Newron Receives FDA Orphan Drug Designation for Sarizotan for the Treatment of Rett Syndrome

Milan, Italy – July 14, 2015 – Newron Pharmaceuticals S.p.A. ("Newron"), a research and development company focused on novel central nervous system (CNS) and pain therapies, today announced that the US Food and Drug Administration (FDA) has granted Orphan Drug Designation to Newron's New Chemical Entity (NCE) sarizotan for treatment of Rett syndrome. Newron also recently announced that it received a positive opinion from the Committee for Orphan Medicinal Products (COMP) from the European Medicines Agency (EMA) for sarizotan.

"Newron believes that sarizotan could demonstrate an improvement in key symptoms of Rett syndrome, including episodes of apnea, hyperventilation and breath-holds," said Ravi Anand, Chief Medical Officer at Newron. "A reduction in respiratory symptoms is likely to improve quality of life of patients, caregivers, and in the long term, we expect that treatment with sarizotan may reduce secondary cardio-respiratory complications and extend the lives of girls and women with Rett Syndrome. Newron is currently in advanced discussions with regulatory authorities in Europe, the US and Canada on the proposed clinical development program."

Rett syndrome is a severe neurodevelopmental disorder primarily affecting females with an estimated prevalence ranging from one in 10,000 to 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 mutation in the MeCP2 gene. Prevalence of episodes of apnea, hyperventilation and disordered breathing are found in approximately 70 percent of patients with Rett syndrome at some stage of their life.

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.

About the Orphan Drug Designation

The Orphan Drug Designation program provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S. Orphan designation qualifies the sponsor of the drug for various development incentives of the Orphan Drug Act (ODA), including tax credits for qualified clinical testing. A marketing application for a prescription drug product that has received orphan designation is not subject to a prescription drug user fee.

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) was granted by the EU Commission in February 2015, followed by the launch in the first key EU country - Germany - in May 2015. The New Drug Application NDA to the U.S. FDA has been accepted for filing by FDA as reported in March 2015. In March 2014, Zambon, a partner of Newron, submitted a 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, including sarizotan for patients with Rett syndrome, sNN0031 for patients with

Parkinson's disease, non-responsive to oral drug treatments, sNN0029 for patients with ALS 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

Media	**Investors and analysts**
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 **Switzerland** Martin Meier-Pfister IRF Communications Phone: +41 43 244 81 40 **Germany** Anne Hennecke MC Services AG Phone: +49 211 52925222 anne.hennecke@mc-services.eu **U.S.** David Connolly LaVoieHealthScience Phone: +1 617 374 8800, Ext. 108 dconnolly@lavoiehealthscience.com	Stefan Weber – CEO Phone: +39 02 6103 46 30 E-mail: ir@newron.com **Germany** Anne Hennecke MC Services AG Phone: +49 211 52925222 anne.hennecke@mc-services.eu **U.S.** Kristina Coppola LaVoieHealthScience Phone: +1 617 374 8800, Ext. 105 kcoppola@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.