



Newron Pharmaceuticals provides update on regulatory status of evenamide for the treatment of schizophrenia

Milan, Italy and Morristown, NJ, USA - May 28, 2019 - [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 and peripheral nervous system, received a communication from the FDA indicating concern on findings from a recently completed study in rats as well as CNS events at higher doses in dogs, and the potential implication of these findings for patients. This led the FDA to request Newron to delay initiation of the proposed Phase II/III pivotal studies with evenamide for the treatment of schizophrenia prior to completing additional short-term explanatory studies in rats and human subjects to address these concerns.

The start of the proposed phase II/III studies will therefore be delayed until after the discussion of the results of such studies with the FDA and making necessary changes in the planned pivotal studies. Newron will be asking for further feedback in a meeting with the FDA shortly and will provide additional details and an update on evenamide afterwards. Ravi Anand, MD, Chief Medical Officer of Newron, stated: “Based on the issues raised by the FDA letter, Newron is confident that they can be addressed satisfactorily”.

Newron management offers a conference call for investors, analysts and journalists on Tuesday, May 28, 3:00 pm CEST/9 am EST. The conference call can be accessed via the following dial-in numbers:

- Switzerland/Europe: +41 (0) 58 310 50 00
- United Kingdom: +44 (0) 207 107 0613
- United States: +1 (1) 631 570 5613
- Italy: +39 (0) 2 805 88 20

About Newron Pharmaceuticals

Newron (SIX: NWRN) 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 US, Australia, Canada, Brazil, and Colombia and is commercialized by Newron’s partner Zambon. US WorldMeds holds the commercialization rights in the USA. 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 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



For more information

Newron

Stefan Weber – CEO
+39 02 6103 46 26
pr@newron.com

UK/Europe

Julia Phillips / Natalie Garland-Collins, FTI Consulting
+44 20 3727 1000
SCnewron@fticonsulting.com

Switzerland

Martin Meier-Pfister, IRF
+41 43 244 81 40
meier-pfister@irf-reputation.ch

Germany/Europe

Anne Hennecke, MC Services
+49 211 52925222
anne.hennecke@mc-services.eu

USA

Paul Sagan, LaVoieHealthScience
+1 617 374 8800, Ext. 112
psagan@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, the timing of commencement of various clinical trials and receipt of data and current and future collaborations for the development and commercialization of its product candidates, (2) the market for drugs to treat CNS diseases and pain conditions, (3) Newron's 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 difficulties in enrolling clinical trials, 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 programs, development activities, commercialization 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.