or subscribe for any securities of Newron and no part of it shall form the basis of or be relied upon in connection with any contract or commitment whatsoever.